FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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25 May 2005

FINAL ASSESSMENT REPORT

APPLICATION A525

FOOD DERIVED FROM HERBICIDE-TOLERANT SUGAR BEET H7-1

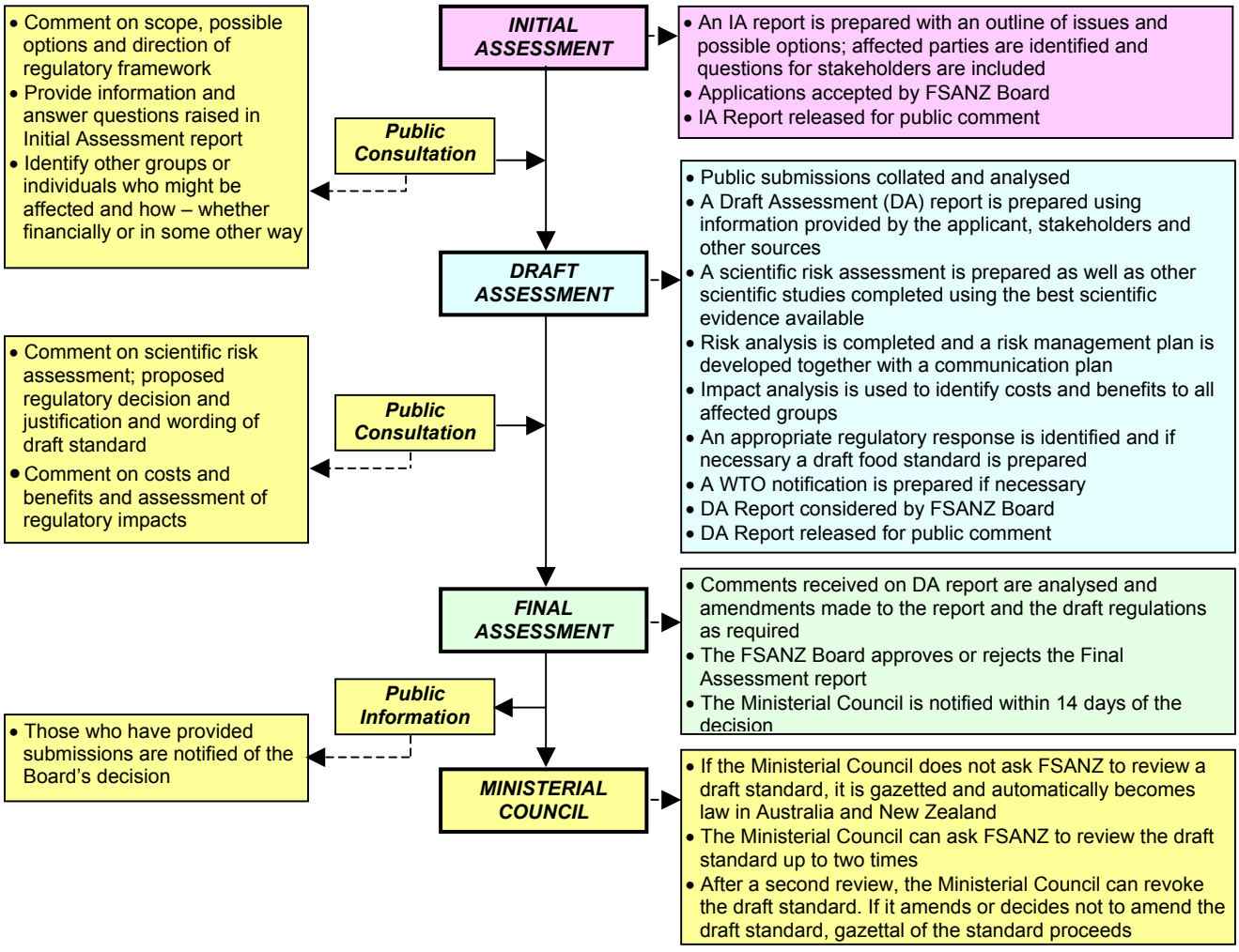
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general inquiries and requests for information.

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Executive Summary and Statement of Reasons

An Application has been received from Monsanto Australia Limited which seeks to vary the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from a genetically modified (GM) herbicide-tolerant sugar beet, sugar beet line H7-1 for inclusion in Standard 1.5.2 – Food Produced Using Gene Technology. This Standard requires that such foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand. This is a cost-recovered Application.

Sugar beet line H7-1 has been genetically modified for tolerance to the herbicide glyphosate. Protection is conferred by the expression in the plant of a bacterially derived enzyme EPSPS (5-enolpyruvylshikimate-3-phosphate synthase), which allows the plant to continue to grow in the presence of the herbicide. Sugar beet line H7-1 does not contain any additional novel genes.

There is currently no listing of food derived from sugar beet line H7-1 in the Code.

Sugar beet line H7-1 has been developed for cultivation overseas. Therefore, if approved, food derived from sugar beet line H7-1 has the potential to enter the Australian and New Zealand food supply through imported food products.

The Applicant does not envisage that sugar beet line H7-1 will be grown in Australia and/or New Zealand.

Safety assessment

FSANZ has completed a comprehensive safety assessment of food derived from sugar beet line H7-1 as required under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The assessment included consideration of:

(i) the genetic modification to the plant;

(ii) the safety of any transferred antibiotic resistance genes;

(iii) the potential toxicity and allergenicity of any new proteins; and

(iv) the composition and nutritional adequacy of the food, including whether there had been any unintended changes.

No potential public health and safety concerns were identified in the assessment of food derived from sugar beet line H7-1. Therefore, on the basis of all the available evidence, including detailed studies provided by the Applicant, it has been concluded that food, namely sugars derived from sugar beet line H7-1 is as safe and wholesome as food derived from other sugar beet varieties.

Labelling

Under Standard 1.5.2, GM food or ingredients must be labelled if novel DNA and/or protein are present in the final food and also where the food has altered characteristics.

No novel protein is present in the refined sugars, derived from sugar beet line H7-1. It is unlikely that novel DNA would be present either. If this is the case, then the sugars will not be required to be labelled as containing GM ingredients.

Impact of regulatory options

Two regulatory options were considered in the assessment: either (1) no approval; or (2) approval of food derived from sugar beet line H7-1; based on the conclusions of the safety assessment. Following cost and benefit analysis of the potential impact of each of the options on the affected parties (consumers, the food industry and government), Option 2 is the preferred option as it potentially offers significant benefits to all sectors with very little associated cost. The proposed amendment to the Code, giving approval to food from sugar beet line H7-1, is therefore considered of net benefit to both food producers and consumers.

Consultation

FSANZ made a Draft Assessment of this Application and called for submissions on 15 December 2004. The closing date for submissions was 9 February 2005. FSANZ received a total of one hundred and two submissions, twenty-eight at Initial Assessment and seventy one at Draft Assessment (a summary of submissions can be found at Attachment 3). Most submissions raised objections to the approval of food derived from sugar beet line H7-1; one submission reserved comments until the release of the Draft Assessment Report and two submissions supported this Application.

Statement of Reasons

An amendment to the Code to give approval to the sale and use of food derived from sugar beet line H7-1 in Australia and New Zealand is recommended on the basis of the available scientific evidence for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the use of sugar beet line H7-1;

- FSANZ considers that food derived from sugar beet line H7-1 is equivalent to food from other commercially available sugar beet varieties in terms of its safety for human consumption and nutritional adequacy;

- a regulation impact assessment process has been undertaken that also fulfils the requirement in New Zealand for an assessment of compliance costs. The assessment concluded that the amendment to the Code is of net benefit to both food producers and consumers; and

- the proposed draft variation to the Code is consistent with the section 10 objectives of the Act, the regulatory impact assessment and requirements of Standard 1.5.2.

It is proposed that the draft variation come into effect on the date of gazettal.

1. Introduction

Application A525 was received from Monsanto Australia Limited on 12 January 2004 seeking approval for food derived from genetically modified (GM) sugar beet line H7-1 under Standard 1.5.2 – Food Produced Using Gene Technology in the Code.

The genetic modification in sugar beet line H7-1 involved the transfer of the *cp4 epsps* coding region derived from the bacterium *Agrobacterium tumefaciens* into the plant. The *cp4 epsps* coding region expresses an enzyme that confers tolerance to the herbicide glyphosate.

A Draft Assessment of this Application, including a detailed safety assessment of food derived from sugar beet line H7-1, has been completed and FSANZ has prepared a draft variation to Standard 1.5.2 of the Code (see Attachment 1).

2. Regulatory Problem

2.1 Current regulations

Monsanto Australia Limited has developed a new variety of herbicide-tolerant sugar beet, known as H7-1. However, there is currently no listing for food derived from sugar beet line H7-1 in the Code. Therefore, Monsanto Australia Limited has applied to have Standard 1.5.2 amended to include food derived from sugar beet line H7-1.

3. Objective

The objective of this assessment is to determine whether Standard 1.5.2 should be amended to approve food derived from sugar beet line H7-1. The assessment will include consideration of the section 10 objectives of the FSANZ Act and the specific requirements of approving GM foods as per Standard 1.5.2.

3.1 Section 10 objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

In addressing the issue of approving the sale and use of food derived from sugar beet line H7-1, the key objectives are the protection of public health and safety and the provision of adequate information to consumers. In fulfilling these objectives, FSANZ will also have regard for the need for standards to be based on risk analysis using the best available scientific evidence and the desirability of an efficient and internationally competitive food industry.

3.2 Requirement of Standard 1.5.2

Standard 1.5.2 requires that a GM food undergo a pre-market safety assessment before it may be sold in Australia and New Zealand. This assessment must be approved by the FSANZ Board, and subsequently be notified to the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council). Any variation to the Code may only be gazetted, once the Ministerial Council process has been finalised.

Foods that have been assessed under this Standard, once approved, are listed in the Table to clause 2 of the Standard.

4. Background

Sugar beet plants have been developed by the applicant that are genetically modified for tolerance to the broad spectrum herbicide glyphosate, the active ingredient in the proprietary herbicide Roundup™. These sugar beet plants are referred to as sugar beet line H7-1.

The herbicide glyphosate acts by binding to the plant 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme and blocking aromatic amino acid biosynthesis. Sugar beet line H7-1 contains a novel gene (*cp4 epsps*) derived from the bacterium *Agrobacterium tumefaciens* sp. strain CP4. This gene expresses the bacterial EPSPS enzyme, which can function under applications of glyphosate, unlike plant-derived forms.

No additional genes have been transferred into sugar beet line H7-1.

Currently sugar beet is the major sugar crop grown in temperate regions of the world. The most important food product derived from sugar beet is sucrose. Sugar beets are processed into white sugar, pulp and molasses. Each of these fractions have multiple uses for food, feed or industrial application, but sugar and to a much lesser degree molasses, are the principal food products derived from sugar beet.

Applications to permit the use of sugar beet line H7-1 for food and feed use have been submitted in the United States, Canada and the EU and are currently being assessed. Food from sugar beet line H7-1 has been approved in Japan.

5. Relevant Issues

5.1 Safety assessment of food from Sugar Beet line H7-1

Food from sugar beet line H7-1 has been evaluated according to the safety assessment guidelines prepared by FSANZ[1]. The safety assessment included the following:

- a detailed characterisation of the genetic modification to the plant;
- a consideration of the safety of any transferred antibiotic resistance genes;
- characterisation of any novel proteins, including their potential toxicity and allergenicity; and
- a consideration of the composition and nutritional adequacy of the food, including whether there had been any unintended changes to the food.

The Applicant submitted a comprehensive data package in support of their application and provided studies on the molecular characterisation of sugar beet line H7-1, the potential toxicity and allergenicity and compositional analyses of sugars from sugar beet line H7-1. In addition to information supplied by the applicant, the evaluation also had regard to other available information and evidence, including from the scientific literature, general technical information, other regulatory agencies and international bodies.

No potential public health and safety concerns were identified in the assessment of the sugars derived from sugar beet line H7-1. Therefore, on the basis of all the available evidence, including detailed studies provided by the Applicant, it has been concluded that food derived from sugar beet line H7-1 is as safe and wholesome as food derived from other sugar beet varieties. The full safety assessment report is at **Attachment 2** to this document.

5.2 Labelling

Under Standard 1.5.2, GM food or ingredients must be labelled if novel DNA and/or protein are present in the final food and also where the food has altered characteristics.

No novel DNA or protein was present in the refined sugars, derived from sugar beet line H7-1, therefore no labelling of the final food will be required.

6. Issues arising from public submissions

Most submissions received voiced opposition to this Application on environmental and/or health grounds. The specific concerns of the New Zealand Food Safety Authority are addressed below.

FSANZ has also developed a Fact Sheet: *Frequently Asked Questions on Genetically Modified Foods – August 2002*, which responds to many of the general issues raised in connection with GM foods. The Fact Sheet may be obtained from the FSANZ website[2].

[1] http://www.foodstandards.gov.au/_srcfiles/ACF6A6.pdf
[2] www.foodstandards.gov.au/mediareleasespublications/factsheets/factsheets2002/index.cfm

6.1 Submission from the New Zealand Food Safety Authority

The New Zealand Food Safety Authority (NZFSA) sought additional information on the molecular characterisation of sugar beet line H7-1, specifically whether FSANZ had assessed the possibility that the transformation event had generated unintended coding regions, either within or adjacent to the inserted DNA.

In addition, the submission from NZFSA requested that the level of glyphosate residues be considered in the assessment of this Application and that this Report contain a summary of the maximum residues limits (MRLs) for glyphosate established in Australia and New Zealand. NZFSA also stated that:

> *It is possible that there are significantly more residues of glyphosate on the herbicide tolerant sugar beet compared with the non-glyphosate tolerant varieties. The significance of any public health issues associated with higher levels of glyphosate needs to be assessed.*

6.1.1 Molecular characterisation

FSANZ acknowledges the importance of a comprehensive characterisation of the insertion event to investigate the possibility that unintended open reading frames (ORFs) could be generated during transformation. Data to assist with this characterisation are therefore a standard requirement under the FSANZ safety assessment guidelines. Complete nucleotide sequence of the inserted DNA including flanking regions may, on a case-by-case basis, be supplemented with additional PCR and bioinformatics analyses as required. Sugar beet line H7-1 contains a single intact copy of the intended gene cassette with no DNA rearrangements or partial fragments of the cassette in the plant and therefore no detailed ORF analysis of the flanking regions is indicated.

Southern blot analysis of line H7-1 confirmed that one intact copy of the gene cassette had been inserted in the sugar beet. The Applicants conducted inverse-PCR targeted to the 5' and 3' ends of the insert and the PCR products were subsequently cloned and sequenced. Analysis of the resulting sequence data was performed using Mac Molly Tetra DNA analysis software (Soft Gene GmbH, Bochold, Germany).

As stated in the safety assessment, comparison of the DNA sequence of the integration region in the plant with the DNA sequence of the transforming plasmid revealed four single nucleotide differences present in the plant. However, the changes do not result in any alteration to the amino acid sequence of the CP4 EPSPS protein. Three of the changes occurred in non-coding regions within the cassette and the fourth single nucleotide change was a conservative substitution in the codon for threonine (see Section 3.3 in the Safety Assessment).

Sequence data from the inverse-PCR technique resulted in DNA sequence representing the entire H7-1 insert, the right and left junction regions, and more extensive 5' and 3' flanking sugar beet genomic DNA. The results showed that no Right border sequences are contained in line H7-1 as homology with plasmid DNA was interrupted 18 nucleotides in front of Right border plasmid sequence. At the opposite end of the inserted DNA, a short sequence of 21 nucleotides of Left border sequence is present in the plant.

The sequence data confirm the presence of a single copy of the *ctp2-cp4 epsps* coding region and its attached regulatory elements, the P-FMV promoter and E9 3' polyadenylation signal, located between the Left and Right border sequences. The data also confirm that, with the exception of the four nucleotides described above, no other unexpected gene rearrangements, deletions or additions were present in the plant.

As the additional flanking sugar beet genomic sequences in combination with the insert sequence allows the establishment of methods for the event-specific identification of glyphosate-tolerant sugar beet line H7-1, these data were considered confidential commercial information (CCI) and not included in the safety assessment report produced by FSANZ.

6.1.2 Maximum Residue Limits

The MRL is the highest concentration of a chemical residue that is permitted. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could possibly result from the registered conditions of use. The concentration is expressed in milligrams of the chemical per kilogram (mg/kg) of the food.

MRLs assist in indicating whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product.

MRLs are also used as standards for the international trade in food. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases. In relation to MRLs, FSANZ's role is to ensure that the potential residues in food do not represent an unacceptable risk to public health and safety.

FSANZ will not agree to adopt MRLs into the Code where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

Sugar beet is not grown in Australia or New Zealand and any imported sugar beet, both GM and conventional, and it's derived foods must comply with the relevant food standards. Therefore, any residues of glyphosate in sugar beet must comply with the relevant MRLs for both Australia and/or New Zealand.

6.1.3 Australian MRLs for glyphosate

The following is the relevant MRL for glyphosate in Standard 1.4.2 – Maximum Residue Limits of the Code:

GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
ROOT AND TUBER VEGETABLES	*0.1

Under the Codex Alimentarius Commission's (Codex) classification of foods and animal feeds, sugar beet is classed as a root and tuber vegetable. Therefore, the MRL for sugar beet and foods derived from sugar beet whether GM or conventional is *0.1 mg/kg.

This MRL is at its limit of quantification. (LOQ) and is indicated by an * in Standard 1.4.2. The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The inclusion of the MRLs at the LOQ means that detectable residues of the relevant chemical should not occur. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

6.1.4 New Zealand MRLs for glyphosate

The *Agreement between the Commonwealth of Australia and the Government of New Zealand to establish a system for the development of joint food standards*, excluded MRLs for agricultural and veterinary chemicals in food from the joint Australia New Zealand food standards setting system. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Both imported and domestically produced food sold in New Zealand must comply with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2004* This Standard lists the MRLs for a range of pesticides and veterinary drugs, but also includes a provision for residues of up to 0.1 mg/kg for veterinary drug or pesticide/food combination not specifically listed.

In addition, the New Zealand Standard recognises MRLs for food imported from Australia and the role of the Codex MRL Standard for imported food in general. Under this New Zealand MRL Standard, pesticide and veterinary drug residues in food must:

- comply with the specific MRLs listed in the NZ Food Standard (including the default MRL of 0.1 mg/kg where no specific MRL is listed); or
- comply with Codex MRLs (for imported food;); or
- comply with the Standard 1.4.2 for food imported from Australia.

Neither New Zealand nor Codex has established a glyphosate MRL for sugar beet. Therefore, in New Zealand, the default MRL of 0.1 mg/kg applies to this commodity and its derived foods.

This agrees with the current Australian MRL of *0.1 mg/kg.

6.1.5 Estimated dietary exposure to residues of glyphosate

FSANZ has undertaken a dietary exposure assessment for the potential residues of glyphosate in the Australian diet. This assessment indicates that the potential residues associated with the established MRLs for this chemical do not represent an unacceptable risk to public health and safety.

7. Regulatory Options

7.1 Option 1 – prohibit food from sugar beet line H7-1

Maintain the *status quo* by not amending the Code to approve the sale and use in food of sugars derived from sugar beet line H7-1.

7.2 Option 2 – approve food from sugar beet line H7-1

Amend the Code to permit the sale and use in food of sugars derived from sugar beet line H7-1, with or without listing special conditions in the Table to clause 2 of Standard 1.5.2.

8. Impact Analysis

8.1 Affected parties

- consumers, particularly those who have concerns about biotechnology;
- food importers and distributors of wholesale ingredients;
- the manufacturing and retail sectors of the food industry; and
- Government generally, where a regulatory decision may impact on trade or WTO obligations and enforcement agencies in particular who will need to ensure that any approved products are correctly labelled.

The cultivation of sugar beet line H7-1 may have an impact on the environment, which would need to be assessed by the Office of the Gene Technology Regulator (OGTR) before cultivation in Australia could be permitted. The Applicant has indicated that they do not intend to undertake field trials of sugar beet line H7-1 in Australia in the future and have not applied for a license from the OGTR to do so.

Sugar beet is not grown in New Zealand, However, if planting in New Zealand ever became likely, a comprehensive environmental risk analysis would be required by various New Zealand government agencies including as the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Fisheries (MAF) in New Zealand.

8.2 Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

The following is an assessment by FSANZ of the costs and benefits of the two regulatory options identified so far. This is based on information supplied by the Applicant and experience FSANZ has gained from consideration of previous applications relating to GM foods.

8.2.1 Option 1

Consumers: Cost in terms of a possible reduction in the availability of certain food products (loss of potential new products).

Cost associated with higher retail prices for segregated foods.

No impact on consumers wishing to avoid GM foods, as food derived from sugar beet line H7-1 is not currently permitted in the food supply.

Government: No immediate impact.

Potential impact if considered inconsistent with WTO obligations but impact would be in terms of trade policy rather than in government revenue.

Industry: Cost in terms of restricting innovation in food/crop production for both growers and other sectors of the food industry. Cost to the food industry to source either segregated or non-GM supplies.

Potential longer-term impact - any successful WTO challenge has the potential to impact adversely on food industry.

8.2.2 Option 2

Consumers: Possible benefit of lower prices, to the extent that savings from production efficiencies are passed on.

Benefit of access to a greater range of products including imported food products containing ingredients derived from sugar beet line H7-1.

Cost to consumers wishing to avoid GM food by a potential restriction of choice of products, or increased prices for non-GM food.

Government: No direct impact.

This decision is unlikely to impact on monitoring resources.

Industry: Possible benefit to growers in lower production costs and reduced exposure to agricultural chemicals used to manage insect pests.

Benefit to importers and distributors of overseas food products as the product range is extended.
Benefit for food manufacturers in that the choice of raw ingredients is extended.

Benefit to food retailers in an increased product range.

8.2.3 Discussion

Option 1 would impose significant costs, particularly on consumers and the food industry sector, without offering any commensurate health benefit. This option is also likely to be inconsistent with Australia's and New Zealand's obligations under the WTO. This option would also offer very little benefit to those consumers wishing to avoid GM foods, as food from other GM sugar beet is already permitted in the food supply.

Option 2 is the preferred option as it potentially offers significant benefits to all sectors with very little associated negative impact.

The proposed amendment to the Code, giving approval to food derived from sugar beet line H7-1, is therefore considered necessary, cost effective and of net benefit to both food producers and consumers.

9. Consultation

The Draft Assessment of this Application was advertised for public comment between 15 December 2004 and 9 February 2005. A total of sixty-eight submissions were received during this period and a summary of these is included in **Attachment 3** to this Report.

FSANZ carried out an assessment of this Application, including a safety assessment of the food, taking into account the comments received in the first round of consultation. These issues have been addressed in section 6 above. No specific issues relating to the food safety of sugar beet line H7-1 were raised in the public submissions.

9.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards for GM foods. However, the Codex Alimentarius Commission has adopted guidelines for GM plants and microorganisms. The proposed amendment to the Code to allow food derived from sugar beet line H7-1 may be of interest to other WTO member nations because it pertains to the safety of GM food and is likely to have a liberalising effect on international trade.

For these reasons, a notification was made under the Sanitary and Phytosanitary (SPS) Agreement, in order to enable other member nations to comment on the proposed changes to standards that may have a significant impact on them. No comments were received in response to the notification.

10. Conclusion and Recommendation

An amendment to the Code to give approval to the sale and use of food derived from sugar beet line H7-1 in Australia and New Zealand is recommended on the basis of the available scientific evidence for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the use of sugar beet line H7-1;

- FSANZ considers that food derived from sugar beet line H7-1 is equivalent to food from other commercially available sugar beet varieties in terms of its safety for human consumption and nutritional adequacy;

- a regulation impact assessment process has been undertaken that also fulfils the requirement in New Zealand for an assessment of compliance costs. The assessment concluded that the amendment to the Code is of net benefit to both food producers and consumers; and

- the proposed draft variation to the Code is consistent with the section 10 objectives of the Act, the regulatory impact assessment and requirements of Standard 1.5.2.

The proposed draft variation is provided in **Attachment 1**.

11. Implementation and review

It is proposed that the draft variation come into effect on the date of gazettal.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Safety assessment report
3. Submission summary

ATTACHMENT 1

DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: on gazettal

[1] ***Standard 1.5.2*** *of the Australia New Zealand Food Standards Code is varied by inserting into* Column 1 *of the* Table to clause 2 –

Food derived from sugar beet line H7-1

ATTACHMENT 2

SAFETY ASSESSMENT REPORT

APPLICATION A525 - FOOD DERIVED FROM GLYPHOSATE-TOLERANT SUGAR BEET LINE H7-1.

SUMMARY AND CONCLUSIONS

Background

Food derived from genetically modified (GM) sugar beet line H7-1 has been assessed for its safety for human consumption. Sugar beet line H7-1, known commercially as Roundup Ready® sugar beet, has been genetically modified to be tolerant to applications of the herbicide glyphosate.

This safety assessment report forms part of the assessment of the Application to FSANZ seeking approval for food derived from sugar beet line H7-1 under Standard 1.5.2 — *Food Produced Using Gene Technology* in the Code. Criteria addressed in the assessment include: characterisation of the transferred genes, their origin, function and stability; changes at the DNA, protein and whole food levels; compositional analyses; evaluation of intended and unintended changes; and the potential for the newly expressed proteins to be allergenic or toxic to humans.

History of use

Sugar beet has a long history of food use, as a source of sugar; it accounts for approximately one-third of world sugar production. Sugar beet is processed to yield white sugar, molasses and pulp. The pulp may be used as food fibre, but is primarily used in animal feed, as is the molasses. By-products from sugar beet (tops, leaves and post-processing trash) are used as cattle feed.

Description of the genetic modification

Glyphosate-tolerant sugar beet line H7-1 was generated by the insertion of one new gene: the bacterial *cp4-epsps* gene. This gene encodes a 5-enolpyruvyl shikimate-3-phosphate synthase enzyme that is not sensitive to glyphosate, allowing the plants to function normally in the presence of the herbicide. The *cp4-epsps* gene is derived from the native soil microorganism, *Agrobacterium* sp. strain CP4.

Detailed molecular and genetic analyses of sugar beet line H7-1 indicate that a single *cp4-epsps* gene was transferred to the plant genome, resulting in the expression of one novel protein, the CP4 EPSPS enzyme. The genetic modification is stable and inherited in a predicted Mendelian fashion from one generation to the next.

Characterisation of novel protein

One novel protein is expressed in sugar beet line H7-1, namely the CP4 EPSPS enzyme. The mature CP4 EPSPS produced in line H7-1 is substantially similar to the EPSPS enzyme naturally present in all food crops, and in foods from fungal and microbial sources.

Protein expression analyses indicate that CP4 EPSPS is expressed at similar levels in the top (161 parts per million, ppm) and the root tissue (181 ppm) of H7-1 sugar beet plants.

Dietary exposure to CP4 EPSPS from consumption of food products derived from sugar beet line H7-1 is expected to be virtually zero, as plant proteins are not present in processed sugar. In addition, the potential toxicity and potential allergenicity of the CP4 EPSPS protein has been assessed previously by FSANZ in relation to its use in other food crops such as corn. Additional biochemical studies relating to sugar beet line H7-1, together with detailed bioinformatic analyses on the protein, demonstrate that the CP4 EPSPS protein is not toxic and is not likely to be allergenic.

Comparative analyses

Compositional analyses were performed on key constituents of sugar beet with a particular focus on the root tissues used for processing into sugar for human consumption.

A comprehensive series of compositional analyses compared key constituents in sugar beet line H7-1 to those in the non-GM counterpart, and to a number of commercial sugar beet reference varieties. The constituents measured in beet top (leaf) and root (brei, the shredded roots used in the first step of sugar processing) tissues were: dry matter, crude protein, fibre, ash and fat, carbohydrates, 18 amino acids and the natural toxicant saponin.

In all parameters measured, the levels in sugar beet H7-1 were equivalent to the corresponding levels in tissues from the conventional counterpart, or to other commercial sugar beet varieties. Minor differences were noted in the levels of two amino acids in the root samples. However, these differences are within the natural range for conventional sugar beets and therefore are not significant with respect to food safety. Moreover, refined sugar contains no detectable plant proteins, including the novel protein introduced into line H7-1.

The detailed compositional studies therefore demonstrate that food derived from sugar beet line H7-1 is compositionally equivalent to food derived from non-GM sugar beet and other sugar beet lines.

Conclusion

No public health and safety concerns have been identified in the assessment of this glyphosate-tolerant sugar beet. Based on the available scientific evidence, food derived from sugar beet line H7-1 is equivalent to that derived from current commercial varieties of sugar beet in terms of its safety for human consumption. These conclusions are consistent with previous assessments of other glyphosate-tolerant food crops that use this genetic modification.

1. INTRODUCTION

Monsanto Australia Ltd has submitted an application to Food Standards Australia New Zealand (FSANZ) seeking approval for sugar beet line H7-1 under Standard 1.5.2 — *Food Produced Using Gene Technology* — in the *Australia New Zealand Food Standards Code*. The sugar beet has been genetically modified (GM) for tolerance to the herbicide glyphosate, and is marketed in the United States under the names Roundup Ready® Sugar Beet and Glyphosate-Tolerant Sugar Beet.

Sugar beet line H7-1 contains the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4, which encodes the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS). The CP4 EPSPS enzyme is structurally and functionally similar to native plant EPSPS enzymes, but has a lower affinity for the herbicide glyphosate (Padgette et al 1996). In non-GM plants, glyphosate binds to the plant EPSPS enzyme and blocks the biosynthesis of aromatic amino acids, thereby depriving plants of essential components (Steinrucken and Amrhein 1980). However, in Roundup Ready® plants, the CP4 EPSPS enzyme is not inactivated by glyphosate, so that growth and development of the plant can continue in the presence of the herbicide.

2. HISTORY OF USE

Sugar beet has been grown for sugar production since the late 18th century, when 'white Silesian beet' was identified as a source of sugar in Europe. Sugar beet currently accounts for approximately one-third of world sugar production, with some 35% being produced in the European Union, 20% in Russia and 10% in the US (Macrae et al 1993). In Australia, sugar is produced entirely from sugar cane.

The root (i.e. the beet) of sugar beet is processed into two major food products — pure sucrose and molasses. Sugar beet pulp is a by-product of processing, which has occasionally been purified and sold as food fibre. Waste products from both pre-processing (leaves and tops) and post-processing (trash) are used as cattle feed.

2.1 Host organism

Roundup Ready® sugar beet line H7-1 was derived from the KWS proprietary multigerm line designated 3S0057, a cultivar of *Beta vulgaris* L. ssp. *vulgaris* (sugar beet). *Beta vulgaris* is normally biennial, developing a large succulent root during the first year and a seed stalk the second year. To induce the reproductive stage of sugar beet, a period of low temperature (vernalisation) is required.

Sugar beet is the major sugar crop grown in temperate regions of the world. Sugar beets are processed into white sugar, pulp and molasses. Each of these fractions has multiple uses for food, feed or industrial applications, but the principal food products derived from sugar beet are sugar and (to a much lesser degree) molasses.

2.2 Donor organisms

Agrobacterium sp. strain CP4 produces an EPSPS enzyme that is naturally tolerant to glyphosate, due to its low binding affinity for the herbicide (Padgette et al 1996).

The bacterial isolate used as the donor organism, CP4, was identified by the American Type Culture Collection as an *Agrobacterium* species. *Agrobacterium* species are not known for human or animal pathogenicity, and are not commonly allergenic.

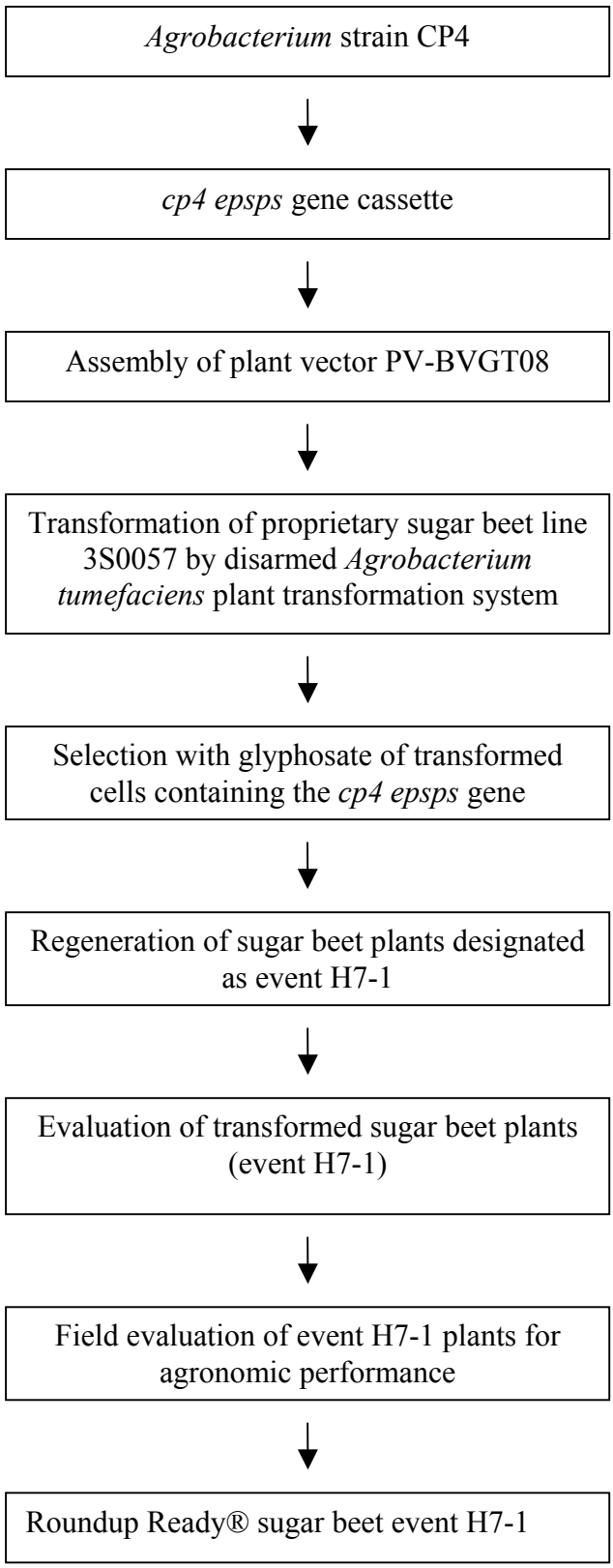
3. DESCRIPTION OF THE GENETIC MODIFICATION

3.1 Method used in the genetic modification

Sugar beet genotype 3S0057 (the KWS proprietary line) was transformed by *Agrobacterium tumefaciens*-mediated transformation, using the binary vector PV-BVGT08.

For transformation, Agrobacteria were co-cultivated with sugar beet explants. After several days, the Agrobacteria were removed by treatment with antibiotics. Stably transformed sugar beet cells were selected for tolerance to glyphosate by using glyphosate as a selection agent in the cell culture media. The tolerant cells were regenerated to fertile plants and further analysed. The flow diagram shown in Figure 1 illustrates the steps used to develop line H7-1.

Figure 1: Development of event H7-1



3.2 Function and regulation of novel genes

The vector PV-BVGT08 used in the transformation contains a region of DNA (T-DNA) that is delineated by left and right border sequences, and contains a single *cp4 epsps* gene with essential regulatory elements necessary for expression in the chloroplasts of the sugarbeet plants. The organisation of the T-DNA, corresponding to approximately 3.4 kb is depicted in Figure 2. The size and function of each of the genetic elements present in the expression cassette are described in Table 1.

Figure 2: Diagram of DNA insert in sugar beet line H7-1

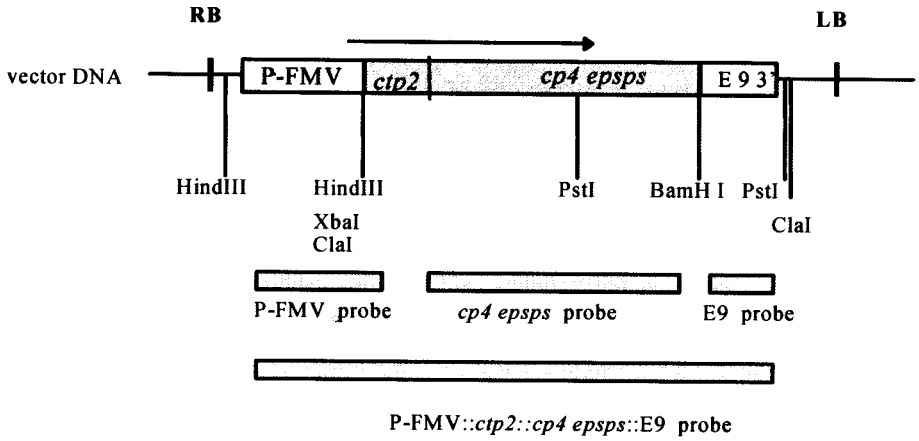


Table 1: Summary of genetic elements used in transformation

Genetic element	Size (kb)	Description and reference
Right border	0.025	A 21–25 bp nucleotide sequence that acts as the initial point of DNA transfer into plant cells, originally isolated from *A. tumefaciens* plasmid pTiT37 (Depicker et al 1982).
P-FMV	0.672	The 35S gene promoter from a modified figwort mosaic virus (FMV) (Sheperd et al 1987; Richins et al 1987; Gowda et al 1989; Sanger et al 1990).
ctp2	0.31	The N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana epsps* coding region (Timko et al 1988).
cp4 epsps	1.363	The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) coding region from *Agrobacterium sp*. strain CP4 (Padgette et al 1995).
E93'	0.63	The 3' end of the *Pisum sativum rbc*S E9 gene, containing polyadenylation sites that direct mRNA processing and polyadenylation (Coruzzi et al 1984, Morelli et al 1985).
Left border	0.025	A 21–25 bp nucleotide sequence that delimits the T-DNA transfer into plant cells, originally isolated from *A. tumefaciens* plasmid pTi 15955, a derivative of the octopine type plasmid, pTiA6 (Barker et al 1983).

The cp4 epsps gene

The *cp4 epsps* coding sequence has been shown to provide high levels of tolerance to glyphosate when introduced into plants (Padgette et al 1996). Glyphosate binds to, and blocks the activity of its target enzyme, EPSPS, which is required for the synthesis of aromatic amino acids in plants.

The mature, active EPSPS enzyme is located in the chloroplasts. Therefore, in the construction of PV-BVGT08, a chloroplast transit peptide coding sequence (*ctp2*, which encodes 76 amino acids) from the *Arabidopsis thaliana epsps* coding region (Klee et al 1987) was joined to the *cp4 epsps* coding sequence, to provide a mechanism for transport to the sugar beet chloroplast.

The initiation of transcription of the *ctp2::cp4 epsps* coding region is controlled by the 35S gene promoter, derived from figwort mosaic virus (FMV). The 35s promoter is constitutively active in plants (Sheperd et al 1987; Richins et al 1987; Gowda et al 1989; Sanger et al 1990).

3.3 Characterisation of the genes in the plant

Traditional molecular techniques were used to analyse the inserted DNA in sugar beet line H7-1. Southern blot analysis was used to determine the insert number; the copy number; the integrity of the promoters, coding regions and polyadenylation sequences; and the presence or absence of the transforming plasmid backbone sequence. Polymerase chain reaction (PCR) analyses were done to verify the sequences at the 5' and 3' ends of the insert.

Insert and copy number

Southern hybridisation was used to determine the number and nature of DNA insertions in line H7-1. The genomic DNA was digested and probed with an internal sequence of the *cp4 epsps* coding region (covering basepairs 447–1555 of the plasmid). Using three different restriction enzymes, only a single hybridisation fragment was detected in each case, indicating that H7-1 represents a single integration event.

Theoretically, one integration site could contain more than one copy of the inserted DNA, but this is unlikely based on the size of the fragments detected in the Southern hybridisation experiments.. Additional analyses were therefore done, to confirm that only one copy of the inserted DNA was present at a single genomic site in sugar beet line H7-1. The presence of a 1.2 kb and a 4.9 kb fragment confirmed that only one copy of the inserted DNA was present in line H7-1.

Integrity of gene cassette

The integrity of the gene cassette, with respect to the P-FMV promoter, *cp4 epsps* coding region and E9 3' polyadenylation signal region, was assessed by digestion with various restriction enzymes. Based on the size of the fragments generated by the digests, all the elements were found to be intact.
In addition, Southern blot analyses showed that bacterial genetic elements from outside of the T-DNA border sequences on the plasmid (i.e. *ori-V*, *ori-322* and *aad*) were not transferred to the sugar beet genome.

PCR and sequence analysis

Study submitted:
Kraus J (2003). Sequencing of the T-DNA insert including plant genome flanking sequences in Roundup Ready® Sugar Beet event H7-1. Plant GmbH Technical Report, Study No. PLT6010-5MA, Einbeck, Germany.

The DNA sequence of the insert in sugar beet H7-1 was compared to the DNA sequence of the PV-BVGT08 plasmid. The aim was to determine whether the transformation process had altered the DNA sequence inserted into the plant.

Based on the alignment of the DNA sequences between the insert and the plasmid, the sequences were found to be almost identical, with the exception of four nucleotide differences. Three of the differences are located in non-coding regions of the introduced DNA, and therefore have no impact on the amino acid sequence of the CP4 EPSPS protein. The fourth difference is a single base change within the *cp4 epsps* coding region, and corresponds to a change from thymidine (T) to a cytosine (C), in the third position within the codon. This change does not affect the deduced protein sequence because the translated amino acid remains as threonine (ACT to ACC). Apart from these four nucleotides, the DNA inserted into the plant does not differ from the plasmid used in the transformation, and the differences noted have not changed the amino acid sequence of the CP4 EPSPS protein.

Flanking regions

Agrobacterium-mediated transformation involves the integration of DNA sequences between the left and right borders into the plant genome. The molecular nature of the left and right borders was examined using inverse-PCR targeted to the 5' and 3' ends of the insert; the PCR products were subsequently cloned and re-sequenced. Sequence data from the inverse-PCR technique resulted in DNA sequence representing the entire H7-1 insert, the right and left junction regions, and more extensive 5' and 3' flanking sugar beet genomic DNA. No Right border sequences were found in line H7-1, as homology with plasmid DNA was interrupted 18 nucleotides in front of the Right border plasmid sequence. At the opposite end of the inserted DNA, a short sequence of 21 nucleotides of Left border sequence was present in the plant.

Conclusion

Detailed molecular characterisation has shown that a single copy of the introduced DNA was inserted into the genome of sugar beet line H7-1. This insert contains one intact copy of the P-FMV*::ctp2::cp4 epsps::*E9 3' gene expression cassette. Backbone sequence from the plasmid used for the transformation was not detected in the plants. In particular, the bacterial origins of replication and the *aad* gene are not present in line H7-1. These results are summarised in Table 2.

Table 2: Summary of sugar beet line H7-1 insert analysis

Genetic element	**Copy number**
P-FMV*::ctp2::cp4 epsps::*E9 3' cassette	One copy
Bacterial origin of replication	Not present
Aad (confers resistance to streptomycin)	Not present
Other plasmid backbone sequences outside the T-DNA	Not present

3.4 Stability of the genetic changes

Conventional breeding techniques were used to examine how glyphosate tolerance is inherited in sugar beet line H7-1. The characteristics studied were the stability of the inserted DNA and the phenotype (determined through segregation analysis).

Stability of inserted DNA

The genetic stability of the insert contained within H7-1 was analysed at the molecular level over three generations. The original transformation line H7-1 was compared to three progenies of this line resulting from self-pollination of the line or crosses with non-transgenic sugar beet lines. Non-transgenic plants were used as controls.

Southern hybridisations were performed on genomic DNA, and probed with a labelled *cp4 epsps* fragment, to detect the presence of the transgene. The results showed no differences in the banding patterns across multiple generations of line H7-1, demonstrating that the inserted DNA was stably integrated into the plant genome.

Segregation analysis

In other glyphosate-tolerant commercial crops, glyphosate tolerance is inherited as a dominant trait in a Mendelian manner. The inheritance of the introduced DNA in the progenies from these crosses or multiplications was monitored phenotypically at the whole-plant level by application of glyphosate at the two-leaf stage in greenhouse experiments.
The results from the analysis show that, of the 27 experiments, 24 resulted in segregation patterns as expected from Chi-square tests, at a probability level of $P = 0.05$. Different results in a few experiments were explained as being due to the small number of plants tested on those occasions.

Conclusion

The results of the segregation analysis are consistent with a single site of insertion for the *cp4 epsps* gene and confirm the results of the molecular characterisation. Analysis of a total of three generations indicates that the single T-DNA insert in sugar beet line H7-1 is integrated in the plant nuclear genome in a stable manner through subsequent generations.

4. CHARACTERISATION OF NOVEL PROTEINS

A single novel protein is present in sugar beet line H7-1. The CP4 EPSPS protein is 47.6 kDa and consists of a single polypeptide of 455 amino acids.

4.1 Biochemical function and phenotypic effects

The EPSPS enzyme is essential in the biosynthesis of the aromatic amino acids, via the shikimate metabolic pathway present in all plants, bacteria and fungi. In plants, the EPSPS enzyme is inhibited by glyphosate (Steinrucken and Armhein 1980), but bacterial EPSPSs, such as the CP4-EPSPS, have a reduced affinity for glyphosate.

In plants, EPSPS is found in the chloroplast. In sugar beet line H7-1, the CP4-EPSPS gene was fused to the *Arabidopsis thaliana* EPSPS chloroplast transit peptide (CTP), which targets the protein to the chloroplast.

In vitro chloroplast uptake assays have shown that the *A. thaliana* EPSPS CTP delivers mature CP4-EPSPS to the chloroplast, following cleavage from the preprotein. (Della-Cioppa et al 1986). The chloroplast transit peptide is rapidly degraded after cleavage *in vivo* by cellular proteases.

4.2 Protein expression analysis

Expression levels in plants

CP4 EPSPS levels were measured in brei (root) and top (leaf) samples from sugar beet line H7-1 treated with glyphosate, grown in six areas of Europe. Protein levels in extracts were estimated using a double-antibody sandwich enzyme-linked immunosorbent assay (ELISA).

The test uses a mouse monoclonal anti-CP4 EPSPS antibody as the capture antibody and a goat polyclonal anti-CP4 EPSPS conjugated to horseradish peroxidase (HRP) as the detection antibody.

On average, levels of CP4-EPSPS protein were similar in the top and root samples. The results are summarised in Table 3. The range of mean levels of CP4 EPSPS protein was not significantly different across the six European sites used.

Table 3: Summary of CP4 EPSPS levels in tissues of sugar beet line H7-1

Tissue type	CP4 EPSPS protein (µg/g tissue fresh weight)
Top[1]	
mean[2]	161
range[3]	112–201
Brei[4]	
mean[2]	181
range[3]	145–202

[1] One leaf approximately 5–10 cm^2 was sampled from 30 sugar beet line H7-1 plants for each replicate. Three replicates were collected per site. Collected leaves were placed in conical tubes and transferred on dry ice to the testing facility.

[2] The mean was calculated from the analyses of three replicate plant samples from each of the field sites.

[3] Range of mean values from the analyses of samples at each site; in top (leaf), $n = 6$ sites and in root (brei), $n = 6$ sites.

[4] Brei was prepared by a French laboratory, AGREN, using a sawing machine. Samples were immediately frozen on dry ice and then stored at ⁻80°C until analysed.

4.3 Protein levels in sugar beet

Protein levels in the sugar derived from sugar beet line H7-1 are anticipated to be very low, due to extensive processing. Using Western blotting (which has a limit of detection at two parts per billion) no CP4 EPSPS protein was detected in the processed sugar from sugar beet line H7-1. Therefore, exposure to CP4 EPSPS from sugar derived from sugar beet line H7-1 is likely to be virtually zero.

4.4 Potential toxicity of novel protein

The mature CP4 EPSPS protein in sugar beet line H7-1 is substantially similar to the EPSPS proteins already consumed in a variety of food and feed sources.

The CP4 EPSPS protein is homologous to plant EPSPS enzymes naturally present in food crops (eg soybean and corn), and in fungal and microbial food sources such as baker's yeast (*Saccharomyces cerevisiae*) and *Bacillus subtilis* (Mountain 1989), which have a history of safe consumption by humans (Padgette et al 1996; Harrison et al 1996).

Equivalence of novel plant proteins with bacterially produced novel proteins

To generate sufficient quantities of the CP4 EPSPS protein required for toxicity, and biochemical studies, it is necessary to produce the protein in bacterial expression systems. Prior to use, the bacterially produced protein is compared to the protein produced in the plant, to demonstrate their equivalence. The CP4 EPSPS used for further analyses was produced in the laboratory using recombinant *Escherichia coli*.

The molecular identity and biochemical characteristics of the protein expressed *in planta* and in the bacterial expression system were examined using a range of biochemical methods. These studies established that microbially-produced CP4 EPSPS protein was equivalent to the protein produced by sugar beet line H7-1.

The amino acid sequence of the mature CP4 EPSPS protein produced in sugar beet line H7-1 is virtually identical to the amino acid sequence of the bacterial CP4 EPSPS protein (homology more than 99%) and to that of the EPSPS protein produced in a number of other glyphosate tolerant food crops that have already been assessed. The CP4 EPSPS protein produced in sugar beet line H7-1 is identical to the CP4 EPSPS protein produced in sugar beet line 77, which was approved for use in Australia and New Zealand in 2001 (Application A378).

Potential toxicity of novel proteins

The potential toxicity of the CP4-EPSPS protein has been assessed by FSANZ in a number of previous safety assessments of GM foods derived from glyphosate tolerant crops. The previous assessments concluded that the CP4 EPSPS protein is not toxic and is therefore safe for human consumption.

Acute oral toxicity was tested in a supplementary evaluation (Harrison et al 1996). The mature CP4 EPSPS protein was administered to mice as a single high dose of 572 mg/kg (more than 1000 times the consumption level of food products potentially containing the protein). Despite this high dose, there was no mortality or morbidity, and there were no significant differences in terminal body weights of animals in the treated and control groups. Upon necropsy, body cavities were opened and organs examined *in situ* and removed. There were no pathological findings attributable to the treatment with the CP4 EPSPS protein.

Similarities with known protein toxins

The amino acid sequence of the CP4 EPSPS protein in sugar beet line H7-1 was compared to sequences in the public domain (ALLPEPTIDES) protein databases using the FASTA algorithm (Pearson and Lipman 1988), in order to assess sequence and structural homology to known proteins including toxins.

Overall, no structural similarities were observed between the CP4 EPSPS protein in sugar beet line H7-1 and pharmacologically active proteins that are known to cause adverse health effects in humans or other animals.

4.5 Potential allergenicity of novel proteins

Similarity to known allergens

The CP4-EPSPS protein was obtained from the naturally occurring soil-borne plant-symbiotic bacterium *Agrobacterium* sp. strain CP4. This source organism is not known to be allergenic to humans.

Bioinformatics analysis investigates whether there are sequence similarities between the introduced CP4 EPSPS protein and proteins that are known allergens.
Using updated versions of the allergen (ALLERGEN3 sequence database) and public domain protein sequence databases, no sequence similarity between CP4 EPSPS and known protein allergens was found.

In vitro digestibility

The *in vitro* digestibility of CP4 EPSPS protein, isolated from large-scale fermentation of *E. coli,* was tested in simulated gastric fluid (SGF), containing pepsin, at pH 1.2. Digestibility was assessed by SDS polyacrylamide gel electrophoresis, Western blot analysis and an assay for EPSPS enzyme activity.

By all three detection methods, CP4-EPSPS protein was rapidly digested after incubation in SGF at 37^{o}C. At least 98% of the *E. coli*-produced CP4 EPSPS protein was digested within 15 seconds, as determined by colloidal blue staining. More than 95% of the protein was digested in SGF within 15 seconds as determined by Western blot analysis. EPSPS activity was reduced by > 90% within 15 seconds of incubation of the CP4 EPSPS protein in SGF.

In summary, the three detection methods all demonstrate that *E. coli*-produced CP4 EPSPS protein is rapidly degraded in SGF.

4.6 Conclusion

Sugar beet line H7-1 expresses one novel protein, CP4 EPSPS, which is targeted to the plant chloroplasts. It is expressed in the root and leaves at low levels, with the highest expression level being 202 μg/g tissue fresh weight, found in brei.

A combination of bioinformatics, toxicity studies and *in vitro* biochemical studies was used to evaluate the potential toxicity and allergenicity of the CP4 EPSPS protein. The results from these studies demonstrate that the CP4 EPSPS protein is unlikely to be toxic or allergenic to humans. This assessment agrees with the conclusions of previous safety assessments of the CP4 EPSPS protein.

5. COMPARATIVE ANALYSES

A comparative approach is considered the most appropriate strategy for assessing the safety and nutrition of GM foods (WHO 2000). This approach examines the similarities and differences between the GM food and its conventional counterpart, to identify potential safety and nutritional issues, based on the history of safe use of the traditional non-GM food.

The critical components to be measured are determined by identifying the main nutrients, toxicants and antinutrients for the food source in question (FAO 1996); these may be major constituents (e.g. fats, proteins and carbohydrates) or quantitatively minor ones (e.g. minerals and vitamins). Important toxicants are any toxicologically significant compounds that are known to be inherently present in the plant, and may be significant to health (e.g. solanine in potatoes, which is toxic if present in high levels). The main components of sugar beet that have been considered in this comparison include proximates, carbohydrates, minerals, quality parameters, 18 amino acids and saponins (OECD 2002).

5.1 Compositional analysis

To determine whether the genetic modification resulted in changes to the nutrient composition of sugar beet line H7-1, a range of compositional parameters in line H7-1 were compared to the non-GM control lines with genetic backgrounds similar to H7-1, as well as to commercially available varieties grown in the same field trials. Components analysed in both top (leaf) and root (brei) samples were: proximate content (moisture, fat, protein, fibre and ash), carbohydrates, minerals (sodium and potassium), quality parameters (percentage sucrose, invert sugar and alpha-amino nitrogen), 18 amino acids and saponins.

Sugar beet line H7-1 and its non-GM control were grown in 1999, in sites in France, Germany, Italy, Spain and the United Kingdom. Sugar beet top and root tissues were collected from sugar beet line H7-1, the non-expressing segregant (control) and eight different commercial sugar beet varieties grown at the same field locations. Root tissue from all sugar beets was processed into brei before analysis.

Replicate samples from each plot were analysed individually, and the results combined to determine mean values across the five sites. Statistical analyses were conducted on the combined mean values, to identify statistically significant differences between sugar beet line H7-1 and its non-GM control at $P < 0.05$ (a P-value of < 5% would indicate that the effect of genotype was statistically significant at the 5% level). The results were also compared with values from the literature.

Proximate and carbohydrate analyses

Tables 4 and 5 summarise the results of the proximate analyses in top and root tissue, respectively. One minor statistically significant difference between sugar beet line H7-1 and the control line was observed in the mean level of dry matter in top tissue. However, the mean for the dry matter in top samples of H7-1 is within the range for controls, reference varieties and the literature, and the range is within that observed for reference sugar beet varieties. There were no significant differences observed in the results obtained for the root (brei) tissue samples.

Table 4: Summary of proximate analyses of top (leaf) tissue from sugar beet line H7-1

Analysis	Unit	Control sample[1]		Line H7-1[1]		Reference varieties[2]		Literature range[3]
		Mean	Range	Mean	Range	Mean	Range	
Dry matter[4]	%	16.37	13.69–19.83	17.98*	13.94–21.23	16.18	11.37–26.81	16–20
Crude protein[5]	% DM	16.02	14.46–19.80	15.27	11.16–18.31	16.65	12.75–24.47	8.4–23.2
Crude fibre[6]	% DM	11.43	9.23–16.82	11.50	8.56–15.99	11.62	7.84–19.71	5.9–15.9
Crude ash[7]	% DM	19.50	15.39–21.96	21.95	17.84–31.90	21.80	16.20–27.91	11.5–34.4
Crude fat[8]	% DM	0.87	0.74–1.15	0.95	0.85–1.09	1.02	0.53–1.46	0–4.7

Control sample = nontransgenic control with a genetic background similar to line H7-1.
[1] n = 5 sites, single analyses of replicate samples.
[2] n = 5 sites, single analyses of replicate samples, eight commercial varieties.
[3] See reference DLG 1991.
[4] Dry matter was determined using an oven method.
[S] Crude protein was determined using a Kjeldahl method.
[6] Crude fibre was determined using the Weende analysis.
[7] Crude ash was determined using an oven method.
[8] Crude fat was determined using a Soxhlet method.
***** indicates a significant difference at 5% level when compared with the corresponding nontransgenic control.

Table 5: Summary of proximate analyses of root (brei) tissue from line H7-1

Analysis	Unit	Control sample		Line H7-1[1]		Reference varieties[2]		Literature range[3]
		Mean	Range	Mean	Range	Mean	Range	
Dry matter[4]	%	24.01	21.75–25.83	25.46	22.87–28.88	22.74	19.05–26.33	23
Crude protein[5]	% DM	5.62	4.13–6.98	5.51	4.50–6.57	5.06	3.72–6.93	1.2–12.4
Crude fibre[6]	% DM	4.84	4.57–5.04	4.54	3.73–5.20	4.75	3.65–5.69	3.4–7.4
Crude ash[7]	% DM	2.54	1.78–3.21	2.51	1.73–3.35	2.41	1.74–3.89	1.3–17.7
Crude fat[8]	% DM	0.20	0.06–0.38	0.13	0.08–0.18	0.16	0.05–0.25	0–1.8

Control sample = nontransgenic control with a genetic background similar to line H7-1.
[1] *n* = 5 sites, single analyses of replicate samples.
[2] *n* = 5 sites, single analyses of replicate samples, eight commercial varieties.
[3] See reference DLG 1991.
[4] Dry matter was determined using an oven method.
[5] Crude protein was determined using a Kjeldahl method.
[6] Crude fibre was determined using the Weende analysis.
[7] Crude ash was determined using an oven method.
[8] Crude fat was determined using a Soxhlet method.

Table 6 summarises the results of the analyses of levels of soluble carbohydrates in top and root tissue samples of sugar beet line H7-1, the control line, reference varieties and those reported in the literature. There were no statistically significant differences between mean levels of soluble carbohydrates in top and root samples of H7-1 when compared to the non GM control samples.

Table 6: Summary of soluble carbohydrate determination from line H7-1

Analysis	Unit	Control sample[2]		Line H7-1[2]		Reference varieties[3]		Literature range[4]
		Mean	Range	Mean	Range	Mean	Range	
Top	% DM	52.18	45.50–58.03	50.35	44.60–54.68	48.92	43.30–56.52	38.3–64.5
Root	% DM	86.80	84.44–89.02	87.31	85.58–89.04	87.62	83.31–90.05	67.3–90.9

Control sample = nontransgenic control with a genetic background similar to line H7-1.
[1] Carbohydrate calculation = 100% – (crude protein + crude ash + crude fibre + crude fat).
[2] *n* = 5 sites, single analyses of replicate samples.
[3] *n* = 5 sites, single analyses of replicate samples, eight commercial varieties.
[4] Reference DLG 1991.

Mineral and quality analysis

The minerals potassium and sodium were analysed, together with sugar content (measured by polarisation), invert sugar (glucose + fructose) and alpha-amino nitrogen. Table 7 shows the results of these analyses. The mean levels of the five components measured in sugar beet root tissues from line H7-1 were not significantly different from the mean levels in the non-GM control samples.

Data on saponins, the principal toxicant in sugar beet root, are considered below (Section 5.2).

Table 7: Summary of mineral and quality analyses of root (brei) tissue from line H7-1

Analysis	**Unit**	**Control sample[1]**		**Line H7-1[1]**		**Reference varieties[2]**		**Literature range[3]**
		Mean	**Range**	**Mean**	**Range**	**Mean**	**Range**	
Potassium[4]	nmol/100 kg FW	3.85	3.08–4.87	3.85	3.08–5.13	4.10	2.82–5.38	2.95–10.21
Sodium[5]	nmol/100 kg FW	0.65	0.26–1.83	0.57	0.16–2.04	0.61	0.19–2.39	0.13–5.48
Polarization[6]	g/100g FW	18.12	16.11–19.23	18.54	16.14–20.21	17.08	14.14–19.51	10.8–20.7
Invert sugar[7]	nmol/100 kg FW	0.83	0.24–2.94	0.78	0.24–2.61	0.67	0.17–2.94	0.3–2.7
Amino-N[8]	nmol/100 kg FW	1.29	0.79–1.71	1.29	0.86–1.93	1.21	0.63–2.50	0.80–5.62

Control sample = nontransgenic control with a genetic background similar to line H7-1.
[1] n = 5 sites, single analyses of replicate samples.
[2] n = 5 sites, single analyses of replicate samples, eight commercial varieties.
[3] See references Marlander et al 1996 and Smed et al 1996.
[4] Potassium was determined using a spectrophotometer.
[5] Sodium was determined using a spectrophotometer.
[6] Polarisation was determined using a polarimeter.
[7] Invert sugar was determined using the Institute of Berlin method.
[8] Amino-N was determined using a spectrophotometer.

Fatty acid analysis

The only food product obtained from sugarbeet is a highly refined sugar. This product does not contain fats and therefore fatty acid analysis is not relevant for this application.

Amino acid analysis

Tables 8 and 9 show the results of analyses of levels of amino acids in sugar beet top and root samples, respectively. For top samples, mean levels of 14 of the 18 amino acids measured were not significantly different between sugar beet H7-1 and non-GM control samples.

Mean levels of four amino acids (alanine, histidine, phenylalanine and tyrosine) were statistically different when compared to the corresponding mean levels from the non-GM control samples.

However, the ranges observed for these four amino acids from sugar beet line H7-1 either mainly overlapped or were completely within the ranges of values for the non-GM control samples and the commercial reference varieties.

Table 8: Summary of amino acid analyses of top (leaf) tissue from line H7-1

Analysis[1]	Unit	Control sample[2]		Line H7-1[2]		Reference varieties[3]	
		Mean	Range	Mean	Range	Mean	Range
Alanine	% total aa	6.44	6.29–6.61	6.67*	6.29–7.07	6.53	5.98–6.97
Arginine	% total aa	5.36	5.13–5.69	5.44	5.06–5.91	5.42	4.68–5.96
Aspartic acid	% total aa	10.29	10.16–10.36	10.53	9.96–11.37	10.55	9.55–11.40
Cystine	% total aa	1.73	1.18–2.24	1.90	0.87–3.20	1.77	1.07–3.05
Glutamic acid	% total aa	13.46	12.20–14.78	13.10	12.35–13.56	13.92	12.29–15.55
Glycine	% total aa	6.86	6.23–7.32	6.80	6.45–7.47	6.78	6.21–7.80
Histidine	% total aa	2.46	2.00–2.73	2.29*	1.73–2.54	2.26	1.75–2.68
Isoleucine	% total aa	4.49	4.26–4.86	4.39	4.12–4.67	4.44	4.11–4.97
Leucine	% total aa	8.20	7.58–9.19	8.13	7.66–9.06	8.01	7.16–9.01
Lysine	% total aa	5.36	4.82–5.81	5.25	3.75–5.81	5.35	4.60–5.85
Methionine	% total aa	1.83	1.37–2.45	2.20	1.13–4.05	1.74	1.06–3.18
Phenylalanine	% total aa	5.12	4.76–5.46	4.98*	4.65–5.30	4.99	4.47–5.40
Proline	% total aa	7.04	5.53–7.95	7.04	6.55–7.47	7.15	5.46–9.58
Serine	% total aa	5.80	5.48–6.24	5.94	5.47–6.33	5.78	5.34–6.21
Threonine	% total aa	4.82	4.42–5.05	4.71	4.09–5.07	4.47	3.39–5.23
Tryptophan	% total aa	1.60	1.30–1.86	1.69	1.17–2.13	1.81	1.37–2.45
Tyrosine	% total aa	3.65	3.28–3.87	3.46*	3.05–3.69	3.63	3.21–4.70
Valine	% total aa	5.51	5.29–6.17	5.49	5.26–5.99	5.37	4.97–6.17

[1] Amino acids were determined using a high-performance liquid chromatography (HPLC) method.
[2] n = 5 sites, single analyses of replicate samples.
[3] n = 5 sites, single analyses of replicate samples, eight commercial varieties
* indicates a significant difference at 5% level when compared with the corresponding nontransgenic control.

For root samples, mean levels of 16 of the 18 amino acids measured were not significantly different between sugar beet H7-1 the non-GM control samples. Mean levels of two amino acids (alanine and glutamic acid) were statistically different when compared to the corresponding mean levels from the non-GM control samples. However, the ranges observed for these two amino acids either mainly overlapped or were completely within the range of values for the non-GM control samples and the commercial reference varieties.

Table 9: Summary of amino acid analyses of root (brei) tissue from line H7-1

Analysis[1]	Unit	Control sample[2]		Line H7-1[2]		Reference varieties[3]	
		Mea	Range	Mean	Range	Mean	Range
Alanine	% total aa	5.29	4.69–6.33	5.91*	5.04–6.73	6.27	4.73–9.43
Arginine	% total aa	4.91	4.50–5.18	5.30	4.94–5.63	4.80	4.02–5.74
Aspartic acid	% total aa	13.35	12.32–14.75	13.21	12.66–14.46	13.19	11.57–15.53
Cystine	% total aa	1.38	1.28–1.53	1.42	1.25–1.72	1.45	0.84–2.28
Glutamic acid	% total aa	18.58	15.66–21.85	16.87*	14.72–19.98	19.21	13.76–25.07
Glycine	% total aa	4.23	3.74–4.54	4.73	4.15–5.21	4.61	3.83–6.18
Histidine	% total aa	2.69	1.58–3.33	2.95	2.00–3.45	2.87	1.78–3.43
Isoleucine	% total aa	4.01	3.90–4.24	4.23	4.15–4.35	3.95	3.27–4.95
Leucine	% total aa	6.09	5.55–6.61	6.47	5.90–7.18	6.07	4.82–6.95
Lysine	% total aa	5.42	3.50–6.88	5.73	4.29–6.52	5.49	3.69–7.11
Methionine	% total aa	1.35	1.23–1.46	1.29	1.05–1.57	1.28	0.70–2.04
Phenylalanine	% total aa	3.36	2.98–3.69	3.45	3.29–3.66	3.26	2.75–3.75
Proline	% total aa	5.94	5.53–6.46	5.39	3.29–7.02	5.11	1.71–9.29
Serine	% total aa	7.34	6.61–8.49	7.55	6.86–8.45	7.58	6.63–8.72
Threonine	% total aa	4.76	4.11–5.30	4.98	4.51–5.28	4.75	3.96–5.51
Tryptophan	% total aa	2.30	1.11–4.26	1.82	1.06–2.44	1.93	1.02–5.40
Tyrosine	% total aa	3.53	3.27–3.86	3.55	3.09–4.23	3.34	2.51–4.23
Valine	% total aa	5.47	5.10–5.82	5.14	3.79–5.87	4.84	1.99–7.49

Control sample = nontransgenic control with a genetic background similar to line H7-1.
[1] Amino acids were determined using a high-performance liquid chromatography (HPLC) method.
[2] n = 5 sites, single analyses of replicate samples.
[3] n = 5 sites, single analyses of replicate samples, eight commercial varieties.
[*] indicates a significant difference at 5% level when compared with the corresponding nontransgenic control.

5.2 Naturally occurring toxicants

Sugar beet naturally contains low levels of toxic saponins. As their name implies, saponins are a group of compounds with properties resembling soap and detergents. They are a complex and chemically diverse group of compounds incorporating both triterpenes and steroids linked to one or more sugar groups. Saponins are found naturally, and in significant amounts, in commonly used food and forage plants such as clover, alfalfa, soybeans, chickpeas, eggplant, silver beet and spinach (Oakenfull and Sidhu 1989), and are characterised by having a bitter and astringent taste.

The predominant sapogenic form in sugar beet is oleanolic acid. Due to their surface-active properties, saponins can cause problems with foaming and turbidity during production of sugar from sugar beet; therefore, efforts are made to reduce saponin levels through processing. The wide range of chemical and physical properties of saponins is reflected in the extent and range of their physiological and pharmacological properties. For example, saponins have been shown to interact with biological membranes (due to their detergent qualities) and to both inhibit and stimulate enzymes and metabolic activity (Oakenfull and Sidhu 1989). There has been a tendency to treat saponins exclusively as antinutritional or toxic constituents; however, recent work has shown several beneficial dietary effects of saponins, including improved nutrient absorption during digestion and lower blood cholesterol levels (Oakenfull and Sidhu 1989).
Table 10 shows the results of analysis of saponin levels in the roots and tops of sugar beet line H7-1 and the non-GM control sugar beet plants. The results show that saponin levels for sugar beet line H7-1 are not significantly different from those of the non-GM control samples, or the values reported in the literature.

Table 10: Summary of saponin analyses of top and root tissues from line H7-1

Analysis[1]	Unit	Control sample[2]		Line H7-1[2]		Reference varieties[3]		Literature range[4]
		Mean	Range	Mean	Range	Mean	Range	
Top	mg/kg FW	65	47–100	58	34–93	76	27–200	50–600
Root	mg/kg FW	90	54–120	92	54–150	99	63–170	75–965

Control sample = nontransgenic control with a genetic background similar to line H7-1.
[1] n = 5 sites, single analyses of replicate samples.
[2] n = 5 sites, single analyses of replicate samples, eight commercial varieties.
[3] See reference Lüdecke et al 1958.
[4] Saponin was determined using a high-performance liquid chromatography (HPLC) method.

5.3 Conclusions

Detailed compositional analyses of sugar beet line H7-1, using the non-GM counterpart as a control, included proximate analyses, carbohydrates, minerals, quality components, 18 amino acids and saponin. All parameters were analysed in both top and root tissues, except for minerals and quality components, which were analysed in root tissue only.

A total of 55 statistical comparisons were made between sugar beet line H7-1 and the non-GM control line for both tissues. Seven of these comparisons were significantly different at $P < 0.05$, but in each case, the ranges overlapped with, or were completely within the range of, values observed for the non-GM control, the commercial reference varieties and available published values for commercial sugar beet varieties. These results indicate that the nutrient composition in top and root tissues of sugar beet line H7-1 is equivalent to that of commercial sugar beet varieties. The minor differences in composition that were noted do not raise any food safety concerns with respect to the sugar product. Minor differences in composition for other constituents (eg amino acids) will not impact on the final food.

6. NUTRITIONAL IMPACT

In assessing the safety of a GM food, a key factor is the need to establish that the food is nutritionally adequate and will support typical growth and well-being. In most cases, this can be achieved through an understanding of the genetic modification and its consequences together with an extensive compositional analysis of the food. Where, on the basis of available data, there is still concern or doubt in this regard, carefully designed feeding studies in animals may provide further reassurance that the food is nutritionally adequate. Such studies may be considered necessary where the compositional analysis indicates significant differences in a number of important components or nutrients, or where there is concern that the bioavailability of key nutrients may be compromised by the nature of the genetic changes to the food.

In the case of glyphosate-tolerant sugar beet line H7-1, no significant compositional differences were evident. On the basis of these findings, feeding studies were not considered warranted in this case.

Furthermore, the principal human food derivative from sugar beet line H7-1 is highly refined sugar which is composed of 96–99% sucrose and 0.6–1.2% other sugars such as glucose and fructose. The extensive processing involved in the production of sugar effectively eliminates all plant proteins, including the novel protein, from the final food product. Refined sugar from any source has a long history of safe use as a human food.

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ATTACHMENT 3

SUMMARY OF PUBLIC SUBMISSIONS

FIRST ROUND

Submitter	Preferred Option	Comments
Stephanie Abbott	1	Did not support the Application. Concerned about the safety of GM foods and the use of herbicides associated with GM crops.
Shushila Ajani	1	Did not support the Application. Concerned about the: • safety of GM food; • labelling of GM food; • contamination of conventional food by GM food; and • possible increase in the use of herbicides associated with GM crops.
Tony and Diane Achtzehner	1	Did not support the Application. Concerned about the contamination of conventional crops by GM crops.
Australian Food and Grocery Council	2	Supported the Application.
Michael, Antoinette and Josephine Beck	1	Did not support the Application. Concerned about the safety of GM food and the labelling of GM food.
J. Carapiet	1	Did not support the Application. Concerned about the: • safety of GM food; • cost of segregation; • contamination of conventional food by GM food; and • lack of independent scientific testing or monitoring.
Helen Chambers	-	Questioned the validity of the long-term research associated with the Application.
Sandy Dobbs	1	Did not support the Application. Concerned about the safety of GM food.
Ecology Design Research Institute	1	Did not support the Application. Concerned about the safety of GM food and considers that there has been insufficient research into the safety of gene technology.
Food Technology Association of Victoria	2	Supported the Application.
GE Free New Zealand in Food and Environment (Claire Bleakley)	1	Did not support the Application. Concerned about the safety of GM food
GE Free New Zealand in Food and Environment (Susie Lees)	1	Did not support the Application. Concerned about the: • safety of GM food; • contamination of conventional food by GM food; and • labelling of food containing GM sugar beet.
GE Free Northland in Food and Environment (Zelak Grammer)	1	Did not support the Application. Concerned about the safety and environmental effects of GM food.

Franz Iseke	1	Did not support the Application. Concerned about the: • safety of GM foods; • cross contamination of GM crops with conventional crops; and • possible increase in the use of herbicides associated with GM crops.
Phillippa Jamieson	1	Did not support the Application. Concerned about: • the safety of GM food; • the labelling of GM food; • possible increase in the use of herbicides associated with GM crops; • contamination of conventional crops by GM crops; and • associated costs of food segregation.
Alexander Janis	1	Did not support the Application. Concerned about the safety of GM foods and the use of herbicides associated with GM crops.
Oraina Jones	1	Did not support the Application. Concerned about the: • safety of GM foods. • costs to farmers who enter into agreement with Monsanto. • labelling provisions for GM foods. Does not agree that consumers would see a financial benefit from purchasing food derived from sugar beet line H7-1.
Fiona Kealy	1	Did not support the Application. Concerned about the safety of GM foods and the use of herbicides associated with GM crops.
Pola Lekstan	1	Did not support the Application. Concerned about the safety of GM foods and the use of herbicides associated with GM crops.
Valerie Morse		Did not support the Application. Concerned about the safety, labelling of, and cost and benefits of GM food.
New Zealand Food Safety Authority	-	Will provide comments on the safety assessment report at the draft assessment stage. Requested that the Draft Assessment Report include a summary of the MRLs for glyphosate for Australia and New Zealand.
H. Penning	1	Did not support the Application. Concerned about the safety of GM foods and the use of herbicides associated with GM crops.
Anita and Jim Reid	1	Did not support the Application. Concerned about the safety of GM foods.
Anna Reid	1	Did not support the Application. Concerned about the: • safety of GM foods; • cross contamination of GM crops with conventional crops; • labelling provisions for GM foods.
Julia Sideris	1	Did not support the Application. Concerned about the safety of GM foods and the use of herbicides associated with GM crops.
Tim and Zee Vallings	1	Did not support the Application. Concerned about the safety of GM foods.

Western Australia Food Advisory Committee	-	The Committee welcomes further summary advice from FSANZ on the safety assessment of food derived from sugar beet line H7-1
Helen Wiseman-Dare	1	Did not support the Application. Concerned about the safety of GM foods.

SECOND ROUND

Submitter	Preferred option	Comments
APC Logistics Pty Ltd (David Graham)	1	Opposed the Application on environmental grounds and concerned about the cross contamination with conventional foods
Erwin Alber	1	Opposed the Application on economic, environmental and health grounds. Concerned about contamination of conventional crops by GM seeds and reduction in consumer choice of food.
Doreen Adams	1	Opposed the Application on environmental grounds and concerned about contamination of conventional crops by GM seeds.
Tom Atkinson	1	Opposed the Application. Concerned about the effects of the potential increased use of glyphosate.
Chris & Maria Aulman	1	Opposed the Application. Concerned about labelling and lack of long-term testing of GM food.
Australian Food and Grocery Council (Downer, Tony)	2	Supported the application
Diana Austring	1	Opposed the Application on environmental grounds.
Graham Bennett	1	Opposed the Application. Concerned about the lack of long-term testing of the safety of/ and labelling of GM food.
Paul Bradley	1	Opposed the Application. Concerned about the lack of long-term independent studies on the safety of GM food.
Lisa Bridson	1	Opposed the Application on environmental and health grounds and the potential of GM crops on the organic food industry.
Kent Briggs	1	Opposed the Application. Concerned about the lack of long-term research on the safety of GM food.
Dayahn Cornelius	1	Opposed the Application
Mona-Lynn Courteau	1	Opposed the Application. Concerned potential damage to the environment, the organic food industry and human health by the introduction of GM plants to New Zealand.
Colin Day	1	Opposed the Application on environmental and health grounds.
Victoria Davis	1	Opposed the Application.
Dept of Human Services Victoria	1	Had no concerns about this Application
Helen Eggers	1	Opposed the Application on environmental and health grounds.
Judy Erasmuson	1	Opposed the Application on bio-ethical and economic grounds.
Jodene Fabian	1	Opposed to the Application. States that public opinion in New Zealand is against the introduction of GM crops, introduction GM foods will affect the choice of foods available and has concerns about the potential of cross contamination with conventional foods.
Food Technology Association of Victoria Inc. (Gill, David)	2	Supported the Application
Ann Fullerton	1	Opposed the Application on environmental grounds.

Genetic Engineering Resource Guide (Charles Drace)		Opposed the Application on health grounds.
William Green	1	Opposed the Application. Wanted to see long term testing of GM foods before they are released.
David Grove	1	Concerned about the ethics of Monsanto, labelling of GM food and effect of GM food on organic food production.
Rob Hanne	1	Opposed to the Application concerned about the lack of long-term independent studies on the safety of GM food and the labelling of GM food.
Annette Hart	1	Opposed the Application.
Julie Hartley	1	Opposed the Application on health and environmental grounds.
Maureen Howard	1	Opposed to the Application. Concerned about the lack of clinical testing of GM food, the labelling of GM food, environmental effects of the use of glyphosate and the patenting of food.
Rita Hunt	1	Opposed the Application.
Hilary Jones	1	Opposed the Application. Concerned about the labelling of GM foods.
Rosie Kaplan	1	Opposed the Application. Concerned about GM foods effect on natural food production.
Martina Keating	1	Opposed the Application.
Janenne Kornfeld	1	Opposed the Application on environmental grounds.
Marlene Laureys	1	Opposed the Application.
Ruth Lawson	1	Opposed the Application health grounds. Considers that public opinion in Australasia is against the introduction of GM food. Concerned about the labelling of foods containing sugar derived from sugar beet line H7-1 and the independent scientific testing of GM food
Lee, Ter, Wal & Associates	1	Opposed the Application on environmental grounds.
Mary McCammon	1	Opposed the introduction of genetically engineered crops into New Zealand. Concerned about the occurrence of allergic reactions.
Ann MaCrae	1	Opposed the Application on environmental grounds.
Mike McCree	1	Opposed the Application. Concerned about the lack of independent safety testing of GM foods.
Shona McKee	1	Opposed the Application. Considers that GM food will contaminate conventional food.
Emily McDowell	1	Opposed the Application.
Wendy McGuinness	1	Opposed the Application on the basis of: • inadequate pre- testing; • lack of genetic stability; • absence of long term feeding studies; and • ineffective separation systems between GM and conventional foods.
Shona McKee	1	Opposed the Application. Concerned about the use of GM ingredients in food.
Mario McMillan	1	Opposed the Application. Concerned long term effects of GM crops. States that there is widespread rejection of GE foodstuffs by consumers.
Mandy McMullin	1	Opposed the Application. Concerned about potential adverse health, environmental and economic effects of GM crops.
Jan Mabey	1	Opposed the Application. Concerned about contamination of conventional plants by GM plants.

Vicki Martin	1	Opposed the Application. Concerned that there are no long-term studies (30 -40 years) of GM foods demonstrating their safety.
Robert Mignault	1	Opposed the Application on health and environmental grounds.
New Zealand Food Safety Authority (Inkster, Carole)	1	Concerned that evidence that inserted DNA may not integrate into the plant genome in such away as to generate un-intended coding regions able to generate novel, unintended proteins was not included in the Draft Safety Assessment Report.
Nicola Owers	1	Opposed the Application based on the safety of GM foods.
Don Paterson	1	Opposed the application on the basis of a GE-free New Zealand and the potential for New Zealand to export GE-free foods.
Fiona Paton	1	Opposed the Application. Concerned about the potential for cross contamination, reduction in consumer choice and the potential damage to the organic food industry in New Zealand.
Anthony Peacocke	1	Opposed the Application on health and environmental grounds.
Jennifer Pearson	1	Opposed the Application.
The Pettinger Family	1	Opposed the Application, unless it can be demonstrated that there is no risk to human health or the environment from material derived from GM beet being present in New Zealand.
Trish Puharich	1	Opposed the Application. Concerned about the labelling of GM food.
Physicians & Scientists 4 Responsible Genetics NZ (Jean Anderson)	2	Opposed the Application health grounds. Concerned that there has been no independent, no long term and peer reviewed studies on the safety of GM food.
Queensland Health	2	Supported the Application.
Tara Ross-Watt	1	Opposed the Application on environmental and quarantine grounds.
Marg Sellers	1	Opposed the Application on health and environmental grounds.
Amanda Semb	1	Opposed the Application. Concerned about the labelling of GM food.
Neil Sloan	1	Opposed the Application. Considers that GM food will contaminate conventional food.
Gillian Somerville	1	Opposed the Application on environmental, economic and health grounds. Concerned about the safety of GM foods, their nutritional and commercial value.
Anita Smith	1	Opposed the Application on environmental grounds. Concerned about the effects use of glyphosate, that there are no long-term studies (10-20 years) of GM food and the labelling GM food.
Hanne Sorensen		Opposed the Application on safety grounds. Concerned that there are no long-term independent studies on the safety of GM food and the labelling of GM food.
Sam Storey		Opposed the Application. Concerned about the potential of cross contamination of GM plants and feeds with conventional crops.
Myles Thomas	1	Opposed the Application on environmental grounds. Concerned about the potential for increased use of glyphosate.

Colin Thomson	1	Opposed to the Application. Concerned about potential adverse effects on health from the consumption of GM food.
Unitec New Zealand (Peter Thompson)	1	Opposed the Application on health and environmental grounds. Concerned about the effects of the potential increased use of glyphosate.
Kevin Tutt	1	Opposed the Application on environmental grounds.
Clare Tyler	1	Opposed the Application on health grounds. Concerned about the nutritional value of GM food.
Walters & Associates (Walters, Grant)	1	Opposed the Application on environmental and health grounds. Concerned about the safety of GM foods and cross contamination.
Liz Westbrooke	1	Opposed the application. Stated that there is no need for GM foods.
Melanie White	1	Opposed the application on health and environmental grounds. Concerned about the safety of GM foods
South Australia Department of Health	2	Supported the application. The issue raised regarding the digestive rate of CPR EPSPS in gastric fluid is adequately covered in the Safety Assessment.