

**28 August 2014**  
**[17–14]**

Approval Report – Application A1094

Food derived from Herbicide-tolerant Cotton Line DAS-81910-7

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Dow AgroSciences Australia Ltd seeking permission for food derived from cotton line DAS-81910-7, which is genetically modified to provide tolerance to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and glufosinate ammonium.

On 18 March 2014, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received 12 submissions.

FSANZ approved the draft variation to the Standard on 13 August 2014. The Australia and New Zealand Ministerial Forum on Food Regulation<sup>1</sup> (Forum) was notified of FSANZ's decision on 27 August 2014.

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

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<sup>1</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

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## Supporting document

The following document, which informed the assessment of this Application, is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/A1094-GM-Cotton.aspx>

SD1 Safety Assessment: Application A1094 – Food derived from Herbicide-tolerant Cotton Line DAS-81910-7

## Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Dow AgroSciences Australia Ltd on 15 November 2013. The Applicant 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) cotton line DAS-81910-7, that is tolerant to the two herbicides 2,4-dichlorophenoxyacetic acid and glufosinate ammonium.

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 a central part of considering an application.

The safety assessment of herbicide-tolerant cotton line DAS-81910-7 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 herbicide-tolerant cotton line DAS-81910-7 is considered to be as safe for human consumption as food derived from conventional cotton cultivars.

The FSANZ Board has approved the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant cotton line DAS-81910-7 in the Schedule.

# 1 Introduction

## 1.1 The Applicant

Dow AgroSciences Australia Pty Ltd is a wholly-owned subsidiary of the Dow Chemical Company and is a technology provider to the agricultural and food industries.

## 1.2 The Application

Application A1094 was submitted by Dow AgroSciences Australia Ltd on 15 November 2013. It sought approval for food derived from herbicide-tolerant cotton line DAS-81910-7 (also referred to as cotton line 81910) under Standard 1.5.2 – Food produced using Gene Technology.

Cotton line 81910 is tolerant to two herbicides 2,4-dichlorophenoxyacetic acid (2,4-D), and glufosinate ammonium. Tolerance to 2,4-D is achieved through expression of the enzyme aryloxyalkanoatedioxygenase-12 (AAD-12) encoded by the *aad-12* gene derived from the soil bacterium *Delftia acidovorans*. Tolerance to glufosinate ammonium is achieved through expression of the enzyme phosphinothricin acetyltransferase (PAT) encoded by the *pat* gene derived from another soil bacterium *Streptomyces viridochromogenes*.

## 1.3 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.

## 1.4 Reasons for accepting the Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- 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.

## 1.5 Procedure for assessment

The Application was assessed under the General Procedure.

## 1.6 Decision

The draft variation to Standard 1.5.2, as proposed following assessment, was approved without change. The variation takes effect in Australia on gazettal and in New Zealand 28 days after gazettal.

The approved draft variation to the Standard is at Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

#### 2.1.1. General issues

The FSANZ safety assessment considers only the safety of GM food for human consumption. Twelve submissions were received. Issues to do with 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.

Responses to nine general issues raised or implied, are provided in Table 1. Two minor typographical errors have been corrected in the SD1.

**Table 1: Summary of general issues raised in submissions**

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<b>Concern with the safety of GM food</b>	FOODwatch Physicians & Scientists for Global Responsibility (PSGR) Nina Camffermann Chris Schraa	<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 (<a href="http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx</a>).</p> <p>For almost two decades, government regulatory agencies around the world have continued to monitor the safety of GM foods. The scientific evidence overwhelmingly confirms that there are no health and safety issues associated with consumption of GM foods.</p>
<b>Horizontal gene transfer to gut bacteria and safety of ingesting recombinant DNA</b>	<ul style="list-style-type: none"> <li>• PSGR</li> </ul>	<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 - <a href="http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx</a></p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p><b>General concern with the use of herbicides</b></p>	<p>Hugh Halliday FOODwatch Kylie Tizard Shirley Collins</p>	<p>FSANZ does not have responsibility for assessing the environmental impacts or safe handling/use of a herbicide, other than in the context of a consideration of any food products that may be derived from a crop sprayed with a herbicide.</p> <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) - overseen in Australia by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and in New Zealand by the Ministry for Primary Industries. 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 (<a href="http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx</a>).</p> <p>In undertaking a risk-based assessment to support an MRL, the key issue is whether, in the context of the Australian/New Zealand diet, the consumption of chemical residues in a food remains below the health-based guidance values. Herbicide MRLs themselves are not food safety limits. They specify the amount of permitted residue remaining in a harvested crop after the minimum amount of herbicide has been applied to control weed growth. Exceeding an established MRL is unusual but it does not necessarily make a food unsafe because the level that is set (and regularly reviewed to take into account changing usage) is designed to ensure the minimum residue level not the maximum permissible before there is a health and safety concern.</p>
<p><b>Labelling of GM food</b></p>	<p>FOODWatch Peter St Clair-Baker PSGR</p>	<p>Information on GM labelling requirements is available on the FSANZ website at :</p> <p>Labelling of GM Foods <a href="http://www.foodstandards.gov.au/consumer/gmfood/labelling/pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/labelling/pages/default.aspx</a></p> <p>An independent Review of Food Labelling Law and Policy was commissioned in 2009 by Australian and New Zealand food regulation ministers. In 2011, the government responded to the recommendations contained in the review; in its response to recommendations 29-33 on GM labelling the government supported the existing regulations in the Code and agreed not to pursue any additional regulatory requirements at this time. Further information on the review and the government response is available on the Food Labelling Review website at: <a href="http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/labelling-logic">http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/labelling-logic</a></p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p><b>Lack of consideration of long term feeding studies in the safety assessment</b></p>	<p>Kerry Beake FOODwatch</p>	<p>There is general consensus among food regulators that the key focus in determining the safety of a GM food is the comparative compositional analysis. This concept was first considered in 1993 (OECD, 1993) and there has not been any change to this thinking (Herman et al., 2009).</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 (<a href="http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx">http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx</a>). 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. Therefore, for most GM foods, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. There are also concerns about the unethical use of animals for feeding studies in the absence of any clearly identified compositional differences (Bartholomaeus et al., 2013; Rigaud, 2008).</p> <p>The European Food Safety Authority (EFSA) is cited by some as advocating animal feeding studies for GM food safety assessments. In the advice issued by EFSA it is stated that the inclusion of a 90-day feeding study is not necessary where molecular, compositional, phenotypic and agronomic analyses demonstrate equivalence of the GM food to its non-GM counterpart (EFSA, 2008; EFSA, 2011). Despite this, the European Commission (EC) decided, in December 2013, to require a 90-day study with each GM food application, pending the outcome of a European Union research project on that issue, due at the end of 2015. Depending on results from the 90-day study or other available nutritional and toxicological studies, a 2-year study in rats may also be requested by the EC on a case-by-case basis (EFSA, 2013).</p>
<p><b>Lack of independent research</b></p>	<p>Kerry Beake</p>	<p>FSANZ requires the developer of any new GM food to demonstrate its safety. The data required in the <i>Application Handbook</i> are specified and must be generated according to quality assurance guidelines that are based on internationally accepted protocols and be able to withstand external scrutiny. FSANZ independently assesses the data provided by the developer to reach a conclusion about the safety of the food.</p> <p>FSANZ complements data generated by the developer with information from the scientific literature, other applications, other government agencies and the public.</p> <p>FSANZ has addressed this issue on the website at <a href="http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx</a></p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p><b>What procedures FSANZ would follow if an approved GM line was subsequently found to raise safety concerns</b></p>	<p>Kerry Beake</p>	<p>From time to time studies claiming to show adverse effects from the consumption of GM foods have been published and FSANZ has procedures in place to review these (see <a href="http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx</a>). The agency also liaises with other national food regulatory agencies to maintain a watching brief on any potential safety issues with internationally traded foods whether GM or not. If it considers that a particular food raises safety concerns, FSANZ would have no hesitation in liaising with the relevant enforcement agencies to initiate action to prevent the food in question from entering the food supply or, if it were already present, to have the food removed.</p>
<p><b>Lack of post-market monitoring of GM foods once they are approved</b></p>	<p>PSGR</p>	<p>In the context of a GM food it has been recognised internationally that the use of pre-market safety assessment provides assurance that a GM food is comparable to its conventional counterpart in relation to health risks and benefits, therefore the likelihood of identifying long-term effects specifically attributable to GM foods would be very low (WHO, 2000). Moreover, the practicality of using post-market monitoring (PMM) to assess the long-term human health impacts of consuming GM foods has not been established.</p> <p>Many chronic health problems have complex causes and it is unlikely that observational epidemiological studies could identify such effects specifically related to GM foods. The same also applies to the identification of potential long-term beneficial health effects.</p> <p>In general, therefore, FSANZ does not consider PMM to be a practical, enforceable or effective risk management option. This is particularly the case where passive monitoring or general health surveillance, which does not address a specific hypothesis, is proposed.</p> <p>Nevertheless it is recognised that PMM may be an appropriate risk management measure in certain circumstances, e.g. where a GM food has been developed specifically to produce a nutritional effect in the population and it may therefore be desirable to confirm assumptions made during the risk assessment. FSANZ decides the need for PMM on a case-by-case basis, taking into account the unique characteristics of the GM food and the feasibility of undertaking such a study.</p>





- The U.S. Environmental Protection Agency (EPA) concluded (EPA, 2005) that, with regard to dietary risk from 2,4-D sprayed on crops, “acute and chronic dietary exposures for food and drinking water do not exceed the Agency’s level of concern; therefore, no mitigation is warranted at this time for any dietary exposure to 2,4-D”.
- The APVMA is currently undertaking Part 2 of a review of 2,4-D which focusses on human health, occupational health and safety, and the environment. The human health report is expected to be available at the end of 2014 (<http://apvma.gov.au/node/1608>). Currently, the APVMA MRL Standard (<http://www.comlaw.gov.au/Details/F2013C00638>) lists MRLs for a number of food crops. This list is the same as that in Standard 1.4.2 of the Code.
- The NZ Maximum Residue Limits of Agricultural Compounds (<http://www.foodsafety.govt.nz/elibrary/industry/nz-mrl-agricultural-compounds-food-standards-07-2014.pdf>) lists two food categories for which there are 2,4-D MRLs.
- While 2,4-D was a component of Agent Orange, it was the contaminating dioxins present in Agent Orange that were the main health concern. Dioxins are a family of around 200 chemicals which vary widely in toxicity with 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) being considered the most toxic.
- While food is one source of dioxins, other common sources include the burning of municipal and industrial waste and tobacco smoke. As dioxins tend to be stored in fat, the main dietary sources are meat, milk products and fish rather than fruit, vegetables and grains. While dioxins, including TCDD, were present as manufacturing contaminants in 2,4-D, since the 1990s there has been regulation to decrease the chance that TCDD is formed during the manufacturing process (EPA, 2005).

#### Glufosinate ammonium

- Glufosinate is a non-selective contact herbicide with uses on both conventional and GM crops (JMPR, 2013).
- Glufosinate MRLs for a variety of plant-derived food commodities have been adopted by Codex ([http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp)), NZ (<http://www.foodsafety.govt.nz/elibrary/industry/nz-mrl-agricultural-compounds-food-standards-07-2014.pdf>) and Australia (<http://www.comlaw.gov.au/Details/F2013C00638>).
- The Joint FAO/WHO Meeting on Pesticide Residues concluded (JMPR, 2013) that “the long-term intake of residues of glufosinate from uses that have been considered by the JMPR [including a consideration of residues on GM glufosinate-tolerant crops] is unlikely to present a public health concern”.

## 2.2 Safety assessment

The safety assessment of herbicide-tolerant cotton line DAS-81910-7 is provided in the supporting document (SD1) and included the following key elements:

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

The assessment of cotton line 81910 was restricted to food safety and nutritional issues.

Any risks related to the release into the environment of GM plants used in food production, or risks to animals consuming feed derived from GM plants have not been addressed in this assessment.

The Applicant for A1094 met all of the data requirements stipulated in the *Application Handbook* (FSANZ, 2011) for the safety assessment of GM food and, after assessing these data, FSANZ is satisfied that sufficient evidence has been provided to demonstrate the safety of the food.

Based on the scientific data provided in the present Application, and other available information, food derived from herbicide-tolerant cotton line DAS-81910-7 is considered to be as safe for human consumption as food derived from conventional cotton cultivars.

## **2.3 Risk management**

### **2.3.1 Labelling**

In accordance with the labelling provisions in Standard 1.5.2, food derived from cotton line 81910 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein, or has altered characteristics. Food from cotton line 81910 does not have altered characteristics.

The main food product from cotton plants is refined cottonseed oil. Extensive processing of cottonseed to produce food-grade oil 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 cottonseed oil from cotton line 81910 would be exempt from labelling under paragraph 4(1)(c) of Standard 1.5.2. Cotton linters, a minor food product, are almost pure cellulose and therefore do not contain novel protein or novel DNA and would also be exempt from labelling.

### **2.3.2 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's Implementation Sub-Committee<sup>2</sup> to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications.

The EAG 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 Applicant for DAS-81910-7 to satisfy the requirement for detection methodology in the *FSANZ Application Handbook* (FSANZ, 2011).

## **2.4 Risk communication**

Consultation is a key part of FSANZ's Standards development process.

The process by which FSANZ considers Standards 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.

Public submissions were invited on a draft variation which was released for public comment between 18 March and 29 April 2014.

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<sup>2</sup> Now known as the Implementation Subcommittee for Food Regulation

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.

Twelve submissions were received, of which 10 objected to the proposed variation. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. All comments are valued and contribute to the rigour of the safety assessment. Every submission on this application was considered by the FSANZ Board.

Documents relating to Application A1094, including submissions received, are available on the FSANZ website.

## **2.5 FSANZ Act assessment requirements**

### **2.5.1 Section 29**

#### **2.5.1.1 Cost benefit analysis**

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need of the OBPR to assess if a Regulatory Impact Statement is required for the approval of additional genetically modified foods (reference 12065). The exemption was provided as applications relating to genetically modified food are considered as minor, machinery and deregulatory in nature.

FSANZ undertook a cost benefit analysis (see below). The analysis concluded that the costs arising from the food regulatory measure varied as a result of the application would not outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation of the food regulatory measure.

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. It is noted that the cost/benefit analysis is based on the assumption that cotton line 81910 will be approved for growing in other countries (see section 2.5.1.4 below).

*Consumers:* Broader availability of imported cotton products as, if cotton line 81910 is approved for commercial growing, there would be no restriction on imported foods containing this line.

For those cotton line 81910 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

If cotton line 81910 is approved for commercial growing in overseas countries, it can be used in the manufacture of products using co-mingled cotton.

This means that there would be no cost involved in having to exclude cotton line 81910 from co-mingling and hence that there would be no consequential need to increase the prices of imported foods that are manufactured using comingled cotton products.

*Government:* Benefit that if cotton line 81910 was detected in food imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of cotton line 81910 would ensure no conflict with WTO responsibilities if the line is approved for commercial growing in overseas countries.

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 cotton derivatives would benefit as foods derived from cotton line 81910 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 cotton products or imported foods manufactured using cotton derivatives.

Possible cost to food industry as food ingredients derived from cotton line 81910 would be required to be labelled if they contain novel DNA or novel protein.

The segregation of raw agricultural commodities of cotton line 81917, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the costs of maintaining various levels of purity.

As food from cotton line 81910 has been found to be as safe as food from conventional cultivars of cotton, not preparing a draft variation would offer little benefit to consumers, as approval of cotton line 81910 by other countries could limit the availability of imported cotton products in the Australian and New Zealand markets.

In addition, this option would result in the requirement for segregation of any products containing cotton line 81910 from those containing approved cotton lines which would be likely to increase the costs of imported cotton-derived foods.

Also, not preparing a draft variation is likely to be inconsistent with Australia's and New Zealand's WTO obligations if cotton line 81910 is approved for commercial growing in other countries (see below).

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

#### **2.5.1.2 Other measures**

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

#### **2.5.1.3 Any relevant New Zealand standards**

Standard 1.5.2 applies in New Zealand.

#### **2.5.1.4 Any other relevant matters**

The Applicant has submitted applications for regulatory approval of cotton line 81910 to a number of other countries, as listed in Table 2. To date, none has been finalised.

**Table 2: List of countries to whom applications for food/feed regulatory approval of herbicide-tolerant cotton line DAS-81910-7 have been submitted**

<b>Country</b>	<b>Agency</b>	<b>Type of approval sought</b>
USA	Department of Agriculture	environment
	Food & Drug Administration	food/feed
Canada	Food Inspection Agency	feed
	Health Canada	food
Japan	Ministry of Agriculture, Forestry & Fisheries	environment
	Ministry of Health, Labor and Welfare	food

It is the Applicant's intention to submit applications to a number of other countries such as Mexico, Korea and EU for food/feed regulatory approvals.

It is the Applicant's intention that cotton line 81910 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. Cultivation in Australia or New Zealand would require independent assessment and approval by the Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority in New Zealand.

#### **2.5.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

##### **2.5.2.1 Protection of public health and safety**

Food derived from cotton line 81910 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 Applicant, food derived from cotton line 81910 is considered as safe and wholesome as food derived from other commercial cotton cultivars.

##### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

In accordance with existing labelling provisions, food derived from cotton line 81910 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.3.1). The main food product from this line is unlikely to contain novel DNA or protein and therefore is unlikely to require labelling.

##### **2.5.2.3 The prevention of misleading or deceptive conduct**

The requirement for detection methodology (see Section 2.3.2) is designed to address this objective.

### 2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **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 cotton line 81910 used the best scientific evidence available. The Applicant submitted to FSANZ, a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicant, 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 genetically modified foods in the food supply, where there are no safety concerns, generally allows for innovation by developers and a widening of the technological base for the production of foods.

- **The promotion of fair trading in food**

The cost/benefit analysis in Section 2.5.1.1 lists a number of considerations that address fair trading with respect to food derived from cotton line 81910

- **Any written policy guidelines formulated by the Ministerial Council<sup>3</sup>**

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

## 3 Transitional arrangements

Attachment C explains the transitional arrangements that will be required for Proposal P1025.

## 4 References

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## Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Transitional arrangements required for Proposal P1025



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



### **Food Standards (Application A1094 – Food derived from Herbicide-tolerant Cotton Line DAS-81910-7) Variation**

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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 A1094 – Food derived from Herbicide-tolerant Cotton Line DAS-81910-7) Variation*.

**2 Variation to a Standard 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 Item numerical order in the Schedule

“

	3.14	Food derived from herbicide-tolerant cotton line DAS-81910-7	
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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).`

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 A1094 which seeks permission for the sale and use of food derived from herbicide-tolerant cotton line DAS-81910-7. 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 the Australia and New Zealand Ministerial Forum on Food Regulation<sup>4</sup> (Forum), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft 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**

The variation inserts a reference to herbicide-tolerant cotton line DAS-81910-7 into the Schedule to Standard 1.5.2 in order to permit the sale, or use in food, of food derived from that cotton line.

### **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 A1094 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 18 March 2014 for a six-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.

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<sup>4</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

## **6. Variation**

The variation inserts Item 3.14 into the Schedule to Standard 1.5.2. Item 3.14 refers to food derived from herbicide-tolerant cotton line DAS-81910-7.

# Attachment C – Draft variation to the Australia New Zealand Food Standards Code in March 2015 following P1025

## Background

FSANZ is reviewing the *Australian New Zealand Food Standards Code* in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. The draft instrument below reflects those changes. A further draft revision of the Code and call for submissions was released in July 2015.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, such as the variation to Standard 1.5.2 proposed by A1094. This is the rationale for the draft variation below.

This draft variation is provided for background only. Its content and structure may change as P1025 progresses.

## Draft instrument

### Food Standards Code—Variation

Made under the *Food Standards Australia New Zealand Act 1991*

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#### 1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 1)*.

#### 2 Commencement

This instrument commences on the day after it is registered.

#### 3 Variation of Schedule 26

Schedule 1 varies Schedule 26 of the Australia New Zealand Food Standards Code – Food produced using gene technology.

#### Schedule 1                      Variation of Schedule 26 (section 3)

#### [1] Table to section S26-3

Insert after Item 3(m)

“                      (n) herbicide-tolerant cotton line DAS-81910-7”