

7-05
5 October 2005

FIRST REVIEW REPORT

APPLICATION A525

**FOOD DERIVED FROM HERBICIDE-TOLERANT
SUGAR BEET LINE H7-1**

1. Introduction

On 15 July 2005, the Australia and New Zealand Food Regulation Ministerial Council requested a first Review of Application A525, which seeks approval of food derived from glyphosate-tolerant sugarbeet line H7-1. Approval of this Application involves a variation to Standard 1.5.2 – Food Produced by Gene Technology, of the *Australia New Zealand Food Standards Code* (the Code).

Following a request for a formal review, FSANZ has 3 months to prepare a response, in this instance, FSANZ is required to review the decision by 15 October 2005.

2. Objectives of Review

The objective of this Review is to reconsider the draft variation to Standard 1.5.2 in light of the Ministerial Council's concerns as outlined in Section 3.

3. Grounds for the review requested by the Ministerial Council

The First Review was requested on the grounds that Application A525 'does not protect public health and safety' and 'does not provide adequate information to enable informed choice'. No specific reasons were given.

4. Issues addressed in First Review

The issues raised by the Ministerial Council in this First Review have been addressed by the measures adopted at Final Assessment, which were re-affirmed at First Review, these are summarised in the following table:

Ministerial Council issue	Measures taken at Final Assessment	Additional measures at First Review
<ul style="list-style-type: none">• Protection of public health and safety	<ul style="list-style-type: none">• FSANZ carried out a full safety assessment and was satisfied that sugarbeet line H7-1 was safe for human consumption, and is not a public health and safety concern.• As for all GM applications, FSANZ called for two rounds of public comments; there were no specific concerns with the public health and safety of sugarbeet line H7-1.	FSANZ reviewed the safety assessment report of Food Derived From Glyphosate-Tolerant Sugar beet Line H7-1 and concluded that all the criteria requested in FSANZ's Guidelines for GM Applications had been satisfied and that no further data was required.
<ul style="list-style-type: none">• Inadequate information to enable informed choice	<ul style="list-style-type: none">• Labelling of GM foods provides information to enable informed choice. Under the labelling regulations of GM foods in Standard 1.5.2, if novel DNA and/or protein were found in the final food then labelling would be required. However, no novel DNA or protein were present in refined sugars derived from sugarbeet line H7-1, and so labelling was not required.	FSANZ re-affirms that labelling is not required on food derived from a GM crop that does not contain novel DNA and/or protein.

5. Review Options

There are three options proposed for consideration under this Review:

1. re-affirm approval of the draft variation to Standard 1.5.2 of the Code as notified to the Council; or
2. re-affirm approval of the draft variation to Standard 1.5.2 of the Code subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the draft variation to Standard 1.5.2 of the Code as notified to the Council.

No additional data has been presented to the Board to justify consideration of Options 2 and 3.

The recommended option is Option 1.

6. The Decision

FSANZ gives approval for the use and sale of food derived from sugar beet line H7-1. This reaffirms the approval of the draft variation to Standard 1.5.2 of the Code to give effect to this decision.

6.1 Statement of Reasons

An amendment to Standard 1.5.2 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 Standard 1.5.2 is of net benefit to both food producers and consumers; and
- the proposed draft variation to Standard 1.5.2 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**.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*.
2. Summary and Conclusions from the Final Assessment Report

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
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SUMMARY AND CONCLUSIONS FROM THE FINAL ASSESSMENT REPORT

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 (beet, 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.