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[24–13]

Approval Report – Application A1081

Food derived from Herbicide-tolerant Soybean Line SYHT0H2

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Pty Ltd and Syngenta Seeds Pty Ltd seeking permission for food derived from soybean line SYHT0H2, which is genetically modified to provide tolerance to the herbicide glufosinate-ammonium and to herbicides, specifically mesotrione, that inhibit *p*-hydroxyphenylpyruvate dioxygenase (HPPD).

On 12 July 2013, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received 53 submissions.

FSANZ approved the draft variation to the Standard on 5 December 2013. The COAG Legislative and Governance Forum on Food Regulation¹ (the Forum) was notified of FSANZ's decision on 18 December 2013.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting document

The following document used to prepare this Report is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/a1081foodderivedfrom5825.aspx>

SD1 Safety Assessment (at Approval)

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Bayer CropScience Pty Ltd and Syngenta Seeds Pty Ltd on 29 January 2013. The Applicants requested a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to permit the sale and use of food derived from genetically modified (GM) soybean line SYHT0H2, conferring tolerance to two herbicides.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment is central to considering an application.

The safety assessment of soybean line SYHT0H2 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided in the present Application, and other available information, food derived from soybean line SYHT0H2 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant soybean line SYHT0H2 in the Schedule.

2. Introduction

2.1 The Applicants

Bayer CropScience Pty Ltd is a subsidiary of Bayer AG. Both Bayer CropScience and Syngenta Seeds Pty Ltd are technology providers to the agricultural and food industries.

2.2 The Application

Application A1081 was submitted by Bayer CropScience Pty Ltd and Syngenta Seeds Pty Ltd on 29 January 2013. It sought approval for food derived from line SYHT0H2 under Standard 1.5.2 – Food produced using Gene Technology.

Soybean line SYHT0H2 is tolerant to two herbicides, namely glufosinate-ammonium and mesotrione. Tolerance to glufosinate ammonium is achieved through expression of the enzyme phosphinothricin acetyltransferase (PAT) encoded by a *pat* gene obtained from the soil bacterium *Streptomyces viridochromogenes*. Tolerance to mesotrione is achieved through expression of the AvHPPD-03 protein encoded by the *avhppd-03* gene from oat (*Avena sativa*).

The *pat* gene has been widely used for genetic modification of a number of crop species, including soybean. An HPPD protein has been previously assessed by FSANZ in Application A1051 where it was used to confer tolerance in soybean to isoxazole herbicides.

2.3 The current Standard

Pre-market approval is necessary before food derived from any genetically modified (GM) line may enter the Australian and New Zealand food supply. Approval of GM foods under Standard 1.5.2 is contingent on completion of a comprehensive pre-market safety assessment. Foods that have been assessed under the Standard, if approved, are listed in the Schedule to the Standard.

Standard 1.5.2 contains specific labelling provisions for approved GM foods. GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words 'genetically modified', if novel DNA or novel protein from an approved GM variety is present in the final food, or the food has altered characteristics. In the latter case, the Standard also allows for additional labelling about the nature of the altered characteristics.

2.4 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

2.6 Decision

The draft variation to Standard 1.5.2, as proposed following assessment, was approved without change.

The approved variation to the Standard is at Attachment A.

An Explanatory Statement is at Attachment B.

3. Summary of the findings

3.1 Risk assessment

The safety assessment of soybean line SYHT0H2 is provided in the supporting document (SD1) and included the following key elements:

- a characterisation of the transferred genes, their origin, function and stability in the soybean genome
- the changes at the level of DNA and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of soybean line SYHT0H2 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production, or any risks to animals that may consume feed derived from GM plants.

No potential public health and safety concerns have been identified. Based on the scientific data provided in the present Application, and other available information, food derived from soybean line SYHT0H2 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

3.2 Risk management

3.2.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2, food derived from soybean line SYHT0H2 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein, or has altered characteristics. Food from SYHT0H2 does not have altered characteristics.

Soybean SYHT0H2 is intended primarily for use as a broad-acre commodity (field soybean) to produce products derived from cracked soybeans, and is not intended for vegetable or garden purposes where food-grade products may include tofu, soybean sprouts, soy milk, and green soybean (e.g. edamame). This latter type of soybean generally has a different size, flavour and texture to field soybean.

The main food product from field soybean is refined oil. Processing during production means novel protein and novel DNA are not likely to be present in the oil; in the absence of novel protein and novel DNA, refined oil from soybean line SYHT0H2 would be exempt from labelling under paragraph 4(1)(c) of Standard 1.5.2. Other products such as protein concentrate, protein isolate and textured flour are likely to contain novel protein and/or novel DNA and if so, would require labelling.

3.2.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee - Implementation Sub-Committee² to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications.

The EAG has indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA is sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicants for SYHT0H2 to satisfy the requirement for detection methodology in the FSANZ *Application Handbook* (FSANZ, 2011).

3.2.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions. Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Public submissions were invited on a draft variation which was released for public comment between 12 July and 6 September 2013. Fifty-three submissions were received, of which two did not object to the proposed variation and two supported the proposed variation. Twenty-eight submissions were closely based on a campaign letter (designated Campaign1) circulated by the Truefood Network³ and The Safe Food Foundation⁴ on 15 July 2013. A campaign letter of unknown origin (designated Campaign2) and with a smaller following (seven submitters) was also received. Eleven submissions objecting to the approval of food derived from SYHT0H2 were received from private, independent submitters and three submissions objecting to the approval were received from non-government organisations.

The FSANZ safety assessment considers only the safety of GM food for human consumption. Some submissions raised issues about: public perception of GM food; maintaining a GM-free trade status, public perception of biotech developers; feeding animals GM feed; alternative technologies, and issues to do with the sustainability and growing of GM crops. Consideration of these issues is outside FSANZ's regulatory authority which deals primarily with the safety of food that is consumed.

Environmental issues related to the growing of GM crops and any possible effects on the environment are considered in Australia by the Office of the Gene Technology Regulator, and in New Zealand by the Environmental Protection Authority.

² Now known as the Implementation Subcommittee for Food Regulation

³ (<https://www.facebook.com/TruefoodNetwork/posts/10151547780856299>)

⁴ (<https://www.facebook.com/safefoodfoundation/posts/532736996791527>)

As a result of comments received, minor changes in the wording of some areas of the safety assessment have been made to improve clarity or address typographical errors.

3.2.3.1 General issues

Responses to seven general issues raised or implied, are provided in Table 1.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Concern with the safety of all GM food	<ul style="list-style-type: none"> • Campaign2 • Physicians & Scientists for Global Responsibility • Caroline Davies • Michelle Denise • Hugh Halliday • Fernando Longo • Claire McFee • Michael McLaren • Biddy Myers • Elizabeth Stewart • John Sutcliffe • Helen Weir 	<p>The approach used by FSANZ to assess the safety of GM food is based on core principles developed almost 20 years ago and published as guidelines by the Codex Alimentarius Commission (Codex, 2003; Codex, 2004). Over time, the assessment protocol has been the subject of scientific scrutiny, however it has proved to be a robust approach for whole food safety assessments. It is widely adopted and implemented around the world. While philosophical opposition to the technology remains, consumers can be confident that GM foods assessed under the protocol and approved for food use are as safe as their conventional counterparts.</p> <p>Studies cited as evidence of safety concerns with certain GM foods have been examined by FSANZ and other scientific experts around the world. The studies have been subject to significant scientific criticism and generally are not supported. Responses to several recent publications are available on the FSANZ website (http://www.foodstandards.gov.au/consumer/gmfood/adverser/Pages/default.aspx).</p>
The conduct of the FSANZ safety assessment	<ul style="list-style-type: none"> • Claire McFee • Hugh Halliday • Biddy Myers • GE Free NZ • Gene Ethics 	<p>The conduct of all FSANZ GM safety assessments is subject to an approach outlined in a Guidance Document (FSANZ, 2007). The data requirements to support this approach are provided in the FSANZ <i>Application Handbook</i> (FSANZ, 2011).</p> <p>A detailed description of the process used by FSANZ for the safety assessment of GM foods is available on the FSANZ website at http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx</p> <p>In 2008, an external review of the FSANZ GM food safety assessment procedure was undertaken and identified a number of strengths (see FSANZ website at http://www.foodstandards.gov.au/consumer/gmfood/Pages/reviueofgeneticallym4394.aspx</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Labelling of GM food	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility • Michael McLaren 	<p>Only those GM foods assessed by FSANZ as safe are approved for sale. Labelling of approved GM food allows consumers to make a meaningful and informed choice about the food they purchase. The labelling requirements for GM foods are set out in Standard 1.5.2 (http://www.comlaw.gov.au/Series/F2008B00628).</p> <p>Various other documents are available on the FSANZ website explaining the labelling requirements for GM foods. Links to these documents are provided below.</p> <p>Labelling of GM Foods http://www.foodstandards.gov.au/consumer/gmfood/labelling/pages/default.aspx</p> <p>GM Labelling Review Report http://www.foodstandards.gov.au/newsroom/publications/gmlabellingreviewrep2460.cfm</p>
General concern with the spraying/use of herbicides	<ul style="list-style-type: none"> • Campaign1 • Physicians & Scientists for Global Responsibility • M McLaren • L.H. Worsley (Note this submitter was concerned about the use of glyphosate, which is not associated with A1081). 	<p>The use of agricultural and veterinary chemicals is subject to strict government regulation in most trading countries. In Australia and New Zealand, residues of agricultural and veterinary chemicals are prohibited in food (both GM and non-GM) unless they comply with specific limits referred to as Maximum Residue Limits (MRLs). The setting of MRLs ensures that residues of agricultural and veterinary chemicals are kept as low as possible and consistent with the approved use of chemical products to control pests and diseases of plants and animals. For further details see the FSANZ website at http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx</p> <p>MRLs are entered into the Schedule in Standard 1.4.2 Maximum Residue Limits in the Code, and apply to the listed food commodity, regardless of whether it is a conventional or GM crop.</p> <p>While the use of a particular herbicide on a tolerant crop typically results in a different pattern of usage of that herbicide compared with conventional crops, it does not necessarily result in any significant change in residues.</p>
Horizontal gene transfer to gut bacteria and safety of ingesting recombinant DNA	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility 	<p>There is no indication that novel genetic material in food will have an impact on human health. This issue has been considered in detail by FSANZ and a summary is available on the FSANZ website http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>Allergies, including food allergies, have increased by epidemic proportions and this may be due to ingestion of GM foods.</p>	<ul style="list-style-type: none"> Physicians & Scientists for Global Responsibility 	<p>While this is often cited as a concern by submitters, clinical allergy experts and those involved in the study of allergy generally do not regard this as a serious hypothesis.</p> <p>The increased prevalence of allergies in people eating Western diets is attributed to major allergens already in the food supply – milk, eggs and tree nuts, particularly peanuts (Mullins, 2007). These commonly allergenic foods are not associated with GM commodities. There is no credible scientific basis to support the notion that food allergies are linked to the introduction of GM crops.</p> <p>The evaluation of newly expressed proteins for potential allergenicity is an integral part of the safety assessment of any GM food. This procedure is designed to identify and screen out any newly expressed protein that is found to raise an allergy concern.</p>
<p>Lack of consideration of long term/feeding studies in the safety assessment</p>	<ul style="list-style-type: none"> Campaign2 Physicians & Scientists for Global Responsibility GE Free NZ Claire McFee 	<p>Many experts in toxicology consider that animal feeding studies with GM foods are difficult to design with adequate scientific integrity and, because of concerns about the unethical use of animals, cannot be justified (Bartholomaeus <i>et al.</i>, 2013; Rigaud, 2008).</p> <p>In 2007, FSANZ convened a workshop to formally examine the usefulness of animal feeding studies to support the safety assessment of GM foods (http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx). The conclusion was that such studies do not contribute meaningful information on the long-term safety of a GM food, with the possible exception of a food in which the modification introduced a desired nutritional change. In these limited cases, the altered nutritional profile of the food may lend itself to investigation in animal diets, or in human volunteers. However, the majority of GM crops with agronomic traits have the same nutritional profile as conventional foods.</p> <p>Recent publications (Séralini <i>et al</i>, Carman <i>et al</i>)⁵ have claimed to show evidence of harm in animals fed GM food. However, assessment of these studies by FSANZ and others indicates these claims are not supported by the data presented by the researchers. In late November 2013, the Séralini <i>et al</i> paper was retracted by the publishing journal on the grounds of poor study design (http://www.prnewswire.co.uk/news-releases/elsevier-announces-article-retraction-from-journal-food-and-chemical-toxicology-233754961.html).</p> <p>FSANZ has published a scientific appraisal of a number of studies claiming to show adverse effects in animals fed GM feed (see http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Dr-Carman's-study.aspx ; http://www.foodstandards.gov.au/consumer/gmfood/seralini/Pages/default.aspx)</p>

⁵ Séralini, G.-E.; Clair, E.; Mesnage, R.; Gress, S.; Defarge, N.; Malatesta, M.; Hennequin, D.; Spiroux de Vendemois, J. (2012). Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically-modified maize. *Food and Chemical Toxicology* 50: 4221 – 4231.

Carman, J.A., Vlieger, H.R., Ver Steeg, L.J., Sneller, V.E., Robinson, G.W., Clinch-Jones, C.A., Haynes, J.I. and Edwards, J.W. (2013) A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. *Journal of Organic Systems* 8(1):38-54.

3.2.3.2 Specific issues raised

Issue 1 – Labelling confusion

The Food Technology Association of Australia commented that it was difficult to reconcile the information in Section 3.2.5.2 of the Call for Submissions that *the main food product from field soybean (such as SYHT0H2) is refined oil...and therefore it is unlikely to require labelling* with the comment under Section 3.2.1.1 that states *Appropriate labelling would allow consumers wishing to avoid certain GM soybean products to do so*. In their view, these comments were contradictory and they noted paragraph 4(1)(c) provides the current labelling exemption.

Response

In Australia and New Zealand, GM labelling requirements are based on foods that contain novel DNA and/or novel protein (GM material), or if the food has altered characteristics. Foods which are produced using GM processes but do not contain any GM material in the final food (and have no altered characteristics) are analytically indistinguishable from their conventional counterpart. This regulatory approach has been taken to ensure that GM labelling is both meaningful to consumers and practical for enforcement purposes.

Under paragraph 4(1)(c) of Standard 1.5.2, the labelling exemption for highly refined food, in this case refined oil from soybean line SYHT0H2, only applies when the refining process has removed all GM material. The onus is on the supplier to determine whether GM material is present in the final food and if so, to apply the mandatory 'genetically modified' labelling statement.

In the statement "*Appropriate labelling would allow consumers wishing to avoid certain GM soybean products*", the use of 'certain' indicated those GM soybean products that contain novel DNA or novel protein and therefore carry the mandatory labelling statement. The wording has been altered slightly in Section 4.1.1 of this Approval Report to avoid confusion.

Issue 2 – Acute oral toxicity study

Ms Claire McFee was concerned the acute 'oral toxicity study' that was done was not included so this could be publicly assessed. GE Free NZ maintains that a toxicity study should be considered.

Response

The FSANZ *Application Handbook* states there is no requirement to conduct acute or short-term oral toxicity studies in animals unless the bioinformatic comparison or biochemical studies indicate a potential safety issue. As stated in the A1081 safety assessment, an acute oral toxicity study in mice, using bacterially-produced AvHPPD-03 protein was submitted by the Applicants but was not included in the safety assessment since no safety concerns were identified in any of the other studies. It is noted that this study indicated there was no evidence of toxicity resulting from oral administration of the protein.

Anyone may request to see any of the studies submitted by an Applicant and for A1081 these studies are now available on the FSANZ website.⁶

⁶ <http://www.foodstandards.gov.au/code/applications/Pages/a1081foodderivedfrom5825.aspx>

Issue 3 – Compositional equivalence

GE Free NZ raised the following issues: ‘*Compositional equivalence*’ that is similar to “*substantial equivalence*” and is a new term (biological significance) not seen before and we do not know what it means. Please could you clarify? Specifically, if there are no feeding studies conducted on mammals/humans how did FSANZ deduce that there were no effects of “*biological significance*”?

Response

The concept of ‘substantial equivalence’ was first established through a Joint FAO/WHO Consultation in 1991 (FAO/WHO, 1991) and was then further elaborated by the OECD (OECD, 1993). Implicit in its meaning is that the safety of GM foods can be assessed, to a large extent, by comparison to a conventional counterpart having a history of safe use. The GM safety assessment comprises a number of parts (e.g. molecular characterisation, assessment of novel proteins, compositional analysis) in which this comparative approach is used. It should be noted that FSANZ does not routinely use either the term ‘substantial equivalence’ or ‘compositional equivalence’ in any of its safety assessments.

The main purpose of the compositional analysis is to determine if any unexpected changes in the composition of the food have occurred (by comparison to a conventional counterpart) and to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health. The levels of various constituents in the GM food are compared to the levels in an appropriate comparator using appropriate statistical analysis, as well as to levels in a number of non-GM lines (reference lines) grown in the same locations at the same time. Any identified statistically significant differences are then assessed to determine their biological relevance/significance.

This can usually be determined by comparing the measured level for the particular constituent against the levels typically found in the food in question.

If the measured level is consistent with that normally found in food then the fact that it may be higher or lower than the level for that constituent in the control will be of no biological consequence to humans, given the variation that already exists in our diet. Should the level of a particular constituent fall outside the range of natural variation, then further assessment may be necessary to determine if it raises a safety or nutritional concern. The type of information required to inform that assessment would have to be determined on a case-by-case basis, taking into account the nature of the constituent, and what is already known about its safety.

Issue 4 – Criticism of the 28 unpublished studies submitted by the Applicants

Mr Bob Phelps (representing Gene Ethics) made a detailed submission in which he provided a review of each of the studies submitted by the Applicants. Mr Phelps was critical of the use of unpublished studies prepared by the Applicants and concluded that FSANZ would not be able to reach any conclusions about the safety of food derived from line SYHT0H2 because, in general, the studies lacked:

- any statement of the goals of the study (in terms of risks, hazards and safety)
- quantification or justification of sample size
- statistical analysis
- tests of significant differences between treatments
- suitable controls
- reasons why data were rejected.

Mr Phelps did not comment on the FSANZ safety assessment or of the conclusions reached by FSANZ in its discussion of the data supplied by the Applicants.

Response

It is the responsibility of an Applicant to demonstrate the safety of the food and to supply FSANZ with the raw data from scientific studies in accordance with the data requirements in the *Application Handbook* (FSANZ, 2011) (see also discussion in point 2 of Table 1). This procedure is consistent with that used to evaluate the safety of new chemicals and drugs and is standard practice for all regulatory agencies around the world. FSANZ experts review the scientific information and form their own conclusions from the results of the studies. FSANZ can, and does, request companies to undertake additional studies, where necessary. In addition, FSANZ complements the company data with information from the scientific literature, other applications and other government agencies.

While relevant peer-reviewed published studies and other sources of information, if available and of good quality, can be used to inform the safety assessment, they are not a substitute for company-supplied studies on the GM line of interest as they rarely address all the issues that are necessary to complete a safety assessment.

The following points are made in relation to the concerns raised by Mr Phelps:

- The studies supplied by an Applicant are those required by FSANZ in order to conduct a safety assessment. Implicit in the requirement is that each study will provide the necessary information to assist in the identification of any potential hazards.
- As stated in the *Application Handbook*, all company-supplied studies must be adequately designed, conducted and documented in a manner that is consistent with the principles and practices of Good Laboratory Practice. This enables FSANZ scientists to be confident about the integrity of the study and to undertake an independent review of the data.

Mr Phelps was critical, for example, of an acute oral toxicity study that used 10 animals while the published study of S eralini *et al* (2012)⁷ was criticised for using groups of 10 animals. The acute oral toxicity study was carried out in accordance with the relevant OECD Guideline (OECD, 2001). Such a study is designed to test the hazardous properties of a single chemical following a single dose. The study done by S eralini *et al.* was not an acute toxicity study therefore direct comparison of the study design is inappropriate.

- In many cases, especially in the more ‘descriptive’ studies of which Mr Phelps is critical (e.g. insert and flanking sequence analysis, Southern blot analyses, genetic stability, method for event-specific detection, comparison of microbially- and plant-produced proteins), it is not appropriate, or sometimes not even possible, to supply a statistical analysis. Where appropriate, the Applicants’ studies reported the statistical analysis used and the probabilities obtained.

In some instances (e.g. compositional analyses and bioinformatic analyses) the statistical significance of a result needs to be placed in a biological context (see e.g. discussion in *Issue 3 Response*). In all cases, the statistical methods used were consistent with the objective of the study.

⁷ S eralini, G.-E.; Clair, E.; Mesnage, R.; Gress, S.; Defarge, N.; Malatesta, M.; Hennequin, D.; Spiroux de Vendemois, J. (2012). Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically-modified maize. *Food and Chemical Toxicology* 50: 4221 – 4231.

- In FSANZ's opinion, based on a knowledge of the controls required in the wide range of experimental methods used to provide supporting data, appropriate controls were used in the studies where controls were required. Some methodologies (e.g. bioinformatic analyses) do not require controls and are based on well-developed and accepted protocols.
- Mr Phelps is concerned that data were "rejected" in cases where, for example, 'three colonies were randomly chosen' or 'extractions were performed on representative aliquots'. The wording used by the Applicants does not imply that a conscious selection of some data and rejection of other data was made, i.e. the Applicants clearly made an unbiased selection of samples in those cases where it was not logistically possible to analyse every sample.

The Applicants for A1081 met all of the data requirements stipulated in the *Application Handbook* (FSANZ, 2011) for the safety assessment of GM food and, upon assessment of these data, FSANZ is satisfied that sufficient evidence has been provided to demonstrate the safety of the food.

Issue 5 – addressing s50 of the Act

GE Free NZ indicated that the information to satisfy section 50 (i)(ii)(iii) was not available to FSANZ.

Response

Section 50 of the Act refers specifically to procedures for variations to nutrition, health and related claims and so is not relevant to Application A1081. It is noted that the three subsections of s50 refer to the same objectives given in s18(1) of the Act and that s18 must be considered by FSANZ for an Application (such as A1081) to vary a Standard. These objectives are specifically addressed in Section 4.2 of this Approval Report.

3.3 Risk communication

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, *Food Standards News*. Subscribers and interested parties were also notified.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Application A1081, including submissions received, is available on the FSANZ website.

4. Reasons for decision

The variation to the Code to permit the sale and use of food derived from herbicide-tolerant soybean line SYHT0H2 in Australia and New Zealand was approved based on available evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce soybean line SYHT0H2.

- Food derived from soybean line SYHT0H2 is equivalent to that derived from the conventional counterpart and other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from soybean line SYHT0H2 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.
- There were no measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

4.1 Section 29

FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application
- any relevant New Zealand standards
- any other relevant matters.

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010 (reference 12065), provided an exemption from the need of the OBPR to be informed about GM food applications made to FSANZ.

4.1.1 Cost/benefit analysis

A consideration of the cost/benefit of approving the draft variation is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

The points below list the effect that approving the draft would be expected to have on various sectors.

Consumers: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line SYHT0H2.

For those soybean line SYHT0H2 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid them to do so.

Government: Benefit that if soybean line SYHT0H2 was detected in soybean imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

If soybean SYHT0H2 is approved for commercial growing in overseas countries it can be used in the manufacture of products using co-mingled soybean. This means that there would be no cost involved in having to exclude SYHT0H2 from co-mingling and hence that there would be no consequential need to increase the prices of imported foods that are manufactured using comingled soybean products.

Approval of soybean line SYHT0H2 would ensure no conflict with WTO responsibilities.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply. The costs of monitoring are thus expected to be comparable, whether a GM food is approved or not.

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from soybean line SYHT0H2 would be compliant with the Code, allowing broader market access and increased choice in raw materials.

Retailers may be able to offer a broader range of soybean products or imported foods manufactured using soybean derivatives.

Possible cost to food industry as some food ingredients derived from soybean line SYHT0H2 may be required to be labelled.

As food from soybean line SYHT0H2 has been found to be as safe as food from conventional cultivars of soybean, not preparing a draft variation would offer little benefit to consumers, as approval of soybean line SYHT0H2 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets.

In addition, this option would result in the requirement for segregation of any products containing soybean line SYHT0H2 from those containing approved soybean lines which would be likely to increase the costs of imported soybean-derived foods.

Also, not preparing a draft variation is likely to be inconsistent with Australia's and New Zealand's WTO obligations if soybean SYHT0H2 is approved for commercial growing in other countries.

Based on the conclusions of the safety assessments, the potential benefits of approving the variation outweighed the potential costs.

4.1.2 Other measures

There were no measures that could achieve the same result other than an amendment to Standard 1.5.2.

4.1.3 Relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

4.1.4 Any other relevant matters

The Applicants have submitted applications for regulatory approval of SYHT0H2 to a number of other countries, as listed in Table 1. To date, none has been finalised.

Table 1: List of countries to whom applications for regulatory approval of soybean line SYHT0H2 have been submitted

Country	Agency	Submitted
USA	United States Department of Agriculture	31-Jul-12
	Food and Drug Administration (Food)	28-Aug-12
Canada	Food Inspection Agency (Environment)	17-Aug-12
	Food Inspection Agency (Animal Feed)	30-Aug-12
	Health Canada (Food)	30-Aug-12
EU	European Food Safety Authority (Import)	31-Jul-12
Japan	Ministry of Health, Labor, and Welfare (Food)	27-Sep-12
	Ministry of Agriculture, Forestry and Fisheries (Feed)	1-Mar-13
Korea	Ministry of Food and Drug Safety (Formerly Korea Food and Drug Administration)	26-Sep-12
	National Fisheries Research & Development Institute	26-Sep-12
	National Inst. of Environmental Research	26-Sep-12
	Korea Center for Disease Control	28-Sep-12
	Rural Development Administration (Env)	28-Sep-12
Taiwan	Food and Drug Administration (Food)	27-Sep-12
South Africa	Agriculture, Forestry and Fisheries (Import)	30-Nov-12
Argentina	Secretariat of Agriculture, Livestock, Fisheries and Food (Food and Feed)	9-Nov-12
	National Advisory Commission on Agricultural Biotechnology (Cultivation)	1-Mar-13
Russia	Food (inc Belarus and Kazakhstan)	26-Apr-13
	Feed	26-Apr-13
Switzerland	Food	23-Jul-13
	Feed	23-Jul-13

The Applicants have indicated they intend to submit applications to a number of other countries such as Colombia, Singapore, Malaysia, Mexico, Philippines, Indonesia, Thailand and China for various regulatory approvals.

It is the Applicants' intention that soybean line SYHT0H2 be commercially cultivated predominantly in North America. There is currently no intention to apply for approval to cultivate this line in either Australia or New Zealand. Such cultivation in Australia or New Zealand would require a separate independent assessment by the Office of the Gene Technology Regulator in Australia and the Environmental Protection Authority in New Zealand, before commercial release in either country could be permitted.

4.2 Addressing FSANZ's objectives for standards setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.2.1 Protection of public health and safety

Food derived from soybean line SYHT0H2 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007).

No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicants, food derived from soybean line SYHT0H2 is considered as safe and wholesome as food derived from other commercial soybean cultivars.

4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

In accordance with existing labelling provisions, food derived from soybean line SYHT0H2 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 3.2.1).

4.2.3 The prevention of misleading or deceptive conduct

The requirement for detection methodology (see Section 3.2.2) is designed to address this objective.

4.2.4 Subsection 18(2) considerations

FSANZ has also had regard to the objectives set out in subsection 18(2):

- *The need for standards to be based on risk analysis using the best available scientific evidence*

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004). Based on these principles, the risk analysis undertaken for soybean SYHT0H2 used the best scientific evidence available. The Applicants submitted to FSANZ, a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicants, other available resource material including published scientific literature and general technical information was used in the safety assessment.

- *The promotion of consistency between domestic and international food standards*

This is not a consideration as there are no relevant international standards.

- *The desirability of an efficient and internationally competitive food industry*

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for the production of foods. Soybean line SYHT0H2 is a new food crop designed to provide growers in a number of countries around the world with an alternative weed management strategy.

- *The promotion of fair trading in food*

The cost/benefit analysis in Section 4.1 lists a number of considerations that address fair trading with respect to soybean line SYHT0H2.

- *Any written policy guidelines formulated by the Ministerial Council*

No specific policy guidelines have been developed since Standard 1.5.2 commenced.

4.3 Implementation

The variation will take effect on gazettal.

5. References

Bartholomaeus, A., Parrott, W., Bondy, G. and Walker, K. (2013) The use of whole food animal studies in the safety assessment of genetically modified crops: Limitations and recommendations. *Critical Reviews in Toxicology* 43(S2):1-24.

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FAO/WHO (1991) *Report of a joint FAO/WHO consultation: strategies for assessing the safety of food processed by biotechnology*. World Health Organisation, Geneva.
www.who.int/foodsafety/publications/biotech/en/1990.pdf.

FSANZ (2007) *Safety assessment of genetically modified foods – Guidance document*. Document prepared by Food Standards Australia New Zealand.
http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf.

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<http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm>.

Mullins, R.J. (2007) Paediatric food allergy trends in a community-based specialist allergy practice, 1995-2006. *Medical Journal of Australia* 186(12):618-621.

OECD (1993) *Safety evaluation of foods derived by modern biotechnology: Concepts and principles*. Organisation for Economic Co-operation and development, Paris.

OECD (2001) *Test No. 420: Acute Oral Toxicity - Fixed Dose Procedure*. OECD Guidelines for the Testing of Chemicals / Section 4: Health Effects. Organisation for Economic Co-operation and Development.

Rigaud, N. (2008) *Biotechnology: ethical and social debates*. OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda". <http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926844.pdf>.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1081 – Food derived from Herbicide-tolerant Soybean Line SYHT0H2) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1081 – Food derived from Herbicide-tolerant Soybean Line SYHT0H2) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

[1] Standard 1.5.2 is varied by inserting in numerical order in the Schedule

“

	7.14	Food derived from herbicide-tolerant soybean line SYHT0H2	
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Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).⁸

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1081 which seeks permission for the sale and use of food derived from herbicide-tolerant soybean line SYHT0H2. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved the variation to Standard 1.5.2.

Following consideration by COAG Legislative and Governance Forum on Food Regulation⁸, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

As it is not listed in the Schedule to Standard 1.5.2, food derived from soybean line SYHT0H2 is not currently permitted for sale or use in food. This variation permits the sale, or use in food, of food derived from soybean line SYHT0H2.

3. Documents incorporated by reference

This variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1081 included one round of public consultation following an assessment and the preparation of a draft variation to the Standard and associated report. Submissions were called for on 12 July 2013 for an eight-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.5.2 is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

⁸ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

This item adds food derived from soybean line SYHT0H2 to the Schedule to Standard 1.5.2.