

**SUBMISSION TO FOOD STANDARDS AUSTRALIA NEW ZEALAND
PROPOSAL P1004
SECOND ASSESSMENT REPORT
PRIMARY PRODUCTION AND PROCESSING STANDARD FOR SEED
SPROUTS (Australia Only)**

The Department of Primary Industries, Victoria provides the following comments in response to the Second Assessment Report for a Primary Production and Processing Standard for Seed Sprouts.

1. General Comments

The Department of Primary Industries, Victoria (DPI) recognises that there are many health benefits that may be derived from eating fresh produce, including sprouted seeds. It is also recognised that sprouts may pose a particular public health challenge if risks are not managed because the sprouting process is ideal for microbiological growth and these products are typically consumed raw.

The DPI therefore supports the objective of assessing the need for through-chain control measures that could further minimise the risk of adverse health effects associated with the consumption of seed sprouts. Acknowledging that there is no system that can unequivocally guarantee that food imposes no risk to public health and safety, the DPI notes that mandatory risk management requirements should only be enforced where there is a need to manage an unacceptable level of risk. The DPI also notes that any proposed approach to manage risks associated with seed sprout consumption must be consistent with the COAG principles for best practice regulation.

Based on these high-level principles the DPI suggests that FSANZ should consider an alternative approach to manage the public health risks associated with sprout production. The reasons for the DPI supporting the consideration of an alternative approach are outlined below and a preferred approach is suggested in the last section of this submission.

2. Lack of current evidence of problem

The Report states that "*seed sprouts contaminated by pathogenic micro-organisms present an unacceptable health risk to consumers*". It is true that all food, if contaminated by pathogenic micro-organisms, could pose an unacceptable risk to consumers; the relevant question is whether seed sprouts intended for consumption in Australia pose an unacceptable level of risk to consumers. The Report does not demonstrate that an unacceptable level of risk exists therefore the need for additional regulation through a Standard is questioned.

The DPI acknowledges that Proposal P1004 has been developed in response to the outbreak of food-borne illnesses associated with the consumption of seed sprouts worldwide, including two outbreaks in Australia in 2005 and 2006. It is not always suitable to use international food-borne illness outbreak data to estimate risk of an outbreak in Australia, unless the differences in production systems, food regulatory

systems, quality of inputs such as water, and other relevant differences are taken into account.

The two isolated outbreaks in Australia are not sufficient to demonstrate that there is an ongoing public health risk associated with consumption of seed sprouts in Australia in the absence of other evidence. The nature of these outbreak incidents indicates that these were confined incidents and do not provide evidence that there is currently widespread risk associated with the production of seed sprouts in Australia. Similarly, data gathered from the two outbreaks in Australia should be interpreted with caution as no information is provided in the Report with regard to the control measures that were/were not in place during these incidents.

Finally, surveillance sampling undertaken to date by a number of states does not suggest that there is an unacceptable level of pathogens in seed sprouts intended for human consumption in Australia.

3. Concerns with proposed approach

The Report states that the proposed approach to develop food regulatory measures for sprout producers *“addresses the public health and safety problem with seed sprouts in the most cost effective manner... and provides measures that are outcomes based and would be consistent with principles of minimum necessary regulation”*. The DPI does not believe that FSANZ has proposed the most cost-effective approach to address risks associated with consumption of seed sprouts and does not agree that the proposed approach is consistent with principles of “minimum necessary regulation”.

While the Report acknowledges that education for consumers and the food service sector should be an accompanying risk management measure of a regulatory approach to addressing the risk associated with seed sprouts, it has not considered education for the seed sprout industry as an alternative option for managing this risk. The DPI believes that an education campaign, directed primarily at the seed sprout industry and accompanied by guidelines, may provide a more cost-effective approach and this is outlined further below.

The Report also states that *“any regulatory measures developed should be commensurate with risk and not impose any unnecessary additional economic burden on the sprout industry”*. The DPI agrees with this statement but does not believe that the regulatory measures proposed in the Report are commensurate with the level of risk associated with consumption of seed sprouts that the Report has demonstrated. This is supported by the negative cost-benefit analysis for the proposed approach (option 2b). This approach is inconsistent with COAG’s principles for best practice regulation.

The DPI acknowledges that the development of a standard for seed sprouts is supported by some members of the seed sprout industry in response to the lower than desired uptake of the *Guidelines for Australian and New Zealand Sprout Producers* across the seed sprout industry. The DPI notes that there may be an opportunity to engage a wider range of seed sprout producers and increase the uptake of good practice if guidelines more suitable for small business could be developed and effectively communicated to the industry. Any requirements that are over and above

the minimum necessary to achieve an acceptable level of risk should not be mandated by the Food Standards Code (the Code). If some members of the seed sprout industry are seeking to achieve a higher level of control to support the reputation of the industry, they could consider setting up a certification scheme that would allow them to differentiate their product. Food safety risks are also managed at a high level of stringency through quality assurance schemes imposed by retailers.

Similarly, it is not appropriate to use the Code for incident management of food-borne illness outbreaks unless it can be shown that there is a systemic, unmanaged and unacceptable level of risk associated with the food vehicle in question. As discussed above, outbreaks of food-borne illness associated with seed sprouts in 2005 and 2006 do not provide sufficient evidence that there is an ongoing, unmanaged risk associated with consumption of seed sprouts. It also indicates that risks associated with the consumption of seed sprouts are spasmodic and it is therefore uncertain that the proposed approach will control the risk of future outbreaks.

4. Concerns with the draft Standard

The Report recommends that draft Standard 4.2.6 be endorsed for inclusion in the Code. The DPI has a number of problems with the Standard as currently drafted:

- The use of the term “unacceptable” is inconsistent with the Model Food Provisions and it is suggested that the term “unsuitable and unsafe” should be sufficient to convey the necessary meaning.
- It is not appropriate for the definition of “sprout producer” to include those businesses that only receive or store seed as this could include seed processors and/or wholesalers, which should not be the intention of the Standard. This definition in Clause 2 of the draft Standard should be clarified accordingly.
- Clause 3 requires that Standards 3.2.2 and 3.2.3 apply to sprout producers. By definition, these Standards only apply to food businesses and, by definition, sprout producers are clearly primary producers. Requiring these Standards to apply to a primary producer is inconsistent with other primary production and processing standards and the Model Food Provisions.
- The DPI does not support the approach of including a Food Safety Management Statement (FSMS) in the Standard. A Standard for seed sprouts should allow for alternative approaches to the FSMS to be considered, taking into account the need to reduce the regulatory cost burden to better align with risk, and the need for consistency, based on risk, across other parts of the food supply chain. The requirement for “*ongoing verification activities*” is not consistent with other standards and is not appropriate to be included here. This kind of requirement is part of the compliance system that is generally included in jurisdictions’ regulatory framework.
- Clause 4(2) requires sprout producers to “*have evidence to show that a systematic examination has been undertaken*”. The DPI does not accept that the level of burden to both industry and government associated with this requirement is commensurate with the level of risk associated with sprout production. This is an additional unnecessary burden over and above the requirement for a FSMS.
- Costs associated with implementation of Clauses 4(2) and (3) have not been included in the Regulation Impact Statement.
- Traceability is an important measure to follow up incidents of food-borne illness, however, a more effective, consistent and suitable approach would be for general

traceability requirements to be included in the Code to apply to all primary production and processing standards.

- It is clear from international studies that the scientific understanding regarding contamination of seeds and subsequent pathogen control in sprout production is still developing. The technical paper (supporting document 1) raises a number of issues that question the reliability of risk mitigation strategies used across the seed sprout supply chain, including in sprout production. For this reason, implementation of the proposed Standard still does not provide confidence that any microbial contamination in the supply chain will be managed.
- The DPI opposes the proposal to implement a Standard for seed sprouts twelve months from gazettal and instead recommends the normal two year lead time to enable industry and government to plan for and implement the necessary systems.

5. Overestimation of health cost savings

The Report notes that option 2(b) is preferred even though it is likely to have a negative net present value based on analysis of the costs and benefits for industry, government and consumers. The DPI notes that this approach is not consistent with COAG principles for best practice regulation and suggests that, due to a number of problems with the estimates of health costs savings, the cost could be even greater than that suggested in the Report. These are outlined below:

- There are deficiencies associated with basing cost-benefit analyses on data collected from spasmodic food-borne illness outbreaks. For example, there is no evidence to suggest that estimates of health costs savings should be based on regularly occurring outbreaks so this assumption should not be used for the estimate.
- Estimates of cost savings are based on an average outbreak number of 924, or seven times the recorded outbreak number based on the incidents in 2005 and 2006. It is likely that 924 substantially overestimates the numbers associated with any one outbreak as the multiplier of seven is derived from surveillance data. Due to the publicity outbreaks receive, a much larger proportion of cases of salmonellosis are likely to come forward. It is therefore inappropriate to use 924 for cost savings estimates. In particular, it should not be used for serious cases of salmonellosis, including hospitalisation, causing other health complications or death, as these cases are likely to be traced back to the outbreak.
- It is unclear why the percentage range of reduction in food-borne illness of 23 to 65 percent was used and the DPI suggests that this range overestimates the potential for health costs savings from the proposal. In particular, a 65 percent decrease in food-borne illness could never be achieved with implementation of the Standard if 60 percent of the seed sprout industry is already managing food safety risks associated with sprout production in a manner that is commensurate with the proposed Standard. The likelihood that this level of health costs savings will be achieved is reduced further if the difficulty associated with achieving widespread compliance with the draft Standard (noting the high turnover of small business in the industry) is taken into account.
- It is not clear from the Report whether the range of reduction in food-borne illness of 23 to 65 percent is based on implementation of regulation on seed processors and sprout producers or just sprout producers.

6. Preferred approach

The DPI supports the objective of minimising the risk of adverse health effects associated with the consumption of seed sprouts and assessing the need for any through-chain control measures. However, given the uncertainty around establishing the extent of the public health risk, the DPI is cautious that any proposed control measures should not result in impractical and onerous requirements on the seed sprout industry or government. While there is insufficient evidence to support the need for a regulatory approach to managing the risk associated with seed sprout production in Australia, the DPI suggests that an alternative approach to the options presented in the Report could be considered by FSANZ.

The Australia New Zealand Sprouters Association (ANZSA) has developed *Guidelines for Australian and New Zealand Sprout Producers* to support the safer production of seed sprouts. ANZSA has advised FSANZ that there has been resistance to voluntary adoption of the Guidelines by a significant proportion of the industry and industry consultation has found that 40 percent of seed sprouts are not produced under a food safety or quality management scheme.

The DPI suggests that there is an opportunity for government, led by FSANZ, to work with ANZSA to develop an additional set of guidelines that draw from the current industry guidelines and the draft Standard to provide a flexible, risk-based approach to manage public health risks associated with sprout production. This should be accompanied by an education initiative that would communicate the benefits of complying with the guidelines to those sections of the sprout industry that are currently the cause for concern to ANZSA.

This approach would provide FSANZ with an opportunity to conduct a baseline study of the risk associated with seed sprouts (e.g. level of microbial contamination of seed sprouts intended for human consumption and incidents of food-borne illness associated with consumption of seed sprouts) and to subsequently evaluate the impact of the approach. This would provide further data that could be used to support the case for a regulatory approach in the future should this be necessary, particularly if it becomes evident that a self-regulatory approach results in unacceptable food safety risks in the sector being left unmanaged.

This approach might also provide a model to trial to help inform the future development of a horticulture standard where similar issues are likely to be encountered.