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

Proposal P1004 – Primary Production and Processing Standard for Seed Sprouts

Regulation Impact Statement

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Executive summary

- This Proposal deals with the problem of food-borne illness associated with the consumption of seed sprouts. Although the costs to the community of outbreaks of food-borne illness vary considerably, the cost to the Australian community from the 2005 and 2006 sprouts-related salmonellosis outbreaks is estimated to be $2.1 million. Outbreaks associated with sprouts can be characterised as low incidence but potentially high impact events.

- The objective of this Proposal is to reduce the likelihood of food-borne illness occurring from the consumption of seed sprouts while avoiding any unnecessary cost burden on industry.

- Options identified are the status quo, industry self-regulation, regulatory food safety measures for seed producers, seed processors and sprout producers; and regulatory food safety measures for sprout processors only.

- An alternative approach to estimating the number of illnesses to that used in the consultation regulatory impact statement has been used. A methodological approach recommended by Professor Jim Butler of the Australian National University (Attachment 6) has been used to explore the potential scale of food-borne illness caused by sprouts. His suggested approach allows FSANZ to better consider the epidemic (outbreaks that are attributed to a single point source) and the endemic (the recurrent and unattributed annual rate of disease) illness associated with sprouts.

- Assessment of options indicates that both status quo and industry self-regulation will not adequately address public health and safety concerns. The present self-regulatory systems contribute significantly to the safety of the sprouts produced by those businesses that have them in place. However, concerns exist about them achieving sufficient coverage to sufficiently reduce the level of risk.

- Through-chain regulatory food safety measures for seed producers, seed processors and sprout processors have been assessed as being extremely costly and potentially inconsistent with principles of minimum necessary regulation.

- The results of the analysis indicate that the regulation of sprout processors only is likely to have the highest net present benefit for the community and it is therefore the preferred option to reduce the risk of future sprouts related food-borne illnesses in Australia. Analysis indicates a mean net present value of $1.7 million over 10 years.

- The costs and benefits used in this report are based on the sprout food-borne outbreaks in Australia (2005 and 2006) that involved *Salmonella*. Analysis of the risk and costs of other pathogens has not been undertaken as they are not as well understood in an Australian context. The analysis of illnesses associated with this single pathogen provides sufficient justification on its own for a regulatory intervention without the need to extend the analysis to a range of other pathogens. If the analysis was extended to other pathogens a stronger justification for regulatory intervention could be shown but this would also significantly increase the complexity of this analysis.

- The costs and benefits associated with a potential outbreak could be much higher or lower. A number of the outbreaks that have occurred internationally have cost numerous lives. The *Escherichia coli* O104:H4 outbreak that began in Germany in May 2011 has caused 46 deaths and around four thousand illnesses as of 27 July 2011.

1. The regulatory problem

1.1 Introduction

The Department of Health and Ageing noted food-borne illnesses are a substantial burden in Australia, with an estimated 5.4 million cases due to food-borne gastroenteritis, costing the community an estimated $1.2 billion per year. (Hall et al., 2005) Of these, there are estimated to be 84,056 cases of salmonellosis[1]. On the basis of the analysis below, these are estimated to cost $2,165 per case or $182 million per year in total.

Food-borne illness is caused by consuming contaminated foods or beverages. Many different disease-causing microbes or pathogens can contaminate foods, so there are many different types of food-borne illnesses. Most food-borne diseases are infections caused by a variety of bacteria, viruses, and parasites. Poisonings caused by harmful toxins or chemicals that have contaminated food can also cause illness. Many food-borne pathogens can also be acquired through drinking water, from contact with animals or their environment, or through person-to-person spread.

The main causes of food-borne illness outbreaks are:

- inappropriate storage (food stored too long or inappropriate temperature control);
- food handler contamination (poor hygiene);
- inadequate cooking or reheating;
- cross-contamination (i.e. when bacteria or viruses are transferred from one object to another by direct or indirect contact); and
- foods from an unsafe source.

Most food-borne illness cases are preventable and only occur because of poor food handling or processing.

This Proposed Standard deals with the problem of food-borne illness associated with the consumption of seed sprouts. Seed sprouts are considered a high-risk food and have been implicated in food-borne illness outbreaks both domestically and internationally. For example:

- in Western Australia and Victoria 141cases of food-borne salmonellosis were linked to the consumption of raw sprouts in 2005/20062;
- the Japanese radish sprouts E. coli O157 outbreak in 1996 caused 12,680 illnesses and resulted in 3 deaths3;
- in the US the consumption of sprouts between 1995 and 2010 led to 2,046 reported cases and 3 deaths due to salmonellosis and 184 reported cases of E. coli O157 illness; and
- in the recent E. coli O104:H4 outbreak that began in Germany in May 2011, the cumulative number of STEC (Shiga toxin-producing E. coli) cases was 3,910, as of 27 July 2011. This includes 782 haemolytic uraemic syndrome (HUS) STEC cases and 3,128 non-HUS STEC cases, with 46 deaths recorded. European authorities concluded that the

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[1] This number is based on the number of attributed cases for 2010 (12,008) in the NNDSS 2010 summary on the DoHA website: http://www9.health.gov.au/cda/source/Rpt_2_sel.cfm multiplied by 7 as per the recommendation of Hall et al (2006) to take into account the level of under reporting.

[2] OzFoodNet, (2006a). OzFoodNet Quarterly report, 1 January to 31 March 2006. *Commun Dis Intell* 30(2):228-232 and OzFoodNet, (2006b). OzFoodNet Quarterly report, 1 April to 30 June 2006. *Commun Dis Intell* 30(3):381-384.

[3] Fukushima, H., Hashizume, T., Morita, Y., Tanaka, J., Azuma, K., Mizumoto, Y., Kaneno, M.M.-U.M., Kazushi, K. and Kitani, T. (1999) Clinical experineces in Sakai City Hosptial during the massive outbreak of enterohemorrhagic *Escherichia coli* O157 infections in Sakai City, 1996. *Pediatrics International* 41(2):213-217 and Michino, H., Araki, K., Minami, S., Takaya, S., Sakai, N., Miyazaki, M., Ono, A. and Yanagawa, H. (1999) Massive outbreak of *Escherichia coli* O157:H7 infection in schoolchildren in Sakai City, Japan, associated with consumption of white radish sprouts. *American Journal of Epidemiology* 150(8):787-796.

most likely common link between the large outbreak of *E. coli* O104:H4 in Germany and smaller outbreak in France was sprouts produced from a single batch of fenugreek seeds imported from Egypt.[4]

Principal hazards affecting seed sprout safety are microbiological pathogens which grow at various points in the production and supply chain of seed sprouts for human consumption. While seed is considered the likely source of contamination, recommended control measures so far emphasise microbiological decontamination of seeds and to a lesser extent monitoring of spent irrigation water for the presence of microbial pathogens at sprout processing premises.

Effective implementation of preventative measures during the phase of seed production and seed processing reduces the chance of contaminated seeds reaching sprout processors. However, if these measures are not in place, then other measures are required, including microbiological decontamination of seeds. Microbiological surveys of seed sprouts, both domestically and internationally, have identified the presence of a variety of food-borne pathogens including *Salmonella* spp., EHEC (Enterohaemorrhagic *E*. *coli*), *Bacillus cereus*, *Cryptosporidium* spp. and *Giardia* spp (Beuchat, 1996; Kim et al., 2004; Samadpour et al. 2006, Prokopowich and Blank 1991).

Microbiological surveys of seed sprouts have been conducted by the Department of Health, Western Australian in 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 survey results revealed seed sprouts are occasionally contaminated with pathogenic microorganisms including *Salmonella* spp, *Listeria monocytogenes*, pathogenic *E*. *coli*, coagulase-positive staphylococci and *B*. *cereus*. The dose of pathogens to cause an illness varies across the community and their growth is dependent on a number of factors identified. The presence of the pathogens indicates that a clear potential exists for consumers to be put at risk if the product is handled inappropriately.

Only illnesses caused by *Salmonella* have been used for the purpose of this analysis. Analysis of the risk and costs of other pathogens has not been undertaken as they are not as well understood in an Australian context. It is asserted that the analysis of illnesses associated with this single pathogen provides sufficient justification on its own for a regulatory intervention without the need to extend the analysis to a range of other pathogens.

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 one of the commonly reported food-borne diseases in Australia.

1.2 Problems with the current practice

Currently there are no national regulations in place for the production of sprouts in Australia. New South Wales (NSW) is the only State which currently regulates seed sprouts processing and seed processing and there are no specific compulsory requirements for other states and territories, although South Australia has a Food Safety Scheme[5] for Plant Products, including seed sprouts. In NSW the Plant and Plant Products Food Safety Scheme regulates high priority, high risk plant food products, including seed sprouts. Under this Scheme sprout processors in

[4] EFSA (2011) Tracing seeds, in particular fenugreek (*Trigonella foenum-graecum*) seeds, in relation to the Shiga toxin-producing *E*. *coli* (STEC) O104:H4 2011 Outbreaks in Germany and France. http://www.efsa.europa.eu/en/supporting/doc/176e.pdf

[5] http://www.pir.sa.gov.au/biosecuritysa/foodsafety/legislation Please note that the South Australian scheme has not been explicitly taken into account in this analysis as it has only recently come into effect and was done in anticipation of the development of this standard. The South Australian Government was not prepared to leave this risk unmanaged.

NSW must demonstrate compliance though implementing a food safety program, based on Codex HACCP or Standard 3.2.1 of the Food Standards Code, which is certified by the NSW Food Authority and audited. NSW has only 6 out of the 40 seed sprouts processors in Australia, meaning only 15% of seed sprouts processors are regulated under the current arrangement.

Following the food-borne illness outbreaks in Australia in 2005-2006, sprout processors formed an industry association and developed industry guidelines to support the safer production of sprouts. However, the seed sprout processing industry consists of many small businesses[6] and to date it has been difficult to achieve adequate coverage of the industry. The industry association has actively sought government intervention and the development of regulatory measures as self-regulatory attempts have been limited by the scale of the industry.

A more comprehensive summary of the existing requirements and guidelines that apply to each of the sectors involved in seed sprout production domestically and internationally is provided in Attachment 1. The problems and shortcomings associated with the current requirements are discussed below:

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 for registered establishments in which mung beans are prepared for export. These requirements are appropriate in terms of reducing the microbiological contamination of the mungbean seed and mungbean sprouts. However, the issuance of export certification for mung beans by AQIS does not necessarily provide assurance of the suitability of the mung beans for domestic consumption.

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

Sprout processing

In New South Wales the *Plant and Plant Products Food Safety Scheme* covers high priority, high risk plant food products, including seed sprouts. Sprout processors in NSW need to 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 other states and territories that specifically apply to sprout production, although South Australia has a Food Safety Scheme[7] for Plant Products, including seed sprouts. This means out of approximately 40 sprout processors only six of them are required by law to implement a food safety program in sprout production.

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. Compliance with these guidelines is voluntary. The industry association has reported a low level of uptake by industry members.

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

7 http://www.pir.sa.gov.au/biosecuritysa/foodsafety/legislation

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*, *L. 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 private label sprout processors 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). However, industry consultation in Australia has revealed that only around 60% of the sprouts produced are under a food safety or quality management scheme.

Due to the present limitations associated with current practice, the level of food-borne illness is not expected to self-correct within a reasonable time period as it is highly uncertain that market forces have the ability to deliver a reasonable level of compliance.

For the purpose of the cost benefit analysis only the prevention and costs of *Salmonella* has been considered. *E*. *coli* O157*,* as indicated above, has been linked with sprout outbreaks overseas. However, there is no epidemiological evidence that this has occurred in Australia to date. Likewise, other pathogens may cause or have caused illness in Australia.

Fresh Seed Sprouts imports

A concern was raised about whether the introduction of regulation could disadvantage Australian processors relative to overseas processors. FSANZ has been informed that currently there are no import conditions for raw sprouts and therefore they are not currently imported. If they were to be imported in the future then they would need to be assessed and if necessary, relevant import conditions determined and applied.

2. Objectives

The objective of this Proposal is to reduce the likelihood of food-borne illness occurring due to the consumption of seed sprouts while avoiding any unnecessary cost burden on industry.

Under statutory requirements *Food Standards Australia New Zealand Act 1991* (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;
- 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.

Under the 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; and
- any regulatory measures developed should be commensurate with risk and not impose any unnecessary additional economic burden on the dairy industry.

The current Proposal aims at achieving all these objectives.

3. Options

3.1 Option 1(a) Abandon the proposal-do nothing option

3.2 Option 1 (b) Abandon the proposal-industry self-regulation

A self-regulatory approach would allow food or primary production 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[8], separation of seed grown for agriculture and sprouting purposes, improvements to premises, adherence to health and hygiene requirements – details of possible food safety control measures are listed under option 2(a)**.**

To be successful a self-regulatory approach needs strong industry wide commitment and involvement. Evidence that voluntary participation can work includes, 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. This option involves voluntary industry compliance, there would be no mandatory requirements for seed producers and processors and sprout processors. A form of industry self-regulation is presently in place but it is not in a form that creates sanctions for those who choose not to comply in part or in full. Likewise there is no reporting on compliance to consumers or other industry participants. Therefore, the self-regulatory option differs from the status quo, given the potential consequences of a major outbreak, in that there is an expectation that any self-regulatory solution would include sanctions and reporting.

Table 1 assesses the industry self-regulation option for seeds sprouts against the Office of Best Practice Regulation (OBPR) assessment criteria. As a result of this analysis it has been precluded from further consideration as the sprout industry does not appear to be a suitable candidate for self-regulation.

8 These could include correct use of chemicals, maintenance and cleaning of farm equipment and machinery.

Table 1: Assessment of self-regulation

Factors to be considered	Analysis
There is no major public health and safety concern.	• 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. • In Western Australia and Victoria 141 cases of food-borne salmonellosis were associated with the consumption of raw sprouts in 2005 and 2006[9]. Thirteen out of the 141 cases were hospitalised. • There is also strong international evidence that sprouts can potentially be a high risk product that can cause death and illness.
Adequate coverage of the sprout industry can be achieved.	• The sprout processing industry is a very small industry comprised of small (many family owned and operated) businesses. • There are currently around 40 sprout processing businesses 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 a high turnover of businesses involved in the sprout processing industry. • A number of businesses have declined to become involved in past attempts by the industry to self-regulate. • Due to the seriousness of the illnesses that can be caused clear justification exists for ensuring that all commercial producers are regulated regardless of their size.
There is a viable industry association.	• An industry association was formed following the *Salmonella* outbreak in Australia in 2005-2006 attributed to seed sprouts – the Australian New Zealand Sprouters Association (Sprouters Association). • The Sprouters Association has indicated that the limited size of the industry makes the funding of an industry association that has sufficient influence impossible. • Currently, just over half the (known) producers are members and to date it has been difficult to achieve adequate coverage of the industry and comprehensive uptake of the guidelines.
There is a cohesive industry with like-minded or motivated participants committed to achieving goals.	• The Sprouters Association has 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 (such as HACCP accreditation, verification testing).
Evidence that voluntary participation can work.	• The 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 guidelines. • The size of many of the participants would suggest that many of the participants in the industry have insufficient regulatory capacity to self-regulate. This comment is made in light of the fact that the rigour of the self-regulatory system needs to reflect the risk that it is attempting to manage. • The present guidelines, whilst a responsible step by many industry participants to protect their customers, lack a number of key elements to make the system equivalent to the more traditional regulatory approach that the industry wishes to transition to. These elements include sanctions and reporting. For an effective self-regulatory system to be put in place the industry would need to be much larger and have access to more funding.

[9] OzFoodNet, (2006a) OzFoodNet Quarterly report, 1 January to 31 March 2006. *Commun Dis Intell* 30(2):228-232 and OzFoodNet, (2006b) OzFoodNet Quarterly report, 1 April to 30 June 2006. *Commun Dis Intell* 30(3):381-384.

3.3 Option 2(a) Prepare draft food regulatory measures for seed production, seed processing and sprout production

Option 2(a) involves the development of food safety regulatory measures in the *Australia New Zealand Food Standards Code* (the Code) for seed producers and processors and sprout processors. These Regulatory measures potentially apply to all the stages in the production chain (on-farm seed production, seed processing, and sprout production).

The technical assessment of Option 2(a) has identified the following food safety control measures to mitigate contamination and risk.

Seed production

- use of good agricultural practices[10];
- 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 to pests or other sources of contamination; and
- demonstration of compliance through, for example, record keeping.

Seed processing

- adequate design, construction and maintenance of premises and equipment (for food purposes);
- traceability system (supporting segregation of seed for food/sprouting purposes from other seed);
- pest control program;
- health and hygiene requirements for personnel;
- management of inputs (including chemical); and
- demonstration of compliance through, for example, record keeping.

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;
- 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;
- implementation of food handling controls from receipt to transport to prevent/minimise contamination; and
- microbiological testing.

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10 These could include correct use of chemicals, maintenance and cleaning of farm equipment and machinery.

3.4 Option 2(b) Prepare draft food regulatory measures for sprout processors only

Regulatory measures could be applied to some or all stages of production considered under Option 2(a). As a result, consideration is being given to Option 2(b) Regulatory Food Safety measures for Sprout Processors only. This approach has been taken in response to industry feedback and to assess what level of intervention would achieve the maximum net benefit to the community as a whole.

The technical assessment of Option 2(b) as already identified in Option 2(a) contained the following food safety control measures to mitigate contamination and risk:

- 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;
- 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;
- implementation of food handling controls from receipt to transport to prevent/minimise contamination; and
- microbiological testing.

3.5 Education

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

- The food safety education messages for consumers are limited to storage (temperature) and consumption (e.g. use by date) information. 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. Therefore there are limited steps consumers can take to reduce the hazards that may be present in seed sprouts.
- 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.
- Industry education initiatives have previously been trialled particularly by the Australian New Zealand Sprouters Association who developed the *Guidelines for Australian and New Zealand Sprout Producers* in July 2008. There was limited uptake and use of the guidelines by sprout processors.
- Additional industry consultation following 2nd Assessment revealed there are education programs and initiatives being conducted by sprout processors involving training of food handlers. However participation in these programs is largely dependent on the capability of the business to develop and fund such programs and it is unlikely that all sprout processors will participate in non-mandatory education programs.

FSANZ therefore considers that education initiatives would complement the recommended food regulatory measures rather than being a viable alternative.

4. Impact analysis

FSANZ has considered the costs and benefits of the risk management options on each of the affected parties. There are assumptions and limitations underpinning the Impact Analysis including:

- The conclusions of the analysis must be regarded as indicative, rather than as definitive, as they are based on data from a number of businesses, jurisdictions and other sources. Regulatory costs were estimated on the basis of a limited number of submissions, information sources and consultation with stakeholders. Some were based on actual costs incurred by business and jurisdictions to comply with some of the current requirements and then extrapolated. Secondly the full implications for regulatory costs may not be evident at this stage and would depend on the nature and details of the implementation arrangements in each state.

- The average cost of food-borne illness due to consumption of seed sprouts was based on outbreak data from one particular outbreak which occurred at a point in time. The actual burden of illness for an outbreak or for illnesses for a particular year is highly uncertain. In some years few illnesses may be attributed to sprouts yet it is possible that the cost of an outbreak could far exceed costs experienced to date. Therefore, the current burden of illness as estimated by FSANZ should not be taken as fully representative of the cost of food-borne illness that may be possible due to consumption of sprouts.

- The *status quo* or 'do nothing' option is the base case against which other options are compared. It represents the prevailing situation and does not imply any changes.

- The impact analysis for options 2(a) and 2(b) is the additional or incremental costs and benefits when compared to the status quo.

- Wherever possible, impacts have been quantified. In the absence of specific information, FSANZ has drawn on the best available evidence, such as secondary studies and other general information.

- Due to lack of Australian data, FSANZ has made use of international data on adverse health outcomes pertaining to countries with comparable levels of health care and disease incidence. However the computation of costs for such health incidents are based on recommended Quality Adjusted Life Years (QALY) values / health care costs in Australia.

- Efficacy of an option means effectiveness in reducing the burden of food-borne disease.

- A discount rate of 7% applies to both costs and benefits in FSANZ's calculations.[11]

- Sensitivity analyses are undertaken to ascertain a range of outcomes for the impact analysis.

- Option 2(a) is estimated to deliver a 23% to 80% efficacy rate (See analysis under Option 2(a))

- Option 2(b) is estimated to deliver a 23% to 65% efficacy rate (See analysis under Option 2(b)).

- Some attempts have been made by industry to self-regulate since the 2005/06 outbreaks. These same industry members, concerned with insufficient industry uptake, approached

[11] Recommended by Office of Best Practice Regulation (OBPR)

government to put in place a standard. Those industry members with measures in place to limit risk will not see as large a reduction in risk within their business as those in the industry with no procedures in place upon the introduction of a regulatory intervention. However, they will likewise most likely not incur as much cost to become compliant.

- A complex gap analysis has not been attempted in relation to attempts to self-regulate as the cost and benefits are assumed to correlate to a high degree for businesses. Additionally, no attempt has been made to attempt to adjust the underlying risk either up or down for the changes made by industry and others since the 2005 and 2006 outbreaks as this would introduce a level of complexity into the analysis that cannot be supported by available data. Data is not available on either the change in practices or the levels of pathogen contamination of end product.

- Validity of the assumptions underlying the probabilistic model is based on the best available information but are still uncertain.

4.1 Affected parties

- consumers
- industry (seed producers, seed processors and sprout processors)
- government, including state and territory jurisdictions

4.2 Industry profile

Consultation with industry indicates that generally sprout processors are sole proprietorships, partnerships and family owned businesses. Therefore most businesses would be defined by the Australian Bureau of Statistics (ABS) as small businesses as they employ less than 20 full time staff.

Most seed producers mainly supply agricultural and non-sprout customers. There were about 30 seed processors identified as supplying at least some of their seeds for sprouting purposes. Out of these 30 about 10 businesses are known to be mung bean seed suppliers and are expected to be already complying with export standards in order to access overseas markets.

Through an industry profiling exercise, FSANZ identified about 30 sprout processors nationally. Subsequent consultations with industry and jurisdictions have indicated that there may be another 5-10 businesses which FSANZ was unable to reach through its survey. Therefore, there may be up to 40 businesses of which 6 are known to be based in NSW. The NSW businesses presently comply with the NSW *Plant and Plant Products Food Safety Scheme*. Therefore, they will also be less affected in terms of additional costs from the introduction of any national standard.

4.3 Costs of Illness Linked to Sprouts Outbreak 2005/06

The overall potential costs of food-borne illness as the result of the 2005/2006 outbreaks are estimated at about $2,137,335 (Table 2). The summary is made up of direct health care, productivity lost, other costs of industry loss and government costs. Cost per case in relation to the 987 cases is about $2,165.

Table 2: Summary of 2005/06 seed sprout food-borne illness outbreaks cost Burden per year

Cost	Amount (2011 $)
Productivity Loss	$638,016
Gastroenteritis individual welfare cost	$290,803
Sequelae individual welfare costs	$372,090
Less allowance for double counting	$-95,702
Total business and individual costs from illness	$1,205,206
Cost to industry	$675,339
Costs incurred by government/states	$256,789
Total cost	**$2,137,335**
Cost per illness	**$2,165**

In Western Australia and Victoria 141 cases of food-borne salmonellosis were associated with the consumption of raw sprouts in 2005 and 2006[12]. Thirteen out of the 141 cases were hospitalised. Most cases of salmonellosis manifests as mild self-limiting gastroenteritis, with about 73% of the affected people seeking medical attention.[13] A diagnosis of salmonellosis requires laboratory confirmation of the presence of *Salmonella* from faeces or rectal swabs. Not all visits to medical practitioners results in the collection of samples for testing. As a result, surveillance data collected by health departments underestimate the true burden of disease. Many studies have shown that the level of under-reporting of food-borne diseases reported on the National Notifiable Diseases Surveillance System (NNDSS) is very high, especially in cases when many minor episodes occurred. In Australia, for every case of salmonellosis notified to a health department there are an estimated 7 infections that occur in the community[14]. However, in order to estimate accurately the impacts of food-borne disease, the quantity and costs of those unreported incidents must be accounted for. Hall et al. (2006)[15] estimated an under-reporting factor for salmonellosis in Australia as 7 (range of 4-16) and used it to calculate the actual number of cases that occurred. That means, for every 100 cases of salmonellosis on the

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[12] OzFoodNet, (2006a). OzFoodNet Quarterly report, 1 January to 31 March 2006. *Commun Dis Intell* 30(2):228-232 and OzFoodNet, (2006b). OzFoodNet Quarterly report, 1 April to 30 June 2006. *Commun Dis Intell* 30(3):381-384.

[13] It must be realised that there are distinct limitations associated with outbreak data which only identify and attribute a proportion of outbreaks that occur. The specific system failure or cause is even more rarely identified. For example, the Victorian outbreak (7 notified cases in total) was only identified after a recall notification from a sprout producer following detection of *Salmonella* Oranienburg during QA testing.

[14] OzFoodNet (2008). Annual Report.

[15] Hall G., Raupach J. and Yohannes K. (2006) An estimate of under-reporting of food-borne notifiable diseases. NCEPH Working Paper Number 52. February 2006.

NNDSS, it is estimated there were 700 cases in the community. Wheeler et al. (1999)[16] estimated that in the UK for every notified case of salmonellosis there were 3.2 cases in the community and Voetsch et al. (2004)[17] estimated that in the US for every notified case of salmonellosis involving bloody diarrhoea there were 9.8 cases in the community.

For the purpose of estimating the impacts of the actual food-borne salmonellosis that occurred in Australia in 2005 and 2006, we use the Hall et al. (2006) under-reporting factor. This implies for every case of food-borne salmonellosis that is reported by the NNDSS, there could be about 7 cases of food-borne salmonellosis in the community. Therefore, taking into account the level of under-reporting, there may be potentially 987 cases of food-borne salmonellosis associated with this outbreak made up of 141 reported and 846 unreported cases in the community due to the consumption of sprouts.

The food-borne illness outbreaks that occurred in Western Australia and Victoria have cost implications to the community. Medical costs were incurred by individuals who suffered from the illness. The direct medical costs incurred relate to the cost of a visit to a General Practitioner, hospital admission, and medication. Costs were also incurred on loss of health and welfare, loss of productivity to business due to shut down, unemployment, investigations into the food-borne illness, media publications and any action taken by government or the states to control the outbreaks. These costs are estimated below.

The burden of illness from 987 cases in outbreak years is estimated as follows:

Productivity costs

- For the estimated 987 salmonellosis cases in the outbreak, 86% will suffer from a mild case of Gastroenteritis illness. From those 849 cases 412 (48.5%)[18] are workers and 85 (10%)[19] are carers. Average lost per condition is $803 ($402 average value of output per day x 2 average working days lost).

- Total productivity cost for a mild case of Gastroenteritis illness is estimated at about $399,000 (412 x 85 x $803). For a moderate case of Gastroenteritis illness total productivity cost is estimated at about $206,000 and for severe Gastroenteritis illness at $33,000.

- Total productivity costs estimated at $638,000 per year.

Gastroenteritis Individual health and welfare cost

- Individual health and welfare cost for a mild case of Gastroenteritis illness is $261 (56% full disability days[20] × $468 value of day in good health)[21].

- Total health and welfare cost for a mild case of Gastroenteritis illness is estimated at about $222,000 (849 cases x $261). For a moderate case of Gastroenteritis illness total productivity cost is estimated at about $60,000 and for severe Gastroenteritis

[16] Wheeler, J.G., Sethi, D., Cowdenm, J.M., Wall, P.G., Rodrigues, L.C., Tompkins, D.S., Hudson, M.J. and Roderick, P.J. (1999) Study of infectious intestinal disease in England: Rates in the community, presenting to general practice and reported to national surveillance. *British Medical Journal* 318:1046-50.

[17] Voetsch, A.C., Van Gilder, T.J., Angulo, F.J., Farley, M.M., Shallow, S., Marcus, R., Cieslak, P.R., Deneen, V.C., Tauxe, R.V. (2004) FoodNet estimate of the burden of illness caused by nontyphoidal Salmonella infections in the United States. Clincal Infectious Diseases 38 (Suppl 3):S127-S134.

18 ABS Cat. No. 4102.0, Australian Social Trends.

19 This assumes that 20% of non working persons would need carer.

20 Australian Institute of Health and Welfare http://www.aihw.gov.au/publications/phe/bdia/bdia.pdf

21 Office of Best Practice Regulation Guidance Note: Value of Statistical Life, 2008. - Value of a life year $170,932 ,inflation adjusted.

illness at $9,000.

- Total Gastroenteritis Individual health and welfare cost is estimated at $291,000 per year.

Sequelae Individual health and welfare cost

- Salmonella can also result in reactive arthritis, inflammatory bowel disease (IBD) or death. Accordingly from 987 cases there are 12 cases of reactive arthritis (9.9 mild cases, 2 moderate cases and 0.2 severe cases), 2 cases of IBD (life long) and 0.015 cases of death.

- Total cost for a reactive arthritis is estimated at $313,000, for an IBD $1,000 and for a death total cost is estimated at $59,000.

- Total Sequelae Individual health and welfare cost is estimated at $372,000 per year.

Cost of industry loss from food-borne illness as a result of seed sprout consumption[22]

Recall and publicity costs

- Industry incurred costs for recalling the contaminated food from consumers. These may include cost of newspaper advertisements, stock value and recovery, additional company testing and stock destruction. Abelson et al. (2006) uses an average cost of $250,000 - 2004 current prices ($337,670 inflation adjusted) per recall to estimate the annual cost of food-borne illness in Australia. Following Abelson et al. (2006, the cost of the recalls in 2005 and 2006 is estimated at about $675,339 (2 x $337,670).

- Fresh sprout produce in Western Australia were recalled after samples of the product tested positive to *Salmonella*, and most producers stopped production until the investigation was completed. Produce such as alfalfa, alfalfa and onion, alfalfa and mustard, alfalfa and broccoli were recalled from the market. For the 2005/2006 food-borne outbreaks, there were 2 recalls: February 2006 in WA and May 2006 in Victoria. There were over 100 cases of illness linked to the February 2006 WA recall but no cases of illness associated with the May 2006 Victoria recall (at the time the recall took place).

- In extreme situations businesses can shut down on being identified as the cause of a food-borne illness. For example a fresh sprout producing company in Western Australia shut down in 2006, thereby causing loss of employment and output but no quantitative amount of loss in regard to this was available for the analysis.

- Industry also suffered from loss of sales, goodwill and consumer confidence.

- Total cost of industry loss from food-borne illness of seed sprout consumption is estimated at about $675,339.

Costs by government/jurisdictions

- Cost of laboratory testing, any measure to control the food-borne illness and business disruption associated with food recalls is estimated by adopting an average cost of

[22] Please not that all the information about the costs are collected in 2009 and adjusted in 2011 prices. - http://www.ato.gov.au/taxprofessionals/content.aspx?doc=/content/1566.htm

$8,12 per case of illness from Abelson et al. (2006). However, with regard to the 2005/2006 Western Australia and Victoria outbreaks, there was no information recorded.

- Cost of investigating food-borne illness is estimated by using an average cost of $1,481 per *Salmonella* infection in Australia (Yohannes, 2002).[23] An industry source indicated that the cost of investigating the Western Australia food-borne illness outbreak together with associated survey on microbiological quality of sprouts was at about $240,440 inflation adjusted.

- Total cost likely to be incurred by government/Jurisdictions is estimated at about $256,790. These costs are however, indicative and not exhaustive.

The overall potential costs of food-borne illness as estimated above are $3,137,335 per annum (made up of productivity cost, Gastroenteritis Individual health and welfare cost, Sequelae Individual health and welfare cost, costs of industry loss and government/states costs and minus allowance for double counting[24]). Cost per case in relation to 987 cases is about $2165.

Please see Attachment 4 for further details of how these figures were calculated.

4.4 Annual cost of illness

The total cost of food-borne illness estimated above is based on Australian outbreak data in 2005 and 2006. While there is international evidence from the US[25] regarding the frequent nature of seed sprouts related food-borne illness outbreaks there are no further Australian data regarding the frequency of reported outbreaks caused by consumption of sprouts per se (see Attachment 3 for other outbreaks worldwide).

Due to the level of uncertainty of the timing and magnitude of outbreaks a methodological approach recommended by Professor Jim Butler of the Australian National University (Attachment 6) has been used to further explore the scale of food-borne illness associated with sprouts. His suggested approach allows FSANZ to better consider the epidemic (outbreaks that are attributed to a single point source) and the endemic (the recurrent and unattributed annual rate of disease) associated with sprouts.[26]

The number of expected food-borne illness associated with seed sprout consumption per year in the future is estimated as 924.2 cases (Table 3). Therefore, the Butler model estimates an annual cost of illness of around 2 million per year.

[23] Yohannes K., (2002) Chapter 3: Salmonellosis in Australia: 'The social cost of illness 'in: A journey in public health: Master of Applied Epidemiology Thesis. Canberra, Australia National University.

[24] 96,000 - Allows for proportion of loss output costs to be borne by households.

[25] http://www.fda.gov/OHRMS/DOCKETS/98fr/05-8103.htm

[26] Butler, J.R.G. (2010) An assessment of the cost-benefit analyses undertaken in support of FSANZ Proposal P 1004.

Table 3: Expected annual Salmonellosis from seed sprout consumption in Australia

Annual cases of salmonellosis in Australia	Expected % of annual salmonellosis cases associated with seed sprout consumption	Potential number of cases in the year (n_j)	Probability of observing corresponding number of cases in that year (p_j)	Expected number of cases
A	B	C= (A x B)	D	E = (C x D)
84,056[27]	0.75%	(n_0) 630.4	1.0	630.4
84,056	0.33%	(n_1) 277.4	0.25	69.3
84,056	1.67%	(n_2) 1403.7	0.1	140.4
84,056	5%	(n_3) 4202.8	0.02	84.1
Total (N)				**924.2**

The total of food-borne illness linked to a single food type consists of an endemic component which is present in the community at all times and not always reported and attributed to a particular type of food and the epidemic which is disease contracted by many people at about the same time from a single source. Butler (2010) argues that the endemic component recurs every year and is always present in the community and should therefore not be averaged over a time period. Because both the timing and magnitude of epidemics are subject to considerable uncertainty, a probabilistic model is required to estimate the number of food-borne illness expected in any time period (t). Please note that more conservative assumptions about the probability of an outbreak have been used than in the traditional model above.

For the purpose of estimating food-borne illness objectively, Butler (2010) proposes a probabilistic modelling approach to estimate the expected number of cases in each time period (t_i) as follows:

$$N = n_0 + \sum_j p_j n_j$$

where N is the total number of cases in time period (j) and is obtained as the sum of the (constant) number of endemic cases each year and the probability weighted sum of different number of cases that potentially will emerge in an epidemic in time period (i).

To accurately estimate the cost burden to the community associated with food-borne illness from consuming seed sprouts, we need to reasonably determine the number of food-borne illness outbreak cases per year. Microbiologists within FSANZ have been consulted regarding the following assumptions:

1. 0.75% of 84,056 (630.4 cases) may constitute the endemic component resulting from consumption of seed sprouts.
2. 0.33% of 84,056 (277.4) may constitute potential number of cases in a small outbreak,
3. 1.67% of 84,056 (1,403.7) may constitute potential number of cases in a medium sized outbreak.

[27] This number is based on the number of attributed cases for 2010 (12,008) in the NNDSS 2010 summary on the DoHA website: http://www9.health.gov.au/cda/source/Rpt_2_sel.cfm multiplied by 7 as per the recommendation of Hall et al (2006) to take into account the level of under reporting.

4. 5% of 84,056 (4202.8) may constitute potential number of cases in a large outbreak.
5. The occurrences of these potential cases, 630.4, 277.4, 1,403.7 and 4,202.8 are subject respectively to probabilities of 1.0, 0.25, 0.1, and 0.02. These probabilities have been utilised for the occurrences of the respective potential cases.
6. The process repeats itself each year.

The estimated number of expected food-borne illness from seed sprout consumption per year in the future is 924.2 cases (Table 3).

These estimated were derived from expert opinion within FSANZ and were considered reasonable estimates for the purpose of this scenario analysis.[28] Overseas evidence informed the size of outbreaks and the relative frequency of outbreaks. The ratios of small (n_1), medium (n_2) and large (n_3) outbreaks was used as these roughly correspond to the ratios of reported small, medium and large outbreaks overseas. If concerns exist about these estimates it must be remembered that these numbers relate to *Salmonella* only. The estimated number of potential cases (924.2) is only 0.017% of the total number of estimated illnesses caused by foodborne pathogens in a given year.

4.5 Option 1(a) – abandon the proposal, thus maintaining the *status quo*

Under this option, the Proposal would be abandoned and the *status quo* maintained. If the *status quo* is maintained the current number of illnesses experienced per annum, as set out above, will continue into the future.

4.6 Option 1 (b) Abandon the proposal - Industry 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.

An assessment of the industry self-regulation option has been undertaken above at Table 1 precluding it from further consideration. The sprout industry does not appear to be a suitable candidate for self-regulation.

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

4.7.1 Costs

The total cost of through chain regulatory measures is estimated to be up to about $10.57 million fixed costs and $11.99 million ongoing costs. The summary of these costs is shown in Table 4.

[28] The consensus view of three FSANZ scientists with subject matter expertise was used to develop the assumptions used in the model. This expert opinion represents the best available information given the clear difficulties that exist in relation to attribution.

Table 4: Costs of producing seed sprouts through chain regulatory measures[29]

Affected party	Upfront costs in $	Ongoing costs in $
Seed Producers / Growers		$1.7 million – 10.33 million
Seed Processors	$1.02 million – 10.14 million	$576,720 – 1.03 million
Sprout Processors	$96,120	$427,200
Government	$309,720 ($192,240 if only sprout processors are regulated)	$288,360 ($181,560 if only sprout processors are regulated)
Consumers	Part or all costs passed on	Part or all costs passed on
Total	**$1.43 million – 10.55 million**	**$2.53 million – 12.08 million**

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 for microorganisms, then costs of microbiological testing and verification for sprout processors may be reduced. The potential for higher regulatory costs to seed producers and seed processors reflect that the majority of their seeds are being used for non-sprouting purposes and their total production may be affected if they were regulated for the safety of sprouts. There is a risk faced with the costs that some seed producers and processors may decide to no longer provide seed to sprout processors.

Industry

Seed producers

- Cost of separating lucerne seeds for human consumption could range from $1.7 million to $10.33 million annually (an industry submission reported that the incremental cost is $1.38 per kg. This could apply to 900 tonnes (including exports) of sprout production only or the entire lucerne crop i.e. 7,500 tonnes annually. The two estimates are given as it may or may not be economically viable to run two separate production systems).

- In addition there may be the cost of demonstrating compliance e.g. record keeping/ auditing and other ongoing costs.

- Total costs for seed producers are estimated at $1.7 million – $10.33 million annually excluding compliance costs.

Seed processors

- Design, construction of premises and other capital equipment is estimated to initially cost $1.02 million – $10.14 million (while a shed that is export registered for mungbeans may incur minimal additional costs, latest industry data suggests a one-off $50,400 – $534,000 may be incurred by the 19 seed processors supplying seeds other than mung beans)

[29] Please not that all the information about the costs are collected in 2009 and adjusted in 2011 prices. - http://www.ato.gov.au/taxprofessionals/content.aspx?doc=/content/1566.htm

- Industry sources have indicated that program design for, and implementation of, tracing systems, health and hygiene training, compliance and record keeping are estimated to cost between $10,680 and $21,360 per business on an ongoing annual basis. Excluding mung bean seed processors 19 business may be affected resulting in an annual cost of at least $202,920 – $405,840 on an ongoing basis.

- Skills and training requirements are estimated to cost in the range of $534 – $961 per business (based on industry Fresh Care Program). Similarly industry indicated that online programs may be accessed at $107 - $214 per business plus cost of staff wages. For 29 businesses, skills and training would cost $16,020– $27,768 per year.

- Based on industry data, seed testing costs are estimated to be $45,640 – $491,280 annually (That is $0.11 – 0.20 per kg for 2,307 tonnes of all seed used for sprout production).

- Management of other hazards that may be specific to each seed type. Industry submissions indicated holding lucerne seed as an alternative to scarification may cost $112,140 ongoing ($0.37 per kg for 300 tonnes of lucerne seed).

- Total costs for seed processors are estimated at $1.2 million – $10.14 million million in the first year and $576,720 – $1.03 million per year thereafter.

Sprout processors

- Additional costs of regulatory measures will largely depend on the existing production practices of the business and compliance arrangements with vendors (e.g. Woolworth's quality assurance requirements). Other local factors may also reduce the incremental cost. For example, NSW businesses have to comply with the *Plant and Plant Products Food Safety Scheme* and their incremental costs are expected to be relatively lower.

- Costs will be incurred to alter premises and equipment (upfront costs). A large sprout processor has indicated that they incurred $1,068 for minor equipment to comply with NSW State requirements. While no further data is available regarding costs incurred by other smaller processors, if the remaining 34 businesses in Australia incur similar costs then costs for this activity is estimated at a minimum of $36,312 (as stated, FSANZ identified about 30 sprout processors nationally through an industry profiling exercise. Subsequent consultations with industry and jurisdictions have confirmed that there may be another 5-10 businesses. Therefore, there may be up to 40 businesses of which 6 are known to be based in NSW. The remaining 34 may have to change practices to comply).

- Costs will be incurred to develop and implement food safety/HACCP type programs (upfront cost). The average cost is estimated at $2,136 per business (industry consultation). This information is consistent with the NSW Plant and Plant Products Food Safety Scheme where the average cost of food safety programs and implementation was identified at $1,610 per business in 2002-03 and inflation adjusted current prices would be about $1,955. However approximately 60% of sprout producers are known to have already implemented a program that includes some food safety controls (personal communication and interview with wholesale market sellers and market auditors across various states). Therefore additional costs should only apply to the remaining 40% of the businesses. As there could be 40 sprout producing businesses, the incremental costs of a food safety or equivalent program for 16 businesses is estimated at $34,176.

- Other Upfront Costs - Costs of auditing, registration and licensing are estimated at $854 per business under current state requirements (FSANZ personal communication). Excluding 6 businesses operating in NSW, if 34 other businesses in Australia are subject to similar upfront costs due to regulatory requirements the estimated total cost is $29,036.

Other ongoing costs

- Costs of skills/knowledge and staff training – industry consultations have indicated that there may be Commonwealth supported or funded programs in general food safety training and development that personnel may be able to enrol in, thereby minimising the additional costs due to regulation. If this is not possible, costs similar to Fresh Care Program training in the range $534 – $961 per business may be incurred. Applying this for 34 businesses (excluding NSW as NSW producers are expected to have already incurred such costs), total skills and training costs are estimated at $18,156 – $33,108.

- Seed sampling costs were reported by industry at $427 per business annually (based on 3kg of seed) under state based requirements. Excluding NSW businesses under the Plant and Plant Products Food Safety Scheme, if the remaining 34 businesses nationally are subject to similar costs total seed sampling costs are estimated at $14,524.

- Similarly for verification, a sprout processor has indicated that under state based requirements additional costs incurred annually were $5,767 (3 batches, cost of each batch $1,922). In this context additional cost of microbiological verification for the 34 other businesses is estimated to be about $192,240.

- Ongoing registration, licensing and audit costs to comply with regulatory requirements in NSW were reported at $1,922 per business annually. If other businesses nationally were subject to similar requirements total estimated costs would be $61,000 (for 34 businesses).

- Record keeping, monitoring and/or demonstrating compliance is estimated at approximately $3,630 (i.e. $3,200 in 2004 NSW Plant and Plant Products Food Safety Scheme). Total costs for 34 businesses are therefore estimated at $122,820.

- The total costs for sprout processors are estimated at $96,120 upfront and about $427,200 ongoing per year.

- The total cost per business translates to about $2,777upfront and about $12,816 ongoing.

- Cost of sprout seed decontamination: Sprout seed decontamination legislation is already in place in NSW and the cost for it is being incurred by sprout processors in NSW. The specific requirements described in the proposed standard for sprout seed decontamination are outcome based and sprout producers (business) are allowed to choose the most effective means or use alternative approaches to sprout seed decontamination. The overall cost of the alternative approaches to sprout seed decontamination is small as these costs are already reflected in items such as capital expenditure.

Impact on small & medium businesses

The industry profile indicates that most seed producers, seed processing and sprouting businesses are either sole proprietorships, partnerships or family owned and operated businesses. Consultation with industry also indicates that nearly all affected businesses would typically employ less than 20 full time employees and would fall under the Australian Bureau of Statistics (ABS) definition of a small business. Therefore no additional or disproportionate impacts to small business are identified.

Government

Additional costs to governments will depend on their approach, existing resources, budgetary considerations and the number of businesses operating in their jurisdictions. Consultations with jurisdictions have indicated that they could potentially incur significant costs to develop, implement and maintain a scheme, legislation or an arrangement to regulate sprout processors in their states. Some of these costs may be recovered through cost recovery from industry (e.g. auditing) and are included as part of industry costs. However other costs such as developing the scheme, license and accreditation (fee for privilege type of services) will not be fully recovered due to the small number of business operating in this sector.

The following estimates are made on the basis of available information:

Upfront costs

A government agency indicated that it had incurred upfront costs of about $213,600 to develop its proposal (which incorporates similar requirements). At the time sprout businesses represented about 16% of all plant processors. Therefore proportionate costs attributable to sprout processors could be $34,176. Other jurisdictions may be able to reduce their upfront costs by adopting elements of the current state based requirements (e.g. food safety program template for businesses) in their jurisdiction. However, if this turns out to not be appropriate, then it is estimated that total additional upfront costs for remaining jurisdictions may be in the range of $192,240 (i.e. base costs of $34,176 scaled up for other jurisdictions, where the remaining 85% of sprout producers are known to be operating). As this cost relates to the regulated sprout processors only a further 50% has been added to the costs (50% of NSW's plus the other jurisdictions' costs) to take into account of regulating the whole supply chain noting that the level of regulatory supervision is likely to be lower further up the supply chain ($113,208). Therefore a total estimate of $305,448 has been used.

Ongoing costs

NSW estimated the Plant and Products Food Safety Scheme enforcement costs at about $162,500[30] annually in 2004. However the Plant and Plant Products Food Safety scheme covered 4 sectors including seed sprouts. As sprout producers accounted for 16% of all plant producers, the indicative costs for a jurisdiction to enforce the regulation of seed sprouts in current prices could be about $32,000. Auditing, sampling and other fee for service costs are excluded as they may be recovered from industry and have been estimated in industry compliance costs. If other states incur additional ongoing costs to implement, then total additional ongoing costs for government may be estimated at $181,560 annually (i.e. base costs of $32,000 scaled up to other jurisdictions, where the remaining 85% of sprout processors are known to be operating). As this cost has been calculated only on the basis of regulating sprout processors a further 50% has been added to the costs to take into account regulating the whole supply chain noting that the level of regulatory supervision is likely to be lower further up the supply chain. As this cost relates to the regulated sprout processors only a further 50% has been added to the costs (50% of NSW's plus the other jurisdictions' costs) to take into account regulating the whole supply chain noting that the level of regulatory supervision is likely to be lower further up the supply chain ($106,800). Therefore a total estimate of $288,360 has been used.

While the above costs for government may not be additional costs requiring a budget allocation, this could be thought of as opportunity costs for developing and enforcing other regulation.

[30] NSWFA Plant and Plant Food Safety Scheme (Page 46) http://www.foodauthority.nsw.gov.au/_Documents/industry_pdf/Plant%20Products%20Regulatory%20Impact%20Statement.pdf

Consumers

Incremental costs of regulatory measures incurred by the industry will be ultimately passed on to the consumers in full or in part. It is unknown to what extent the costs will be passed on.

4.7.2 Benefits

For the purposes of this analysis it is important to consider the number of food-borne illness outbreaks that are expected to occur in Australia within the next 10 years of the application period. Under the Butler model 924.2 cases of foodborne illness are associated with sprouts at a cost of around $2million per year. For the purpose of estimating the benefits FSANZ has assumed an effectiveness rate in the range of 23% up to 80%.[31] Therefore we could expect to achieve a benefit in the range of $430,000 to 1.5 million per annum with mean benefit of around $964,000.

Benefits not quantified

Benefits which were not quantified and valued include:

- The value of managing food safety business risk to the business. The value of managing this business risk is evidenced by the fact that many industry participants have voluntarily decided to put management systems in place. The concern is that some industry participants potentially do not understand the nature of the risk nor how to manage it.
- The negative externalities avoided flowing from the negligent activities of one or more industry participant. Past outbreaks associated with other commodities have shown negative business outcomes for businesses in the same industry or in related industries not associated with the disease outbreak.
- Consumer expenditure for redress potentially saved, psychological effects on victims and relatives and cost of uncertainty to consumers.
- Any cost to business and unemployment costs as a result of factory shut downs.
- The cost saving associated with the likely prevention of pathogens other than *Salmonella*.

4.7.3 Conclusion

Costs summary presented in Table 4 indicate a total upfront cost of $1.43 million to $10.55 million and ongoing cost of $2.53 million to $12.08 million per year will be incurred on seed sprouts through chain regulatory measures. However, only up to 1.5 million per year of benefits may be realised if all parties involved in the production of seed sprouts comply with similar preventative control measures (based on the reduction level in illness of 23% – 80% discussed in the benefits section). This means there is only a small probability of benefits exceeding costs. If mean estimates of cost and benefit are applied over a period of 10 years a net present loss of around $53 million is expected. See Attachment 5 for further details of these calculations.

Taking into consideration the potential for significant costs to seed producers and seed processors, it is likely that costs of regulatory measures for seed producers and seed processors will not achieve the maximum net benefit for the community as a whole. Though

[31] The US have experienced about an 80% decline in their reported food-borne illness cases due to consumption of sprouts since their industry (all parties involved in production of seed sprouts) incorporated similar preventative controls in the production of sprouts.

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.

Also, the practicality and effectiveness of regulating seed processors is uncertain as they may be able to prevent further contamination, but could not necessarily address existing contamination passed on to them from the seed production stage (See Section 9. of the First Assessment Report for more information on the effectiveness and practicality of proposed food safety measures).

Adoption of an extremely conservative approach in this case would not be cost effective and go against the principles of minimum necessary regulation. Therefore FSANZ recommends that seed producers and seed processors not be subject to regulatory measures in the Code.

4.8 Option 2(b) Regulatory food safety measures for sprout processors only

4.8.1 Costs

As estimated under Option 2(a) total costs to sprout producers are in the order of $96,100 upfront and another $427,000 ongoing. These costs are much lower compared to seed producers and seed processors. In addition costs to government are estimated to be $192,240 upfront and $181,560 ongoing. Therefore total costs of option 2(b) are estimated to be about $288,360 upfront and $608,760 ongoing.

4.8.2 Benefits

A 23% - 65% reduction range in the burden of illness is used to estimate benefits. For high risk plant products (including sprouts), a 23% – 65%[32] reduction may be possible from food safety regulations incorporating a HACCP/equivalent food safety type of program. Please note that the upper range of effectiveness has been reduced from the 80% used in option 2(a).

If the numbers estimated under the Butler approach are used benefits, of $460,205 – 1.3 million per year may be realised (i.e. 23%-65% of the estimated $2million burden of illness) with a mean estimate of $880,392.

Net benefit/cost estimates

The following calculations are based on 3 scenarios, varying the effectiveness the intervention with an upper (65%) and lower bound (23%) and a mean effectiveness (44%). The results show the expected net present value over a 10 year period. Sensitivity tests were carried out for four scenarios with the 3% and 11% discount rates and the results presented in Table 5. The full workings of how these figures were calculated are included in Attachment 5.

[32] NSWFA Plant and Plant Food Safety Scheme (Page 24) http://www.foodauthority.nsw.gov.au/_Documents/industry_pdf/Plant%20Products%20Regulatory%20Impact%20Statement.pdf

Table 5: Summary of sensitivity analysis for net benefits/costs at 3%, 7% and 11% discount rates in 2011$

Burden of Illness	Net Present Value		
	3%	7%	11%
Low reduction @23%	-1.5 m	-1.4 m	-1.2 m
Mean reduction @44%	2 m	1.7 m	1.2 m
High reduction @ 65%	5.7 m	4.9 m	4.2 m

Break even estimates and analysis

As the above calculations have indicated the possibility of net benefit as well as the likelihood of net cost from sprout processor measures break even analysis is also provided. If the same cost assumptions are made as in the Butler model used over a ten year period 298.91 cases of illness caused by *Salmonella* will need to be avoided per year to fully offset the cost of the regulatory intervention.

The full workings of how this figure was calculated are also included in Attachment 5.

4.8.3 Conclusion

Based on the overall analysis, regulatory measures of sprout processors only is most likely to give the highest net benefit and give less cost burden to the community than any other option. If the assumptions of the Butler model are accepted as reasonable clear positive net present values are achieved at even relatively modest level of efficacy.

4.9 Comparison of options

A comparison of options indicates that the status quo would not be preferred as it continues to expose the community to the risk of food-borne illness due to seed sprouts consumption. An assessment of industry self-regulation option has been undertaken above at Table 1 precluding it from further consideration. The sprout industry does not appear to be a suitable candidate for self-regulation.

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 processors) 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.

Regulatory measures for sprout processors are the only option that is likely to generate net benefits for the community and it is more cost effective than the through-chain option. It is expected to create a net present value of $1.7 million over 10 years. The costs and benefits associated with a potential outbreak could be much higher or lower depending on circumstances. A high cost scenario is not unrealistic as large scale food-borne illness outbreaks associated with sprouts or salad components have occurred in developed countries in recent years some of which have resulted in deaths and severe illness.

5. Consultation

Proposal P1004 has included two public consultation processes. During the development of this Proposal extensive consultation has been undertaken with all stakeholders through Standard Development Committee meetings, public consultation and targeted consultations with industry.

Public comments on the draft standard and RIS
Public comments were sought on the draft standard and draft RIS starting from 6 September 2010 to 18 October 2010.

FSANZ received comments from 13 departments and organisations on the draft standard and the RIS which have been incorporated where appropriate (see Attachment 7). The comments were generally supportive of the regulatory measures and provided some suggestions on how to improve upon the quality of the proposed regulatory measures and the RIS. Eight of the thirteen submissions were in support of Option 2(b) regulatory measures for sprout producers only. Three submissions objected to the Proposed Standard. Reasons given for objecting to the preferred Option included the following:

- the Option may be too cost prohibitive for small businesses;
- the Proposal should be abandoned in favour of work on a broader plant and plant products Proposal; and
- FSANZ should consider alternatives to regulation such as working with the Australian New Zealand Sprouters Association on industry food safety initiatives.

There were 5 main issues raised by stakeholders and the public concerning the RIS and FSANZ responded to each as follow:

1. Stakeholders and the public were concerned about the omission of decontamination costs of sprout seed.

   FSANZ had responded to this by including the decontamination costs of seed sprouts in the RIS.

2. Omission of implementation costs of Clauses 4(2) and (3) (relating to control measures).

   FSANZ believes the implementation costs of Clauses 4(2) and (3) have already been considered as part of the implementation costs to be incurred by sprout processors and government respectively.

3. The use of 7 as a multiplier of epidemic diseases to obtain the total number of cases that occurred.
   FSANZ cited additional literature which used 7 or higher figures as a multiplier of epidemic diseases to obtain the total number of cases that occurred. The number of food-borne illness associated with sprout consumption was also further considered and expert advice sought. FSANZ used a probabilistic model suggested by Butler (2010) to predict the future annual number of seed sprout food-borne illness in Australia.

4. Overestimation of health cost saving.
   FSANZ sought expert advice on this point and adjusted them accordingly.

5. The application of 23% to 65% illness reduction rates.

   FSANZ used 23% to 65% reduction rates in food-borne illness as used by NSW for the analysis in the Regulation Impact Statement for Food (Plant Products Food Safety Scheme) Regulation 2004. This is not an unreasonable range given that an 80% reduction in illness was achieved in the US as a result of regulation intervention.

A number of other comments were made that did not relate directly to the RIS. FSANZ has responded to all the public comments regarding the the standard as well. These are set out in more detail in Attachment 7 of this RIS. The standard and RIS were revised to reflect recommendations and comments from stakeholders and the public. There were a number of improvements made to the standard to improve its clarity.

A further opportunity was provided to the Standards Development Committee (SDC) (made up of jurisdictional, community and jurisdictional representatives) in July 2011 to comment on the draft RIS. Most members of the SDC had no further comments beyond small amendments and clarifications. However, Victorian Department of Primary Industries (Vic DPI) had a number of concerns which have been address where possible. Vic DPI's comments and FSANZ response are included at Attachment 8.

6. Conclusion and recommended option

Based on the risk and impact analyses, it was clear that the regulatory measures for sprout processors only option is likely to give the highest net benefits to the community. However, the inherent limitations in extrapolating from limited data as a basis for estimating costs of potential future events should be noted.

The industry self-regulation option was not considered as adequate in addressing health and safety concerns of the community and the status quo represents an unacceptable public health and safety risk to leave unmanaged. The present self-regulatory systems contribute significantly to the safety of the sprouts produced by those businesses that have them in place. However, concerns exist about them achieving sufficient coverage to sufficiently reduce the level of risk.

Based on the costs associated with the 2005-06 outbreaks and government and industry cost estimates, through chain regulatory measures (requirements for seed producers, seed processors and sprout processors) may be too costly to implement as the costs associated with this option is expected to be extremely high. As such this option is not likely to give the community any net benefits and therefore not an appropriate option for achieving the objectives of this proposal.

The regulatory measures for sprout processors only option is being recommended because it is most likely to result in the large net present value for the community as a whole. Consequently FSANZ sees merit in regulatory measures in the Code for sprout processors only and recommends this as the preferred option. This option is preferred because:

- it addresses public health and safety concerns arising from consumption of sprouts;
- it does not place an undue burden on seed producers and seed processors;
- it is consistent with principles of minimum necessary regulation; and
- it is practical, less costly and can recover its costs within the range of benefits identified in the Proposal.

7. Implementation and Review

Implementation of the standards in Chapter 4 of the Code is the responsibility of authorities in the states and territories. The Implementation Sub-Committee of the Food Regulation Standing Committee (ISC) facilitates the consistent national implementation of these standards by developing nationally consistent implementation approaches. An implementation period is provided from the date standards are gazetted and registered as a legislative instrument. This implementation period enables industry and government authorities adequate time to put measures in place to meet the requirements of the standard.

In conjunction with the FSANZ process of standards development for seed sprouts, State and Territory authorities have been developing an implementation plan for the seed sprout standard. This means that Ministerial Council may be presented with implementation information along with an approved standard for seed sprouts, at the time Ministers are asked to make a decision on the standard.

The implementation package for the primary production and processing requirements for seed sprouts has been considered by ISC. All documents within the implementation package are not legal documents in their own right, but provide the direction for consistent implementation of the seed sprouts standard. The implementation package for the seed sprout standard comprises:

- compliance plans which describe how compliance with the national food standards will be demonstrated or measured;
- reference materials which are existing industry and government guidance material on producing seed sprouts;
- response materials which are documents that provide direction to government in facilitating national consistency in response to specific incidents.

When the finalised implementation package is publicly available on the ISC website, FSANZ will provide a link to it on the FSANZ website.

ISC will institute a national survey of the seed sprout industry under the Co-ordinated Food Survey Plan two years following the commencement date of the standard for seed sprouts. This survey will assist in collecting data to allow for the review of the standard and its associated implementation package. ISC has further undertaken to review the effectiveness and impact of the implementation package on regulators and impacted businesses as part of this process.

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Attachments

Attachment 1

Summary of existing requirements for seed sprout production (International and Australian)

1. Table A1: Summary of existing requirements applicable to each sector

Requirements	Seed Production	Seed Processing	Sprout Production
Australia and New Zealand Food Standards Code Chapter 1 – General Food Standards • including Standard 1.6.1 - Microbiological Limits for Food	**No**	Refer to discussion in Section 4.3 of 2nd Assessment Report	**Yes**
Chapter 3 – Food Safety Standards • **including Standards 3.2.2 - Food Safety Practices and General Requirements and 3.2.3 - Food Premises and Equipment** http://www.foodstandards.gov.au/foodstandards/foodstandardscode/	**No**		**No**
State and Territory requirements **NSW Food Regulation 2004** **Plant Products Food Safety Scheme** and associated **Plant Products Safety Manual** http://www.foodauthority.nsw.gov.au/_Documents/industry_pdf/Plant+Products+Manual.pdf (March 2010)	**No**	**No**	**Yes**
Primary Produce (Food Safety Schemes) Act 2004 (South Australia)	**No**	**No**	**Yes**
Export requirements **Export Control (Plant and Plant Products) Orders 2005** http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/0/7BE1D9C554F67735CA2573860003F987/$file/ExpContPlantsPlantProd2005.pdf	**Yes**	**Yes**	**Yes**
International and codes of practice **Codex Alimentarius** Code of Hygienic Practice for Fresh Fruits and Vegetables Annex Sprout Production. http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10200	**Yes**	**Yes**	**Yes**
Reducing Microbial Food Safety Hazards for Sprouted Seeds – Guidance for Industry (US FDA) http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm120244.htm	**Yes**	**Yes**	**Yes**

Canadian Code of Practice for the Hygienic Production of Sprouted Seeds http://www.inspection.gc.ca/english/fssa/frefra/safsal/sprointe.shtml	**Yes**	**Yes**	**Yes**
Code of Practice for Food Safety in the Fresh Produce Supply Chain in Ireland (Chapter 4: Microbiological Safety of Sprouted seed Production) http://www.fsai.ie/assets/0/86/204/7332e0dd-fc90-45a0-a633-79c8066863ec.pdf	**No**	**No**	**Yes**
Industry			
Code of Hygienic Practice for Whole Mung Beans http://www.mungbean.org.au/pdf/Code%20of%20hygienic%20practice%20for%20mungbeans.pdf or via http://www.mungbean.org.au/foodsafetyandhygiene.html	**Yes**	**Yes**	**No**
Australian New Zealand Sprouters Association Guidelines for Australian and New Zealand Sprout Producers Update 7 July 2008	**No**	**No**	**Yes**
Woolworths (2007) WQA Product Category Requirement - Produce,	**No**	**No**	**Yes**

2. Australia New Zealand Food Standards Code

Chapter 3 – Food Safety Standards

Standards 3.2.2 Food Safety Practices and General Requirements and 3.2.3 Food Premises and Equipment set out specific requirements for food businesses, food handlers and the food premises and equipment with which they operate to ensure the safe production of food. Standard 3.2.2 specifies process control requirements to be satisfied at each step of the food handling process:

- receipt
- storage
- processing
- display
- packaging
- transportation
- disposal
- recall

In addition there are requirements for skills and knowledge, health and hygiene of food handlers and the cleaning, sanitising and maintenance of premises and equipment.

Standard 3.2.3 sets out requirements to ensure that food premises, fixtures, fittings, equipment and transport vehicles are designed and constructed to minimise opportunities for food contamination and are cleaned and sanitised where necessary.

The food safety standards apply to all food businesses in Australia. A food business is defined in the Code as follows:

food business means a business, enterprise or activity (<u>other than primary food production</u>) that involves:

(a) the handling of food intended for sale, or
(b) the sale of food,

regardless of whether the business, enterprise or activity concerned is of a commercial, charitable or community nature or whether it involves the handling or sale of food on one occasion only.

Primary food production means the growing, cultivation, picking, harvesting, collection or catching of food, and includes the following:

(a) the transportation or delivery of food on, from or between the premises on which it was grown, cultivated, picked, harvested, collected or caught,
(b) the packing, treating (for example, washing) or storing of food on the premises on which it was grown, cultivated, picked, harvested, collected or caught, and
(c) any other production activity that is regulated by or under an Act prescribed by the regulations for the purposes of this definition.

While the operation of a seed sprout business may involve a number of the food handling activities generally undertaken by food businesses, State and Territory jurisdictions (excepting NSW) have not been able to apply Chapter 3 requirements to them because, in accordance with these definitions, seed sprout businesses have been regarded as a primary food producers (a grower of sprouts).

Chapter 1 – General Food Standards

The food standards in Chapter 1 of the Code generally apply to all food sold or traded at retail and wholesale level in Australia and cover labelling requirements, the use of additives and processing aids, contaminants and natural toxicants, MRLs, articles and materials in contact with food and microbiological limits for food. The only provision in Chapter 1 that is specific for seed sprouts is a microbiological limit in Standard 1.6.1.

Standard 1.6.1 - Microbiological Limits for Food specifies a microbiological limit for *Salmonella* in “cultured seeds and grains” (alfalfa sprouts, bean sprouts etc.):

Food	Micro-organism	n	c	m	M
Cultured seeds and grains (bean sprouts, alfalfa etc.)	*Salmonella*/25g	5	0	0	

Where:
n means the minimum number of sample units which must be examined from a lot of food
c means the maximum allowable number of sample units that can exceed m
m means the acceptable microbiological level in a sample unit
M means the level, when exceeded in one or more samples, would cause the lot to be rejected.

3. State and Territory requirements

New South Wales food safety scheme- seed sprouts

The NSW Food Regulation 2004 was amended in September 2005 to include the Plant Products Food Safety Scheme, applying to specified high risk plant product industries including sprouting and processing of seed sprouts.

Businesses that produce, store or transport seed sprouts for supply to the retail and food service sectors must hold a licence with the New South Wales Food Authority stating the activities that they are authorised to undertake and specific controls relevant to the industry. Businesses producing or handling unsprouted seed, unsprouted beans or wheatgrass do not require a licence.

Businesses that receive seeds for sprouting and produce seed sprouts must comply with the NSW Food Act 2003, Food Regulation 2004, the Australia New Zealand Food Standards Code and the Plant Products Safety Manual[33]. The manual outlines and explains the requirements of the Plant Products Food Safety Scheme. Sprout producers must demonstrate compliance though implementing a food safety program, based on Codex HACCP or Standard 3.2.1, which is certified by the Authority and audited. Businesses that only transport, distribute or store seed sprouts do not require a food safety program and are inspected for compliance with the legislation and the manual.

As part of their food safety program, sprout producers must address the following:

- raw material receival and storage;
- seed pre-screening for *Salmonella* (this may be certified by the seed supplier);
- raw material quality either by obtaining Authority approval to source seed from a supplier that can provide evidence that seed is produced under an audited HACCP-based food safety program or sanitising seed as specified in the manual;
- washing and sprouting;
- testing of spent irrigation water for *Salmonella*;
- post harvest washing;
- sprout storage;
- cleaning and sanitising of equipment and processing surfaces; and
- finished product testing for *E. coli*.

Sprout producers must also ensure that they have documented procedures for notifying the Authority of tests that fail to meet the microbiological testing requirements in the manual and the microbiological and chemical standards in the Australia New Zealand Food Standards Code. Laboratories testing these products are also required to notify failures to the Authority.

Specific requirements, detailed explanations and guidance for these activities are provided in the manual.

South Australia - food safety scheme

Under the Primary Produce (Food Safety Schemes) Act 2004 (South Australia), a Primary Produce (Food Safety Schemes)(Plant Products) Regulations 2010 has been developed and commenced on 1 July 2010. The regulations establish a food safety scheme for businesses undertaking the production of seed sprouts intended for human consumption. Specific elements of the scheme include:

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[33] Plant Products Safety Manual NSW/FA/FI012/0711 version 1 issued 12/11/07 available on the website of the NSW Food Authority at www.foodauthority.nsw.gov.au/industry/industry-sector-requirements/plant-products/

1. An obligation for a business to be accredited to undertake seed sprouts production (an accredited producer);
2. The accredited producer developing arrangements for the production of seed sprouts and ensuring these arrangements are approved;
3. Auditing of the accredited producer for compliance with the approved arrangements;
4. A specific requirement for the accredited producer to comply with Standard 3.2.2 – Food Safety Practices and General Requirements and Standard 3.2.3 – Food Premises and Equipment of the Australia New Zealand Food Standards Code.

4. Export requirements

Schedule 3A of the *Export Control (Plant and Plant Products) Orders 2005* prescribes structural requirements and operational and hygiene requirements for establishments preparing mung beans aimed, primarily focussed on pest control, effective cleaning and personal hygiene. Clause 6 of this schedule specifies the following:

- A registered establishment in which mung beans are prepared or inspected for export:
  (a) must be equipped and operated in a manner which permits effective pest control and hygienic conditions to be maintained at the establishment; and
  (b) must have a defined program of hygiene and pest control.
- All machinery, equipment and surrounding floor area must be thoroughly cleaned of all waste material and debris at intervals not exceeding one week, or at such other times as an approved inspector considers necessary.
- Mung bean debris and waste must be removed from areas where mung beans are prepared each day and removed from the establishment each week.
- Any material likely to contaminate, infest or provide a source of infestation of mung beans must not be stored or handled in a building or area used for their preparation or storage or in any area likely to create a source of contamination.
- Toxic substances and other substances which may contaminate mung beans must not be stored in an area or a building where mung beans are handled or stored.
- Animals (including birds and rodents) must not be present in the establishment where preparation of mung beans takes place.
- A person who:

  (a) is suffering from a communicable disease; or
  (b) is a carrier of a communicable disease; or
  (c) may transmit pathogenic organisms to mung beans;

- must not enter any registered establishment used for the preparation of mung beans.
- All persons handling mung beans must maintain a high degree of personal cleanliness.
- Handwashing facilities and toilet facilities must be kept in a clean and sanitary condition at all times.

Additionally there are specific packaging requirements for mung beans (packaging materials must adequately protect the mung beans from contamination) as well inspection procedures for pests and contaminants (Schedule 6A).

4.1 Industry measures

4.1.1 *Seed producers*

Mung bean producers have formed an industry association (Australian Mungbean Association) that comprise all sectors of the mung bean industry. An industry Code of Hygienic Practice for Whole Mung Beans[34] has been developed and is promoted by the Australian Mungbean Association as a minimum standard with which the industry should comply. The mung bean Code of Hygienic Practice covers:

- hygiene requirements on the farm and during transport to the mung bean grading establishment;
- design and facilities of the mung bean processing establishment;
- hygienic requirements for the mung bean processing establishment;
- hygienic processing requirements in the mung bean processing establishment;
- storage and transport of the end-product; and
- reference sampling of finished product.

Lucerne producers have also formed an industry association (Lucerne Australia) to represent all sectors of the lucerne industry. Lucerne seed is primarily grown as a non-food crop for pasture. However, as lucerne seeds have been used to produce alfalfa sprouts, and problems with contaminated lucerne seeds have been raised, microbiological testing (coliforms, *E. coli*, *Salmonella*, *L. monocytogenes*) of seed lots has been implemented by some lucerne seed producers and/or processors. Additionally, growers have been investigating on-farm measures they can implement to minimise contamination of lucerne seeds by microbial pathogens on-farm.

4.1.2 *Sprout producers*

The production of seed sprouts in Australia is a relatively small industry undertaken by small, often family owned businesses (there are approximately 30 sprout producers located throughout Australia). Historically, they have had no industry association or representation. Following the outbreaks of *Salmonella* in Australia in 2005-2006 attributed to seed sprouts; sprout producers have formed an industry association[35] and in consultation with State jurisdictions have developed a set of industry guidelines to support the safer production of seed sprouts. Currently, this Association represents just over half of the industry.

The Guidelines prepared by the Australian New Zealand Sprout Producers Association categorise sprouts into four risk categories:

- Category A – alfalfa
- Category B – all others including sunflower
- Category C – snow pea shoots/sprouts
- Category D – sprouts/shoots grown using a growing medium

The guidelines essentially specify seed sanitation, sampling and microbiological testing protocols for each category, with an overarching requirement for the business to implement a HACCP based food safety program. Uptake of these guidelines is voluntary. There are currently no certification mechanisms for demonstrating compliance.

34 Code of Practice is available on the Australian Mungbean Association website at: http://www.mungbean.org.au/foodsafetyandhygiene.html

35 Australian New Zealand Sprouters Association

4.1.3 Retailers

One large retailer has developed produce specifications for seed sprout products supplied to it. While these specifications cover a number of quality attributes, they also cover 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). Where sprout businesses supply product under the retailers own label, they must 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). Currently only one supermarket chain supplies seed sprout products (not alfalfa sprouts) under its own label.

5. Summary of international Guidelines/Codes of Practice

Codex Alimentarius

Codex has developed a Code of Hygienic Practice for Fresh Fruits and Vegetables which includes an Annex for Sprout Production. The annex recommends control measures to occur in two areas: during seed production and during sprout production. During seed production, conditioning and storage, the application of Good Agricultural Practices (GAPs) and good Hygieninc Practices (GHPs) are aimed at preventing microbial pathogen contamination of seeds. During sprout production, good hygienic practices are aimed at preventing the introduction of microbial pathogens and minimising their potential growth with a microbiological seed decontamination step included to reduce potential contaminants. A summary of the measures included in the annex is provided below.

Table A2: Codex Code of Hygienic Practice for Fresh Fruits and Vegetables – ANNEX II Annex for Sprout Production

Codex Code of Hygienic Practice for Fresh Fruits and Vegetables – ANNEX II Annex for Sprout Production	
Step in production chain	**Control measures included (additional to those specified in the Code of Hygienic Practice for Fresh Fruits and Vegetables)**
Primary production of seeds:	
• Hygienic production of seeds	○ Manure and biosolids: Wild or domestic animals should not be allowed to graze in the fields, Manure, biosolids and other natural fertilizers should only be used when they have undergone a pathogen reduction treatment. ○ Agricultural chemicals: Only chemicals (e.g. pesticides, desiccants) which are acceptable for seeds intended for the production of sprouts for human consumption should be used.
• Handling, storage and transport	○ Segregation of seed intended for sprout production from seed intended for forage crops and clear labelling. ○ Maintain sanitation in drying yards.
• Analyses	○ Lots of seeds should be tested for microbial pathogens (seed producers, distributors and sprout producers). If contamination found, seeds to be diverted or destroyed.
• Recall Procedures	○ Recall procedures in place to enable complete and rapid recall of implicated seed. ○ Practices should minimise the quantity of seed identified as a single lot and avoid mixing of multiple lots. Records kept for each lot. Lot number, producer and country of origin should be indicated on each container. ○ System in place to effectively identify lots, trace production sites and inputs.
Establishment for Sprout Production:	
• Design and layout of establishment	○ Storage, seed rinsing, microbiological decontamination, germination and packaging area should be physically separated.
Control of Operation	
• Water use	○ Quality of water used dependent on stage of operation (clean water for initial washing staged, potable water in later production processes).
• Initial rinse	○ Seeds rinsed and thoroughly agitated in large volumes of clean water (maximise surface contact). Process should be repeated until rinse water remains clear.
• Microbiological decontamination	○ Recommended that seeds are treated prior to use. Seeds should be agitated in large volumes of antimicrobial agent to maximise surface contact. Duration of treatment/concentration of agent should be accurately recorded.
• Rinse after seed treatment	○ As appropriate to eliminate any antimicrobial agent
• Pre-germination soak	○ Seeds should be soaked in cleaned water for the shortest possible time (to minimise microbial growth). After soaking seeds should be rinsed with potable water.
• Germination	○ Only potable water should be used ○ Soils and other matrices should be treated to achieve a high degree of microbial reduction
• Harvest	○ Harvesting should be done with dedicated, cleaned and disinfected tools.
• Final Rinse and cooling	○ As appropriate, rinse with cool potable water ○ Water should be changed to prevent cross-contamination ○ Drain sprouts using appropriate equipment ○ Steps to facilitate rapid cooling should be taken (if additional cooling time necessary)
• Storage	○ Sprouts should be kept under cold temperature (5ºC to minimise microbial growth for the intended shelf life of the product (as appropriate)

• Microbiological and other specifications	○ Recommended that seed and sprouts or spent irrigation water be tested for the presence of pathogens. ○ Each new lot of seeds received at the sprouting facility should be tested before entering production ○ Producers should have in place sampling/testing plan to regularly monitor for pathogens at one or more stages after the start of germination (e.g. spent irrigation water, finished product). Recommended that every production lot is tested.
• Microbiological cross-contamination	○ Traffic patterns should prevent cross-contamination of sprouts
Incoming Material Requirements	
• Seed specifications	○ Sprout producers should require evidence from seed producers that product was grown in accordance with measures outlined under primary production of seeds (assurance that chemical residues are within limits and certificates of analysis for microbial pathogens)
• Control of incoming seeds	○ Seed containers should be examined for physical damage and signs of contamination (particularly from pests). ○ Seed lots analysed for the presence of microbial pathogens should not be used until results available.
• Seed storage	○ Seeds should be stored to prevent mould and bacterial growth and facilitate pest control ○ Open containers should be stored such that they are protected from pests and other sources of contamination
Documentation and Records	
• Documentation and Records	○ Records should be maintained of the seed supplier, the lot number and country of origin to facilitate recall procedures. ○ Records must include seed sources and lot numbers; water analysis results, production volumes, storage temperature monitoring, product distribution and consumer complaints.
Awareness and responsibilities	
• Awareness and responsibilities	○ Producer should have a written training program that is routinely reviewed and updated. Systems should be in place to ensure food handlers remain aware of all procedures necessary to maintain safety of product.

Attachment 2

Incidence, health outcomes and duration of food-borne salmonellosis

Table A3: Incidence, health outcomes and duration of food-borne salmonellosis

Outcomes	Incidence	Number of days with illness	Disability weights	Total QALDs lost per Illness	Total $ QALDs lost per Illness
Gastroenteritis					
Mild	0.86	6	0.093	474	$256,446
Moderate	0.127	11	0.093	128	$69,435
Severe	0.013	16	0.093	19	$10,338
Reactive Arthritis					
Mild	0.01	222	0.21	460	$249,154
Moderate	0.002	222	0.37	162	$87,797
Severe	0.0002	222	0.94	45	$24,536
Inflammatory Bowel Disease	0.002	365	0.224	178	$96,130
Total					**$793,856**

Explanatory Notes

Outcomes: A range of adverse health outcomes have been reported to be associated with human illness resulting from a food-borne salmonellosis. An occurrence could vary from a mild gastroenteritis illness (GE) to extreme consequences like death. Long term adverse health complications include reactive arthritis and irritable bowel Syndrome. These outcomes have been derived from the Dutch study (Kemmeren, et al. 2006[36]).

Incidence: A Mild case of Gastroenteritis illness is classified as one that involves no visit to a general practitioner (GP), a moderate case involves a GP visit and a severe case would be one that requires hospitalisation. The breakdown of cases into Mild, Moderate and Severe cases of illness is based on Kemmeren et al. (2006) estimate of 35,000 community cases of *salmonella*- associated gastroenteritis and sequelae illness. For example out of the 35,000 most likely community wide cases, 30,000 or approximately 0.857 or (approximately 86%) could experience mild symptoms.

Number of days with illness: The estimated number of days with illness has also been derived from the Dutch study where a mild case of Gastroenteritis illness may only impact about 6 days whereas a severe illness could affect up to 16 days of an individual's life (Kemmeren, et al. 2006).

Quality Adjusted Life Day (QALD) lost per illness: QALD refers to a day of life adjusted for its quality or its value. A day in perfect health is considered equal to 1.0 QALD. Accordingly from 987 potential cases, 849 will be deprived of about 6 days of perfect health each or 5,094 days. The Australian Institute of Health and Welfare (AIHW) average disability weight for an uncomplicated gastroenteritis illness is estimated at about 9.3%[37]. Therefore adjusting for disability weights, about 464 days of perfect health or QALDs may be lost due to mild cases.

Value of QALD lost per illness: The value of a QALD is estimated at $541. Value of 474 days at $541 per day is about $56,446 per year.

36 http://www.rivm.nl/bibliotheek/rapporten/330080001.pdf : Pg. 58
37 http://www.aihw.gov.au/publications/phe/bdia/bdia.pdf :Pg. 18

Attachment 3

International sprout outbreaks from 1995 to 2010.

In the rest of the world, there were 15,972 identified cases of food-borne salmonellosis which were associated with the consumption of raw sprouts from 1995 to 2010 (Table A3)**.** The 15,972 cases resulted in 722 hospitalisations and 6 deaths.

Table A4: International sprout outbreaks 1995 – 2010

Year	Pathogen	Number cases	Number fatalities	Number of hospitalizations	Sequelae	Location	Type of sprout	Reference
2010*	*Salmonella* I 4,[5],12:i:-	94	0	23	-	US	Alfalfa	(CDC, 2010a)
2010	*S.* Bareilly	231	-	-	-	UK	Bean sprouts	(Cleary *et al*., 2010)
2010	*S.* Newport	44	0	7	-	US	Alfalfa	(CDC, 2010b)
2009	*S.* Saintpaul	228	-	9	-	US	Alfalfa	(CDC, 2009)
2008	*E. coli* O157:NM	21	0	2	-	US	Alfalfa	(CDC, 2011)
2008	*S.* Typhimurium	24	-	-	-	US	Alfalfa	(CDC, 2011)
2007	*S.* Weltevreden	45	-	-	-	Norway, Finland, Denmark	Alfalfa	(Emberland *et al*., 2007)
2007	*S.* Stanley	51	-	-	-	Sweden	Alfalfa	(Werner *et al*., 2007)
2007	*S.* Mbandaka	20	-	-	-	US	Bean sprouts	(CDC, 2011)
2007	*S.* Mbandaka	15	0	-	-	US	Alfalfa	(CDC, 2011)
2007	*S.* Montevideo	24	0	3	-	US	Bean sprouts	(CDC, 2011)
2006	*S.* Bareilly & *S.* Virchow	115	0	13	7 cases of sepsis	Sweden	Mung beans	(de Jong *et al*., 2007)
2006	*S.* Braenderup	4	0	0	-	US	Bean sprouts	(CDC, 2011)
2006	*S.* Oranienburg	15	-	2	-	Australia (VIC)	Alfalfa	(Kirk, 2009; OzFoodNet, 2006a)
2005-2006	*S.* Oranienburg	126	-	11	-	Australia (WA)	Alfalfa	(Kirk, 2009; OzFoodNet, 2006b)
2005	*S.* Braenderup	2	0	0	-	US	Mung beans	(CDC, 2011)
2004	*S.* Bovismorbificans	35	-	5	-	US	Alfalfa	(CDC, 2011)
2004	*E. coli* O157:NM	2	0	0	-	US	Alfalfa	(CDC, 2011)
2003	*E. coli* O157:H7	7	0	2	-	US	Alfalfa	(CDC, 2011)
2003	*E. coli* O157:NM	13	0	1	-	US	Alfalfa	(CDC, 2011)

Year	Pathogen	Number cases	Number fatalities	Number of hospitalizations	Sequelae	Location	Type of sprout	Reference
2003	*S.* Chester	26	1	3	-	US	Alfalfa	(CDC, 2011)
2003	*S.* Saintpaul	16	0	0	-	US	Alfalfa	(CDC, 2011)
2003	*E. coli* O157:H7	20	0	3	-	US	Alfalfa	(CDC, 2011)
2002	*E. coli* O157:H7	5	0	3	-	US	Alfalfa	(CDC, 2011)
2002	*S.* Abony	13	0	3	-	Finland	Mung bean	(Ministry of Agriculture and Forestry, 2003)
2001	*S.* Enteritidis	35	-	2	-	US	Mung bean	(CDC, 2011)
2001	*S.* Kottbus	32	-	3	-	US	Alfalfa	(CDC, 2011)
2001	*S.* Enteritidis	21	0	0	-	US	Mung bean	(CDC, 2011)
2000	*S.* Enteritidis PT4b	27	-	4	-	Netherlands	Bean sprouts	(van Duynhoven et al., 2002)
2000	*S.* Enteritidis	8	0	-	-	Canada	Alfalfa	(Harris et al., 2003)
2000	*S.* Enteritidis	75	-	3	-	US	Mung bean	(CDC, 2011)
1999	*S. paratyphi* B var *java*	46	0	-	-	Canada	Alfalfa	(Harris et al., 2003)
1999	*S.* Muenchen	157	0	6	-	US	Alfalfa	(Proctor et al., 2001)
1999	*S.* Mbandaka	83	0	9	-	US	Alfalfa	(CDC, 2011)
1999	*S.* Enteritidis PT913	84	0	5	-	Canada	Mung beans	(Honish and Nguyen, 2001)
1999	*S.* Saintpaul	36	0	2	-	US	Clover	(CDC, 2011)
1999	*S.* Typhimurium	112	0	3	-	US	Clover	(CDC, 2011)
1999	*Salmonella* spp.	34	-	-	-	US	Alfalfa	(CDC, 2011)
1998	*S.* Havana	18	1	4	-	US	Alfalfa	(Mohle-Boetani et al., 2001)
1998	*S.* Cubana	22	0	0	-	US	Alfalfa	(Mohle-Boetani et al., 2001)
1998	*E. coli* O157:NM	8	0	2	-	US	Clover	(Mohle-Boetani et al., 2001)
1997-1998	*S.* Senftenberg	60	0	2	-	US	Clover	(Mohle-Boetani et al., 2001)
1997	*E. coli* O157:H7	108	0	36	2 cases of HUS, 1 case TTP**	US	Alfalfa	(CDC, 1997)
1997	*S.* Infantis & *S.* Anatum	109	-	-	-	US	Alfalfa	(Taormina et al., 1999)
1997	*S.* Meleagridis	124	0	-	-	Canada	Alfalfa	(Harris et al., 2003)
1996	*E. coli* O157:H7	12680	3	>425	121 cases of HUS	Japan	Radish	(Fukushima et al., 1999; Michino et al., 1999)
1996	*S.* Stanley	30	-	-	-	US	Alfalfa	(CDC, 1996)
1996	*S.* Montevideo	417	1	42	-	US	Alfalfa	(Mohle-Boetani et al., 2001)
1996	*S.* Meleagridis	75	0	5	-	US	Alfalfa	(Mohle-Boetani et al., 2001)
1995-1996	*S.* Newport	133	0	-	-	US, Canada, Denmark	Alfalfa	(van Beneden et al., 1999)

Year	Pathogen	Number cases	Number fatalities	Number of hospitalizations	Sequelae	Location	Type of sprout	Reference
1995	*S.* Stanley	242	-	79	-	US, Finland	Alfalfa	(Mahon et al., 1997)
1995-2010		**15972**	**6**	**>722**				

* This outbreak is continuing in 2011

** TTP = thrombotic thrombocytopenic purpura

Attachment 4

Burden of illness from 987 cases

Table A5: Burden of illness from 987 cases

Cases of salmonellosis from consumption of seed sprouts					
Losses of Productivity	**Unit**	**Mild**	**Moderate**	**Severe**	
Proportion of cases	%	0.86	0.127	0.013	
Proportion working (paid work) [38]	%	0.485	0.485	0.485	
Proportion requiring carers[39]	%	0.10	0.10	0.10	
Average days ill	No.	6	11	16	
Average working days lost per illness	No.	2	7	11	
Average earnings lost per day[40]	$	321	321	321	
Overhead costs as % of earnings[41]	%	0.25	0.25	0.25	
Average value of output per day	$	402	402	402	
Average loss of output for condition	$	803	2811	4417	

Estimated incident and annual costs	Unit	Mild	Moderate	Severe	Total
Number in 2005/06 epidemic	No.	849	125	13	987
Number of workers	No.	412	61	6	479
Number of carers	No.	85	13	1	99
Total cost of 2005/06 epidemic	$'000	399	206	33	638

Draft report forecast 1: cost per annum	Unit	Mild	Moderate	Severe	Total
Equals 2005-06 outbreak each 2 years	$'000	199	103	17	319
Equals 2005-06 outbreak each 5 years	$'000	80	41	7	128

Individual health and welfare cost					
Gastroenteritis	**Unit**	**Mild**	**Moderate**	**Severe**	**Total**
Days with illness	No.	6	11	16	
Gastroenteritis disability factor	No.	0.093	0.093	0.093	
Equivalent full disability days	No.	0.56	1.02	1.49	
Individual health and welfare cost	$	261	479	697	

Total health and welfare cost	Unit	Mild	Moderate	Severe	Total
Total cost of 2005/06 epidemic	$'000	222	60	9	291

Draft report forecast 1: cost per annum	Unit	Mild	Moderate	Severe	Total
Equals 2005-06 outbreak each 2 years	$'000	111	30	4	145

[38] ABS Cat. No. 4102.0, Australian Social Trends.
[39] This assumes that 20% of non-working persons would need carer.
[40] ABS, Cat. No. 6302, Average Weekly Earnings (avr. full time earnings $1357 per week).
[41] Allows for super contribution, employee leave, workers compensation etc.

Equals 2005-06 outbreak each 5 years	$'000	44	12	2	58

Sequelae	Unit	Mild	Moderate	Severe	Total
Reactive arthritis: Number	No.	9.9	2.0	0.2	12
Reactive arthritis: total cost	$'000	215	76	21	313
Inflammatory bowel disease: Number	No.			2.2	2
IBD: total costs	$'000			0.79	1
Death: number	No.				0.015
Death total cost	$'000				59

Sequelae: total cost	Unit	Mild	Moderate	Severe	Total
Cost of 2005/06 epidemic	$'000				372

Draft report forecast 1: cost per annum	Unit	Mild	Moderate	Severe	Total
Equals 2005-06 outbreak each 2 years	$'000				186
Equals 2005-06 outbreak each 5 years	$'000				74

Summary of base case costs		
2005/06 epidemic	Unit	Total
Productivity costs	$'000	638
Gastroenteritis individual welfare costs	$'000	291
Sequelae individual welfare costs	$'000	372
Less allowance for double counting[42]	$'000	-96
Total business and individual costs	$'000	1205
Total business and individual costs per case	$	1221

Draft report forecast 1: cost per annum	Unit	Total
Equals 2005-06 outbreak each 2 years	$'000	603
Equals 2005-06 outbreak each 5 years	$'000	241

42 Allows for proportion of loss output costs to be borne by households.

Attachment 5

Estimates of net benefits/costs under different scenarios

Table A6: Option 2A - Estimates of net benefits/costs under different scenarios

Year	Min Cost Per year	Max Cost per year	Min Benefit per year BM	Max Benefit per year BM	Discount rate	NPV Min cost	NPV Max Cost	NPV Min Benefit BM	NPV Max Benefit BM	Mean NPV Benefit BM
0	$3,871,161.07	$22,641,600.00	$430,482.13	$1,497,329.13	1.0000	$3,871,161.07	$22,641,600.00	-$3,440,678.94	-$21,144,270.87	-$12,225,920.64
1	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.9346	$2,365,570.09	$11,298,841.12	-$1,963,250.35	-$9,899,468.10	-$5,869,158.98
2	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.8734	$2,210,813.17	$10,559,664.60	-$1,834,813.41	-$9,251,839.34	-$5,485,195.31
3	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.8163	$2,066,180.53	$9,868,845.42	-$1,714,778.89	-$8,646,578.83	-$5,126,350.75
4	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.7629	$1,931,009.84	$9,223,220.02	-$1,602,597.09	-$8,080,914.79	-$4,790,982.01
5	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.7130	$1,804,682.10	$8,619,831.79	-$1,497,754.29	-$7,552,256.81	-$4,477,553.28
6	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.6663	$1,686,618.78	$8,055,917.56	-$1,399,770.37	-$7,058,183.94	-$4,184,629.24
7	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.6227	$1,576,279.24	$7,528,894.92	-$1,308,196.60	-$6,596,433.59	-$3,910,868.44
8	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.5820	$1,473,158.17	$7,036,350.39	-$1,222,613.65	-$6,164,891.20	-$3,655,017.24
9	$2,531,160.00	$12,089,760.00	$430,482.13	$1,497,329.13	0.5439	$1,376,783.33	$6,576,028.40	-$1,142,629.58	-$5,761,580.56	-$3,415,903.96
					Total	$20,362,256.33	$101,409,194.23	-$17,127,083.17	-$90,156,418.03	-$53,141,579.85

Table A7: Option 2B - Estimates of net benefits/costs under different scenarios

Butler Model LR Benefits				Net Present Value Discount Rates		
Year	Benefits	Costs	Total	0.03	0.07	0.11
0	$460,205.39	$897,120.00	-$436,914.61	-$436,914.61	-$436,914.61	-$436,914.61
1	$460,205.39	$608,760.00	-$148,554.61	-$144,227.81	-$138,836.02	-$133,833.00
2	$460,205.39	$608,760.00	-$148,554.61	-$140,026.98	-$129,753.39	-$120,570.19
3	$460,205.39	$608,760.00	-$148,554.61	-$135,948.56	-$121,264.83	-$108,621.79
4	$460,205.39	$608,760.00	-$148,554.61	-$131,988.84	-$113,331.57	-$97,857.53
5	$460,205.39	$608,760.00	-$148,554.61	-$128,144.54	-$105,917.36	-$88,159.88
6	$460,205.39	$608,760.00	-$148,554.61	-$124,412.11	-$98,988.18	-$79,423.39
7	$460,205.39	$608,760.00	-$148,554.61	-$120,788.56	-$92,512.38	-$71,552.52
8	$460,205.39	$608,760.00	-$148,554.61	-$117,270.35	-$86,460.12	-$64,461.71
9	$460,205.39	$608,760.00	-$148,554.61	-$113,854.78	-$80,803.90	-$58,073.71
			Total	-$1,593,577.14	-$1,404,782.36	-$1,259,468.32

Butler Model UR Benefits				Net Present Value Discount Rates		
Year	Benefits	Costs	Total	0.03	0.07	0.11
0	$1,300,580.45	$897,120.00	$403,460.45	$403,460.45	$403,460.45	$403,460.45
1	$1,300,580.45	$608,760.00	$691,820.45	$671,670.49	$646,560.86	$623,261.74
2	$1,300,580.45	$608,760.00	$691,820.45	$652,107.19	$604,262.96	$561,496.70
3	$1,300,580.45	$608,760.00	$691,820.45	$633,113.95	$564,731.65	$505,852.89
4	$1,300,580.45	$608,760.00	$691,820.45	$614,673.48	$527,786.36	$455,723.58
5	$1,300,580.45	$608,760.00	$691,820.45	$596,770.55	$493,258.30	$410,561.54
6	$1,300,580.45	$608,760.00	$691,820.45	$579,388.56	$460,989.02	$369,875.58
7	$1,300,580.45	$608,760.00	$691,820.45	$562,513.67	$430,831.19	$333,220.85
8	$1,300,580.45	$608,760.00	$691,820.45	$546,129.29	$402,645.73	$300,198.88
9	$1,300,580.45	$608,760.00	$691,820.45	$530,222.95	$376,304.66	$270,449.91
			Total	$5,790,050.57	$4,910,831.18	$4,234,102.11

Butler Model Mean Benefits				Net Present Value Discount rates		
Year	Mean Benefits	Costs	Total	0.03	0.07	0.11
0	$880,392.92	$897,120.00	-$16,727.08	-$16,727.08	-$16,727.08	-$16,727.08
1	$880,392.92	$608,760.00	$271,632.92	$263,721.34	$253,862.42	$244,714.37
2	$880,392.92	$608,760.00	$271,632.92	$256,040.10	$237,254.79	$220,463.25
3	$880,392.92	$608,760.00	$271,632.92	$248,582.69	$221,733.41	$198,615.55
4	$880,392.92	$608,760.00	$271,632.92	$241,342.32	$207,227.40	$178,933.03
5	$880,392.92	$608,760.00	$271,632.92	$234,313.00	$193,670.47	$161,200.83
6	$880,392.92	$608,760.00	$271,632.92	$227,488.22	$181,000.42	$145,226.10
7	$880,392.92	$608,760.00	$ 271,632.92	$220,862.55	$169,159.40	$130,834.17
8	$880,392.92	$608,760.00	$ 271,632.92	$214,429.47	$158,092.80	$117,868.59
9	$880,392.92	$608,760.00	$ 271,632.92	$208,184.09	$147,750.38	$106,188.10
			Total	$2,098,236.71	$1,753,024.41	$1,487,316.89

Table A8: Break Even Analysis

Break Even Analysis	
Discount Rate	7.00%
Upfront costs	$288,360
Ongoing costs	$608,760
Benefit per illness avoided	$2,165
Number of illness	298.91

Year	Benefits	Cost	Total	Discount rate	NPV
0	$647,130.07	$897,120.00	-$249,989.93	1.0000	-$249,989.93
1	$647,130.07	$608,760.00	$38,370.07	0.9346	$35,859.88
2	$647,130.07	$608,760.00	$38,370.07	0.8734	$33,513.91
3	$647,130.07	$608,760.00	$38,370.07	0.8163	$31,321.41
4	$647,130.07	$608,760.00	$38,370.07	0.7629	$29,272.34
5	$647,130.07	$608,760.00	$38,370.07	0.7130	$27,357.33
6	$647,130.07	$608,760.00	$38,370.07	0.6663	$25,567.60
7	$647,130.07	$608,760.00	$38,370.07	0.6227	$23,894.95
8	$647,130.07	$608,760.00	$38,370.07	0.5820	$22,331.73
9	$647,130.07	$608,760.00	$38,370.07	0.5439	$20,870.78
				Total	$0.00

Attachment 6

An assessment of the cost-benefit analyses undertaken in support of FSANZ Proposal P 1004

James RG Butler, PhD

29 June 2010

Contents

Executive Summary

Proposal P 1004 recommends new regulations be imposed on producers of sprouts in order to reduce food-borne illness attributable to consumption of sprouts. However, the cost-benefit analyses of this regulation generally show negative net present values (NPVs), raising a question as to whether the benefits of introducing the new regulation may have been underestimated in the cost-benefit analyses provided by Food Standards Australian and New Zealand (FSANZ).

In considering this question, this paper argues that the estimation of benefits in the cost benefit analyses undertaken by FSANZ appears to have been very conservative. Hence there is a distinct possibility that the benefits of the proposed new regulation have been substantially underestimated.

The two main reasons for this underestimation are as follows:

- The methods employed in the assessment are based on Australian data for only two years and do not distinguish between endemic and epidemic disease. This latter feature in particular means that the analyses do not adequately incorporate low probability, high impact outbreaks of a type that have been observed overseas and hence do not make adequate allowance for more severe outbreaks in Australia in future.

- The assessment of the economic costs of food-borne disease attributable to sprouts excludes both business losses and the costs of epidemic control measures commonly borne by government in response to epidemics.

It is suggested that serious consideration be given to undertaking a quantitative re-assessment of the benefits in these analyses, as the revised analyses may usefully inform decision-making regarding the adoption of this proposal.

Context

Food Standards Australia and New Zealand (FSANZ) have been considering the merits of introducing new regulations of sprout producers. The case for introducing such regulations is based on the problem of food-borne illness caused by the consumption of seed sprouts. In the document entitled *Proposal P 1004 – Primary Production & Processing Standard for Seed Sprouts: Consultant Regulation Impact Statement*, FSANZ presents economic assessments of four options:

Option 1(a) – Abandon the proposal, maintain the status quo

Option 1(b) – Abandon the proposal, rely on industry self-regulation

Option 2(a) – Adopt through chain regulatory measures (regulate seed producers, seed processors and sprout producers)

Option 2(b) – Adopt regulatory measures for sprout producers only

FSANZ has proposed the adoption of Option 2(b), based on cost-benefit analyses of these various options.

However, based on an analysis of eight different scenarios under Option 2(b), the net present value (NPV) of the new regulations ranges from a net benefit (positive NPV) of $595,000 to a net cost (negative NPV) of $3.48 million with only one of the eight analyses showing a positive NPV.[43] While these results are more favorable than those for Option 2(a), they still suggest a strong possibility that the new regulations will give rise to negative net benefits. In considering the case for Option 2(b), the Office of Best Practice Regulation in the Department of Finance of Deregulation has requested a more thorough justification for the selection of Option 2(b) as the preferred option by FSANZ.

Purpose of this paper

The purpose of this paper is to further explore the potential scale of food-borne illness caused by sprouts and whether an economic case for regulation exists. Having considered carefully the analyses presented by FSANZ, the paper argues that such a case can indeed be made. There are three grounds for this conclusion. The two main reasons relate to the conservative estimates of the disease reduction benefits included in the FSANZ analyses – one dealing with the estimation of the number of cases of disease in the absence of the proposed regulation and the other with the economic costs of the disease. The third relates to an issue regarding discounting in cost-benefit analysis.

Measuring benefits – endemic vs epidemic disease

The benefits of introducing regulations on sprout producers arise from a reduction in food-borne disease attributable to sprout consumption. The method employed in the proposal to estimate these benefits is follows:

(i) Estimate the cost of food-borne disease attributable to sprout consumption under the *status quo*;

(ii) Estimate the proportion of this disease burden that would be avoided if Option 2(b) was to be adopted.

Regarding (ii), the proposal refers to experience in the USA where an 80% reduction in disease burden was achieved with through chain regulatory measures – the measures considered under Option 2(a) in the FSANZ paper. Since Option 2(b) would apply new regulatory measures to sprout producers only, some fraction of this 80% disease reduction burden could be expected to be realised in Australia. Given the uncertainty surrounding what this fraction might be, the FSANZ analyses use a range of 23% to 65% reduction in disease attainable under Option 2(b). This is a defensible approach and will not be subject to any further comment in this paper.

Regarding (i), the analyses estimate, first, the quantity of food-borne disease attributable to sprout consumption and, second, the economic costs associated with that quantity of disease. The current section of this paper deals with the first of these two aspects — the quantity of disease attributable to the consumption of sprouts. The economic costs are considered in the following section.

The FSANZ paper cites evidence that, in Australia in 2005 and 2006, there were 132 cases of food-borne salmonellosis associated with the consumption of raw sprouts in the states of Western Australia and Victoria. Using an estimate based on epidemiological research that, for every reported case, there are another six cases that are unreported, the analysis

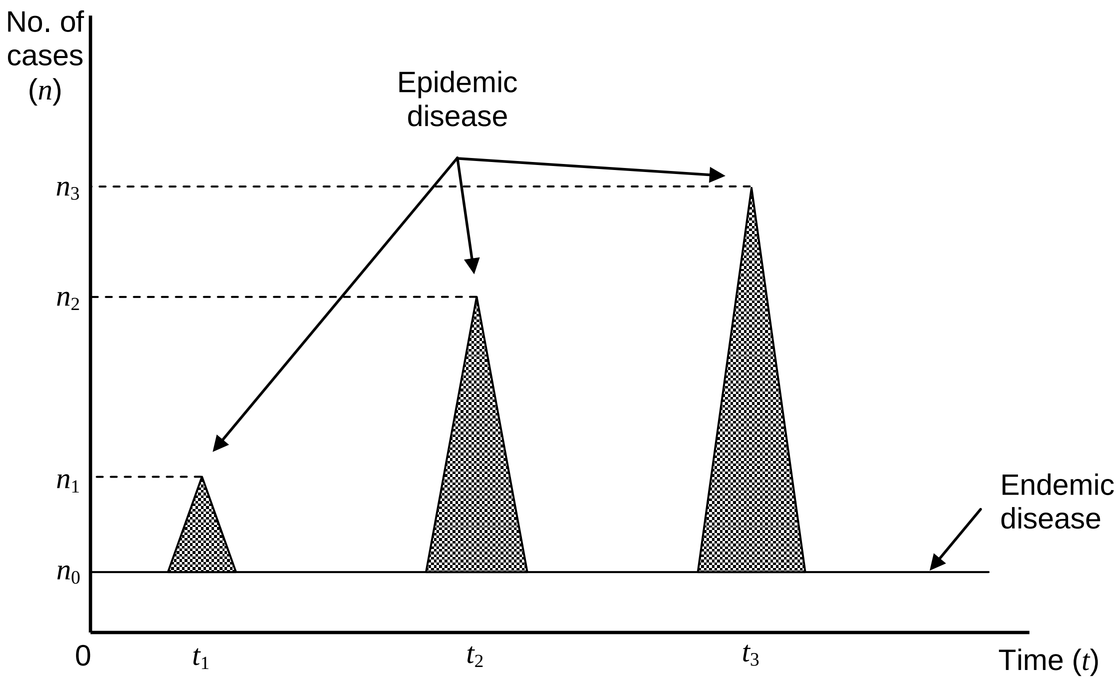
[43] In this paper, all monetary values are expressed in Australian dollars unless otherwise stated.

conclude there were potentially 924 cases of disease over that two-year period. If these outbreaks are assumed to occur biennially (i.e. once every two years), then on average there would be 462 cases of disease each year.[44] Alternatively, if such outbreaks occur once every five years, then the average number of cases would be 185 each year.

This is a very conservative approach to estimating the quantity of food-borne disease attributable to sprout consumption for two reasons. First, it is based upon the disease experience in Australia across 2005 and 2006 only and there is no reason to believe that the limited number of cases observed in those two years is necessarily representative of the quantity of disease in any two-year period. Second, the approach does not distinguish between endemic and epidemic disease. Endemic disease refers to disease that is present in a community at all times but in relatively low frequency.[45] It can be thought of as the background rate of disease that is ever-present in a community. Epidemic disease is an outbreak of disease that attacks many people at about the same time and may spread through one or several communities.[46]

An alternative modeling strategy would be to separate the endemic and epidemic components of food-borne disease attributable to sprouts. An illustration of this approach is shown in Figure 1. Endemic disease occurs at a constant rate of n_0 cases per time period. This is the background rate if disease in the population and may comprise mainly, if not wholly, unreported cases. Disease 'spikes' occur when there is an outbreak of epidemic disease with numbers of cases n_1, n_2 and n_3 occurring at times t_1, t_2 and t_3 respectively. Epidemics can vary greatly in magnitude as illustrated in Figure 1.

Figure 1: Endemic and epidemic disease



44 The FSANZ paper (p.9) refers to such events occurring biannually (i.e. twice each year) rather than biennially but the calculations clearly indicate that biennially is meant.

45 A formal definition is "The constant presence of a disease or infectious agent within a given geographic area or population group; may also refer to the usual presence of a given disease within such area or group" (JM Last (ed.), *A Dictionary of Epidemiology*, 3rd edn, Oxford University Press, New York, 1995).

46 Again, a formal definition from the dictionary by JM Last: "The occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events in excess of normal expectancy."

The number of cases reported in the FSANZ paper represents a conflation of the endemic and epidemic components of disease. If, for example, it is assumed that the unreported cases represent the endemic component (n_0 in Figure 1), this number of cases may recur every year and therefore should not be averaged over the time period. The two-year reported total of reported cases (132 cases) may then represent the epidemic component (n_1, n_0 or n_3 in Figure 1).

The timing and magnitude of epidemics are both subject to considerable uncertainty. Implementation of this alternative approach would require a probabilistic approach be adopted so as to estimate an expected number of cases in each time period t_i as follows:

$$N = n_0 + \sum_j p_j n_j$$

where N is the total number of cases in time period i and is obtained as the sum of the (constant) number of endemic cases each year and the probability weighted sum of different number of cases that potentially will emerge in an epidemic in time period i. A simple numerical example is provided in Table A9. The number of endemic cases in this example is set at 800, and the probabilities of an epidemic occurring with 200, 2,000 and 8,000 cases in any one year are set at 0.20, 0.05 and 0.02 respectively. The expected number of cases in this year is then 1,100.

Table A9: Illustrative calculation of expected number of cases for one year

	Potential number of cases in the year (1)	Probability of observing corresponding number of cases in that year (2)	Expected number of cases (3) = (1) x (2)	
n_0	800	1.00	800	Endemic component
n_1	200	0.20	40	
n_2	2,000	0.05	100	Epidemic component
n_3	8,000	0.02	160	
Total (N)			**1,100**	

The problem of uncertainty has been mentioned above, but an advantage of this approach is that the estimated probabilities and scales of epidemic that underlie the calculations are clear and transparent. In fact, this type of calculation is of the same nature as that undertaken by insurance companies that must set their premiums based upon estimates of probabilities of the occurrence of various future events. To be sure, the evidence base on the numbers of food-borne disease cases that have arisen in the past is deficient and provides only a short time series on which to base estimates of numbers of cases and, as already mentioned, the timing and magnitude of epidemics are uncertain. However, this should not be seen as precluding the calculations of estimates that are more realistic than the very conservative estimates contained in the FSANZ paper.

The conservative nature of the estimates is recognised by FSANZ in the document *Proposal P1004 Primary Production & Processing Standard for Seed Sprouts - 2nd Assessment Report*. On pp.11-12 of that report, it is stated:

> *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. (Emphasis added)*

The method suggested in this paper would allow the incorporation of the possibility that an outbreak of the magnitude of that which occurred in Japan in 1996 could occur in Australia. Data from the experience of the other countries could also be used to inform estimates of the timing and magnitude of epidemics.

Measuring benefits – estimating the economic costs of disease

The FASNZ analysis estimates the economic cost associated with food-borne disease attributable to the consumption of sprouts in the following categories:

- Direct health care/medical costs
- Productivity
- Health, welfare and loss of life (based upon willingness-to-pay and the monetary value of a quality-adjusted life-day (QALD) lost to illness

The overall mean cost per case based on these estimates is $1,300.

Two other types of costs relevant to the analysis but not included are:

- Loss to industry from food-borne illness
- Direct outbreak control costs to government

The FSANZ paper does mention losses to industry from food-borne illness but does not attempt to quantify the loss, imparting further conservatism to the benefit estimates. This is a difficult category of costs to estimate. The conceptually correct measure is the loss of producer and consumer surplus in the markets affected by the illness. Revenue losses by firms may or may not approximate this loss of surplus depending upon the underlying conditions of supply and demand in the market.[47]

[47] A lucid discussion of this issue can be found in W Harrington, AJ Krupnick and WO Spofford, *Economics and Episodic Disease: The Benefits of Preventing a Giardiasis Outbreak*, Resources for the Future, Washington DC, 1991.

Direct outbreak control costs to government are not mentioned in the FSANZ paper but can constitute an important source of cost savings from increased regulation. This omission may be explicable by the approach taken to estimating the number of cases which, as discussed in the preceding section, does not distinguish between endemic and epidemic disease. While control costs may not be relevant to endemic disease, they are likely to assume some importance in the face of an epidemic. Evidence supporting the importance of control costs in epidemics of food-borne illness was found recently in a review of seven studies of the cost of such epidemics attributable to outbreaks of hepatitis A.[48] Three of the studies related to food-borne outbreaks. The authors found that the relative importance of direct control costs varied widely across the outbreaks covered in the reviewed papers, but in general they concluded:

> *… the costs per case in an outbreak situation ranged from USD3,824 to USD200,480. These costs were typically found to be substantially higher than estimates from cost-of-illness studies (i.e. costs from sporadic cases) and estimates used in cost-effectiveness analyses, mostly because of costly outbreak-control measures.*

Again, the use of a method which distinguishes between endemic and epidemic disease lends itself to inclusion of direct control costs for the epidemic component.

Discounting

The FSANZ paper uses extant discounting techniques to render the different 10-year time streams of costs and benefits commensurate and obtain net present values for the relevant options. These techniques use a constant-through-time discount rate which, in the base case, is set at 7% per annum. Sensitivity analyses employ discount rates of 3% per annum and 11% per annum. The results of the cost-benefit analyses are moderately sensitive to the choice of discount rate. Table 2 shows the NPVs from different scenarios in which only the discount rate and no other parameters are varied. A four percentage point change in the discount rate in either direction changes the NPV by 14% to 19% in absolute terms.

Two aspects of the discounting in the paper warrant comment. First, the base case discount rate of 7% per annum, and the discount rates used in the sensitivity analyses, accords with those recommended in the government's *Best Practice Regulation Handbook* (2007). However, the base case rate recommended in the government's *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee* (ver.4.3, December 2008) is 5% per annum (see section D4 of the *Guidelines*). While the lower discount rate worsens the NPV when NPV is negative (as is evident in Table A10), it could be expected to improve the NPV if it were positive.

Table A10: Effect of discount rate on NPV(a)

	Discount rate (per annum)	NPV	% change in NPV from base case
Scenario 6	7%	-$2.08m	
Scenario 8	3%	-$2.48m	-19%
Scenario 1	7%	-$2.70m	
Scenario 7	11%	-$2.31m	+14%

Note: Base case discount rate is 7%. Only the discount rate varies between the two scenarios in each comparison.

48 J Luyten and P Beutels, "Costing infectious disease outbreaks for economic evaluation: A review for Hepatitis A", *Pharmacoeconomics*, Vol.27 No.5, 2009, pp.376-89.

The second aspect of discounting is recent research on time-varying discount rates, with more distant time periods into the future being discounted at lower rates. In a paper published in the *American Economic Review* in 2001, Weitzman showed that variation across individuals on the choice of an appropriate discount rate leads to a declining social discount rate through time even though each individual's discount rate is constant through time.[49] Over the time period used in the FSANZ analyses (10 years), this line of argument would make little difference. Also, time-varying discount rates have not yet incorporated into 'recommended practice' for economic evaluation. Nevertheless this is a development in the economics literature on discounting that may become relevant in the future.

Conclusion

Conservatism in the estimation of benefits for purposes of economic evaluation is common practice, reducing the risk of making poor investments and improving the chances of making high-yielding investments. However, it also carries with it the risk of under-investing in projects that, with a less conservative but still defensible approach to benefit estimation, would otherwise pass a cost-benefit test.

This assessment of the FSANZ assessment of a proposed new regulation to govern sprouts producers, thereby reducing food-borne disease from the consumption of sprouts, argues that the valuation of benefits in the FSANZ assessment is likely to be very conservative. The two main reasons for this are as follows:

- The methods employed in the assessment are likely to under-enumerate the number of cases of food-borne disease attributable to the consumption of sprouts because they are based on Australian data for only two years and do not distinguish between endemic and epidemic disease. This latter feature in particular means that the analyses do not adequately incorporate low probability, high impact outbreaks of a type that have been observed overseas and hence do not make adequate allowance for more severe outbreaks in Australia in future.

- The assessment of economic costs excludes both business losses and the costs of epidemic control measures commonly borne by government in response to epidemics.

The scope of this paper does not allow for further detailed analyses of this issue to estimate quantitatively the extent of this underestimation or its impact on the NPVs from the cost-benefit analyses. Based on this qualitative assessment, however, it does appear that a reassessment could have a considerable effect on the results. Such a reassessment, therefore, would appear to worth undertaking to inform a decision about the proposed new regulation for sprout producers.

49 Weitzman ML (2001), "Gamma discounting", *American Economic Review*, Vol.91 No.1, March, pp.260-71. The issue is also discussed in a recent Visiting Researcher Paper released by the Productivity Commission (M. Harrison, *Valuing the Future: the social discount rate in cost-benefit analysis*, Visiting Researcher Paper, Productivity Commission, Canberra, 2010).

Attachment 7

Summary of Submissions following 2nd Assessment and FSANZ Response

The 2nd Assessment Report for Proposal P1004 PPPS for Seed Sprouts was released for a six week consultation from 6 September to 18 October 2010. Thirteen (13) submissions were received from the following:

- Food Technology Association of Australia
- Coles Group Limited
- Australian Food and Grocery Council
- New Zealand Food Safety Authority
- Mr George Seymour (Consumer Liaison Committee Representative)
- New South Wales Food Authority
- Australian Government, Department of Agriculture, Fisheries and Forestry
- Victorian Department of Primary Industries and Department of Health
- Department of Primary Industries Food Safety South Australia
- Queensland Government
- South Australian Research Development Institute
- Department of Health Western Australia
- Department of Health and Human Services Tasmania

The key issues raised are described below and comments provided by individual submitters are listed in the attached Table. The FSANZ response to the issues is detailed in the table. The submitter comments on the RIS have been incorporated into the RIS.

Summary

Having regard to the issues raised in submissions, FSANZ considers that the Code should be amended to include food regulatory measures for the primary production and processing of seed sprouts. This was the preferred approach of FSANZ at 2nd Assessment. At this Approval stage, the draft variation to the Code was amended following 2nd Assessment to:

- use the term ‘sprout processor’ rather than ‘sprout producer’ in the proposed measures as this is more consistent with the activities of businesses that produce seed sprouts;
- ensure that seed related requirements only apply to seed that is to be used for producing seed sprouts;
- clarify that a sprout processor does not include a business that chills or stores seed sprouts, unless that business also produces seed sprouts;
- retain the term ‘unacceptable’ and align it to ‘unsafe’ and ‘unsuitable’ which are used as part of enabling food legislation;
- to commence the alignment of the definitions used throughout Chapter 4, recognising that some terms will need to remain in existing standards pending their review at a later time
- delay the commencement of the food regulatory measures for seed sprouts.

Table A11: Summary of issues raised in public submissions and the FSANZ Response

Submitter	Comments	FSANZ Response
Food Technology Association Australia	• Supports regulatory food safety measures for sprout producers only • The draft standard should use definitions that are consistent with other standards in the Code • Suggest all standards quoted on the draft standard should either reproduce in full all the relevant clauses or modify the other standards and then reference the modified clauses.	• Support for regulatory measures is noted. • Food regulatory measures have been amended to align with other Chapter 4 definitions, including the preliminary provisions in Standard 4.1.1.
Coles Group Limited	• Supports Option 2 (b) the development of primary production and processing standard for seed sprouts • Believes it is important for the implementation plan to include a communication strategy to ensure all producers of sprouts are covered and that small producers have access to implementation materials. • Any food safety systems should identify all potential hazards e.g. Listeria • Standard is based on outcomes which will provide opportunities to demonstrate that different processes will not adversely affect the microbiological safety of sprouts • More prescribed standards would be too restrictive and restrict alternative methods or cause OH&S issues.	• Support for regulatory measures is noted. • FSANZ considers that implementation materials would need to be developed but not necessarily by FSANZ. • FSANZ notes support for outcomes based standards.
Australian Food and Grocery Council	• Supports the development of a primary production and processing standard for seed sprouts. • Recommends FSANZ in conjunction with the Jurisdictions develops education initiatives for consumers and industry as an accompanying risk management measure in the implementation of the Standard	• Support for regulatory measures is noted. • FSANZ considers that implementation materials would need to be developed but not necessarily by FSANZ.
New Zealand Food Safety Authority	• Queries whether there is sufficient scientific data available to support the development of the Standard at this time • Suggests consideration be given to making no change to the Code at this time in favour of developing broader plants and plant products standard. • Agrees with the current definition of seed sprouts.	• FSANZ considers that both domestic and international evidence supports the identification of unacceptable seed sprouts as a potential risk to public health and safety. • Preliminary scoping identified the production of seed sprouts as an area of public health concern (two outbreaks of foodborne illness in Australia were attributed to the consumption of seed sprouts in 2005-2006). The Implementation Sub-Committee (ISC) of the Food Regulation Standing Committee supported work on seed sprouts progress as a priority. • Support for seed sprout definition is noted.

Submitter	Comments	FSANZ Response
Mr George Seymour	• Agrees with Option 2(b) regulatory measures for sprout producers only and agrees regulatory measures would place responsibility on all sprout businesses. • Suggests the risk to public health and safety necessitates regulation of industry despite the analysis that such measures could impose a net cost. • Suggest traceability mechanism must require contaminated products to be identified in a timely manner and suggest ' A sprout producer must have a system to *immediately* identify'	• Support for regulatory measures is noted. • As with other traceability requirements in primary production and processing standards, FSANZ considers that a performance based measure is adequate.
New South Wales Food Authority	• Supports Option 2 (b) regulatory measures for sprout producers • Queries the implementation period of 12 months and suggests it may not be sufficient to implement standard where there is no history of sprout regulation. Considers gazettal times for PPP Standards are inconsistent • Suggests commencement dates may be problematic for implementation as Standard 4.2.6 relies on the definitions in Standard 4.1.1 • Requests clarification of the definition of seed sprout as it is not clear whether all or part of the seed must be eaten at the time of consumption • Query if there is a potential issue with the definition of 'unacceptable' as reference to definitions of 'unsuitable' and 'unsafe' in accordance with Standard 3.1.1 may be difficult to apply to Chapter 4 as 3.1.1. definitions are for the purposes of Chapter 3 Standards • Suggest consistent definitions of 'validate' and verify' across all PPP Standards • The definition of sprout producer is too broad and may capture seed storage businesses • Clause 7 uses the term 'effective' without specifying what 'effective' means	• Support for regulatory measures is noted. • FSANZ has amended the proposed food regulatory measures to delay the commencement of the food regulatory measures for seed sprouts. • Food regulatory measures have been amended to align with other Chapter 4 definitions, including Standard 4.1.1 and a definition for 'unacceptable'. • FSANZ has amended the proposed food regulatory measures to clarify that the scope of seed related activities only extends to those activities related to seed sprout production. • FSANZ does not consider that there is a need to further articulate the degree of decontamination as this is covered by the definition of 'decontamination' and other measures (e.g. sale or supply restrictions, general food safety requirements).
South Australian Research and Development Institute	• Suggest definition of sprout producer is too broad and captures businesses that only store seed, grow seed or transport sprouts • Questions the need for the inclusion of a requirements for storage of sprouts at a certain temperature	• FSANZ has amended the proposed food regulatory measures to clarify that the scope of seed related activities only extends to those activities related to seed sprout production. • FSANZ considers that Standard 3.2.2 already includes these requirements, albeit as performance-based measures.
South Australian Government	• Strongly supports Option 2 (b) regulatory measures for sprout producers only • Suggest definition of sprout producer should be amended as it captures seed processors and merchants and retailers and transporters that are not	• Support for regulatory measures is noted. • FSANZ has amended the proposed food regulatory measures to clarify that the scope of seed related activities only extends to those activities related to seed sprout production.

Submitter	Comments	FSANZ Response
	sprout producers	
Department of Health & Human Services Tasmania	• Supports Option 2(b) regulatory food safety measures for sprout producers and suggests other risk management strategies should also be considered • Suggest meaning of sprout producer should exempt business that solely transports seed sprouts and does not engage in any other activity listed. • Supports use of the term 'food safety management statement' or alternatively support reference to Standard 3.2.1, for consistency throughout all Chapter 4 Standards • Query definition of verify when definition of verification is provided in Standard 4.1.1.	• Support for regulatory measures is noted. • FSANZ has amended the proposed food regulatory measures to clarify that the scope of seed related activities only extends to those activities related to seed sprout production. • FSANZ agrees that the application of the food safety management statement is appropriate and consistent with other primary production and processing standards • Food regulatory measures have been amended to align with other Chapter 4 definitions, including Standard 4.1.1
Australian Government, Department of Agriculture, Fisheries and Forestry	• Supports the development of a primary production and processing standard for seed sprouts • Clause 1(2) and 7 Decontamination clause does not specify an outcome. Suggest 'decontamination means a process that reduces the level of pathogenic organisms that may be present in seed sprouts to a level that does not present a food safety risk' • Clause 1(2) Notes that the definition of 'unacceptable' is not consistent with definitions in other proposed PPP Standards and should reference the definitions of 'unsafe' and 'unsuitable' • Clause 1(2) Does not support the definition of 'validate' or 'verify' as not consistent with other PPP Standards. Support single definition in Clause 4.1.1 • Clause 8 Suggests the wording for traceability Clause is not consistent with other PPP Standards and should be included in Standard 4.1.1	• Support for regulatory measures is noted. • FSANZ does not consider that there is a need to further articulate the degree of decontamination as this is covered by the definition of 'decontamination' which stipulates an outcome 'to reduce the level of pathogenic organisms', and operates with other measures in the standards that ensure seed sprout safety (e.g. sale or supply restrictions, general food safety requirements). This decontamination outcome is consistent with the Codex guidelines which state that 'During sprout production, the purpose of microbiological decontamination of seeds step is aimed at reducing potential contaminants' (Code of Hygienic Practice for Fresh Fruits and Vegetables, Annex for sprout production). • Food regulatory measures have been amended to align with other Chapter 4 definitions, including Standard 4.1.1 and a definition for 'unacceptable'. • The traceability requirements are consistent with the traceability requirements for an egg processor as agreed by Ministerial Council. Given the scope and timing of P1004, general traceability requirements in Standard 4.1.1 will need to be revisited in a future standards development process; to ensure that there are no unintended consequences with other primary production and processing sectors.

Submitter	Comments	FSANZ Response
Department of Primary Industries Victoria	• Suggest FSANZ should consider an alternative approach to manage the public health risks associated with sprout production (FSANZ to work with Australian New Zealand Sprouters Association (ANZSA) to support safer production of seed sprouts) • Suggests there is lack of evidence that sprouts present an unacceptable risk for consumers. The outbreaks in 05/06 do not provide sufficient evidence that there is a constant systemic unmanaged and unacceptable level of risk associated with sprouts • Does not believe FSANZ has proposed the most cost effective approach to address the risks consistent with 'minimum necessary regulation' • Considers and education campaign directed at seed sprout industry accompanied by guidelines may provide more cost effective approach • Considers the development of an industry self-certification scheme would support the reputation of the industry • Suggests working with the ANZSA would provide an opportunity to collect baseline data on the risk associated with seed sprouts. • Use of the term unacceptable is inconsistent with the Model Food Provisions, suggests 'unsafe' 'unsuitable' should be sufficient. • Considers the definition of sprout producer should not capture businesses that only receive or store seed • Requiring sprout producers to comply with Standards 3.2.2 and 3.2.3 is inconsistent with Model Food Provisions as these Standards apply to food businesses and sprout producers are primary producers • Does not support the approach of including Food Safety Management Statement in the Standard. The Standard should allow for alternative approaches to be considered other than FSMS. • The requirement for ongoing verification activities is not consistent with other Standards and should be a requirement of the compliance system • Does not accept that the level of burden to industry for Clause 4(2) 'have evidence to show that a systematic examination has been undertaken' is commensurate with the level of risk associated with sprout production. • Suggests traceability requirements should apply to all PPP standards. • Scientific understanding of microbiological contamination of seed sprouts is developing and proposed Standard does not provide confidence that any microbial contamination in the supply chain will be managed. • Opposes an implementation period of 12 months and suggests two year implementation time frame.	• FSANZ considers that food regulatory measures are appropriate and costs and benefits have been adequately taken into consideration in the Regulation Impact Statement. • FSANZ considers that both domestic and international evidence supports the identification of seed sprouts as a potential risk to public health and safety. • Preliminary scoping identified the production of seed sprouts as an area of public health concern (two outbreaks of foodborne illness in Australia were attributed to the consumption of seed sprouts in 2005-2006). The Implementation Sub-Committee (ISC) of the Food Regulation Standing Committee supported that work on seed sprouts progress as a priority. • The development of education campaigns or an industry self-certification scheme (self-regulation) is not considered a viable option by FSANZ. As stated in the 2nd Assessment Report, there is not a cohesive sprout production industry which could effectively adopt this type of self-regulation option. In addition, there has been previous market failure which demonstrates the industry is unable to support self-certification or self-regulatory arrangements. • Food regulatory measures have been amended to align with other Chapter 4 definitions, including Standard 4.1.1 and a definition for 'unacceptable'. • A sprout producer, now sprout processor, would need to comply with Standards 3.2.2 and 3.2.3. • FSANZ considers that the application of the food safety management statement is appropriate and consistent with other primary production and processing standards. • Given the scope and timing of P1004, general traceability requirements in Standard 4.1.1 will need to be revisited in a future standards development process; to ensure that there are no unintended consequences with other primary production and processing sectors. • FSANZ has amended the proposed food regulatory measures to delay the commencement of the food regulatory measures for seed sprouts.

Submitter	Comments	FSANZ Response
Queensland Government	• Opposed to the development of regulatory measures for seed sprouts in isolation of a more general review of the need for primary production and processing standards related to horticulture • Suggests there is a significant risk that the proposed Standard would not be able to be implemented in Queensland due to the costs of a new food safety scheme not being able to be recovered from a low number of businesses expected to be captured by the Standard • Opposed to ad hoc approach to developing standards in response to food borne illness outbreaks with potential to unfairly affect single commodities and undermine development of horticultural products PPP Standard • Inconsistent with previous food borne illness outbreaks such as paw paw (WA and QLD 06/07), rockmelons (06), semi-dried tomatoes (2009) • Proposed regulatory measures for seed sprouts exclude micro greens and snow pea sprouts which are also usually produced by sprout producers. Subsequent costs to the industry are likely to be imposed to implement additional requirements at a later stage. • Notes small producers in the retail sector such as in restaurants may not have been considered • Notes that practical guidance would be required to implement the standard • Suggests 2nd Assessment did not provide a solution to minimising contamination of seed used for sprouting during primary production • Suggest limited industry comment was made at Initial Assessment • The draft Standard is inconsistent with the primary production and processing standard templates used to develop the egg and poultry meat standards.	• Preliminary scoping identified the production of seed sprouts as an area of public health concern (two outbreaks of foodborne illness in Australia were attributed to the consumption of seed sprouts in 2005-2006). The Implementation Sub-Committee (ISC) of the Food Regulation Standing Committee supported that work on seed sprouts progress as a priority. • As stated at 2nd Assessment, FSANZ considers that micro greens should be excluded from the definition of seed sprouts as they vary in a number of physiological aspects from seed sprouts. FSANZ also considers that snow pea sprouts should be excluded as the characteristics of growth and harvest are more similar to other vegetables. • As detailed in the 2nd Assessment Report, the proposed food regulatory measures include requirements to ensure seed is acceptable for producing seed sprouts and for effective decontamination processes i.e. reduce the level of pathogens. FSANZ considers that these represent adequate and cost-effective measures to manage seed sprout safety, including microbiological contamination. • Retail sale activities undertaken by businesses such as restaurants are not within the scope of this Proposal or the proposed food regulatory measures. FSANZ has publicly consulted with industry through industry visits, industry surveys and the membership of the SDC. • FSANZ considers that the application of the food safety management statement and other regulatory measures is appropriate and consistent with other primary production and processing standards.

Submitter	Comments	FSANZ Response
Department of Health Western Australia	• Supports Option 2 (b) based on cost benefit analysis • Suggests the requirement for through chain food safety of seed sprouts should be reviewed following implementation of the Standard • Clause 1 Definition of 'Unacceptable' – the use of the term unacceptable is not in context with any similar expression in the Code. If food is not fit for human consumption, it is either 'unsafe' or 'unsuitable' and unacceptable should be replaced with 'unsuitable or unsafe' • Clause 2 Recommend replacing 'involves' with 'includes' for consistency with other PPP Standards • Recommend amending 'seed' to 'seed for sprouts' in Clauses 2 (a) (c) (d) as these activities may be performed in other activities not associated with seed sprouts. • States that the application of Standard 3.2.3 requires a food business to only use potable water in the premises which entails the water supply complying with the drinking water guidelines • Clause 4 Recommend that the requirement is for 'written evidence' to be provided of the systematic examination being undertaken • Clause 5 Receiving seed is passive in context and recommend amending to 'A sprout producer must take all practicable measures to ensure that the seed is not of a nature or in a condition that would make the seed sprouts unsafe or unsuitable' • Clause 7 Decontamination is a prescriptive requirement contrary to outcomes based approach. Suggest if this Clause is retained it includes a requirement for the sprout producer to validate the decontamination process • Clause 8 Traceability, suggest requirement is amended to enable complete traceability of inputs and outputs including name and address of businesses that supplied food, unique number or code assigned to batch, date on which the food was received.	• Support for regulatory measures is noted. • Through chain food safety of seed sprouts could be further considered in any future primary production and processing requirements for plant and plant products. • Food regulatory measures have been amended to align with other Chapter 4 definitions, including Standard 4.1.1 and a definition for 'unacceptable'. The term 'includes' is used in existing Chapter 4 standards. • FSANZ has amended the proposed food regulatory measures to clarify the definition of 'sprout processor' so that the activities apply in relation to the production of seed sprouts. • As detailed in the 2nd Assessment Report a sprout producer, now sprout processor, would need to comply with Standards 3.2.2 and 3.2.3. • In relation to validation, FSANZ is of the view that this is already required by the general food safety management requirements (i.e. 'must verify the effectiveness of the control measures'). • FSANZ is of the view that Clause 5 is sufficient to require a sprout processor to source seed that is acceptable for producing seed sprouts. • FSANZ does not consider that there is a need to further articulate decontamination requirements as this covered by the definition of 'decontamination' and other measures (e.g. sale or supply restrictions, general food safety requirements). • As with other traceability requirements in primary production and processing standards, FSANZ considers that a performance based measure is adequate and that there is no need to prescriptively list the required details.

Attachment 8

Comments from the Victorian Department of Primary Industries

Table A12: Comments from the Victorian Department of Primary Industries

No.	Comment	Response
1.	The premise for developing a PPP standard appears to be based on anecdotal evidence from the sprout industry association that there are sprout processors in Australia not managing food safety risks. However, the report does not provide any assessment on the extent to which, and adequacy of, risk management measures have been put in place by processors not covered by existing QA or regulatory schemes pre or post the 2005/06 outbreak.	Extensive consultation was undertaken with the industry and the best available information has been used. To the best of our knowledge base line data was not collected on sprout businesses safety performance or safety schemes before the 2005/06 outbreak. Therefore we have little idea, with the exception of NSW's regulatory intervention, whether safety has been improved by the voluntary system. Data does not exist either in relation to changes in systems nor in relation to post production outcomes. This data has most likely not been collected because it would be extremely difficult and costly to do.
2.	No context has been provided for the cause of the 2005/06 outbreak so it is impossible to deduce whether or not this outbreak would have been prevented by regulation.	The exact cause of the Victorian and Western Australian outbreaks is not known which is typical of most outbreaks.
3.	The report states that pathogens have been detected in seed sprouts in microbiological surveys but does not provide detail about which, if any, of these samples contained levels of pathogens that pose a risk to food safety.	The presence of pathogens is indicative of the fact that if they are mishandled by consumers there is a risk of illness.
4.	Insufficient consideration has been given to the option for self-regulation, specifically the extent to which the effectiveness of industry self-regulation could be improved by reviewing the industry guidelines and promoting these in parallel with an education campaign. While the RIS considers self-regulation, it only considers this option as the status quo with no further effort from governments or the sprout industry (i.e. options 1a and 1b are essentially the same).	The feasibility of self-regulation has been assessed under the criteria set in the Australian Government *Best Regulation Handbook* – June 2010. Businesses of this scale often do not have the regulatory capacity to self-regulate especially when a high risk product is involved.
5.	The report identifies an efficacy rate for regulatory measures in reducing food borne illness in sprouts of 23 to 65%. This efficacy rate is applied equally to options 2a and 2b even though 2a represents much more stringent levels of regulation and should therefore have a greater impact on reduction of food borne illness. In addition, in the report this efficacy rate has been applied to the total current estimate of food borne illness from	We have moved the upper range of the efficacy of the through chain regulation (Option 2a) up to 80% to reflect the US experiences. However, even at the increased rate of efficacy, through chain regulation is still not the preferred option under the proposal. The present schemes are unlikely to be

	seed sprout consumption even though it advises that 60% of sprout processors are already covered by comparable QA or food safety schemes. The regulation would therefore have no impact on their contribution to food borne illness associated with sprout consumption and, as such, the report significantly overestimates the benefits from regulation.	comparable to regulatory HACCP schemes. Likewise, the spread of risk is unlikely to be evenly spread across industry participants.
6.	What is the rationale for including two separate methodologies for estimating the costs of food borne illness associated with consumption of seed sprouts? This appears to complicate an already overly complex analysis.	A single methodology has been applied in the revised report.
7.	The report represents the costs of food borne illness associated with sprout consumption under the status quo (option 1a) as a cost to society. It subsequently represents the reduction in costs of food borne illness associated with sprout consumption due to introduction of regulatory requirements under options 2a and 2b as a benefit. This is misleading as it results in the costs estimated for the status quo not being comparable to the costs and benefits estimated for options 2a and 2b. It would be more appropriate to have no costs or benefits attributed to the status quo so that the reduction in costs of food borne illness associated with sprouts consumption due to regulatory intervention could be accurately represented as a benefit in options 2a and 2b.	We will alter the wording to remove the possibility of any misunderstanding.
8.	The ANU model identifies expected number cases of salmonellosis associated with sprouts (based on a percentage of all cases) and the probabilities of small, medium and large outbreaks associated with sprouts occurring annually. The factual basis for these figures needs to be disclosed.	Additional words have been added to explain more fully where the assumptions underpinning the model have been drawn from. However, it must be remembered that this approach is largely a scenario modelling exercise due to the actual amount of information that is available.
9.	The RIS flatly asserts that it is 'inappropriate to apply a voluntary code of conduct to the safety of food consumed by the community' (p. 18) - a sweeping statement seemingly more driven by a philosophical position that regulation is morally preferable to a voluntary approach than a consideration of outcomes. The role of a RIS is to examine regulatory options from an evidence-led perspective and to assess the effects of various options, and it is difficult to have any confidence in the rigour of an analysis which rejects non-regulatory approaches on principle.	We will alter the wording. Please see comments at item 4.
10.	A double standard is applied to the assessment of regulatory and non-regulatory approaches. The	We will alter the wording. Please see comments at item 4.

	benefits of self-regulation are described as 'very negligible' (p. 18) on the basis that it will be ineffective in 'addressing fully the health and safety needs of the consumers' (p. 18). The quantitative effects of a self-regulation approach, supported by an extension program, are not explored. In contrast, the regulatory approach - which the RIS argues to result in a 23-65% reduction in the incidence of illness - is regard as perfectly viable, in spite of not "fully" addressing the issue. The RIS tests non-regulatory options against the measure of whether or not they can totally eliminate risk and discounts them from serious consideration because they fail this hurdle; regulation, however, is not expected to meet the same standard of zero residual risk. Regulation is the only plausible recommendation for action from an analysis with this design.	
11.	There is no context given for the 2005-06 salmonella outbreak. Was it an outlier? How often are outbreaks like this detected? In a number of places the RIS suggests that an outbreak of this sort every 2-5 years is plausible - if so, shouldn't we have more information on similar outbreaks, if they are relatively routine? If not, why not?	Overseas evidence informed the bounds of outbreaks and the relative frequency of outbreaks. There could be a number of reasons why we have not recorded an outbreak since 2005/06. This could be because sicknesses have not occurred or be because we have been unable to attribute sprouts as the cause. The vast majority of illnesses that go unattributed. The Victorian outbreak was only attributed after end product testing triggered a recall. Likewise, we could experience multiple outbreaks in a future year which would confirm the assumptions are sound.
12.	The RIS does not trouble to describe the status quo of no government action and treats industry self-regulation as the equivalent of doing nothing. The inadequacy with which self-regulation is developed as an option is a real deficiency. We have no sense what the marginal effectiveness of regulation is - given that the report presents a lower-bound estimate of a 23% incidence reduction, the marginal contribution of regulation may actually be pretty low. If industry's actions are reducing infections by even as little as 10 or 15%, this makes the case for regulation even more doubtful.	No data exists to assess the change in risk over time in response to various changes. The cost of creating such a data set would be prohibitive. Please also see our comment at items number 1 and 4.
13.	Page 12 reports a cost per annum from infections of $3,675,520. This does not accord with the figures reported on p.17 (range of $0.7-1.8m per year). The $3,675,000 figure appears to be the cost of the 05-06 outbreak; this is the cost per annum only if we assume that a similar outbreak occurs each year (which the RIS does not). In building these estimates (p.14-17) the report seems to switch back and forth between whether	We will redraft this section to make it clearer.

	figures are the total cost of the 05-06 outbreak or if they are annualised costs (it is hard to see how they could be the latter based on the methodology used). In either event the 10 year cost of $22.6 million from no action given on p.12 does not appear to follow from any of the annual costs presented in the following section using a discount rate of 7%. There were a few other instances like this; the report needs to be clearer on its workings in such instances.	
14.	The estimate of a frequency of outbreak similar to 05-06 of being every 2-5 years (p.17) is not discussed. This is a key assumption and deserves more attention.	Overseas evidence informed the bounds of outbreaks and the relative frequency of outbreaks. However, it must be remembered that this approach is largely a scenario modelling exercise due to the actual amount of information that is available.
15.	There seems to be some issues with the estimated health & welfare costs associated with salmonellosis. Page 15 states that there is a chance of acquiring Irritable Bowel Syndrome (IBS) from a salmonellosis infection; but then uses figures for Inflammatory Bowel Disease (IBD) in accounting for costs. The cost-per-incident used is 40% of the value of a statistical life - about $1.7 million. This is a significant contributor to the overall cost estimate: IBS acquisition is about 10 per cent of the estimated total cost of the outbreak. The per-case costs look to be simply the 05-06 total cost divided by the estimated number of cases, so this number filters through the report. There are two major issues with this estimate: • IBS and IBD are not the same condition. IBD is mostly caused by Crohn's disease and ulcerative colitis and is a serious condition, shortening life expectancy and significantly reducing quality of life. IBS is a functional syndrome which is managed through diet and lifestyle changes and is nowhere near as serious as IBD. In short, a significant fraction of a statistical life is a plausible estimate of costs associated with IBD, but it is a dramatic overestimate of IBS. IBS does not appear to be listed as a disability category in the source the RIS uses. • The figure used for IBD appears not to be for a typical case - it is for a case with 'active exacerbation'. The figure for a typical case is 22.4%, not 40%. In short - there is an error here of potential significance. If it is just a typo and the first reference should be to IBD, then it is simple to fix. If it is an accidental conflation of two quite different conditions, then a large number of the RISs	We will correct this error. It is meant to be IBD in all instances. The disability weight has also been adjusted.

	estimates of costs associated with foodborne illness (and in turn the benefits of regulation) could be out by about 10%. This could have implications for the very thin cost-benefit ratios.	
16.	No effort is made to assess the effectiveness of industry's actions since the 05/06 outbreak (p.18) and what the reduction to risk associated with these efforts has been. This is crucial to understanding the marginal effectiveness of the proposed regulation.	The collection of such information is too difficult and costly to contemplate. Please see comment at item 1.
17.	A key piece of information missing from the analysis is some indication of what the coverage of current safety measures is, in terms of total sprout consumption. The RIS suggests half of growers are participating in the Australian New Zealand Sprouters Association (p.9) - but what volume of production does this represent? It is conceivable that this half of producers represents a much larger fraction of production (if the industry follows the common pattern of most production coming from a small number of larger producers). This has a major bearing on the case for regulation: if we are seeking a regulatory approach which is really about mopping up the last 10 or 20 per cent of production, the case for regulation is severely undermined. Universal coverage would not necessarily be required to achieve adequate risk management.	We are not making the assumption that risk is evenly spread according to volume. Risk may be concentrated with a few small processors with a low regulatory capacity. In respect to not regulating small businesses, an alternative view could be put that in a range of regulatory areas, where a clear risk exist to human health and safety, leaving businesses unregulated because of their size is not appropriate.
18.	For the non-regulatory options, the RIS uses a single methodology to assess the costs of sprout-related illness: an estimate of the costs of the 05-06 outbreak, combined with a guesstimate of the frequencies of such outbreaks. When estimating the benefits of regulation, however, the RIS introduces a second methodology - "Butler's approach". The approach yields a dramatically higher average number of infections per year than the previous estimates - 889 infections on average each year, compared with a range of 197.4-493.5 in previous estimates. For context, the Butler approach gives an estimate suggesting that there are almost as many sprout-driven illnesses every year as in the 2005-06 outbreak. Why this estimate is only introduced here is unclear. It gives the appearance having been introduced to increase the estimated benefits of regulation. Calculations based on the lower estimates are very sensitive to variations in the model and it would be difficult to make the case for regulation without relying on the Butler estimate of infection rates.	We have amended the report to overcome this inconsistency. Through chain regulation (option 2a) is still not the recommended option.
19.	The parameters feeding into the Butler approach are given no discussion at all (p.24) - even though they are crucial to the outcome of the analysis.	Please see comments at item 8.

	Where do these numbers come from? The selection of a endemic rate of infection at 605 cases/year in particular seems quite arbitrary. Is there some link between epidemic and endemic rates which drives this? If not, why has the number been chosen?	
20.	As an overall observation regarding estimates of the costs of sprout-related illness: the RIS takes an approach which is opaque and far more difficult to follow than necessary for what is, conceptually, a relatively simple exercise. The key numbers are: • The expected cost per infection • The expected number of infections per year. The report should estimate the numbers up front, discuss the methodology used and why the assumptions it uses are valid, and then use the resulting numbers throughout the RIS. The approach used in the current draft is highly and unnecessarily complex.	We will reorder the RIS to make this clearer.
21.	NPV calculations look to be highly sensitive to estimates of the total number of infections, with lower estimates yielding negative NPVs or razor-thin cost-benefit ratios. This parameter needs a great deal more attention in the RIS.	The analysis has been made on the basis of a single pathogen (*Salmonella*) as this is the best understood in Australian context. It is asserted that this provides sufficient justification for a regulatory intervention on its own. If the analysis was extended to all pathogens there is little doubt that the recommended intervention is warranted.