



6 September 2010
[19-10]

PROPOSAL P1004

PRIMARY PRODUCTION & PROCESSING

STANDARD FOR SEED SPROUTS

2nd ASSESSMENT REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) has prepared this 2nd Assessment Report on Proposal P1004 – Primary Production & Processing Standard for Seed Sprouts which includes a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

This Report is prepared in accordance with the principles of best practice regulation recommended by the Council of Australian Governments: identifying the problem that has prompted government action; the objectives of such action and possible options for achieving the objectives. A summary of the scientific report and an impact analysis of risk management options are included.

FSANZ invites public comment on this 2nd Assessment Report and supporting documents particularly FSANZ's preferred option of varying the Code to include Standard 4.2.6 – Production and Processing Standard for Seed Sprouts.

Introduction

This 2nd Assessment Report is the next assessment stage to improve the safety of seed sprouts for sale in Australia, following outbreaks of illness attributed to these products. The work has progressed with the advice and guidance of a Standard Development Committee (SDC) comprising representatives from the seed sprout industry including seed producers, seed processors and sprout producers, government regulators and consumers.

The Problem

Seed sprouts contaminated by pathogenic micro-organisms present an unacceptable health risk to consumers. In recent years, outbreaks of food-borne illness have been associated with the consumption of seed sprouts both in Australia and overseas. The resultant cost to the Australian community from the 2005 and 2006 outbreaks is estimated to be \$1.19¹ million.

¹ All dollar values in this report are Australian dollars unless otherwise indicated

Objective

The objective of this Proposal is to reduce the incidence of food-borne illness from the consumption of seed sprouts.

Options

The options are:

- **Option 1 – Abandon the Proposal thus making no change to the Code.**
-
- This option is further subdivided into:
-
- **Option 1(a) – *Status quo***

No change is made to the existing requirements.

- **Option 1(b) – Self regulation**

Greater voluntary uptake of requirements for production and processing by industry, based on industry formulated recommendations and guidance.

- **Option 2 – Prepare draft food regulatory measures**

These measures could potentially apply to some or all of the stages in the production chain for seed sprouts including on-farm seed production, seed processing, and sprout production.

As a result, Option 2 has been further subdivided into:

- Option 2(a) 'Through-chain' regulatory food safety measures for seed producers, seed processors and sprout producers
- Option 2(b) Regulatory food safety measures for sprout producers only

The outcome of this option would be an amendment to the Code.

Impact analysis

All Australian Government departments and agencies need to demonstrate that their proposals deliver net benefits to the community. This includes an analysis of the impact of each proposed risk management option on different affected parties. The parties likely to be affected by the proposed options are consumers of seed sprouts; businesses involved in seed production, seed processing and sprout production; and State and Territory agencies.

Option 1(a) – Abandon the Proposal, thus maintaining the *status quo* is not supported by FSANZ because it does not support public health and safety objectives. Although there will be no additional imposed costs, if this is determined to be the preferred option, the overall potential costs of food-borne illness associated with the consumption of seed sprouts will remain unchanged. The resultant cost to the Australian community from the 2005 and 2006 outbreaks is estimated to be \$1.19 million. If the costs of these outbreaks are used as an illustration, the annual costs of food-borne illness due to consumption of sprouts may be \$600,000 per year (if such events occur biannually) or about \$240,000 (if such outbreaks occur once in every 5 years). In addition, there are ongoing costs for government in relation to the ongoing investigation of food-borne illness if no action is taken.

Option 1(b) – Abandon the Proposal. Self regulation is not a viable option because there currently is not a cohesive sprout production industry which could effectively adopt a self regulation option.

The Australian New Zealand Sprouters' Association has sought government intervention and the development of regulatory measures for the industry, because there has been resistance to the voluntary adoption of industry guidelines by a significant proportion of the industry. In addition, the industry is characterised by a high turnover of a small, but significant, proportion of the sector which would make identifying and targeting these opportunistic and often short term entrants difficult.

Option 2 – The assessment of this option recommending food regulatory measures involved assessing the impact and costs and benefits for 2(a) Through chain regulatory measures (requirements for seed producers, seed processors and sprout producers) and 2 (b) Food regulatory measures for sprout producers only.

The analysis of 2(a) Through chain regulatory measures found that it would not be cost effective to regulate the whole chain and would go against the principles of minimum effective regulation. In addition, regulating seed producers and processors is less effective than controlling contamination at the sprouting stage. Although imposing requirements on seed producers and processors may be able to prevent further contamination occurring during the seed processing stage, for some types of seed production, particularly for paddock-based production, prevention of all contamination during the growing stage is impractical. The production of lucerne seed for alfalfa sprout production comprises of less than 5% of total lucerne seed production and the imposition of food safety requirements in this sector could potentially result in withdrawal of seed producers and processors from the market.

The analysis of 2(b) Food regulatory measures for sprout producers revealed that including government, the costs of the proposed requirements would be in the vicinity of \$150,000 upfront and \$455,000 ongoing per year. FSANZ estimates that following implementation of requirements for sprout producers a 23%-65% reduction in burden of illnesses or benefits of \$55,000–\$390,000 per year may be realised (i.e. 23%–65% of estimated \$240,000–\$600,000 burden of illness). Sensitivity analysis indicated that the net present values (NPV) accruing from this option are subject to a high degree of uncertainty and are estimated to range between a positive NPV of \$595,000 and a negative NPV of (-) \$3.48 million over 10 years.

Although this option is likely on present estimates, using data based on outbreaks occurring in 2005 and 2006, to impose a net cost on the community, the adoption Option 2(b) Food regulatory measures for sprout producers is the preferred option for managing the risk associated with seed sprout production. As discussed in the body of this report, estimating costs and benefits is problematic given the unpredictable and variable impacts on individual food-borne illness outbreaks. This is reflected in the NPV estimate range developed through sensitivity analysis of more than \$4 million.

FSANZ considered developing an education initiative for consumers and industry as a standalone risk management option. However, following consultation, it was determined that education initiatives were best as an accompanying risk management measure for each of the options.

Preferred Approach

To prepare draft Standard 4.2.6 - Production and Processing Standard for Seed Sprouts for sprout producers only.

Reasons for Preferred Approach

At 2nd Assessment, FSANZ recommends that draft Standard 4.2.6 – Production and Processing Standard for Seed Sprouts (Attachment 1) in Chapter 4 be prepared because the proposed amendment:

- addresses the public health and safety problem identified with seed sprouts in the most cost effective manner
- is consistent with the section 18 objectives of the FSANZ Act to protect public health and safety
- provides a nationally consistent legislative framework to address seed sprout product safety
- provides measures that are outcome based and would be consistent with principles of minimum necessary regulation.

Conclusion

Option 2(b), to prepare draft Standard 4.2.6 – Production and Processing Standard for Seed Sprouts for sprout producers only, is the preferred Option. Despite the impact analysis indicating that the status quo option appears on the face of it to have the highest net benefit for the community, regulation of sprout producers only is the preferred option to reduce the risk of future sprouts related food-borne illnesses.

The proposed Standard also addresses the public health and safety risk posed by seed sprouts; meets FSANZ's statutory considerations, provides a nationally consistent legislative framework for seed sprout safety and provides measures that are outcome based and would be consistent with principles of minimum necessary regulation.

Implementation

Implementation of the Code is the responsibility of the State and Territory governments. The Implementation Sub-Committee² (ISC) facilitates the consistent national implementation of the Code and is responsible for developing nationally consistent implementation approaches.

A recent initiative of ISC to harmonise the processes of standard development and implementation is the integrated model for standards development and consistent implementation (the integrated model). The integrated model is built on the concept that a 'package' of information is provided to Food Ministers, rather than just a draft standard and has been piloted on the Primary Production and Processing Standard for Eggs and Egg Products. In March 2010, FRSC endorsed the development of implementation plans for other primary production and processing standards, which would include this Proposal.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

² The Implementation Sub-Committee (ISC) is a sub-committee of the Food Regulation Standing Committee. Its role is to develop and oversee a consistent approach across jurisdictions to implementation and enforcement of food regulations and standards, regardless of whether food is sourced from domestic producers, export-registered establishments or from imports.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 18 October 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636**

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SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1004primary4361.cfm>

- SD1: Technical Paper
- SD2: Consultation Regulatory Impact Statement
- SD3: Summary of existing requirements for seed sprout production
- SD4: Summary of standard development committee membership

Introduction

1. Introduction

This 2nd Assessment Report describes the second stage of the assessment of this Proposal, P1004 – Primary Production & Processing Standard for Seed Sprouts. The work commenced in May 2009 to improve the safety of seed sprouts for sale in Australia. A Standard Development Committee (SDC) consisting of representatives from the industry, retail, government regulators and consumers was established by FSANZ to assist with this standard development process.

The 1st Assessment Report was released for public comment in July 2009 and can be viewed on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1004primary4361.cfm>.

Following the release of the 1st Assessment Report, fifteen submissions were received from the seed sprout industry, State and Territory enforcement agencies and consumers. Submissions generally supported the Proposal and the comments have informed the second stage of the Proposal work. A discussion of key issues raised during the first round of consultation is provided in Attachment 3.

The second stage of the Proposal work has involved further assessment of the hazards and risks associated with the production of seed sprouts in Australia and identifying food safety measures to manage these risks. The identified food safety risks are described in the Technical Paper (Supporting Document 1).

This 2nd Assessment Report describes how the hazards involved in the production chain for seed sprouts are best controlled through food safety measures, and the available risk management options, including the preferred option. In considering risk management options for improving food safety, FSANZ uses an internationally agreed risk analysis approach embodied in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

A Regulatory Impact Statement (RIS) has been completed as part of the second stage of the Proposal work. The RIS is provided as Supporting Document 2 and includes an assessment of the impacts of the proposed risk management options, including an analysis of the costs and benefits for each of the main stakeholder groups being industry, government and consumers.

The SDC has provided input and comment in relation to the development and assessment of the risk management options and also in relation to the proposed Draft Standard.

2. Background

2.1 Background to this Proposal

To date, FSANZ has developed primary production and processing standards for the seafood and dairy sectors and is currently assessing and developing standards for the poultry meat, egg and meat sectors.

Preliminary scoping activities looking at the area of plants and plant products (e.g. fruit, vegetables, nuts, seed sprouts, fresh cuts) to consider how best to progress work on such a wide range of plant commodities identified the production of seed sprouts as an area of public health concern (two outbreaks of food-borne illness in Australia were attributed to the consumption of seed sprouts in 2005-2006).

Seed sprouts under consideration are sprouted seeds or beans (such as mung beans, alfalfa, mustard seed, onion, radish, soya bean etc) generally used and consumed as a salad vegetable.

2.2 Primary production and processing standards

A primary production and processing standard is a set of obligations on primary producers and processors of food commodities. It includes measures to control food safety hazards that could occur during the production and processing of agricultural produce. Primary production and processing standards are incorporated into Chapter 4 of the *Australia New Zealand Food Standards Code* (the Code) and apply in Australia only. In addition to other standards in the Code, they provide an approach to managing food safety and suitability³ in Australia that extends from production on the farm through to sale to the consumer.

The implementation of primary production and processing standards is discussed in Section 13.

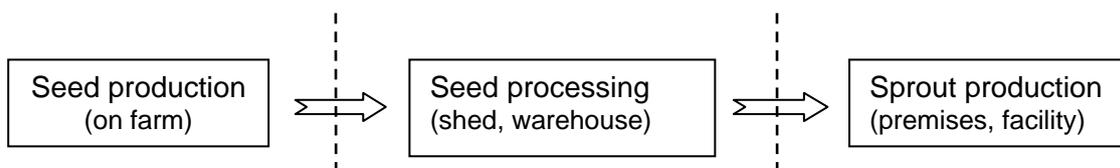
3. Scope of this Proposal

The submissions received on the 1st Assessment Report queried the scope of the Proposal in relation to the businesses affected and the definition of seed sprouts. This information was requested to help assist with determining 'who is in' and 'who is out'. The description of the seed sprout production chain, the definition of seed sprouts below provides further clarification.

3.1 Seed sprout production chain

This Proposal is examining the possible food safety measures that can be applied along the primary production and processing chain for seed sprouts (a through-chain approach). At the 1st Assessment stage, the seed sprout production chain was described as being in two parts: the production of seed and the production of sprouts.

Following further analysis, FSANZ has refined the original breakdown to better reflect the type of businesses and activities as follows:



3.1.1 Seed production (seed growing)

In general, seed production involves on farm activities including pre-harvest and post-harvest activities such as field preparation/planting, growth (including flowering and seed setting), seed harvest, storage and transport. **Seed producers** are involved in this part of the chain.

3.1.2 Seed processing

Seed processing involves the receipt of harvested seeds from seed producers through to the supply of seed to sprout producers.

³ The term 'unsafe and unsuitable' covers hazards that could affect the health of consumers as well as levels of contaminants and residues which, while not unsafe, are in excess of the limits in the Code.

Seed processors are involved in seed processing activities including receiving the harvested seeds from seed producers, storing, cleaning, segregation, grading, and bagging of seeds. Seed conditioning and seed scarification are also a part of the business operation of seed processors and occur to maximise the rates of seed germination. The seed can be purchased directly by sprout producers for sprouting or is purchased by seed merchants.

Seed merchants (or suppliers) specialise in supplying seeds to various markets and customers. Seed merchants receive cleaned/graded seeds from seed processors, match customer requirements, and sell seeds to customers including sprout producers. Seed merchants are involved in the management of the transportation and delivery of cleaned/graded seeds to their customers.

3.1.2 *Sprout production*

Sprout production includes receiving the seed from seed processors or seed merchants, storage, seed decontamination, seed soaking, germination/growth, harvest, washing/drying (depending on the variety and how it is grown), packaging, chilling/storage and transport. **Sprout producers** are involved in this part of the chain.

3.2 The definition of seed sprouts

The scope of this Proposal aims to capture the types of seed sprouts that are ready to eat and are particularly high risk. The proposed definition of seed sprouts is 'seed sprouts are sprouted seeds or beans for human consumption, that include all or part of the seed'.

Outbreak investigations have identified seed as the likely source of microbial contamination of seed sprouts. The seed may be contaminated in the field, during harvest, storage or transportation. Seed decontamination activities can reduce the level of microbiological hazards present. However, literature indicates that current seed decontamination treatments cannot guarantee total elimination of microbial pathogens (Codex, 2003). Even if a few microbial pathogens survive the microbiological decontamination treatment, they can grow to high numbers during the seed germination and sprout growth phase because of the favourable growth environment and conditions.

This is particularly relevant for the types of seed sprouts in which parts of the seed or seed husk remain as a component of the final ready to eat product. Experimental studies have demonstrated that although bacteria can migrate through the sprout plant, it is more concentrated at the roots and seed of the sprout (Gorski *et al.*, 2004; Warriner *et al.*, 2003). Consequently the production of "sprouted seeds or beans for human consumption that includes all or part of the seed" is captured in the scope.

3.2.2 *Exclusions from this Proposal*

This Proposal deals largely with food safety problems associated with seed sprouts consumed as vegetables and garnish. As such, sprouted cereal grains used for brewing (e.g. malts of barley, oats, sorghum, wheat etc.) or for juice making (e.g. wheat grass) are excluded from the scope.

Microgreens are a relatively new type of salad garnish that have been introduced in fine dining restaurants over the past decade. They are described as tiny young plants and as the smallest sort of salad green, leafy vegetable or herb. While microgreens and seed sprouts are similar as young plants, they differ in a number of physiological aspects, described in the Technical Paper. Due to these differences, microgreens are excluded from the scope of this Proposal.

Snow pea sprouts and snow pea shoots are commonly classified and referred to as 'sprouts' and are also consumed as salad vegetables and used as a garnish for other foods. There are differences in the production of snow pea sprouts compared to sprouts such as alfalfa and mung beans. Snow pea sprouts are generally grown in a growth medium (enriched soil); they are harvested by cutting the main stem away from the roots and the soil, and the seed used to grow the snow pea sprouts is not a part of the final ready to eat product.

The characteristics of the growth and harvest of snow pea sprouts are similar to the growth and harvest of other vegetables such as cauliflower, celery and fresh herbs and as such, are excluded from the scope of this Proposal. These types of products will be assessed in future work FSANZ plans to conduct in relation to the broader plant and plant products area.

The Problem

Seed sprouts contaminated by pathogenic micro-organisms present an unacceptable health risk to consumers. In recent years, outbreaks of food-borne illness have been associated with the consumption of seed sprouts both in Australia and overseas.

In Western Australia and Victoria 132 cases of food-borne salmonellosis were associated with the consumption of raw sprouts in 2005-06 (Kirk M, 2006). The Japanese radish sprouts outbreak in 1996 caused 3 deaths (FAO/WHO, 2002) and in the United States consumption of sprouts resulted in 1364 illnesses between 1996 and 1999 (USFDA).

Since the most recent food-borne illness outbreaks in Australia in 2005-2006, sprout producers have formed an industry association and developed industry guidelines to support the safer production of their products. However, the seed sprout industry consists of many small businesses⁴ and to date it has been difficult to achieve adequate coverage of the industry and comprehensive uptake of the guidelines. The industry association has sought government intervention and the development of regulatory measures (as appropriate) for the industry.

Currently there are no consistent national requirements for production of seed sprouts. In New South Wales the Plant and Plant Products Food Safety Scheme covers high priority, high risk plant food products, including seed sprouts. Under this Scheme sprout producers in New South Wales must demonstrate compliance through implementing a food safety program, based on Codex HACCP or Standard 3.2.1, which is certified by the Authority and audited.

4. Significance of the problem

4.1 Cost of food-borne illness attributable to seed sprouts

Outbreaks of food-borne illnesses are sporadic and unpredictable. In this Proposal, the potential cost of adverse health consequences due to consumption of contaminated seed sprouts is estimated using data from outbreaks of food-borne illness associated with sprouts that occurred in 2005 and 2006. However it should be noted that as the extent and severity of individual outbreaks are unpredictable and therefore likely to vary significantly, basing costings on the Australian 2005-06 outbreaks does not provide a true indication of the likely costs of any future outbreaks. For example, the Japanese outbreak in 1996 resulted in 9000 cases of illness and three deaths. Therefore it is difficult to estimate with any confidence the potential net benefit of introducing regulatory measures.

⁴ The Australia Bureau of Statistics (ABS) defines a small business to be any business with less than 20 employees.

In Western Australia and Victoria 132 cases of food-borne salmonellosis were associated with the consumption of raw sprouts in 2005-06 (Kirk M, 2006). For every case of food-borne Salmonellosis that is reported on the National Notifiable Diseases Surveillance System, there could be about 7 cases of food-borne salmonellosis in the community (Hall G. et al. 2006). Therefore, taking into account under-reporting, there may have been around 924 cases of food-borne salmonellosis in the community due to the 2005-06 outbreak.

For the 2nd Assessment, FSANZ has consulted with the Office of Best Practice Regulation on the most appropriate methodology to determine an annual cost of food-borne illness given the reliance on outbreak data for a two year period only. This has resulted in a revision of the community costs outlined at 1st Assessment. At 2nd Assessment, FSANZ estimates the community costs of food-borne illness associated with consumption of seed sprouts may be \$600,000 per year (if such events occur biannually) or about \$240,000 per year (if such outbreaks occur once in every 5 years). An explanation of how this estimation has been calculated can be found in the Regulatory Impact Statement.

4.2 Public health risk

In the period 1988 to 2008, there have been over 40 reported outbreaks of food-borne illness worldwide attributed to consumption of contaminated seed sprouts. The most commonly reported aetiological agents in these outbreaks have been various serovars of *Salmonella* spp. and enterohaemorrhagic *Escherichia coli* (EHEC). Alfalfa and mung bean sprouts have been the most commonly reported seed sprouts implicated in these outbreaks of food-borne illness.

Salmonella are pathogenic bacteria causing gastroenteritis. Symptoms of salmonellosis are usually mild but, in a small number of cases, *Salmonella* infection can lead to more severe invasive diseases characterised by septicaemia and, sometimes, death. Salmonellosis is the second most commonly reported food-borne disease in Australia. In 2007, there were 9484 notifications, corresponding to a rate of 45 cases per 100,000 population (OzFoodNet Working Group, 2008).

Most recently there have been two outbreaks of *S. Oranienburg* in Australia attributed to the consumption of alfalfa sprouts. From November 2005 to January 2006, there was an outbreak in Western Australia with 125 cases of salmonellosis reported, resulting in 11 hospitalisations. In May 2006, another outbreak of *S. Oranienburg* was reported in Victoria, with a total of 7 cases and two hospitalisations.

Microbiological surveys of seed sprouts, both domestically and internationally, have identified the presence of a variety of food-borne pathogens including *Salmonella* spp., EHEC, *Bacillus cereus*, *Cryptosporidium* spp. and *Giardia* spp (Beuchat L.R. 1996, Kim et al;Robertson *et al* 2004;Prokopowich and Blank 1991;Samadpour *et al.*2006).

In Australia microbiological surveys of seed sprouts have been conducted by the Department of Health Western Australian 2000, (261 samples), ACT Health in 2001 (62 samples) and NSW Food Authority in 2005 (30 samples), 2006 (36 samples) and 2008 (122 samples). The surveys revealed seed sprouts are occasionally contaminated with pathogenic Micro-organisms. Pathogenic microorganisms detected in some of these surveys include *L. monocytogenes*, *Salmonella* spp, pathogenic *E. coli*, *B. cereus*, coagulase-positive staphylococci.

4.3 Existing international and Australian requirements

A summary of the existing requirements that apply to each of the sectors involved in seed sprout production domestically and internationally is provided below. Further detail about the measures specified and discussion about the existing requirements is provided in Supporting Document 3.

4.3.1 Existing requirements for seed production and seed processing

The existing requirements in Australia that apply to seed production and seed processing include:

- Export Control (Plant and Plant Product) Orders 2005
- Code of Hygienic Practice for Whole Mung Beans
- The *Australia New Zealand Food Standards Code*.

Clarification was sought during the 2nd Assessment stage in relation to the application of Chapter 3 requirements (Standards 3.2.2, 3.2.3) to seed processing businesses.

Depending on the activities undertaken by seed processing businesses and the nature of the product, some seed processing businesses may already be required to comply with food legislation, including certain requirements in Chapter 3. However, this will depend on the requirements in the individual State and Territory Food Acts or any other applicable State or Territory food legislation.

International requirements of relevance to seed production and processing include:

- Code of Hygienic Practice for Fresh Fruits and Vegetables, Annex Sprout Production
- United States Food and Drug Administration, Guidance for Industry, Reducing Microbial Food Safety Hazards for Sprouted Seeds
- Canadian Code of Practice for the Hygienic Production of Sprouted Seeds.

These documents all specify measures for seed production and seed processing of seed used for sprout production.

4.3.2 Sprout production

The existing requirements in Australia that apply to sprout production include:

- *Australia New Zealand Food Standards Code*, Chapter 1 – General Requirements
- *NSW Food Regulation 2004*, Plant Products Food Safety Scheme and associated Plant Products Safety Manual (sprout producers in NSW only)
- Australian New Zealand Sprouters Association, Guidelines for Australian and New Zealand Sprout Producers, July 2008
- Retailers Quality Assurance requirements, for example Woolworths (2007) WQA Product Category Requirement – Produce.

The international requirements that are applicable for sprout production include:

- Code of Hygienic Practice for Fresh Fruits and Vegetables, Annex Sprout Production
- United States Food and Drug Administration, Guidance for Industry, Reducing Microbial Food Safety Hazards for Sprouted Seeds
- Canadian Code of Practice for the Hygienic Production of Sprouted Seeds

- Code of Practice for Food Safety in the Fresh Produce Supply Chain in Ireland (Chapter 4: Microbiological Safety of Sprouted seed Production)

4.4 Gaps and inadequacies in existing requirements

4.4.1 Seed production and seed processing

The requirements in the Export Control (Plant and Plant Product) Orders 2005 (Orders) and the Code of Hygienic Practice for Whole Mung Beans include hygienic requirements on farm, adequate design and construction of facilities and operation and hygiene requirements. These requirements are appropriate in terms of reducing the microbiological contamination of the mungbean seed and mungbean sprouts.

Domestically there are no existing regulatory or industry requirements for the production and processing of any other types of seed used for sprout production such as onion seed, broccoli seed and radish seed.

4.4.1 Sprout production

In New South Wales the Plant and Plant Products Food Safety Scheme covers high priority, high risk plant food products, including seed sprouts. Sprout producers in NSW must demonstrate their compliance with the legislative requirements. These businesses are required to implement a food safety program, based on Codex HACCP or Standard 3.2.1, which is certified by the Authority and audited.

There are no existing legislative requirements in any other Jurisdictions that specifically apply to sprout production. This means out of approximately 30–40 sprout producers only six sprout producers are required to implement a food safety program.

The Guidelines for Australian and New Zealand Sprout Producers, July 2008, specify requirements for seed sanitation, sampling and microbiological testing protocols for categories of seed, with an overarching requirement for the business to implement a HACCP - based food safety program. Uptake of these guidelines is voluntary and the industry association has reported a low level of uptake by industry members.

The large retailers in Australia have developed produce specifications for seed sprout products supplied to them. While these specifications cover a number of quality attributes, they also cover food safety and generally specify microbiological limits (generally for *E. coli*, *Listeria monocytogenes* and *Salmonella*) and criteria for Use By Dates (e.g. not to exceed a certain number of days from date of packaging).

Retailers require sprout producers to be accredited and audited against food safety and quality management schemes such as Woolworths Quality Assurance (WQA), Safe Quality Food (SQF) 2000 and BRC (British Retail Consortium). Industry consultation has revealed the percentage of sprouts produced in Australia under a food safety or quality management scheme is approximately 60%.

Objectives

5. Objective of the Proposal

The objective of this Proposal is to reduce the incidence of food-borne illness from the consumption of seed sprouts.

Possible regulatory and non-regulatory options to achieve the objective are identified in Section 7. Any regulatory measures developed should be commensurate with risk and not impose any unnecessary additional economic burden on the sprout industry.

5.1 Statutory considerations

5.1.1 FSANZ Act

Where regulatory interventions are required (e.g. by developing or varying a food standard), FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

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

In developing and varying food regulatory measures, FSANZ must also have regard to

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

5.2.2 Policy guidelines

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) developed an *Overarching Policy Guideline on Primary Production and Processing Standards*. This policy guideline specifies a number of high order principles for primary production and processing standards outlining that they will:

- be outcomes-based
- have a consistent regulatory approach across the Standards
- be consistent with the approach outlined in Chapter 3 of the Code
- be consistent with Codex standards
- address food safety across the entire food chain where appropriate
- facilitate trade and comply with Australia's obligations under World Trade Organization (WTO) agreements
- promote consumer confidence

- ensure the cost of the overall system is commensurate with the assessed level of risk
- provide a regulatory framework that only applies to the extent justified by market failure
- any regulatory measures developed should be commensurate with risk and not impose any unnecessary additional economic burden on the dairy industry.

Options

As a preliminary step to manage the risk from contaminated sprouts FSANZ undertook a through-chain analysis of food safety hazards and measures for their control in the production and processing of seed sprouts for human consumption.

6. Technical Assessment

The Technical Paper provides technical and scientific information aimed at maximising seed sprout safety.

The submissions received on the 1st Assessment Report suggested numerous food safety controls that could be applied from seed production to sprout production. They also suggested FSANZ should consider the existing international requirements in order to identify the type of food safety controls. FSANZ has taken these comments into account in completing the Technical Paper.

6.1 Summary of the hazards and controls

As outlined in the introduction, the sectors involved in seed sprout production include seed production, seed processing and seed sprout production. A summary of the hazards and controls for each sector is provided below.

6.1.1 Seed production

Epidemiological investigations suggest contaminated seed is the likely source of most, if not all, sprout-associated outbreaks. Seeds and beans used for sprouting are raw agricultural products. Pathogenic micro-organisms such as *Salmonella* species, Shigella Toxic Escherichia Coli, and to a lesser extent *Cryptosporidium*, *Giardia* and *Yersinia* are found in animal faeces. These microbial pathogens may contaminate the seeds if untreated animal manure is used for seed crop production or animal grazing occurs in the same field as seed crop production. Other sources of contamination include water, farming and processing equipment, rodents, insects, wild birds, and agricultural waste.

The following controls have been identified to reduce the hazards associated with seed production:

Activity	Control measures
Field preparation, planting and plant growth	<ul style="list-style-type: none"> - Manure, biosolids and other natural fertilizers should not be used on paddocks unless sufficient time is allowed for the destruction of pathogens to occur before the crop is sown - Crops should be protected from contamination by human, animal, domestic, industrial and agricultural wastes - Ensure water quality is suitable for use - Ensure that any chemicals including pesticides used for seed production are suitable if the seed is intended for sprout production

Activity	Control measures
Seed harvest	<ul style="list-style-type: none"> - Equipment and machinery should be maintained, cleaned and adjusted to minimise soil intake to minimise and/or avoid the contamination of seeds - Bins and equipment used for harvest are cleaned (sanitised when necessary) and kept in dry condition and bins filled with seeds are covered to minimise contamination of the seed - Seed produced for the production of sprouts for human consumption should be identified and segregated from seeds to be planted for animal feed - Products used as desiccants for crops must be approved and registered with the APVMA and used in accordance with the approved and registered use patterns and as appropriate for seed used for sprouting. - Maintain sanitation in drying yards, and avoid exposure of seeds to mist, high humidity or fog

6.1.2 Seed processing

During seed processing and transport activities, seeds can become contaminated by microbial pathogens through the mixing of different harvest lots, contaminated equipment, activities of rodents, birds, chemical hazards, other animals or pests or from personnel.

Seed scarification, a seed treatment by either mechanical or chemical means to improve germination rate, if carried out, creates cuts on the seed surface that present additional space and environment to harbour microbial pathogens.

The following controls have been identified to reduce the hazards associated with seed processing;

Activity	Control measures
Seed processing	<ul style="list-style-type: none"> - Seed for seed sprout production should be segregated from seed to be planted for animal feed and clearly labelled. - If seeds are scarified, equipment must be maintained in a clean condition to minimise microbial contamination - Any chemicals that may come into contact with seed for sprouting must be approved for use.
Seed storage, seed supply	<ul style="list-style-type: none"> - Bags used to store seed should prevent external moisture from entering the internal space of the bag, i.e. solid wall bags are desirable. Contaminated or recycled bags should not be used. - All bags of seed should be visibly inspected for evidence of contamination and contaminated bags of seed should not be used for sprout production. - Seed lots used for sprout production should be analysed for the presence of microbial pathogens of concern, using internationally accepted analytical methods. Lots of seeds for which positive results are obtained should not be used for sprout production. Other lots being produced under similar condition which present a similar hazard shall not be used for sprouting. These lots should be held and detained until they are disposed of properly. - Diseased and damaged seed should not be supplied for sprout production
Seed transport	<ul style="list-style-type: none"> - Vehicles used to transport seeds for sprouting purposes should not transport other goods at the same time that may contaminate the seeds.

Activity	Control measures
General	<ul style="list-style-type: none"> - Facilities and equipment used for seed processing, storage and transport are to be maintained in a clean, dry condition and be inaccessible to rodents, birds, vermin and other pests. - Seed handling personnel should handle seed for sprout production in a hygienic manner

6.1.3 Sprout production

If pathogenic bacteria are present on the seed or in the sprouting environment, the environmental conditions applied during the sprouting of seeds (moist conditions at temperatures of 20-30°C) promote exponential bacterial growth. Therefore, even with very low initial numbers of pathogenic bacteria, there is the potential for pathogens to grow rapidly to high numbers during the sprouting process.

During production and processing the seed sprouts may be contaminated from the seeds used for sprout germination, from premises and equipment, inputs (chemicals, water) or by personnel. As sprouts are a raw ready-to-eat product, there are no terminal processing steps (such as heat treatment) that can then be applied to eliminate any pathogenic micro-organisms that may be present.

The following controls have been identified to reduce the hazards associated with seed sprout production:

Activity	Control measures
Seed receipt and storage	<ul style="list-style-type: none"> - Sprout producers should obtain from seed producers or seed merchants where appropriate, certificates of analysis for microbial pathogens of concern. - Seeds should be examined for physical damage and signs of contamination. If seed is found to be damaged or contaminated, seed should not be used for the production of seed sprouts. - Seed lots should not be used until the seed is analysed for the presence of microbial pathogens of concern and the results of analysis are available. - Seed should be handled and stored to prevent damage and contamination. - Seed should be stored in an area that is clean, dry and inaccessible to pests and other sources of contamination - Chemical residues for seed lots must be within the limits established by the relevant authorities.
Decontamination of seed and germination soak	<ul style="list-style-type: none"> - Seed should undergo a process of decontamination prior to the sprouting process to reduce and/or eliminate any microbiological pathogens present - Water used for sprout production should be pathogen free
Germination and growth	<ul style="list-style-type: none"> - Solid media to support sprout growth should be appropriately treated to eliminate pathogenic microorganisms - Sprout producer should have in place a sampling/testing plan to regularly monitor for microbial pathogens at one or more stages after the start of germination. The analysis can be performed on spent irrigation water or on finished sprouts
Harvest, wash, dry, cooling, packaging	<ul style="list-style-type: none"> - The final water rinse, where appropriate should be with cold water to reduce sprout temperature and slow microbial growth.
Transport and distribution	<ul style="list-style-type: none"> - Regular and effective monitoring of temperature of transport vehicles should be carried out to ensure sprouts are transported at 5°C or below
Retail sale	<ul style="list-style-type: none"> - Sprouts should be kept under cold temperature (e.g. 5°C) to minimise microbial growth

Activity	Control measures
General	<ul style="list-style-type: none"> - Sprout production premises should be constructed and maintained to facilitate cleaning and prevent the access of rodents, insects or pests or animals. - Sprout production personnel should handle sprouts in a hygienic manner to prevent contamination and should not handle sprouts if they are suffering from an food-borne disease - The seed storage, seed rinsing, microbiological decontamination, germination and packaging areas should be physically separated to prevent cross contamination. - Effective cleaning and sanitising and pest control programs should be implemented - Appropriate precautions should be taken to prevent physical contamination

6.2 Chemical hazards

Chemical hazards such as residues of agricultural and veterinary chemicals on seeds and beans, contaminants, processing aids, food additives and packaging material which are likely to be associated with seed sprouts, have been reviewed.

The review was published as Attachment 5 to the 1st Assessment Report and concluded that *There are limited data currently available but these data do not indicate that chemical hazards are a major concern for seed sprouts.*

7. Risk management options

In order to decide the most effective and efficient approach for achieving the objectives stated in Section 5, FSANZ must consider various risk management options available to implement the identified food safety measures. These options are compared to the situation if no action is taken. At First Assessment three options were identified:

- Option 1 – Self regulation
- Option 2 – *Status Quo*
- Option 3 – Food regulatory measures

As the *status quo* provides a benchmark against which other alternatives can be compared, this option is now presented as Option 1(a). No additional options have been identified at 2nd Assessment. At 2nd Assessment, the options are:

- **Option 1(a) – Abandon the Proposal, thus maintaining the *status quo***

No change is made to the existing requirements.

- **Option 1(b) – Abandon the Proposal. Self regulation**

Greater voluntary uptake of requirements for production and processing by industry, based on industry formulated recommendations and guidance.

- **Option 2 – Prepare draft food regulatory measure**

These measures could potentially apply to some or all of the stages in the production chain for seed sprouts including on-farm seed production, seed processing, and sprout production.

As a result, Option 2 has been further subdivided into:

- Option 2(a) 'Through-chain' regulatory food safety measures for seed producers, seed processors and sprout producers
- Option 2(b) Regulatory food safety measures for sprout producers only

7.1 Option 1(a) – Abandon the Proposal, thus maintaining the *status quo*

Option 1(a), is largely characterised by the current requirements outlined in Supporting Document 3 which reflect a mixture of regulatory and self-regulatory approaches developed for different parts of the production chain of seed sprouts. If the Proposal is abandoned, under this option, there will be no nationally-consistent set of food safety control measures for sprout production.

7.2 Option 1(b) – Abandon the Proposal. Self regulation

A self regulatory approach would allow businesses to implement and enforce (e.g. through certification schemes) industry guidelines or codes of practice aimed at improving the safety of seed sprouts. This option could include additional measures being adopted by industry on farm, at processing and at the sprout production stage. These measures could include the adoption of good agriculture practices, separation of seed grown for agriculture and sprouting purposes, premises and health and hygiene requirements. Details of potential food safety control measures are identified in Section 6.

The success of such an approach needs strong industry wide commitment and evidence that voluntary participation can work through, for example, the ability to apply sanctions or incentives (such as using a product logo which demonstrates compliance with a food safety scheme) to achieve maximum participation. Under this option industry would be responsible for enforcement and there would be no government applied food regulatory measures.

7.3 Option 2 – Prepare draft food regulatory measure

At 1st Assessment the submissions generally supported Option 3. There were no written objections to any of the Options. Written submissions stating their support for Option 3 were received from Coles, the Australian Government Department of Agriculture Fisheries and Forestry, Food Technology Association of Australia, New South Wales Food Authority, New Zealand Food Safety Authority, QA Plus Pty Ltd, South Australian Department of Health and from the SDC Consumer Representative.

7.3.1 Identification of food regulatory measures

Options 2 (a) and (b) involve the development of food safety regulatory measures in the Code. In order to assess the impacts of these options, it is necessary to determine the food safety measures that would be introduced as regulatory requirements. These measures could potentially apply to some or all of the stages in the production chain (on-farm seed production, seed processing, and sprout production).

7.3.1.1 Seed production

- use of Good Agricultural Practices (for example, correct use of chemicals, maintenance and cleaning of farm equipment and machinery)
- managing potential contamination from animal effluent through removal of grazing animals from paddocks (completely or within a minimum time from harvest) and similar controls on the application of fertilisers/manures

- segregation of seed grown for agricultural purposes from seed grown for human consumption
- storage of seed so that it is inaccessible by pests or other sources of contamination

7.3.1.2 Seed processing

- adequate design, construction and maintenance of premises and equipment (for food purposes)
- a traceability system (supporting segregation of seed for food/sprouting purposes from other seed)
- pest control program
- health and hygiene requirements for personnel
- testing of seed lots for presence of microbiological pathogens
- management of inputs (including chemical)

7.3.1.3 Sprout production

- the adequate design, construction and maintenance of premises and equipment to prevent/minimise contamination
- implementation of health and hygiene practices of workers to prevent/minimise contamination
- implementation of cleaning and sanitising programs
- implementation of sampling/testing programs
- control of pests
- the management of inputs (water and chemicals) to prevent/minimise contamination
- appropriate skills and knowledge of workers for the activities they undertake
- traceability system

To assess what level of intervention would achieve the maximum net value to the community as a whole, Option 2 Regulatory food safety measures has been further subdivided into

Option 2 (a) Through chain regulatory food safety measures (for seed producers, seed processors and sprout producers)

Option 2 (a) would mean that regulatory requirements would be included in the Code that control the hazards arising during seed production, seed processing and sprout production.

Option 2 (b) Regulatory food safety measures for sprout producers only.

Under Option 2 (b) the Code would only include requirements that apply to sprout producers.

7.4 Education initiatives

During the 2nd Assessment, FSANZ considered developing an education initiative for consumers and industry as a standalone risk management option. However, it was not pursued for the following reasons:

- There are limited food safety education messages that are relevant to consumers. Sprouts are ready-to-eat products and are not usually subjected to a terminal pathogen control step such as cooking by consumers and consumers are unable to detect whether contamination has occurred prior to purchase.

- In the case of food handlers, the food service industry is already required to take measures under the Food Safety Standards in Chapter 3 of the Code and there is guidance on compliance with these standards already available.
- The use of education initiatives to help manage the risk from seed sprouts is best suited as an accompanying risk management measure for each of the options.

Therefore, FSANZ will discuss education initiatives with the most appropriate agencies for developing educational materials and dissemination to consumers. These include the Food Safety Information Council and State and Territory food and health authorities. FSANZ will seek the advice of the SDC on education initiative approaches.

7.4.1 Education initiatives for consumers

The key messages for communicating to consumers would be:

- to adhere to the use by date displayed on seed sprout packaging
- to adhere to storage directions on the seed sprout packaging and store seed sprouts at 5°C or below
- to avoid cross contamination involving seed sprouts in the home

Education initiatives to increase consumer awareness of how sprouts should be handled following their purchase would be appropriate to address the risk of pathogen growth.

There is currently very little information on consumer handling of sprouts, however research into consumer handling of fresh produce and more general food safety behaviour is available from Australia and overseas. This research suggests that a high proportion of fresh vegetables are refrigerated (Johnson et al., 2008; Li-Cohen & Bruhn, 2002).

The reading of use by dates, as measured with self-report methods, is high in Australia and New Zealand (Food Standards Australia New Zealand, 2008). Research from the United Kingdom which asked consumers specifically about fresh fruit and vegetables, found that 80 percent claimed to always or often read the 'food date' on these items (Johnson *et al.*, 2008). Of those who read the food date, 85% said that they always or often follow it. Frequency of checking use by dates varies by the type of food and also by whether the food is being checked at the time of purchase or before serving the food (Kosa et al., 2007). Additionally, use by dates may not be the deciding factor in whether food is thrown away (Kosa et al., 2007), as consumers may prefer to use other methods, such as their senses (e.g. smell) to test for freshness.

Available evidence suggests that consumer education, when well designed and implemented, can be effective in increasing consumer awareness of specific food safety issues (Safefood, 2007) and consequently on their behaviour (Food Standards Agency, 2006; Nauta, 2009; Redmond et al., 2001; McCurdy et al., 2006). However, consumers cannot detect whether sprouts are contaminated with pathogenic bacteria prior to purchase as the bacteria are not visible and therefore, education would be of limited effectiveness.

7.4.2 Industry education initiatives

The most appropriate avenues for developing and/or communicating information to the seed industry sectors and retailers could include:

- the Food Safety Information Council
- seed sprout industry associations

- seed production and seed processing associations, federations
- State and Territory food and health authorities
- accredited food safety auditors and training authorities.

These communications could include information about seed sprout production in food safety manuals, fact sheets, in newsletters and on relevant web pages.

The key messages⁵ for industry and retailers would include:

- for the seed production chain businesses to adhere to Good Manufacturing Practices, and Good Agricultural Practices for seed sprout production
- to ensure food handlers adhere to good health and hygiene practices
- for seed sprout producers to have knowledge of how to develop and implement a food safety program for their business
- to only purchase seed for sprouting from an approved supplier program.

In the case of food handlers, the food service industry is required to take measures under the Food Safety Standards in Chapter 3 and there is guidance on compliance with these standards already available.

Evidence to demonstrate the effectiveness of training and education in improving the food safety practices of food handlers is mixed, with some studies finding significant improvements in food handling practices following training (as observed by researchers) (Egan et al., 2007; Nieto-Montenegro, Brown and LaBorde, 2008; Vaz et al. 2005) and others finding no change (Ashraf et al., 2008; Microbiological Safety of Food Funders Group, 2008).

Coleman and Roberts (2005) argue that adequate food handling training is only one of many factors that determines whether proper food handling behaviours are actually carried out. Research suggests that the attitude of the staff member themselves, and the behaviour and attitudes of their co-workers and supervisors are likely to be just as important in determining whether guidelines are followed (Coleman & Roberts, 2005). These factors, along with other aspects of the food handling workplace (such as the design of the workspace and time constraints) go some way to explaining why so many food handlers report 'sometimes' or 'often' not carrying out food safety actions that they know and understand (Clayton et al., 2002). However, a well-planned training and education intervention can significantly improve food handling practices among food handlers (Egan et al., 2007; Nieto-Montenegro et al., 2008; Vaz et al., 2005).

Increasing food workers' awareness and understanding of food safety behaviours related to sprouts may be an effective strategy for reducing contamination of sprouts by personnel. International research shows that education initiatives can be effective in increasing the food safety awareness and knowledge of consumers' (Food Standards Agency, 2006) and of food workers (Ashraf et al., 2008; Campbell et al., 1998; Food Consumer Behaviour and Health Research Centre, 2005; Nieto-Montenegro et al., 2008). Furthermore, better knowledge of appropriate food safety measures can lead to improved food handling practices (Fischer et al., 2007) thereby reducing the risks of cross-contamination (Ismail & Abdullah, 2004).

⁵ Some suggestions for key messages have been included which are not exclusive, others may be considered.

Impact Analysis

The Assessment Reports for this Proposal will provide information to comply with the Council of Australian Governments (COAG) requirements for regulatory impact analysis. FSANZ will consult with the Australian Government's Office of Best Practice Regulation on meeting these requirements.

The preferred option decided through the assessment of Proposal P1004 has been based on an analysis that considers:

- who is affected by the problem and the proposed solution
- technical assessment of the risks and identification of food safety control measures
- consideration of the efficacy and practicality of food safety control measures identified
- costs and benefits to affected parties of the interventions associated with each option.

8. Affected parties

Parties that have been identified as being affected by this Proposal include: industry (including those involved in seed production, seed processing, seed sprout production and retail of seed sprouts), consumers of seed sprouts, State and Territory Governments, and member nations of the WTO.

8.1 Industry

8.1.1 Seed production

Seed producers are potentially affected by this Proposal if they produce/supply seed for sprouting. Members of both groups are represented on the SDC and have provided input into the assessment of Proposal P1007 through SDC and other (targeted) consultations.

8.1.2 Seed processors

Consultation with industry has revealed there are approximately 30 businesses (including seed processors and seed merchants) that supply seeds for sprouting purposes to seed sprout producers. About 10 businesses supply mung bean seed and the remaining 20 businesses supply lucerne, radish, onion and broccoli seeds for seed sprout production.

8.1.2 Sprout production

The seed sprout industry consists of mainly small businesses (around 30 to 40 businesses known to FSANZ) located throughout Australia. An industry association has been established (Australian New Zealand Sprouters Association) and FSANZ has consulted (through the SDC and targeted consultation as required) with the members and other sprout producers in assessing impacts on this sector.

8.1.3 Wholesalers and Retail

While seed sprouts may be distributed directly to retail outlets from seed sprout businesses, a large proportion is distributed via fresh food wholesale markets.

Some supermarkets have implemented requirements for seed sprouts, particularly for their own brand products. While this is an issue of market access and the impacts on the retail sector may not be assessed directly, any implications on the existing arrangements and requirements are considered in the cost benefit analysis.

8.2 Consumers

People generally consume seed sprouts because of health and culinary factors (e.g. the use of bean sprouts in Asian dishes). There is also 'indirect' consumption of seed sprouts where they are incorporated in dishes as a garnish.

There is very limited Australian or international information on the extent of sprout consumption. Data from the 1995 National Nutrition Survey (Australia) indicates that, at that time, approximately 4% of respondents consumed seed sprouts.

Alfalfa sprouts were consumed most frequently whereas mung bean sprouts were consumed in the largest quantities. Since that time the range of seed sprout products has grown as has their availability at retail outlets and use by the food service sector.

8.3 Government

The State and Territory government agencies responsible for investigating cases of food-borne illness associated with sprouts and for the implementation and enforcement of any regulatory food safety measures will be affected by the outcome of this Proposal.

9. Assessment of options

A detailed Regulatory Impact Statement (RIS) has been completed for this Proposal and is provided in Supporting Document 2. The RIS assesses the impact of each risk management option proposed for each of the affected parties. The impact assessment includes a cost and benefit analysis for each of the options.

A summary of the key findings of the impact and cost benefit analysis is provided below.

9.1 Option 1(a) – Abandon the Proposal, thus maintaining the *status quo*

The major advantage of this option is that it imposes no additional costs. However, the disadvantages are that the outbreaks of food-borne illness and the associated cost burden will remain unchanged. In addition, there is the continuing cost to government of investigation of food-borne illnesses.

The resultant cost to the Australian community from the 2005 and 2006 outbreaks is estimated to be AUD 1.19 million. Therefore the costs of food-borne illness associated with the consumption of seed sprouts are estimated to be about \$600,000 per year (if events of the same magnitude as the 2005-06 events were to occur biannually) or about \$240,000 per year (if outbreaks of the same magnitude as in 2005-06 were to occur every 5 years). In addition there is loss and damage of reputation to industry and consumer confidence when outbreaks occur.

This option is not supported by FSANZ because it does not support public health and safety objectives.

9.2 Option 1(b) – Abandon the Proposal. Self regulation

Self regulation may be considered where there is no strong public health and safety concern and the problem can be addressed by the market itself through, for example, the development of and compliance with self-regulatory arrangements.

The following table assesses the industry self-regulation option for seeds sprouts against the Council of Australian Governments (COAG) Regulatory Impact Statement guidelines.

Table 1: Assessment of self regulation

Factors to be considered	Analysis
There is no major public health and safety concern.	<ul style="list-style-type: none"> • Outbreaks of food-borne illness associated with the consumption of contaminated seed sprouts have been identified as the problem to be addressed by this proposal. • An expanded self-regulatory industry scheme would need to cover all necessary controls for food safety management. If there are any gaps or irregular compliance, the risk of food-borne illness occurring is maintained.
Adequate coverage of the sprout industry can be achieved.	<ul style="list-style-type: none"> • The seed sprout industry is a very small industry comprised of small (many family owned and operated) businesses. • There are around 30-40 seed sprout businesses known to be operating throughout Australia (there is no easy way to identify all sprout businesses, particularly those not supplying to major retailers or wholesale markets). • There is high turnover of businesses involved in the sprout production industry • It only takes one outbreak of food-borne illness (one business) associated with the consumption of seed sprouts to impact on the entire industry.
There is a viable industry association.	<ul style="list-style-type: none"> • An industry association was formed following the <i>Salmonella</i> outbreak in Australia in 2005-2006 attributed to seed sprouts – the Australian New Zealand Sprouters Association (Sprouters Association). • The Sprouters Association has raised the issue, that the limited size of the industry makes the funding of an industry association that has sufficient influence impossible. • Currently, just over half of the (known) producers are members.
There is a cohesive industry with like-minded or motivated participants committed to achieving goals.	<ul style="list-style-type: none"> • The Sprouters Association has developed a set of guidelines to support the safer production of seed sprouts. • The Sprouters Association have reported that there has been a very low level of uptake of their guidelines because it is voluntary and businesses do not want to meet the expenses involved in implementation (such as HACCP accreditation, verification testing).
Evidence that voluntary participation can work.	<ul style="list-style-type: none"> • The Sprouters Association has sought government intervention and the development of regulatory measures (as appropriate) for the industry, because there has been resistance to the voluntary adoption of guidelines.

Self regulation is not a viable Option because there currently isn't a cohesive sprout production industry which could effectively adopt a self regulation option. The Australia New Zealand Sprouters Association has sought government intervention and the development of regulatory measures for the industry, because there has been resistance to the voluntary adoption of industry guidelines by a significant proportion of the industry. In addition, industry consultation has revealed the percentage of sprouts produced in Australia under a food safety or quality management scheme is approximately 60%, therefore a large proportion of sprouts are not currently being produced under an industry or self regulatory arrangement.

9.3 Option 2 – Prepare draft food regulatory measure

Option 2 is the development of through chain regulatory measures.

9.3.1 *Option 2 (a) Through chain food regulatory measures (for seed producers, seed processors and sprout producers).*

A review of the effectiveness and practicalities as implemented by the three sectors involved in production has been undertaken. This review is in response to advice from industry that some of the food safety control measures may not be practical or effective in practice. The Jurisdictions have also advised there may be enforcement issues with some measures.

The main point of microbiological contamination of the seed used for sprout production is likely to be during the seed production process. The main issue of concern is the use of animal manure, either as a fertilizer or from grazing animals on paddocks or incidental contamination from wind drift, rodents, birds and other animals. The manure can contain pathogenic organisms such as *Salmonella* and *E. coli* which may become attached to the seed.

The removal of grazing animals is impractical for seed producers as different fields for grazing animals would need to be available. Also, the animals need to be removed for considerable amounts of time as pathogens are able to survive in the soil for quite some time. Preventing birds and wild animal contact with growing fields is impractical.

The food safety measures discussed in Section 7.3.1 for seed processing may prevent the seed from becoming additionally contaminated during seed processing but they may not contribute significantly to a reduction of existing level of microbiological contamination on the seed.

Microbiological screening by seed processors has a limited capacity to detect and exclude contaminated seed given the difficulties in detecting low levels of pathogens in these samples. However, the control measures available to seed processors have the potential to minimise an increase in pathogen contamination of seeds during seed processing, storage and distribution.

There may also be considerable outlay of time and money for seed processors to set up facilities and equipment that could support the segregation of the seed used for sprouting from the seed used for other purposes.

Sprout producers' operations have the capacity to reduce pathogens and better detect whether pathogens were present (for example, seed decontamination and testing of spent irrigation water after the sprouts have been grown). Studies have demonstrated that the level of *Salmonella* and *E. coli* O157:H7 in irrigation water is similar to the level on sprouts (Fu *et al.*, 2008, Fu *et al.*, 2001). As such the implementation of sampling/testing plans is the most effective measure to prevent outbreaks as contaminated batches of sprouts can be identified. The total costs identified for each affected party are in the range of:

Table 2: The cost associated with regulating all sectors

Affected Party	Upfront Costs (\$AUD)	Ongoing Costs (\$AUD)
Seed Producers / Growers		1.16 million – 9.68 million
Seed Processors	960,000 – 9.5 million	540,000 – 970,000
Sprout Producers	90,000	400,000
Government	60,000	55,000
Consumers	Some or all costs passed on	Some or all costs passed on
Total	1.24 million – 9.69 million	2.21 million – 10.93 million

From Table 2 above, the estimated higher end of costs to all affected parties could be up to about \$9.7 million upfront and another \$10.93 million ongoing.

The total costs to all parties involved in the production of sprouts are likely to be overestimated due to the shifting of costs. For example, if seed processors are thoroughly testing the seed for the presence of microorganisms, then the costs of microbiological testing and verification of seed for sprout producers may be reduced.

The significant costs estimated for seed production and seed processing is linked to the fact that the majority of seed produced and processed is for non sprouting purposes.

Taking into consideration the potential costs to seed producers and seed processors, it is likely that costs of regulating seed producers and seed processors will not achieve the maximum net benefit for the community as a whole. Though ideal from a food safety perspective, the burden of illness or the estimated risk is not commensurate to justify regulatory requirements on seed producers and seed processors.

9.3.2 *Option 2(b) Food regulatory measures for sprout producers only.*

As discussed above, the sprout production stage is the most appropriate stage in the production of seed sprouts to manage the hazards.

As indicated in Table 2 the total costs to sprout producers to implement food regulatory measures for sprout production is estimated to be in the order of \$90,000 upfront and another \$400,000 ongoing. In addition the cost to government is estimated at \$60,000 upfront and \$55,000 ongoing. Therefore the total estimated costs of regulatory measures for sprout producers are \$150,000 upfront and \$455,000 ongoing.

FSANZ estimates that by regulating sprout producers a 23%-65%⁶ reduction in burden of illnesses or benefits of \$55,000 – \$390,000 per year may be realised (i.e. 23% - 65% of estimated \$240,000 – \$600,000 burden of illness).

As outlined above the estimated costs to implement food regulatory measures are \$150,000 upfront - \$455,000 ongoing. The estimated benefits are \$55,000 - \$390,000 per year.

Sensitivity analysis indicates that the net present values (NPVs) accruing from this option are subject to a high degree of uncertainty and are estimated to range between a positive NPV of \$595,000 and a negative NPV of (-) \$3.48 million over 10 years. This option would require preventing about 239 cases of food-borne illness annually to completely offset costs. Depending on the assumptions made, this would require outbreaks to occur between 0.79 to 5.6 times more regularly than they are estimated to currently occur (or be of 0.79 to 5.6 times the magnitude of previous outbreaks).

Therefore there is a net cost to the implementation of food regulatory measures⁷.

9.4 **Consultation on regulatory impact analysis.**

FSANZ would like to provide a further opportunity for stakeholders to provide feedback regarding the costs, benefits and any other information provided in the Regulatory Impact Statement. The following questions have been provided to prompt consideration:

⁶ Please refer to Supporting Document 2 for information on how the range of 23% - 65% has been determined and its limitations.

⁷ There are limitations and uncertainty to some of the key cost and benefit estimates, further details and calculations of net benefits are presented in the limitations and sensitivity analyses section in Supporting Document 2.

Are there any other affected parties that have not been identified in this regulatory impact statement that should be included?

Are there any other costs or benefits that should be considered in the regulatory impact statement?

Do you have any additional data or information in relation to the costs and benefits? FSANZ welcomes the opportunity to consider any additional information.

Are there any other costs or benefits for business that have not been covered in the regulatory impact statement?

Are there any other costs or benefits for government that have not been considered in the regulatory impact statement?

Are the sensitivity analyses appropriate to cover the range of outcomes for the preferred option?

Consultation and communication

10. Communication

This 2nd Assessment Report contains a draft Production and Processing Standard for Seed Sprouts. This will be the first time that most people with an interest in the seed sprout industry will become aware of the proposed national, mandatory food safety requirements. FSANZ therefore intends to use every available communication channel to let industry (and other players) know that regulatory changes are being contemplated.

FSANZ will place advertisements in the national press inviting submissions. This invitation will also be carried on the FSANZ website, with links to the report and to how interested parties can make submissions.

Organisations or individuals with an interest in this Proposal can seek to have their names listed as an interested party (to receive direct notifications about this Proposal) by emailing the Standards Management Officer at standards.management@foodstandards.gov.au with their full contact details.

In its communication, FSANZ recognises the following main target audiences: the seed sprout industry, government agencies within the food regulatory system, consumers, retail and food service industry, the media and public health professionals. The main communication messages are summarised below:

Target audiences	Communication messages
Seed sprout industry	<ul style="list-style-type: none">• A national approach to seed sprout safety will provide businesses with regulatory certainty.• Food safety requirements will be consistent with international requirements.• The new Standard will be enforceable.• The Standard will impose a minimum impost on industry.• FSANZ and State/Territory agencies will prepare support materials to assist with compliance.

Target audiences	Communication messages
Compliance agencies	<ul style="list-style-type: none"> • The Standard is outcomes-based and represents minimum effective regulation. • It is underpinned by a rigorous scientific risk assessment. • The Standard forms part of a whole-of-chain approach to the seed sprout industry.
Consumers, the media and health professionals	<ul style="list-style-type: none"> • The Australian seed sprout industry and government have developed a national approach to seed sprout safety. • The new regulations increase the protection of consumers from seed sprouts by minimising contamination. • The national regulations will apply across Australia to domestic produce and for imported seed sprouts.

10.1 World Trade Organization notification

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

The proposed draft Production and Processing Standard for Seed Sprouts has been developed recognising the internationally agreed Codex Code of Hygienic Practice for Fresh Fruits and Vegetables, Annex for Sprout Production.

FSANZ has determined that there may be implications should an application be received to import seed sprouts. Therefore a notification to the WTO will be made in accordance with Australia's obligations under the Sanitary and Phytosanitary Measures Agreement. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

11. Consultation

The FSANZ process for the development of a standard involves a consultative and transparent process that reaches the industry concerned, State and Territory Government enforcement agencies, as well as consumers. A Standards Development Committee (SDC) is established for each primary production and processing standard with representatives from the industry sector, the relevant State and Territory government agencies and consumer organisations to provide ongoing advice to FSANZ throughout the standard development process. The SDC contributes a broad spectrum of knowledge and expertise covering industry, government, research and consumers (a list of SDC members for this standard development Proposal is provided in Supporting Document 4).

11.2.1 Submissions at 1st Assessment

Fifteen submissions were received from industry, government and consumers. A summary of the individual submissions and the key issues and the FSANZ response to the submissions is provided in Attachment 3.

The main issues raised in the submissions related to:

- support for Option 3 – development of food regulatory measures in the Code.

scope of the Standard

- reference to international standards
- risk management – seed and seed sprout production, various suggestion to manage the hazards associated with seed sprout production.
- seed decontamination processes
- costs to industry, government and consumers
- water use.

Conclusion

12. Conclusion and the preferred approach

A comparison of options considered indicates that the status quo would not be the preferred option as it continues to expose the community to the risk of food-borne illness, with an average cost of food-borne illness estimated to be \$240,000– \$600,000 annually due to consumption of sprouts.

As discussed above, industry self regulation is not an adequate option to address health and safety concerns.

A through-chain regulation option incorporating preventative control measures for all sectors involved in the production of sprouts (i.e. seed producers, seed processors and sprout producers) may be ideal from a food safety perspective. However this option is estimated to be cost ineffective and could be inconsistent with principles of minimum necessary regulation for achieving the maximum net benefit for the community as a whole.

Regulation of sprout producers only is likely on present estimates to impose a net cost on the community; however it is more cost effective than the through-chain option. It is likely to result in less illness than would be recorded in the status quo and reduce the risk of future sprouts related food-borne illnesses.

The proposed Standard also meets FSANZ’s statutory considerations, provides a nationally consistent legislative framework for seed sprout safety and provides measures that are outcome based and would be consistent with principles of minimum necessary regulation.

Therefore Option 2(b) regulation of sprout producers only is the preferred option.

<p>Preferred Approach</p>

<p>To prepare draft Standard 4.2.6 – Production and Processing Standard for Seed Sprouts for sprout producers only.</p>
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12.1 Reasons for preferred approach

At 2nd Assessment, FSANZ recommends that the Standard 4.2.6 – Production and Processing Standard for Seed Sprouts (Attachment 1) into Chapter 4 for the following reasons. The proposed amendments:

- address the public health and safety problem identified with seed sprouts in the most cost effective manner

- are consistent with the section 18 objectives of the FSANZ Act to protect public health and safety
- provide a nationally consistent legislative framework to address seed sprout product safety
- provide measures that are outcome based and would be consistent with principles of minimum necessary regulation.

12.2 Draft Standard 4.2.6 - Production and processing of seed sprouts

FSANZ has prepared a draft variation to the Code, Standard 4.2.6 Production and processing standard for seed sprouts (Attachment 1) for consultation. FSANZ has become aware that there are some issues in the draft standard which need to be addressed. We would particularly welcome comments on the scope and food safety management requirements of the draft standard.

Draft Standard 4.2.6 is a standard with requirements for sprout producers only, for the production and processing of seed sprouts. The activities and scope of the Standard are outlined in Section 3 for sprout production and the definition of seed sprouts. Sprout producers will be required to demonstrate that they control potential food safety hazards associated with their business activities.

Sprout producers will be required to produce safe sprouts through ensuring that the hazards arising during sprout production are managed. The specific hazards that should be managed include hazards associated with the seed and from inputs during production and processing. Effective decontamination processes for seed and sprouts must also be implemented. The control measures used to control the hazards should be validated and monitored to verify that they are working.

Sprout producers will be required to comply with the requirements of Standards 3.2.2 and 3.2.3 which includes requirements for, premises, equipment, health and hygiene requirements, storage and requirements for skills and knowledge to minimise contamination.

The Standard specifies a traceability requirement which means sprout producers will be required to implement a system within their operations to account for the seed or sprouts supplied to or by the business to be rapidly accounted for in the event of a food safety incident.

13. Implementation and review

13.1 Implementation of primary production and processing standards

Submissions received on the 1st Assessment Report requested the development of guidance and implementation materials to assist businesses comply with any proposed regulatory measures.

Implementation of the Code is the responsibility of the State and Territory Governments. ISC facilitates the consistent national implementation of the Code and is responsible for developing nationally consistent implementation approaches.

A recent initiative of ISC to harmonise the processes of standard development and implementation is, the integrated model for standards development and consistent implementation (the integrated model).

The integrated model is built on the concept that a 'package' of information is provided to Food Ministers, rather than a just a draft standard.

The 'package' includes the draft Standard, but also contains information on implementation matters associated with the standard so that Ministers may be informed on 'how' the Standard is to be implemented at the time the standard is provided for consideration. The 'package' also contains a comprehensive regulatory impact statement (RIS) where the states and territories have provided cost information on what the standard will cost to implement.

The provision of implementation documents describing 'how' the standard is to be implemented along with a RIS describing the cost impost to Food Ministers will allow Ministers to make more fully informed decisions on national food standards at the time they are asked to consider them.

The Food Regulation Standing Committee (FRSC) has agreed that the integrated model be piloted on the Primary Production and Processing Standard for Eggs and Egg Products (the Egg Standard).

In March 2010 FRSC endorsed the development of implementation plans for other primary production and processing standards, which would include this Proposal.

The pilot implementation package developed for the Egg Standard comprises:

- Compliance Plan
- Model food safety management statements (food safety management statement templates)
- Reference materials (existing prescriptive government and industry documents), and
- Response materials

It should be noted that all documents contained in the implementation package are statements of intent. They are not legal documents in their own right, but provide the direction for consistent implementation of a national food standard in Australian states and territories.

The Compliance Plan describes the minimum requirements for compliance with the Primary Production and Processing Standard and provides for a regulator's intent to implement monitoring procedures for determining industry compliance. The scope of issues that may be considered by the compliance plan is defined by the scope of the corresponding Primary Production and Processing Standard.

The intent of the model food safety management statement templates is to translate the Primary Production and Processing Standard and the compliance plan into a practical document for businesses to complete. These templates are prepared for industry use only. To assist businesses in completing the templates, a list of key reference materials is provided with the templates. Reference materials, where matters of prescription and detail may be found, are existing government and industry documents. Businesses may use these documents to assist in completing the templates when they apply the templates to their individual business operations.

Response materials provide direction to government in facilitating national consistency in response to specific incidents. Direction is provided with respect to enforcement proceedings through the Australia New Zealand Enforcement Guideline and in national food incidents through the National Food Incident Response Protocol.

13.1 Rural Industries Research and Development Corporation Project

A requirement of the draft Standard for sprout producers, as part of their food safety management is for the validation of the control measures they put in place to control the hazards arising during seed sprout production.

Validation is the process of confirming a control measure is effective in controlling the food safety hazard. To validate the control measures identified, a sprout producer would usually refer to existing scientific literature or published information that confirms the control measure will be effective.

A Rural Industries Research and Development Corporation (RIRDC) funded project, with contributions from the sprout industry, Horticulture Australia Limited, Primary Industries Resources South Australia and FSANZ, officially started in July 2009 and will run over three years.

During the first phase of the project industry visits to seed cleaning businesses in SA and sprout producers in Western Australia, South Australia, Victoria, New South Wales, Queensland and Tasmania were conducted. The information collected builds on previous work by the ISC Working Group on Sprouts (2006) and FSANZ' First Assessment Report (2009).

The industry visits were followed by a literature review of seed decontamination processes. During late March and April 2010 seed samples from before and after seed cleaning will be microbiologically tested to assess the effectiveness of cleaning processes. Later in 2010, alternative decontamination treatments to 20,000 ppm calcium hypochlorite will be assessed.

One of the intended outcomes of this work (due for completion in 2012) is to provide industry guidance on the effectiveness of seed decontamination processes which will help sprout businesses with the validation of control measures.

13.2 Implementation period of 1 year

It is suggested at this stage that a 12 month period will be provided from the date the proposed production and processing Standard for seed sprouts is gazetted and for the Standard to take effect. This time is provided to enable industry and the jurisdictions to have measures in place to implement the requirements of the Standard. This is due to support from industry and the majority of Jurisdictions for the requirements of the Standard to commence as soon as possible.

14. Review

FSANZ is committed to undertaking evaluation of the impact of implementing key new food regulatory measures and outlines the program for evaluation activities in its Evaluation Strategy documents available on the FSANZ website.

FSANZ will consider review and evaluation strategies for this Proposal with members of the SDC in the next Proposal development phase.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Memorandum
3. Summary of issues raised in public submissions on the 1st Assessment Report

References:

- Australian Bureau of Statistics (1995) National Nutrition Survey, Foods Eaten, Australia. Accessed on 31 March 2010
[http://www.ausstats.abs.gov.au/Ausstats/subscriber.nsf/0/CA25687100069892CA256888001CD460/\\$File/48040_1995.pdf](http://www.ausstats.abs.gov.au/Ausstats/subscriber.nsf/0/CA25687100069892CA256888001CD460/$File/48040_1995.pdf)
- Ashraf, H.R.L., Atwood, S., Bloom, J., Blaise, D. and Salazar, J. (2008) Efficacy of HACCP-based food handling training program for front-line foodservice workers: a report on a collaborative work between regulatory agencies and academia. *Journal of Culinary Science & Technology* 6(1):63-76
- Beuchat, L.R. (1996) Pathogenic microorganisms associated with fresh produce, *Journal of Food Protection* Volume 59 (2): 205-216.
- Campbell, Monica E.; Gardner, Charles E.; Dwyer, John J.; Isaacs, Sandy M.; Krueger, Paul D.; Ying, Jane Y. (1998). Effectiveness of public health interventions in food safety: a systematic review. *Canadian Journal of Public Health* 89 (3):197-202
- Clayton, D.A., Griffith, C.J., Price, P. and Peteres, A.C. (2002) Food handlers' beliefs and self-reported practices. *International Journal of Environmental Health Research* 12(1):25-39
- Codex. (2003) Code of hygienic practice for fresh fruits and vegetables (CAC/RCP 53-2003).
- Coleman, P. and Roberts, A. (2005) Food hygiene training in the UK: a time for change. *Food Service Technology* 5(1):17-22
- Egan, M.B., Raats, M.M., Grubb, S.M., Eves, A., Lumbers, M.L., Dean, M.S. and Adams, M.R. (2007) A review of food safety and food hygiene training studies in the commercial sector. *Food Control* 18(10):1180-1190.
- FAO/WHO, 2002, Global Forum of Food Safety Regulators. Agenda Item 4.2. a) Hygiene Practice Manual for Radish Sprouts Production in Japan. Marrakesh, Morocco, 28 - 30 January 2002
- Fischer, A.R.H., Aarieke, E.I.D.J., Van Asselt, E.D., De Jonge, R., Frewer, L.J. and Nauta, M.J. (2007) Food safety in the domestic environment: an interdisciplinary investigation of microbial hazards during food preparation. *Risk Analysis* 27(4):1065-1081.
- Food Consumer Behaviour and Health Research Centre (2005) *Final Report: Evaluation of UK food hygiene and safety training*. Report No. Project Code: B13001, University of Surrey. Accessed on 30 March 2010 from http://www.foodbase.org.uk/admintools/reportdocuments/186-1-320_Evaluation_of_UK_food_hygiene_and_safety_training-FINAL_REPO.pdf
- Food and Drug Administration (2005) *Sprout Safety Public Meeting*, Accessed on 30 March 2010 from <http://www.fda.gov/OHRMS/DOCKETS/98fr/05-8103.htm>
- Food Standards Agency (2006) *4C's strategy - promoting food hygiene in the home with a particular focus on working with schools and promoting local initiatives*. Accessed on 30 March 2010 from <http://www.food.gov.uk/multimedia/pdfs/4cstrategydoc.pdf>, United Kingdom.
- Food Standards Australia New Zealand (2005) *Benchmark research on the poultry industry*. Report No. Evaluation Report Series No.11, 1-333. Accessed on 30 March 2010 from http://www.foodstandards.gov.au/_srcfiles/Poultry_Benchmark_Res_FULL_REPORT.pdf.
- Food Standards Australia New Zealand (2008) Consumer attitudes survey 2007. *A benchmark survey of consumers' attitudes to food issues*. Accessed on 30 March 2010 from http://www.foodstandards.gov.au/_srcfiles/Consumer%20Attitudes%20Survey.pdf

- Fu, T., Reineke, K.F., Chirtel, S. and Vanpelt, O.M. (2008) Factors influencing the growth of Salmonella during sprouting of naturally contaminated alfalfa seeds. *J Food Prot* 71(5):888-896.
- Fu, T., Stewart, D., Reineke, K., Ulaszek, J., Schlessner, J. and Tortorello, M. (2001) Use of spent irrigation water for microbiological analysis of alfalfa sprouts. *Journal of Food Protection* 64(6):802-806.
- Gorski, L., Palumbo, J.D. and Nguyen, K.D. (2004) Strain-specific differences in the attachment of *Listeria monocytogenes* to alfalfa sprouts. *Journal of Food Protection* 67(11):2488-2495 Hall G. et al. 2006. An Estimate of under-reporting of food-borne notifiable diseases. *NCEPH Working Paper Number 52*. February 2006
- Ismail, Z. and Abdullah, M.R. (2004) A study on hygienic standard of food premises and microbiological quality of food in Kota Bharu. Working Paper. Universiti Sains Malaysia.
- Jay, S.J., Comar, D. and Govenlock, L.D. (1999) A video study of Australian domestic food-handling practices. *Journal of Food Protection* 62(11):1285-1296.
- Johnson, D., Hipps, N. and Hails, S. (2008) Helping consumers reduce fruit and vegetable waste: final report. Retail Programme - Food Waste. Report No. RTL044-001, WRAP, United Kingdom, 1-94.
- Kim, H.J.; Lee, D.S.; Paik, H.D. (2004) Characterization of *Bacillus cereus* isolates from raw soybean sprouts. *Journal of Food Protection* Volume 67 (5): 1031-103
- Kirk M., 2006, Outbreaks Associated with Raw Sprouts. Ozfoodnet presentation.
- Kosa, K.M., Cates, S., Karns, S., Godwin, S.L. and Chambers, D. (2007) Consumer knowledge and use of open dates: results of a web-based survey. *Journal of Food Protection* 70(5):1213-1219
- Li-Cohen, A.E. and Bruhn, C.M. (2002) Safety of consumer handling of fresh produce from the time of purchase to the plate: a comprehensive consumer survey. *Journal of Food Protection* 65(8):1287-1296
- McCurdy, S.M., Takeuchi, M.T., Edwards, Z.M., Edlefsen, M., Kang, D.-H., Mayes, V.E. and Hillers, V.N. (2006) Food safety education initiative to increase consumer use of food thermometers in the United States. *British Food Journal* 108(9):775-794
- Microbiological Safety of Food Funders Group (2008) *UK publicly funded research relating to food preparation practices and behaviour in relation to the microbiological safety of food. Research between 1992 and 2007*. Accessed on 30 March 2010 from <http://www.food.gov.uk/multimedia/pdfs/09finalreportmsffg>
- Nauta, M.J. (2009) Food safety in the domestic environment: the effect of consumer risk information on human disease risks. *Risk Analysis* 28(1):179-192.
- Nieto-Montenegro, S., Brown, J.L. and LaBorde, L.F. (2008) Development and assessment of pilot food safety educational materials and training strategies for Hispanic workers in the mushroom industry using the Health Action Model. *Food Control* 19:616-633.
- NWC Research (2008) Food safety awareness - a research report. the third of three tracking reports that chart changes in consumer knowledge. Report No. 08141.REP, State Government of Victoria, Australia. Department of Human Services, Melbourne, Australia, i-21.
- Prokopowich, D.; Blank, G. (1991) Microbiological evaluation of vegetable sprouts and seeds. *Journal of Food Protection*: 54 (7) 560-562

Redmond, E., Griffith, C.J., Slader, J. and Humphrey, T. (2001) The evaluation and application of information on consumer hazard and risk to food safety education. Report No. B02010, Produced by the University of Wales, Cardiff (UWIC) and PHLS, Exeter on behalf of the Food Standards Agency, United Kingdom, 1-236.

Robertson, L.J.; Johannessen, G.S.; Gjerde, B.K.; Loncarevic, S (2002) Microbiological analysis of seed sprouts in Norway *International Journal of Food Microbiology* 25:119-126

Samadpour, M.; Barbour, M.W.; Nguyen, T.; Cao, T.M.; Buck, F.; Depavia, G.A.; Mazengia, E.; Yang, P.; Alfi, D.; Lopes, M.; Stopforth, J.D. (2006). Incidence of enterohemorrhagic *Escherichia coli*, *Escherichia coli* O157, *Salmonella*, and *Listeria monocytogenes* in retail fresh ground beef, sprouts, and mushrooms. *Journal of Food Protection* 69 (2):441-443

Terpstra, M.J., Steenbekkers, L.P.A., de Maertelaere, N.C.M. and Nijhuis, S. (2005) Food storage and disposal: consumer practices and knowledge. *British Food Journal* 107(7):526-533.

United States Food and Drug Administration (USFDA), Department of Health and Human Services, Sprout Safety Public Meeting Federal register Online <http://www.fda.gov/OHRMS/DOCKETS/98fr/05-8103.htm>

Vaz, M.L.S., Novo, N.F., Sigulem, D.M. and Morais, T.B. (2005) A training course on food hygiene for butchers: measuring its effectiveness through microbiological analysis and the use of an inspection checklist. *International Association for Food Protection* 68(11):2439-2442.

Warriner, K., Spaniolas, S., Dickinson, M., Wright, C. and Waites, W.M. (2003) Internalization of bioluminescent *Escherichia coli* and *Salmonella* Montevideo in growing bean sprouts. *Journal of Applied Microbiology* 95(4):719-727.

Draft variation to the *Australia New Zealand Food Standards Code*

Subsection 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence: 12 months from gazettal

[1] *The Australia New Zealand Food Standards Code is varied by inserting –*

STANDARD 4.2.6

PRODUCTION AND PROCESSING STANDARD FOR SEED SPROUTS

(Australia only)

Table of Provisions

Division 1 – Preliminary

1 Interpretation

Division 2 – Production and processing of seed sprouts

- 2 Meaning of sprout producer
- 3 Application of food safety standards
- 4 General food safety management
- 5 Receiving seed
- 6 Inputs
- 7 Decontamination
- 8 Traceability
- 9 Sale or supply

Clauses

Division 1 – Preliminary

1 Interpretation

(1) Unless the contrary intention appears, and subject to Standard 4.1.1, the definitions in Chapter 3 of this Code apply in this Standard.

(2) In this Standard –

decontamination means a process using a controlled environment to reduce the level of pathogenic organisms that may be present in seed sprouts.

food safety management statement means a statement, which at a minimum, has been approved or recognised by the relevant authority and subjected to ongoing verification activities by a supplier or producer, as the case may be, and the relevant authority.

Editorial note:

'Authority' is defined in Standard 4.1.1.

premises means any premises used for the production or processing of seed sprouts.

seed means seed for use in the production of seed sprouts.

seed sprouts means sprouted seeds or beans for human consumption that include all or part of the seed.

sprout producer has the meaning given by clause 2.

unacceptable means –

- (a) seed sprouts that are not suitable in accordance with clause 2 of Standard 3.1.1; or
- (b) seed sprouts that are in a condition, or contain a substance or an organism, that a person would ordinarily regard as making the seed sprouts unfit for human consumption; or
- (c) seed sprouts that are unsafe in accordance with clause 2 of Standard 3.1.1.

validate means confirming a control measure for a critical control point or process is effective to control a food safety hazard.

verify means the application of methods, procedures, tests and other tools for evaluation to determine compliance with the relevant requirement.

Division 2 – Production and processing of seed sprouts

2 Meaning of sprout producer

A **sprout producer** means a business, enterprise or activity that involves any or all of the following –

- (a) receipt or storage of seed;
- (b) decontamination of seed or seed sprouts;
- (c) soaking of seed;
- (d) germination or growth of seed;
- (e) harvest of seed sprouts;
- (f) washing, drying or packing of seed sprouts;
- (g) chilling or storage of seed sprouts; or
- (h) transport of seed sprouts.

3 Application of food safety standards

Standards 3.2.2 and 3.2.3 apply to a sprout producer.

4 General food safety management

- (1) A sprout producer must systematically examine all of its processing operations to identify potential hazards and implement control measures to address those hazards.
- (2) A sprout producer must also have evidence to show that a systematic examination has been undertaken and that control measures for those identified hazards have been implemented.
- (3) A sprout producer must validate and verify the effectiveness of the control measures.
- (4) A sprout producer must operate according to a food safety management statement that sets out how the requirements of this Division (including clause 3) are to be or are being complied with.

5 Receiving seed

A sprout producer must not produce or process seed sprouts if the producer ought reasonably know or suspect that the seed is of a nature or in a condition that would make the seed sprouts unacceptable.

6 Inputs

A sprout producer must take all reasonable measures to ensure inputs do not make the seed sprouts unacceptable.

Editorial note:

See Standard 4.1.1 for the definition of 'inputs'.

For guidance on what constitutes acceptable water in processing see the *Australian Drinking Water Guidelines 2004* of the National Health and Medical Research Council of Australia.

7 Decontamination

A sprout producer must implement effective decontamination processes prior to sale or supply of seed sprouts.

8 Traceability

A sprout producer must have a system to identify –

- (a) from whom seed or seed sprouts were received;
- (b) to whom seed or seed sprouts were supplied.

9 Sale or supply

A sprout producer must not sell or supply seed sprouts for human consumption if the sprout producer ought reasonably know or reasonably suspect that the seed sprouts are unacceptable.

Explanatory Memorandum

To commence: 12 months from gazettal

Item [1]

This item inserts a new Standard 4.2.6 in the Code. The purpose of each of the clauses is explained below.

Clause 1

This clause contains the definitions for this Standard. The purpose of subclause (1) is to apply the definitions in Chapter 3 of the Code (the Food Safety Standards), unless there is a definition in Standard 4.1.1 or Standard 4.2.5.

Subclause (2) contains a number of definitions for words used in this Standard. **Seed sprouts** are defined as sprouted seeds or beans for human consumption that include all or part of the seed. The intent of this definition is to limit the seed sprout producers that are required to comply with the standard to those that produce alfalfa, mung bean, broccoli, radish, onion or any other type of sprout that includes the seed or part of the seed in the final product.

The definition of **unacceptable** clarifies that seed sprouts are unacceptable if they are 'unsuitable' or 'unsafe' as defined in clause 2 of 3.1.1 and also if they are in a condition, or contain a substance or an organism, that a person would ordinarily regard as making the seed sprouts unfit for human consumption. For example seed sprouts would be unacceptable if they contain pathogenic organisms.

Clause 2

This clause sets out the activities which make a business a **sprout producer**.

Clause 3

This clause makes it clear that sprout producer is required to comply with Standards 3.2.2 and 3.2.3 in Chapter 3 of the Code.

Clauses 4

Subclauses (1), (2), and (3) set out the elements a sprout producer must develop and incorporate in a food safety management statement. This statement becomes the vehicle whereby sprout producers demonstrate compliance with the elements of the Standard.

The sprout producer will need to prepare a food safety management statement setting out how the requirements of this Division (i.e. Division 2 – Production and processing of seed sprouts) are being complied with. This statement must be approved or endorsed by the Authorities.

Clause 5

The intent of this clause is to ensure the sprout producer sources seed that is acceptable for producing seed sprouts. The sprout producer must include the control measures that are taken to ensure that seed is acceptable, including any seed testing programs. The control measures must be validated and verified.

Clause 6

This intent of this clause is to make it clear that, when preparing the food safety management statement, producers are required to examine and show how they are managing the inputs into their production and processing practices. For example, how they deal with water that is used to wash seed and irrigate the germinating seeds.

Clause 7

The intent of this clause is to ensure that seed sprouts do not contain pathogenic organisms.

The sprout producer must ensure that the decontamination processes used will reduce the level of pathogens. For example if chemicals are used to treat seeds prior to germination then the chemical concentration and contact time must be validated.

Clause 8

The intent of this clause is to ensure that sprout producers have systems which will enable them to identify the sources of the seed they use for sprouting and the businesses they supply with seed sprouts. This will enable the business to trace seeds and seed sprouts in the event of a food safety problem. The requirement is in addition to the requirement for a recall system in Standard 3.2.2.

Clause 9

The intent of this clause is to prevent the transfer of unacceptable product from the producer to other parts of the supply chain, for example, for retail sale or use in catering.

Summary of Submissions at 1st Assessment

1. Introduction

The 1st Assessment Report for Proposal P1004 was released for a seven-week consultation from 15 July to 2 September 2009. Fifteen submissions were received from the following:

- Cherikoff Bioactives – Cherikoff Food Services
- Coles Supermarkets
- Department of Agriculture, Fisheries and Forestry
- Department of Food Science, University of Guelph
- Victorian Government (including the Department of Primary Industries and Department of Health)
- Food Technology Association of Australia
- New South Wales Food Authority
- New Zealand Food Safety Authority
- Parilla Fresh
- QA Plus P/L
- Queensland Government
- South Australian Department of Health
- Department of Health Western Australia
- Mr George Seymour (Consumer Liaison Committee Representative)
- CSIRO

Some submissions indicated support for (or objections to) courses of action described in the 1st Assessment Report and this has been taken into account during the 2nd Assessment stage. Others provide information or data or suggestions for control measures which have also been taken into account.

2. Issues raised in submissions

The main issues raised are described below and comments provided by individual submitters are listed in Table 1. FSANZ responses below are in italics.

Support for Option 3 development of food regulatory measures in the Code.

There were no objections to any of the stated options in the 1st Assessment Report. The majority of submissions supported Option 3 Development of food regulatory measures in the Code to minimise the adverse health risk associated with the consumption of seed sprouts.

FSANZ has taken into account the support received for Option 3 in proposing Option 3 as the preferred option at 2nd Assessment.

A jurisdiction commented that regulatory measures should be clearly stated e.g. food safety programs in accordance with Standard 3.2.1.

The 2nd Assessment Report includes the proposed drafting. The draft Standard outlines general food safety management requirements. These are similar to the requirements of Standard 3.2.1.

An industry submission commented that current voluntary arrangements have not been observed by many parties.

The lack of uptake of voluntary arrangements is a factor in support of Option 3, regulatory measures.

Scope of the Standard

The scope of products covered by the Proposal is green sprouts (alfalfa sprouts, onion sprouts, radish sprouts etc), bean sprouts and snow pea shoots. One submission asked whether the scope as described in the Report is broad enough to allow the future inclusion of other varieties of sprouts and shoots.

FSANZ has discussed the scope of the Proposal in Section 3 of the 2nd Assessment Report and a definition of seed sprouts is provided in Section 3.2.

Reference to international standards

In the interest of harmonisation of trade between countries it was suggested that FSANZ considers the requirements of various International Standards and Codes of Practice currently used in other countries. These include the Australia New Zealand Sprouters' Association *Guidelines for Australian and New Zealand Sprout Producers* (used by NZ Seed Sprouters'), Canadian Food Inspection Agency, *Code of Practice for the Hygienic Production of Sprouted Seeds (2007)*, US Food and Drug Administration *Guidance for Industry: reducing the Microbiological Food Safety Hazards for Sprouted Seeds*.

FSANZ has taken these standards and codes of practice into account to determine food safety measures for the sprout production chain.

Risk management – seed and seed sprout production

Submissions included suggestions to manage the risks from sprouts including:

- Seed sprout production should be categorised according to type of sprouts and the risk the different types present. It may be inefficient to regulate all seed sprouts in the same manner.

The primary production and processing standards express the control measures as outcome-based measures. This enables the hazards presented by the specific products (i.e. those included in the scope of the standard) to be addressed.

- Seed and seed sprout contamination could be minimised by education of consumers and industry personnel about good food hygiene practices and safe handling, storage and serving practices.

A discussion of education initiatives and their associated application is provided in Section 7.4 of the 2nd Assessment Report.

- Adequate recall procedures by seed sprout producers and traceability of contaminated batches of sprouts grown from particular seed lot

Traceability measures and recall procedures for seed sprouts are part of the draft Standard.

There were comments in support of the following measures and also views that they were impractical or not achievable in light of the current industry:

- restricting grazing animals and manure on fields used to grow seeds
- segregation of seed whereby seed grown for human consumption is separated from seed grown for animal fodder
- microbiological sampling and testing of spent irrigation water and of batches of sprouts in a 'test and hold' regime.

Section 9 in the 2nd Assessment Report discussed why some measures, or regulation on specific sectors of the seed sprout industry are not being pursued.

Seed decontamination

Numerous submissions raised issues associated with seed decontamination (disinfection, sanitation). These included requests for additional research and information on appropriate chemicals and concentrations required, occupational health and safety issues associated with the use of chemicals in high concentration (e.g. 20,000 ppm free chlorine), irradiation of seed, use of novel technologies and the effect of seed scarification on disinfection.

The South Australian Research & Development Institute (SARDI) under the Rural Industries Research and Development Corporation (RIRDC) program is currently examining agricultural practices in growing seeds for sprouting, post harvest treatments, handling, storage and transportation of seed, seed sanitation regimes and seed growing practices. This work (due for completion in 2012) is intended to resolve some of the questions raised above.

Costs to industry, government and consumers

Some submissions requested that consideration is given to the costs and benefits associated with any additional measures imposed, particularly in relation to the size of the industry.

Section 7 and the Regulatory Impact Statement (Supporting Document 2) provides an analysis of the costs and benefits associated with the regulatory options proposed for industry, government and consumers.

One Jurisdiction queried the practicality and cost of implementation for developing a primary production and processing standard that is a commodity based standard. The Jurisdiction proposed that the risks for the larger plant and plant products area should be assessed as a Proposal and that the assessment for seed sprouts should be within the larger Proposal work

FSANZ has undertaken preliminary scoping activities in relation to the broader plant and plant products area. Following discussions with ISC, it was decided to progress this Proposal ahead of a plant and plant product Proposal. The decision for progressing this Proposal was largely based on the identified food safety problem and priority for intervention.

Water use

Some submissions noted that the seed sprout industry utilises large volumes of water and it was suggested that the water should be potable water although this may be difficult to achieve if the water is recycled water.

The draft Standard requires sprout producers to take all reasonable measures to ensure inputs do not make the seed sprouts unacceptable. This would include ensuring water does not contaminate the product. Recycling of water would not want to be discouraged, but the primary consideration is ensuring the safety of the seed sprouts.

Table 1: Summary of issues raised in the public submissions

Submitter	Comments
Cherikoff Bioactives	<ul style="list-style-type: none"> The Proposal should recommend alternative means to reduce the microbial load potential of sprouts
Coles Supermarkets	<ul style="list-style-type: none"> Supports the development of a Primary Production and Processing Standard for Sprouts based on HACCP principles Observes that the current voluntary industry arrangements have not been observed by many parties Current industry guidelines may not take into account all the risks associated with sprouts for example <i>Listeria monocytogenes</i>
Australian Government Department of Agriculture, Fisheries and Forestry	<ul style="list-style-type: none"> Supports the development of a PPPS for Sprouts within the appropriate <i>Australia New Zealand Food Regulation Ministerial Council – Overarching Policy Guidelines on Primary Production and Processing Standards</i> and in particular the that the development of PPP Standards should take into account the objectives of the COAG Food Regulation Agreement Recommends FSANZ consider other relevant international standards to enable harmonisation where possible.
Department of Food Science, University of Guelph	<ul style="list-style-type: none"> Provided several publications of their research in the area of sprouts. The research is primarily focused on seed decontamination and sampling of spent irrigation water
Victorian Department of Primary Industries and Department of Health	<ul style="list-style-type: none"> Recognises that although there are many health benefits that may be derived from consumption of fresh produce including sprouts, that sprouts pose a particular public health challenge because the sprouting process is ideal for microbiological growth and the products are typically consumed raw Acknowledges that the Proposal work has arisen following the outbreak of food-borne illness associated with the consumption of seed sprouts. Suggests that other risk management strategies to achieve the objectives should be considered as part of this process. For example, include additional information to consumers. Caution should be taken when developing through chain control measures making sure they are not overly prescriptive resulting in impractical requirements and / or excessive costs inevitably passes on to consumers Effort should be made to identify and contact as many sprout producers as possible as well as organisations that represent organic growers Reports that seed sprouts can be purchased on the internet Requests that when evaluating the scientific risk for sprouts and developing risk mitigation measures, consideration is given to the different risk profiles associated with each type of sprout and whether it is inefficient to regulate all seed sprouts in the same manner The efficacy and practicality of risk mitigation measures should be considered particularly in relation to: <ul style="list-style-type: none"> Removal of grazing animals' negative impact on sprout yield and possible segregation of growing seed for sprouting The cost of microbiological testing and subsequent cost to the consumer Use of chemical sanitisers in chemical settings Occupational health and safety issues arising from the use of sanitisers Suggests further research into the method and use of sanitisers and the use of existing or novel technological solutions to eradicate pathogens. Suggests if Option 3 is pursued there may be increased cost to industry and therefore the consumer. Costs associated with on farm practices, segregation of seeds, decreased germination, use of sanitisers and prescribed testing should be assessed
The Food Technology Association of Australia	<ul style="list-style-type: none"> Agrees with Option 3 which involves the development of food safety regulatory measures. Suggests pathogenic microorganisms in seeds sprouts may be reduced through irradiation.

Submitter	Comments
New South Wales Food Authority	<ul style="list-style-type: none"> • Supports Risk Management Option 3 providing regulatory measures are clearly stated e.g. food safety programs in accordance with Standard 3.2.1 Food Safety Programs • NSWFA introduced food safety scheme requirements for NSW sprout producers to implement audited food safety programs in accordance with HACCP or Standard 3.2.1 Food Safety Programs • Notes that Guidelines produced by the Australia New Zealand Sprout Growers Association state members need to implement an externally audited HACCP program • Seed sprout production is subject to NSW Plant Products Food Safety Scheme. Snow pea sprouts are not captured by the Regulation. The Food Safety Scheme does not apply to growing, harvesting, cleaning, storing and transporting of seeds used to produce seep sprouts. • FSANZ should be able to demonstrate the efficacy of any proposed regulatory measures and that the benefits of implementing those measures clearly outweigh the costs particularly in relation to seed growing, harvesting, cleaning storage and transport • Report mung bean sprouts may be served lightly cooked • NSWFA has conducted a scoping study on plant and plant products and this study classifies the production of seed sprouts as a high risk microbiological risk rating • Looks forward to the results of research into the efficacy of different but comparable seed disinfection processes • NSWFA was able to demonstrate a positive benefit to cost ratio for the introduction of the Plant Products Food Safety Scheme (2005) and has previously prepared a regulatory impact statement.
New Zealand Food Safety Authority	<ul style="list-style-type: none"> • Supports the objective of the Australian Government to minimise adverse health effects associated with seed sprouts through primary production and processing control measures • Suggests that the existing guidelines for Australian and New Zealand Sprout producers are considered when developing any food regulatory measures and that they are provided as an attachment to the Second Assessment Report. Reference to the guidelines will help maintain equivalence between Australian and New Zealand sprout production methods. • Asks if the current scope of products included in the First Assessment report should be broadened to include 'sprouted seeds'. Not all sprouts are green and the current definition excludes non green sprouts like red cabbage, sango or pop corn sprouts. • Suggests that for seed disinfection, the chemical concentration and application times are validated and further scientific evidence is also provided to develop an outcome statement for microbiological treatment.
Parilla Fresh	<ul style="list-style-type: none"> • Suggests it is hard to differentiate between status quo and self regulation • Suggests sprouting industry is not able to self regulate and regulatory measures with clearly defined standards and requirements are the only way to minimise the risk of potential adverse health effects with seed sprouts • Suggests categorising sprouts according to their relative risk • Considers NSWFA requirements are a 'reasonable' guide for an industry standard apart from the 20,000 ppm free available chlorine requirement (too high) • Recommends seed should be tested pre-production in accordance with Codex and FDA guidelines. Seed sampled should be 'grown out for 24 – 48 hours and then sample of discharge water taken to be tested for <i>Salmonella</i> and <i>E coli</i>. • Suggests sprout growers should be required to implement an audited HACCP based food safety program that includes verification processes. • Suggests positive test releasing for all crops is not practical or feasible • Reports some of the difficulties associated with using 20,000 ppm chlorine for seed disinfection include OH&S issues and restricted access to seed.

Submitter	Comments
	<ul style="list-style-type: none"> • Reports current research is being conducted by Parilla overseen by NSWFA into the use of 20,000 ppm and outcomes will warrant further investigation and discussion • Recommend use of a multiple hurdle approach to risk minimisation is the way forward • Suggests it may be appropriate to consider seed according to risk categories • Suggests a HACCP food safety program should be considered for seed cleaners / processors, storage and transport. • Suggest a requirement to report contaminated seed should be considered
QA Plus P/L	<ul style="list-style-type: none"> • Prefers outcome driven regulation • Suggest water usage should be considered and implication of water recycling / reuse • Currently there is no active monitoring or auditing of smaller producers apart from in NSW • Outlines some issues with international markets • Suggests Option 3 Food regulation is the preferred option with sprout producers being licensed by State and Territory Governments dependant on various requirements. • Suggests benefits to regulation include creating a level playing field for producers, industry being able to grow, innovation encouraged, sprout producer brands underpinned by scientific knowledge
Queensland Government	<ul style="list-style-type: none"> • Acknowledges seed sprouts contaminated by pathogenic microorganisms present an unacceptable health risk to consumers and supports measures which minimise adverse health effects associated with the consumption of seed sprouts. Supports a national approach to this issue and agree to through chain control measures that can be implemented by industry to maximise safety of seed sprouts. • Does not have a preferred option at this time • Notes there are references in the Report to there being little data available to make recommendations. Suggest use of 1995 National Nutrition Survey has limited value. • Suggests given the small size of the industry it may be appropriate to make a concerted effort for businesses to take up the industry guidelines rather than develop regulatory measures. If this is non productive, government intervention may be considered necessary. • Suggest consultation with Australian Mungbean Association and Lucerne Australia • Suggests various risk management considerations including discarding pathogen contaminated sprouts, cleaning equipment and surfaces that have come into contact with contaminated sprouts, purchasing seed in compliance with requirements, procedures to evaluate seed before use, training of staff. In relation to seed lots, keeping adequate records and disinfection and cleaning of seed. • Suggests all seed sprout production should use potable water • Suggests considering use of test and release procedures • Provided and outline of the Canadian three pronged risk mitigation approach • Provided some risk management considerations for the retail sale of sprouts including; storing of seed sprouts in clean dry environment, mandatory labelling, visible inspection, good personal hygiene practices • Believes it is imperative to include consumer and industry education to maximise seed sprout safety. • Will be better positioned to provide indication of impacts on government when more detailed information about the proposed measures is known • Proposed that the risks for the larger plant and plant products area should be assessed as one Proposal and that the assessment for seed sprouts should be included within the larger Proposal work

Submitter	Comments
South Australian Health	<ul style="list-style-type: none"> • Strongly supports Option 3. • Is currently proposing a food safety scheme for seed sprouters to be included under State Regulations but would prefer to adopt a national standard. • Supports in principle three areas of control identified being; testing of seed sprouts, seed sanitisation and pathogen testing of spent irrigation water and supports further examination of the detail in these areas.
Department of Health Western Australia	<ul style="list-style-type: none"> • Has no issues or concerns with the Report
Mr George Seymour	<ul style="list-style-type: none"> • Suggests Options 1 and 2 are not suitable in present circumstances and that food regulatory measures as per option 3 are required to minimise the adverse health risks associated with the consumption of seed sprouts. • Suggests land usage during seed production requires attention and may be addressed by similar measures as outlined in the Canadian Code of Practice for Hygienic Production of Sprouted Seeds • Suggest seed production for human consumption should be separated from seed production for animal feed • Suggests control measures should include seed disinfection and testing of spent irrigation water • Suggests some alternative chemical treatments for disinfection of seed • Suggests measures should be in place to ensure recall of product is swift and rapid
CSIRO	<ul style="list-style-type: none"> • Suggests FSANZ captured the most relevant information relating to the microbiological hazards of seed sprout production in the 1st Assessment Report. • Acknowledges there is lack of specific scientific information in relation to the prevalence and quantity of microbiological contamination in seed sprouts • Suggest the most likely source of seed contamination is from grazing animals • Suggests testing of seed lots may discover high levels of contamination but cannot guarantee that low levels of microbial contamination will be detected