Health Canada Santé Canada

Food Directorate

Policy on Managing Health Risk Associated with the Consumption of Sprouted Seeds and Beans

Food Directorate
Health Products and Food Branch
Health Canada

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This document is available at: http://www.hc-sc.gc.ca/fn-an/legislation/pol/sprouts_pol_pousses_e.html

1. Scope

This policy on sprouted seeds and beans was developed following a health risk assessment (Health Canada, 2001, updated 2006). Health Canada's current opinion is that the contamination of sprouted seeds and beans originates from poor hygienic practices, in the field during seed production or in the plant during sprout production, including the lack of a disinfection step, and that the risk of transmission can be reduced to a minimum using Good Agricultural and Good Manufacturing Practices.

2. Introduction

Sprouts have been involved in several foodborne disease outbreaks of bacterial origin. In Canada, between 1995 and 2005, about 1,000 cases of sprout-borne illness were reported in eight outbreaks from five provinces.[1] Sprout-associated outbreaks have also been reported in other countries, including the USA, UK, Sweden, Finland, Japan and Denmark, and have been directly implicated in the deaths of at least 7 people (6 in Japan, and 1 in the USA)[2] and caused over 9,000 cases. Sprouts are at a high risk of being contaminated with pathogenic bacteria due to the particular conditions required for germinating seeds and beans (thus producing sprouts), which also provide ideal conditions for the exponential growth of bacteria.

If pathogens such as *Salmonella* species (spp.) or *Escherichia coli* (*E. coli*) O157:H7 are present and viable, on or in the seed, the sprouting conditions may allow for their proliferation. Seed processing, shipping and selling practices often involve mixing multiple seed lots of different origins, thereby complicating traceback and providing greater opportunity for cross-contamination. Adding to the problem is the fact that some seeds used for sprouting are harvested for animal feeding, therefore, not handled to become food for human consumption. Another critical factor is the limited ability of disinfection treatments to reach pathogens in the seeds. While it is generally recognized that sanitizing the seeds should be an essential part of a health risk analysis-based plan for producing safe sprouts, studies have found that high exposure to concentrations of sanitizers may not always eliminate pathogens because bacteria get trapped in cracks and crevices, and the sanitizers do not come into contact with bacteria protected by such seed coat structures. There is currently no treatment that can ensure pathogen-free seeds and beans.

Microbial profile surveys have shown the presence of a variety of foodborne pathogens in sprouts. *Escherichia* spp., *Salmonella* spp.*, Listeria monocytogenes, Staphylococcus aureus, Bacillus cereus*

[1] Qualitative Risk Assessment on Seeds/Beans and Sprouted Seeds/Beans (BMH-Health Canada, 2001, updated 2006).

[2] Issue Identification Paper on Sprouted Seeds and Beans (Policy Team on Sprouted Seeds and Beans, August 15, 2001) pp.3.

and *Aeromonas hydrophila* have been isolated from sprouted seeds, including alfalfa, mung bean, cress, soybean, and mustard (Beuchat,1997). All segments of the population are susceptible to *Salmonella* spp. and *E. coli* O157:H7. However, young children, the elderly and the immuno-compromised are the most susceptible.

3. Risk Assessment Overview

A risk assessment entitled "Qualitative Risk Assessment of Seeds/Beans and Sprouted Seeds/Beans"[1] was prepared by Health Canada in collaboration with the Canadian Food Inspection Agency (CFIA) and was finalized in May, 2001 (updated 2006). This qualitative risk assessment was prepared using information from current scientific publications and documents. The development of the risk assessment involved an extensive literature review and Internet search, as well as consultation with industry, Provincial/Territorial health agencies and the CFIA. It was used as the basis for the development of appropriate risk management options that could minimize the contamination of sprouted seeds and beans. The sprout industry, consumer groups, scientists and regulators are actively seeking effective preventive measures to ensure the safety of sprouted seeds and beans.

The most common pathogens involved in outbreaks of sprouted seeds and beans have been identified as *E. coli* O157:H7 and *Salmonella* spp. These pathogens can get into seeds from contaminated irrigation water, reptiles, birds, rodents, carcasses in the field, etc. Based on the relatively high attack rates during outbreaks, it appears that the number of bacteria required to cause illness from these two foodborne pathogens is very low.

The intestinal tract of animals, primarily cattle, is the principal reservoir for *E. coli* O157:H7. Transmission by contaminated water supplies, person-to-person transmission, as well as direct animal-to-human transmission, have also been documented. Even though the infectious dose for *E. coli* O157:H7 is not yet known, it is estimated to be less than 10 cells. *E. coli* O157:H7 can cause severe damage to the lining of the intestine resulting in a condition called haemorrhagic colitis, the symptoms of which can include stomach cramps, vomiting, fever, and bloody diarrhea (Doyle and Padhye, 1989). In a small percentage of people, haemolytic uremic syndrome (HUS) can develop, which may require patients to undergo blood transfusions and kidney dialysis. The disease can lead to permanent loss of kidney function and is fatal in some cases (Doyle and Cliver, 1990; Doyle and Padhye, 1989).

Salmonella spp. are commonly found in the intestinal tract of humans and animals. Environmental sources of the organism include, but are not limited to, water, soil, insects, animal feces, raw meats, raw poultry, and raw seafood. All known species of *Salmonella* spp. are pathogenic to humans (Doyle and Cliver, 1990) and the infectious dose appears to be around 1-10 cells. The type of *Salmonella* infection that has been most commonly associated with sprouts outbreaks is the gastroenteritic type that is caused by non-typhoid strains of *Salmonella* spp. The severity of non-

typhoid salmonella infection (known as salmonellosis) varies with the number of bacteria ingested and the susceptibility of the individual. The incubation period is 8 to 72 hours before symptoms occur (D'Aoust, 1989; D'Aoust *et al*., 2001). The most notable symptoms are nausea, vomiting, abdominal pain, dehydration and non-bloody diarrhea that can appear suddenly. The duration of illness is usually from 1- 4 days. Human infections resulting in enterocolitis from non-typhoid salmonellae are generally self-limiting (D'Aoust *et al.*, 2001).

The estimated percentage of the Canadian population that consumes sprouts is at least 2.5%. Because most cases of foodborne illness go unreported, the actual incidence of illness resulting from sprout consumption in the Canadian population is unknown.

The current system used to sprout seeds and beans for human consumption cannot guarantee the absence of *Salmonella* spp., *E. coli* O157:H7 or any other pathogen. Consequently, there is a need to address control measure issues such as seed quality, the sprouting process (including a disinfection step and/or testing spent irrigation water), sanitation and growing practices, final product (sprouted seeds) testing and storage/transportation of the final product.

4. Consultations

In the development of the risk assessment on sprouts, and throughout the development of the policy, consultations have taken place with the Canadian Food Inspection Agency (CFIA), the Federal Provincial Territorial Committee on Food Safety Policy, the Canadian Food Inspection System Implementation Group**,** and the sprouts industry. The input received from these consultations was considered in the development of Health Canada's policy for sprouted seeds and beans.

5. Policy for Sprouted Seeds and Beans

Goal of the policy:

The goal of this policy is to protect the health of Canadian consumers by reducing the probability of contaminated sprouts being sold in Canada. Any finished, ready-to-eat products found to be contaminated with *Salmonella* spp. or *E. coli* O157:H7, are to be considered in direct violation of Sections 4 and 7 of the Food and Drugs Act.

A Three-Pronged Approach:

A three-pronged approach has emerged from discussions and analysis of the sprouts issue. They are:

1) Development of a Code of Practice for the Hygienic Production of Sprouted Seeds. The Code outlines practices that address good hygienic manufacturing practices.

2) Guidance for Industry: Sample Collection and Testing of Sprouts and Spent Irrigation Water. This element addresses food safety issues relating to the microbial quality of water used to make sprouts, and therefore, the microbial quality of sprouts available to consumers. When foodborne pathogens such as *Salmonella* spp. or *E. coli* O157:H7 are found in spent irrigation water, such a situation is an indication that the finished product has also been contaminated by these pathogens. Therefore, sprouts that have been in contact with contaminated spent irrigation water are considered to be in direct violation of Sections 4 and 7 of the Food and Drugs Act.

The finished product (sprouted seeds and beans) may also be sampled and analysed for the presence of foodborne pathogens. Compliance actions will be taken when pathogens are found in spent irrigation water or finished product.

3) Consumer and industry educational material, which will help create an understanding of food safety issues within the context of the public's right to know about potential dangers in food available at the retail level and industry's responsibility for producing a safe food.

The Policy on Sprouted Seeds and Beans was developed based on a series of risk mitigation approaches that seek to address each of the above three points. These include:

1) Implementation and use of the CFIA's *Code of Practice for the Hygienic Production of Sprouted Seeds* in Canada[3]

This Code of Practice outlines the specific steps that should be implemented by sprout producers to reduce the possibility of contamination of sprouts. To achieve compliance with Sections 4 and 7 of the *Food and Drugs Act*, the CFIA's Code of Practice for the Hygienic Production of Sprouted Seeds is used to assess practices which reduce the potential risk for contamination of the final food product. The Code of Practice presents voluntary guidelines for good manufacturing practices. This places the onus on industry to demonstrate its ability and willingness to reduce potential risks associated with sprouts.

The CFIA's Code of Practice as well as a forthcoming video will serve as educational tools for the sprouts industry on the hazards associated with the production of sprouts, and on the industry's responsibility to produce safe food products.

[3] http://www.inspection.gc.ca/english/plaveg/fresh/safsal/sprointe.shtml

2) Guidance for Industry: Sample Collection and Testing of Sprouts and Spent Irrigation Water for the foodborne pathogens *Salmonella* spp. and *E. coli* O157:H7

Testing of spent irrigation water is considered to be one of the most practical and acceptable testing techniques currently available. Such testing should be done by industry. It may also be done by anyone using this policy, including CFIA and the provinces. Spent irrigation water provides a representative sample of the entire microbial population, including pathogens, in a batch of sprouts. Spent irrigation water should be sampled and tested according to procedures outlined in the document *Guidance for Industry: Sample Collection and Testing for Sprouts and Spent Irrigation Water*[4].

The microbial testing of spent irrigation water has been validated as a reliable indicator of the microbial profile of sprouts (Fu *et al.*, 2001; Stewart *et al.*, 2001). Therefore, sprouts that have been in contact with contaminated spent irrigation water are considered to be in direct violation of Sections 4 and 7 of the Food and Drugs Act.

3) Development of consumer and industry education material by Health Canada

Health Canada's Food Directorate, in collaboration with CFIA, will develop educational material to inform and educate consumers as well as industry, of the risks associated with the consumption of raw sprouted seeds and beans.

The objective is to inform consumers in general, and more specifically parents and guardians of young children, the elderly and people with weakened immune systems, so that they may be in a better position to make informed choices. While some information has already been provided by various levels of government, industry, and consumer associations, collaboration on the development of educational material between the federal and provincial levels of government will ensure that consumers have reliable and consistent information with which to make an informed choice.

In addition, in order to help this sector of the industry improve the safety of their product, new training material such as a video and a brochure, will be developed.

[4] http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/sprout_water_testing_analyse_pousses_eau_e.html

6. Policy Implementation

Successful implementation of the policy depends on effective collaboration between Health Canada, the CFIA, the provincial/territorial Ministries of Health and Agriculture and their regional units. CFIA, along with provincial and territorial governments, can also consider supplementary strategies to address specific regional issues. Industry associations will clearly be vital partners in assisting governments to communicate this new policy within their sector.

There is a need to coordinate plant inspections among various levels of governments and to provide producers with consistent information that will help them make improvements that will reduce the risk.

The first two approaches mentioned in Section 5 of this policy (Code of Practice for the Hygienic Production of Sprouted Seeds in Canada and Testing of Spent Irrigation Water) will be primarily implemented by the sprout industry. Currently, under the umbrella of the CFIA's Sprout Project, the CFIA will be inspecting sprout producers in Canada, as well as collecting samples of finished product. In addition, whenever deemed necessary, the CFIA may also decide to collect samples of spent irrigation water.

On-going disease surveillance by the Public Health Agency of Canada (PHAC) and Provincial/Territorial disease surveillance agencies will continue to provide details concerning any future outbreaks linked to sprouts.

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