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Code of Practice for the Hygienic Production of Sprouted Seeds

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Amendment Records

The following Code of Practice for the Hygienic Production of Sprouted Seeds replaces the Draft Code of Practice for the Hygienic Production of Sprouted Seeds, which was issued on September 11, 2001.

Introduction

In recent years, sprouted seeds have enjoyed increasing popularity in Canada. These crunchy newborn plants are favoured for their nutritional value, however, raw sprouts have been linked to outbreaks of food borne illness. In 1996, radish sprouts were associated with the world's largest *E. coli* O157:H7 outbreak, affecting over 6,000 people in Japan. In the United States, between 1995 and 1999, more than 10 outbreaks of food borne diseases have occurred due to contaminated sprouts.

The first Canadian outbreak associated with sprouts occurred in 1995. This outbreak was linked to the consumption of alfalfa sprouts contaminated with *Salmonella* Stanley. In this episode, 30 cases were reported in the province of British Columbia. During January of 1996, cases of *Salmonella* Newport food poisoning were reported in the provinces of British Columbia (58 cases) and Quebec (60 cases) due to contaminated alfalfa sprouts. During the fall of 1997, 124 cases of *Salmonella* Meleagridis infections across Canada and, during August and September 1999, 51 cases of *Salmonella* Java infections in Western Canada were linked to the consumption of alfalfa sprouts. Between April and June 2000, at least 12 cases of *Salmonella* Enteritidis PT 11B in Alberta and Saskatchewan, were associated with the consumption of mung bean sprouts produced from 2 different sprout manufacturers who used seeds from the same supplier. In February and March 2001, 84 cases of *Salmonella* Enteritidis PT 913 in Saskatchewan, Alberta and British Columbia were linked to consumption of mung bean sprouts. In the fall and winter of 2005, an outbreak of *Salmonella* Enteritidis PT 13, in Ontario was linked to the consumption of

raw and lightly-cooked mung bean sprouts.

The microbial pathogens associated with sprouted seeds include *Salmonella* spp. and *E. coli* O157:H7. Outbreak investigations have indicated that microorganisms found on sprouts most likely originate from the seeds. Most seeds supplied to sprout manufacturers are produced primarily for field planting where the good agricultural practices (GAP) necessary to prevent microbial contamination of seeds intended for sprouting are not followed. As a result, the seeds may be contaminated in the field or during harvesting, storage or transportation. The germination process in sprout production involves keeping seeds warm and moist for four to seven days. In these conditions, low levels of microbial contaminants present on seeds can quickly reach levels high enough to cause illness.

Sprouted seeds must comply with the *Food and Drugs Act and Regulations*. Health Canada establishes microbial standards and guidelines to address potential risks. Those are published in the Health Canada's Interpretive Summary of Health Protection Branch Standards and Guidelines for Microbial Safety of Food. It is the industry's responsibility to put the necessary controls in place to produce safe sprouts. Through its inspection and product sampling activities, the Canadian Food Inspection Agency (CFIA) enforces the *Food and Drugs Act with respect to Health Canada's guidelines*.

This present Code recommends control of pathogens to occur in two areas: during seed production and during sprout production. Section 3 of this Code outlines several steps in the production of seeds where the application of GAP is aimed at preventing microbial pathogen contamination of seeds. Section 8 of this Code describes the various steps in the sprout production, including antimicrobial treatment of seeds, and provides good hygienic practices aimed at preventing the introduction of microbial pathogens and minimizing their potential growth. Antimicrobial treatment of seeds is one of various steps in the overall approach to minimize the risk associated with sprouts. A combination of steps, including antimicrobial treatment, is necessary in order to produce a safer product. During sprout production, the antimicrobial treatment step is aimed at reducing potential contaminants and the good hygienic practices at preventing the introduction of microbial pathogens and minimizing their potential growth. Sprout manufacturers must be aware that the degree of control in these two areas has a significant impact on the safety of sprouts.

The recommendations of this code do not guarantee the production of safe sprouts; rather, they provide a sound basis for risk mitigation and the hygienic production of sprouts. The scientific literature proposes antimicrobial treatments for seeds which can achieve different levels of pathogen reduction and minimize the risks associated with sprouted seeds. There is currently no treatment available that can guarantee pathogen free seeds. Much research is on-going to find efficient antimicrobial treatments which would provide sufficient pathogen reduction on seeds.

This Code is subject to change as additional scientific information becomes available on safe sprout production.

2. Scope and Definitions

2.1 Scope

This code addresses good agricultural practices (GAP) and good hygienic practices for the production of sprouted seeds that may be consumed raw. It sets out specific recommendations for the production of sprouts and general recommendations for the growing of seeds destined for sprout production.

2.2 Definitions

For the purpose of this Code, the following expressions have the stated definitions:

Agricultural inputs: any incoming material (e.g., fertilizers, water, agricultural chemicals, etc.) used for the production of seeds.

Contamination: the transfer of harmful substances or disease-causing microorganisms to sprouts by hands, food-contact surfaces and utensils that touch contaminated seeds and sprouts.

Cross-contamination: contamination of seeds or sprouts by direct or indirect contact with material from an earlier stage of the process. A regulated process flow and good employee practices will minimize chances of cross-contamination occurrences.

Food contact surface: any equipment or utensil, which normally comes in contact with the food product or surfaces normally in contact with the product.

Good Agricultural Practices (GAP): refer to the general practices used in the planting, growing, harvesting, sorting, packing, storage and transportation of seeds which will reduce and minimize the risks of microbial, chemical and physical contamination.

Hazard Analysis Critical Control Points (HACCP): a worldwide recognized, science based, systematic and preventive approach to food safety that addresses biological, chemical and physical hazards by anticipating and preventing, rather than by inspecting finished product.

Microorganisms: include yeasts, moulds, bacteria, viruses and parasites. When used as an adjective the term "microbial" is used.

Potable water: water which meets the requirements of the "Guidelines for Canadian Drinking Water Quality" published by Health Canada and any applicable provincial requirements.

Pre-packaged product: as per the *Food and Drugs Act*, any food that is contained in a package in the manner in which it is ordinarily sold to or used or purchased by a person.

Refrigeration: means exposure to a temperature of 4°C or less, but does not mean frozen (*Food and Drug Regulations*, B.27.001).

Sanitizing: the application of heat or chemical treatments to destroy or substantially reduce the number of microorganisms that have the potential to cause adverse health effects.

Seed distributor: any person responsible for the distribution of seeds (handling, storage and transportation) to sprout manufacturers. Seed distributors may deal with single or multiple seed producers and can be producers themselves.

Seed producer: any person responsible for the management of activities associated with the primary production of seeds including post harvest practices.

Seed lot: a quantity of seeds produced and handled under uniform conditions with as little variation as possible (e.g., seeds grown under similar agricultural practice, on the same land and harvested during the same period).

Spent irrigation water: the water that has flowed over and through the sprouts.

Sprout lot: a quantity of sprouts produced and handled under uniform conditions with as little variation as possible and harvested on the same day (e.g., sprouts produced from a single seed lot, germinated, grown and harvested at the same time using the same disinfection and growing methods and type of equipment).

Sprout manufacturer: any person responsible for the management of the activities associated with the production of sprouted seeds.

Sprouted Seed: any seed that has been sprouted for human consumption. This includes seeds grown in soil.

3. Seed Production

Microbial and chemical contamination may occur during the cultivation and harvesting of seeds in fields or during storage and transportation. The safety of sprouts is highly influenced by the degree of preventive measures used on farm to avoid contamination of seeds. Seeds used for sprout production should be produced using GAP at all stages during the planting, growing, harvesting, cleaning, storage and transportation. Sprout manufacturers should prescribe seed producers to adopt GAP and provide evidence that the product was grown according to specifications. The general aspects of GAP to minimize the risk of contamination of seeds for sprout production include:

3.1 Land usage

Whenever possible, potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in or on seeds after harvest.

Where possible, seed producers should evaluate the previous uses of the sites (indoor and outdoor) as well as adjoining sites in order to identify potential microbial, chemical and physical hazards. The potential for other types of contamination (e.g., from agricultural chemicals, hazardous wastes, etc.) should also be considered.

To the extent possible, steps should be taken to prevent the access of farm and wild animals to the sites to avoid potential faecal contamination of the soil and the risk of contaminating the crop. Runoff or wind contamination from intensive livestock operations and flooding by contaminated water sources should also be considered.

3.2 Natural fertilizer

Composting and other treatments may reduce but may not eliminate pathogens in manure. It is particularly important to prevent microbial contamination during the production of seeds because of the potential for pathogens to grow during the sprouting process. Consequently, manure, bio solids and other natural fertilizers should only be used when they have undergone treatments or undergone environmental conditions which achieve a high level of pathogen reduction.

3.3 Agricultural water

Water used for irrigation and other agricultural uses is a potential source of microbial contamination. Seed producers should evaluate the source of water used on farm (well, open canal, reservoir, reused irrigation water, municipality, rivers, lakes, ground water, etc.), monitor its safety and control potential sources of contamination. Water known or suspected to be contaminated with animal or human waste shall not be used.

3.4 Chemical Control

Seed producers and distributors should only use chemicals for agricultural purposes and post-harvest treatments acceptable for seeds intended for sprout production. These chemicals should

be used according to manufacturer's instructions for the intended purpose. Their use must not result in exceeding Maximum Residue Limits in sprouts. Seed producers and distributors should keep records of chemical applications (agricultural or post-harvest chemical used, rate and date of application, etc.).

3.5 Worker hygiene

Hygiene and health requirements should ensure that people who come directly or indirectly into contact with seeds do not contaminate them. People known or suspected to be carriers of a disease or illness should not be allowed access to areas of the fields or indoor premises where there is a potential for contaminating seeds for sprout production. To ensure good personal hygiene, seed producers should provide toilets and hand washing facilities easily accessible to all workers who come directly into contact with seeds.

3.6 Harvesting

Harvesting equipment should be adjusted to minimize soil intake and should be cleaned from any debris or earth before harvesting. Handling equipment (augers, conveyors, etc.) should be cleaned and inspected. Transport trucks, wagons, etc. should be cleaned and sanitized if used to haul manure and soil. Storage bins, totes, etc. should be clean and be bird and rodent proof or stored in a rodent controlled facility.

Diseased or damaged seeds which could be susceptible to microbial contamination shall not be used for sprout manufacture. Seed lots intended for sprouting should be segregated from product to be used as animal feed (e.g., for hay production).

3.7 Conditioning

Seeds for sprouting should be free to the extent possible from foreign matter including soil, insect fragments, bird and rodent droppings, metal and glass fragments. Conditioning utilizes a variety of equipment to remove soil, weed seeds and other debris from seeds. Conditioning should be carried out in a hygienic manner employing practices that minimize potential sources of contamination.

- Equipment should be constructed to allow for easy cleaning and, when necessary, sanitizing.
- Equipment should be protected from pests.
- All equipment should be thoroughly dry cleaned (compressed air, brushes, etc.) between lots and sanitized if required.
- Seed conditioning facilities should ensure that the equipment has not been used to handle animal products. If it has, it should be thoroughly cleaned and sanitized before cleaning seeds.

3.8 Packaging

- Packaging of seeds for sprouting should be carried out in a hygienic manner.
- Equipment should be constructed to allow for easy cleaning and when necessary, sanitizing.
- Equipment should be protected from pests.
- Use solid bags - open weave bags should not be used.
- Do not use contaminated or recycled bags.
- Each package should be marked to identify source and lot. Any seed that has been treated must clearly state this on the label.
- Packaged seeds should be stored in clean and dry area and protected from vermin and pests.

3.9 Transportation and storage

Seeds should be packaged in bags or containers that are impermeable to contamination during storage and transportation. Containers, vehicles, and storage facilities should be cleaned and sanitized before use. At all times, seeds, equipment, storage bins and shipping bags should be protected from rodents and birds with a complete pest control program that includes monitoring, eradication, cleaning, sanitation and record keeping.

3.10 Analyses, documentation and records

Seed distributors should analyse each lot for the presence of microbial pathogens of concern such as *Salmonella* and *E. coli* O157:H7 using internationally accepted analytical methods. Microbial analysis of seeds may help identify highly contaminated lots. Seed producers and sprout manufacturers must be aware that negative results do not guarantee pathogen free seeds because of analytical and sampling limitations. It is important to use random sampling techniques, sufficient sample sizes and sub sample numbers to represent the lot as best as possible. Lots of seeds for which positive results are obtained shall not be used for sprout production. Other lots which were produced under similar conditions (e.g., on the same sites or with the same agricultural inputs) which present a similar hazard shall not be used for sprouting. These lots should be held and detained until they are disposed of properly. Seed producers should keep current all records on agricultural activities such as the site of production, suppliers' information on agricultural inputs, lot numbers of agricultural inputs, irrigation data, agricultural chemical and fertilizer usages, water quality data, cleaning schedules for premises, facilities, equipment and containers, and details of disposition of rejected lots. Records shall be retained for a minimum of five years.

3.11 Trace-backs and recalls

Producers of seed for sprout production must ensure that trace-back records and recall procedures are in place to effectively respond to health risk situations. Procedures must enable the complete and rapid recall of any implicated seed lots and provide detailed information to assist in the identification and investigation of any contaminated seeds and sprouts. The following should be adopted:

- Seed production and distribution practices should minimize the mixing of multiple lots of different origins, which could complicate trace-back and provide greater opportunity for cross-contamination.
- The CFIA and the required provincial or municipal authorities should be notified of all recalls.
- Seed producers and distributors, and sprout manufacturers should maintain a record of traceability for each lot. The lot number, the producer and the country of origin should be indicated on each bag.
- Seed producers should have a system to: effectively identify lots; trace the sites and agricultural inputs associated with the lots; and allow physical retrieval of the seeds in case of a suspected hazard.
- Where a lot has been recalled because of a health hazard, other lots which were produced under similar conditions (e.g., on the same sites or with the same agricultural inputs) and which may present a similar hazard should be evaluated for safety. Those presenting similar risks (i.e., containing a pathogen) must be recalled. Blends with potentially contaminated seeds also must be recalled.
- Seeds which may present a hazard must be held and detained until they are disposed of properly.

4. Establishment for Sprout Production

The internal design and layout should permit good hygienic practices during production, including protection against cross-contamination between operations and during cleaning and sanitation of utensils and equipment. It is important to disinfect seeds in areas separated from other process areas to minimize cross-contamination. Storage, seed disinfection, germination and packaging areas should be physically separated from each other. The sprout processing facility should be fully protected from outside contaminants.

Floors should be smooth, non-porous, impervious to water and properly drained. Walls, doors and ceilings should be smooth, non-porous, non-chipping and impervious to water. Doors should be close fitting, and self closing where appropriate. Light bulbs and fixtures should be protected to prevent contamination of sprouts in case of breakage.

4.1 Premises

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4.2 Equipment

All equipment and utensils used during sprout production should be cleaned, rinsed and sanitized between batches and as frequently as required during production, according to a written sanitation program. Sanitizers should be rinsed from the equipment and utensils unless otherwise instructed by the manufacturer's directions. Equipment should be visually inspected to determine adequacy of cleaning and records of the sanitizing treatments and inspections should be kept.

Equipment and containers coming in contact with sprouts should be made of materials which have no leaching toxic effect. Equipment and containers should also be designed and constructed to ensure that they can be adequately and easily cleaned, sanitized and maintained. Specific hygienic requirements should be identified for each piece of food-contact equipment.

Containers for waste, by-products and inedible or dangerous substances, should be identified, suitably constructed, and where appropriate, made of impervious material. Where appropriate, such containers should be stored in a manner to prevent malicious or accidental contamination.

4.3 Water quality

Water shall meet the requirements of Health Canada's Guidelines for Canadian Drinking Water Quality. Water should be analysed by the manufacturer at a frequency adequate to confirm its potability. Municipal water should be analysed semi-annually and other water sources on a monthly basis. Records of potable water quality checks should be kept. Water treatment chemicals, where used, should be those found in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products published by the CFIA.

Sprout manufacturers should have contingency plans in place to deal with provincial orders to boil water and unsatisfactory water analyses.

4.4 Air quality

Adequate ventilation should be provided to prevent condensation, dust, and to minimize entry of contaminated air. Ventilation systems should be constructed to avoid air flow from contaminated to clean areas and designed to be adequately maintained and cleaned. Ventilation openings should be equipped with close-fitting screens or filters to reduce the risk of contaminated air intakes.

5. Sanitation and Pest Control

5.1 Sanitation program

Cleaning and sanitation programs should ensure that all equipment and all parts of the establishment are clean. Cleaning and sanitation programs should be periodically reviewed and modified as needed.

- The manufacturer should follow a written cleaning and sanitation program for all equipment and premises (production and storage areas) which includes: the name of the responsible person; the frequency of the activity; the procedures for cleaning and sanitizing; the chemicals and concentrations used; the temperature requirements; and the type and frequency of inspection to verify the effectiveness of the program.
- Procedures for cleaning and sanitizing should be as follows: identify lines, equipment and utensils; follow disassembly/reassembly instructions as required for cleaning and inspection; identify areas on equipment requiring special attention; and follow method described in the sanitation program for cleaning, sanitizing and rinsing.
- Chemicals must be used in accordance with manufacturer's instructions and be listed in the Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents published by CFIA unless the manufacturer has a letter of no objection from Health Canada.
- The sanitation program should be carried out in a manner that does not contaminate food or packaging materials during or following cleaning and sanitizing (e.g., aerosols, chemical residues).
- The effectiveness of the sanitation program should be verified by a pre-operational inspection of premises and equipment or, where appropriate, by microbiological sampling. The sanitation program should be adjusted accordingly when it fails the verification process.

5.2 Pest control program

- The manufacturer should follow a written pest control program for the premises and equipment which includes: the name of the responsible person; where applicable, the name of the pest control company or the person contracted for the pest control program; the list of chemicals used and the concentrations; the location where chemicals are applied; the method and frequency of application; a map of trap locations; the type and frequency of inspection to verify the effectiveness of the program; and specifications for the records that are required.
- Pesticides must be used in accordance with manufacturer's instructions, be registered under the Pest Management Regulatory Agency, Pest Control Products Act and Regulations and be listed in the Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents published by CFIA.
- Treatment of equipment, premises or ingredients to control pests must be conducted in a manner to ensure that the maximum residue limit as listed in the Food and Drug Regulations is not exceeded.
- All pests (birds, insects, reptiles and animals) must be excluded from establishments.

5.3 Waste management

Suitable provision must be made for the storage and removal of waste. Waste must not be allowed to accumulate in seed and sprout handling and storage areas or the adjoining environment. Storage areas for waste should be separated from the plant, kept clean and all waste containers should be properly labelled.

6. Personal Hygiene

Hygiene and health requirements should be followed to ensure that people coming into direct or indirect contact with seeds before, during and after germination are not likely to contaminate the product. All plant personnel and visitors, where appropriate, should wear protective clothing and adhere to the personal hygiene provisions in this section.

6.1 Personal hygiene and sanitary facilities

Hygienic facilities and toilets must be available to personnel so as to maintain an appropriate degree of hygiene and to avoid product contamination.

- Adequate and conveniently located changing facilities and toilets should be provided.
- Facilities should provide adequate means of hygienically washing and drying hands and include wash basins, soap, disposable towels and a supply of hot and cold water (or suitably controlled temperature) adjacent to toilets.
- Toilet facilities should be designed to allow hygienic removal of waste and be segregated from production and storage areas to avoid contamination of food or premises.
- Toilet facilities should be maintained under sanitary conditions and good repair at all times.
- Hand washing notices should be posted adjacent to the toilet facilities and in a position such that personnel must pass it when returning to their working stations.

6.2 Sanitizing stations

Pathogen contamination after seeds have been disinfected could be due to employee handling.

- Hand washing and hand sanitizing stations should be located at all entrances and throughout the sprouting and packaging rooms and be properly maintained.
- Boot sanitizing troughs or mats should be at all entrances to post seed disinfection areas.
- Sanitizer chemical levels should be as specified by the label and measured as necessary to maintain the specified levels.

6.3 Health status

People known to be or suspected of being a carrier of a disease or illness likely to be transmitted through food should not be allowed access to areas of indoor premises where there is a likelihood of directly or indirectly contaminating sprouts. Any person so affected should immediately report the illness or symptoms of illness to management. Employees having open cuts, wounds or sores should not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering (e.g., rubber gloves).

6.4 Cleanliness and personal behaviour

- Personal effects and street clothing should not be kept in food handling areas.
- Protective clothing, hair covering, footwear and gloves, appropriate to the operation in which the employee is engaged, should be worn and maintained in a sanitary manner.
- Hand sanitizing stations should be used to prevent cross-contamination (see 6.2). People

should wash and sanitize their hands:

- before starting work each day;
- after any visit to toilet facilities or blowing their nose;
- after any other absence from the work station (e.g. breaks, lunch, etc.);
- after handling contaminated materials (e.g., picking objects off the floor).
- Waterproof gloves should be washed and sanitized similarly to hand washing.
- Personal behaviour which could result in the contamination of food, such as eating, using tobacco, chewing gum, or unhygienic practices such as spitting in food handling areas must be prohibited.
- People entering food handling areas should not wear jewellery or other objects which could fall into or otherwise contaminate food. Jewellery which cannot be removed, such as wedding bands or medical alerts, should be covered.
- The traffic pattern of employees must prevent cross-contamination of the product. Access of non plant personnel and visitors should be controlled to prevent contamination.

7. Training

7.1 Awareness and responsibilities

Food handlers should be trained in personal hygiene and hygienic handling of food such that they understand the precautions necessary to prevent the contamination of sprouts.

- The manufacturer should have a written training program that is routinely reviewed and updated. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety of sprouts.
- Appropriate training in personal hygiene and hygienic handling of food should be provided to all food handlers at the beginning of their employment and be followed by reminders or periodic refresher training.
- Personnel and supervisors should be trained to have the adequate technical knowledge and understanding of the operations or processes for which they are responsible.
- Personnel and supervisors responsible for the sanitation program should be appropriately trained to understand the principles and methods required for effective cleaning and sanitation.
- Personnel who handle potentially hazardous chemicals should be instructed in safe handling and disposal techniques.

7.2 Management and supervision

Periodic assessments of the effectiveness of training and instruction programs should be made as well as routine supervision and checks to ensure that procedures are being carried out effectively. Managers and supervisors for sprout manufacturing should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

8. Control of Sprouting Operations

8.1 Control of food hazards

Sprout manufacturers should control food hazards through a system based on Hazard Analysis and Critical Control Point (HACCP) principles. They should:

- Identify hazards that may be associated with sprouts and the sprouting process;
- Identify any steps in their operations which are critical to control the safety of sprouts;
- Implement effective control procedures at those steps by establishing critical limits;
- Monitor control procedures to ensure their continuing effectiveness;

- Have procedures in place for dealing with deviations that may occur with the critical limits;
- Verify control procedures periodically and whenever the operations change; and
- Maintain records as specified in section 9 of this Code.

A Hazard Analysis and Critical Control Point (HACCP) type program will reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.

8.2 Prevention of cross-contamination

During sprout production, effective measures should be taken to prevent cross-contamination of seeds and sprouts. To prevent cross-contamination, sprout manufacturers should adhere to the recommendations presented in this code and the following:

- The traffic pattern of employees should prevent cross-contamination of sprouts. For example, the employees should avoid going back and forth to various stages of production. The employees should not go from a potentially contaminated area to the germination and/or packaging area unless they have washed their hands and changed to clean protective clothing. Boot sanitizing stations shall be located at the entrance to germination and packaging areas.
- Protective clothing (e.g., coats, aprons, etc.) should stay in the germination or packaging areas when the employee leaves these areas (e.g., before breaks, etc.).

8.3 Incoming seeds

8.3.1 Specifications

- Sprout manufacturers should recommend that seed producers adopt GAP and provide evidence that the product was grown according to section 3 of this Code.
- Sprout manufacturers should obtain certificates of analysis for microbial pathogens of concern from seed producers or distributors for each incoming lot.
- The sprout manufacturer should maintain a documented history of seed suppliers' adherence to specifications (e.g., analytical results, GAP records, etc.).
- Each bag of seeds should be labelled with the name of the seed producer or distributor, the lot number and the country of origin. That information should be available also for all components constituting seed blends.
- Records should be kept to facilitate trace-back and recall procedures.

8.3.2 Control of incoming seeds

Each bag should be examined at its arrival to minimize the potential for introducing obvious contaminants into the establishment. If certificates of analysis are not provided by seed producers or distributors or if sampling and analyses are not done according to section 3.10 of this code, sprout manufacturers should analyse the seed lots for the presence of microbial pathogens of concern according to section 3.10 of this code.

- Each bag should be examined for physical damage (e.g., holes from rodents) and signs of contamination (e.g., stains, rodent, insects, feces, urine, foreign material, etc.) upon arrival. If found to be damaged, contaminated or potentially contaminated, its contents should not be used for sprout manufacture.
- If seed lots are analysed for the presence of microbial pathogens of concern, these should not be used until results of analysis are available. Lots of seeds for which positive results are obtained shall not be used for sprout production.
- Results of analysis and disposition of contaminated seeds should be documented.
- Statistically valid sampling methods should be used.

8.3.3 Seeds storage

The storage area for seeds should be clean, dry, protected against pests and separate from the rest of the facility. It should not be used to store equipment, chemicals or personal items.

- Seeds should be handled and stored in a manner that will prevent damage and contamination.
- Seeds should be stored off the floor, away from walls and in proper storage conditions to prevent mould and bacterial growth and facilitate pest control inspection.
- Open bags should be stored in closed containers or otherwise protected from contamination.

8.4 Specific steps in sprout production

All steps involved in antimicrobial treatment for seeds (e.g., initial rinse and disinfection) should be carried out in an area separate from the germination and packaging areas and designed to avoid contamination of sprouts by non disinfected seeds or chemical disinfectants.

8.4.1 Initial rinse

The seeds should be rinsed thoroughly before the antimicrobial treatment to remove dirt and increase the efficiency of the antimicrobial treatment.

- Seeds should be rinsed and agitated in large volumes of potable water. The process should be repeated with potable water until most of the dirt is removed and rinse water remains clear.
- The rinsing process should be carried out in such a way to maximize surface contact with water (e.g., use large buckets of water and sieves).

8.4.2 Antimicrobial treatment for seeds

If seeds for sprouting have been grown under GAP and stored and transported in closed containers, the likelihood of being contaminated with pathogenic bacteria is minimized but not eliminated. Seeds should undergo an antimicrobial treatment to reduce the potential for pathogenic microorganisms. There is currently no treatment available that can guarantee pathogen free seeds. An antimicrobial treatment for seeds that can achieve a minimum 3 log reduction of the microbial pathogens of concern should be considered. Examples of such treatments are the use of 2,000 ppm of calcium hypochlorite or sodium hypochlorite for 15-20 minutes or 6-10 % hydrogen peroxide for 10 minutes. Other antimicrobial treatments for seeds may be evaluated by the Food Directorate, Health Products and Food Branch, Health Canada, if enough data is provided.

During the antimicrobial treatment, sprout manufacturers should adhere to the following:

- A fresh solution of disinfectant should be used for each sprout lot.
- Seeds should be well agitated in large volumes of disinfectant solution to maximize surface contact. There should be at least five times the volume of disinfectant for the amount of seeds (e.g., for each 5 kg of seeds, at least 25 litres of disinfectant should be used).
- Disinfectants must be approved for use on foods.
- The duration of treatment and the concentration of disinfectant used must be accurately measured and recorded.
- Strict measures should be in place to prevent re-contamination of seeds after the antimicrobial treatment.
- Chemical disinfectants could be hazardous. People handling chemicals must follow the label directions and take appropriate precautions.

- Protective equipment should be worn such as: waterproof gloves, chemical-resistant footwear and socks, protective clothing such as coveralls over long sleeve shirt and long pants, protective eye wear, and chemical-resistant headgear for overhead use.

8.4.3 Rinse after Antimicrobial treatment

The seeds must be thoroughly rinsed with potable water after the antimicrobial treatment. Rinsing should be repeated sufficiently with potable water to eliminate disinfectant.

8.4.4 Pre-germination soak

Soaking is often necessary to improve germination. When soaking, the sprout manufacturer should adhere to the following:

- All containers used for soaking should be sanitized prior to use.
- Seeds should be soaked in water for a short period to minimize microbial growth.
- This step may also include an additional antimicrobial treatment.
- After soaking, seeds should be rinsed thoroughly with potable water.

8.4.5 Germination

During germination, it is critical to keep the environment and equipment clean to avoid potential contamination. All equipment should be cleaned and sanitized before each new batch.

- The germination, harvesting and packaging areas should be physically separated from the receiving, storage and disinfecting areas and should be protected from outside contaminants.
- Only potable water must be used. If recirculating water is used, proper water treatments must be in place to maintain the potability of the water. Monitoring systems should be in place to ensure the adequacy of the treatment.
- When used, soils should be pathogen free.
- As a means to monitor the presence of pathogens in the finished product, it is recommended that the spent irrigation water be collected after 48 hours of germination and analysed for the presence of microbial pathogens.

8.4.6 Harvesting

All equipment should be cleaned and sanitized before each new batch. Harvesting should be done with cleaned and sanitized tools dedicated for this use.

8.4.7 Final rinse and cooling

A final water rinse will remove hulls and may reduce microbial contamination on sprouts. Cold water will lower sprout temperature and slow down potential microbial growth. When the final rinse is being carried out, the following should be adopted:

- Sprouts should be rinsed in cold potable water.
- Water should be changed as needed (e.g., between lots or batches) to prevent cross-contamination.
- Where applicable, sprouts should be drained using a sanitized food grade centrifugal dryer.

8.4.8 Bulk cooling

- Sprouts should be placed in a cool room to further lower the temperature.
- Sprouts should be placed in small, shallow containers to allow for rapid cooling and to

minimize the potential growth of pathogens.

8.5 Packaging

Packaging design and materials should provide adequate protection for sprouts to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials must be clean, non-toxic and pose no threat to the safety and suitability of sprouts under the specified conditions of storage and use. There should be no unnecessary delays between harvesting and packaging.

8.6 Labelling

Prepackaged sprouts should be labelled with clear instructions to enable the next person in the food chain to handle, display, store or use the product safely.

- Each prepackaged sprout product, as defined under the Food and Drug Regulations, must have permanently and legibly marked on the label, package or container: the common name, the establishment responsible for the production or marketing of the product and a code from which the production date can be determined. Lot identification (code) is essential in the event of a product recall and also helps effective stock rotation.
- Each container should be labelled with a "use-by" date.
- Sprouts should be labelled with the statement: "Keep Refrigerated."

8.7 Storage of finished product

The cold storage room used for sprouts should allow for adequate maintenance and cleaning; prevent pest access and harbourage; and consistently provide an environment which minimizes microbial growth (e.g., by temperature control and air circulation).

- Sprouts should be kept refrigerated during storage to minimize microbial growth. A thermometer should be installed and the storage room temperature should be monitored daily.

8.8 Analysis of spent irrigation water and finished product

Sprout manufacturers should have a sampling plan to ensure the consistent collection of samples in an appropriate manner. Spent irrigation water is the water that has flowed over and through the sprouts and is a good indicator of the types of microorganisms in the sprouts themselves. It should be analysed for microbial pathogens of concern by collecting a representative sample from each production lot or batch. Finished product samples may also be collected and analysed.

Refer to Appendix A for guidance on sample collection and testing of spent irrigation water and sprouts.

8.9 Transportation

Transportation vehicles used for sprouts should permit adequate maintenance and cleaning and provide an environment which minimizes microbial growth.

- Sprouts should be kept refrigerated during transport to minimize microbial growth. The temperature should be monitored and recorded for each shipment.
- Transportation vehicles should be designed and constructed so that they can be effectively cleaned and sanitized. They should be cleaned and sanitized frequently.
- Transportation vehicles should be designed to protect sprouts from microbial and chemical

contamination from untreated seeds, other raw foods (e.g., raw meat), chemicals, dust and fumes, etc.

9. Documentation and Records

Written records that accurately reflect product information and operational controls should be available to demonstrate the adequacy of the manufacturing activities. Records should be available on demand.

- Records should be legible, permanent, accurate and be signed and dated by the individual (s) responsible.
- Records should include written procedures, controls, limits, monitoring results and subsequent follow-up documents. Records must include: seed sources and lot numbers, water analysis results, sanitation checks, pest control monitoring, sprout lot codes, sprout and spent irrigation water analysis results, production volumes, storage temperature monitoring, product distribution and consumer complaints.
- Records should be retained for at least one year for each lot of sprouts.

10. Trace-Backs and Recalls

Sprout manufacturers should ensure that effective trace-back and recall procedures are in place to respond to food safety hazards. They should enable the complete and rapid recall of any implicated lot of sprouts from the market and provide detailed information to assist in the investigation of any identified sprout contamination. Written recall procedures should include the following:

- The CFIA and the required provincial or municipal health authorities should be notified of all food recalls.
- Sprout manufacturers should maintain an effective system of control so that they are able to notify all their affected clients to quickly recall any product posing a health risk. Mock recalls should be conducted periodically to verify the recall procedures and efficiency.
- Where a product has been recalled because of a health hazard, other products which were produced under similar conditions, and which may present a similar hazard, should be evaluated for safety.
- Depending on the health hazard involved, public warnings may be required.
- Recalled sprouts should be held under supervision and segregated until disposed of properly.

Appendix A: Guidance on Sample Collection and Testing of the Spent Irrigation Water and Sprouts

Microbial testing of spent irrigation water is considered to be one of the most practical and acceptable testing techniques currently available. Health Canada recommends that sprout manufacturers regularly test the spent irrigation water, because water that has flowed over and through the sprouts is a good indicator of the types of microorganisms in the sprouts themselves, including pathogens of microbial concern (*Salmonella* spp., *E. coli* O157:H7). Sprouts should not be tested in place of spent irrigation water unless the production methods make it impossible to test the spent irrigation water. However, the recommendation to test spent irrigation water does not preclude additional testing of sprouts (either sprouts collected during production or finished product). Representative samples should be collected from each production lot and analysed for microbial pathogens of concern.

Sampling Equipment and Containers

Equipment and containers used to collect samples should be clean and sterile. They may be purchased pre-sterilized or, alternatively, they may be sterilized at 121°C (250°F) for 30 minutes in an autoclave, prior to use. Heat-resistant, dry materials may be sterilized in a dry-heat oven at 140°C (284°F) for 3 hours. Once sterilized, the sampling equipment and containers should be protected from contamination at all times before and during use. Ensure that the used sampling equipment, containers and the collected samples do not contaminate remaining sterile equipment and containers.

The type of sample containers to be used depends on whether spent irrigation water or sprout samples are being collected. Containers may include pre-sterilized plastic bags, bottles, tubes, cups and flasks. They should be dry, leak-proof, wide-mouthed, and of a size suitable for the samples. Containers should also seal properly to ensure the integrity of the sample. The containers should be properly labelled prior to collecting the sample.

When to Sample

Samples of spent irrigation water can be collected as early as 48 hours after the start of sprouting. If the seeds are pre-soaked (e.g., soaked in water for a short time and then transferred to growing units for sprouting), include the pre-soak time. Early results will allow the sprout manufacturer to take corrective actions sooner, thus minimizing the potential for one lot of sprouts to contaminate other lots.

Procedures for Sample Collection

Sample collection of spent irrigation water and sprouts should be done on site by trained personnel. Aseptic sampling procedures should be used to avoid contaminating the sample and the product being sampled.

Personnel should wear a clean lab coat, hair net and sterile gloves. Hands should be washed immediately prior to putting on sterile gloves. The sterile gloves should be put on in a manner that does not contaminate the outside of the glove. During sample collection, hands should be kept away from the mouth, nose, eyes and face. After sample collection, the gloves should be properly discarded.

The sterile sample container should be opened only sufficiently to allow for the sample to be collected. The sample should be placed directly in the container. Once the sample is collected, it should immediately be closed and sealed. If collecting samples in a container with a lid, the lid should NOT be completely removed. The lid should not be held separately or placed on a counter.

The sample container should be filled no more than 3/4 full to prevent overflow. The air from the container should not be expelled when sealing, particularly for plastic bags.

Once collected, the samples should be delivered to the laboratory promptly. The sample should be kept at an appropriate temperature, preferably between 0 and 4°C (32° to 40°F). To avoid cross-contamination from melting ice, sealed coolant packs should be used.

Pooling samples from different sprout lots may reduce the number of lab analyses to be performed, however if a presumptive positive is found, all sprouts lots represented by the pooled sample are suspect. The suspect sprout lots should either be discarded or each sprout lot should be analysed separately to determine which lot(s) is (are) contaminated.

Sample Size

The volumes given below for spent irrigation water and sprouts represent a sufficient sample size to test for the presence of the microbial pathogens of concern (i.e., *Salmonella* spp., and *E. coli* O157:H7).

A. Spent Irrigation Water

One (1) litre of water should be aseptically collected as the water leaves a drum or tray(s) during the irrigation cycle. Spent irrigation water samples should be collected directly into clean, sterile, pre-labelled containers.

Drums:

One (1) litre of spent irrigation water may be collected from the drum.

Trays with Common Trough

One (1) litre of spent irrigation water may be collected at the common trough.

Trays with no Common Trough

If there is no common trough, spent irrigation water samples from individual trays should be collected and pooled. If the tray is large, spent irrigation water samples from different areas of the tray should be collected.

When Ten (10) or fewer trays make up a production lot, approximately equal volumes of spent irrigation water should be collected from each of the 10 trays to make a total sample volume of one (1) litre. For example:

- Ten (10) trays: Collect 100 ml of spent irrigation water samples from each tray to make up one (1) litre sample.
- Eight (8) trays: Collect 125 ml of spent irrigation water samples from each tray to make up one (1) litre sample.

When there are Ten (10) or more trays, collect ten (10) spent irrigation water samples throughout the entire production lot. For example: if there are 20 trays in a production lot, collect samples from every other tray in the rack, moving from top to bottom, side to side, and front to back.

B. Sprouts

Five (5) sample units of approximately 200 grams each should be aseptically collected from different locations in the drum or growing trays, to ensure the sample collected is representative of the lot. The sample units should be collected throughout the entire production lot (e.g., from top to bottom, side to side, and front to back of the drum or trays). Each 200 gram sample unit should be placed directly into individual clean, sterile, pre-labelled containers.

Microbial Testing Procedures

All microbial testing for pathogens should be conducted in an external, certified, independent laboratory, and meet the following criteria:

- The laboratory should be physically separated from the food production facility to prevent cross-contamination.
- Second, the laboratory should be staffed by personnel with training and experience in analytical microbiology techniques to ensure that tests are performed correctly and that all appropriate safety precautions, including appropriate waste disposal, are followed.
- Third, the laboratory should have appropriate resources and be able to demonstrate that they follow a quality management system.
- If the microbial analysis is done by the sprout manufacturer, the laboratory facilities, personnel, and quality management system should meet the above mentioned criteria, to ensure that testing is reliable and does not create food safety hazards.

The testing procedures described below can be used to obtain results as simply and quickly as possible on the presence or absence of the microbial pathogens of concern (*i.e.*, *Salmonella* spp. and *Escherichia* O157:H7). These methods are described in the [Health Canada](http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php) (HC) Compendium of Analytical Methods: <http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php>

Please keep in mind that seasonal or regional differences in water quality, type of seed being sprouted, and variations in sampling and analytical conditions may all impact on the effectiveness of the screening tests.

Test Kits

***Escherichia coli* O157:H7:**

1. MFLP-87 VIP EHEC. Biocontrol Systems, Inc., Bellview, WA.
2. MFLP-94/95 Reveal *E. coli* O157:H7, Neogen Corp., Lansing, MI.
3. MFLP-91 Tecra UVA method for *E. coli* O157:H7.
4. Any other methods listed in the Compendium for *E. coli* O157:H7.

***Salmonella* spp.:**

1. MFHPB-24 Vidas SLM method, Biomerieux, Montreal.
2. MFLP-96 Reveal kit for *Salmonella*.
3. MFLP-97 Alert kit for *Salmonella*.
4. MFLP-35 Tecra VIA for *Salmonella*.
5. Any other methods listed in the Compendium for *Salmonella* spp.

General Laboratory Instructions

Follow instructions in each method.

Dividing Samples into Sample Units for Analysis

Spent Irrigation Water

Total of one (1) L of spent irrigation water should be collected. Two (2) 100 ml sample units should be analysed for the presence of *E. coli* O157:H7. Two (2) 375 ml sample units should be analysed for the presence of *Salmonella* spp. Any unused portion of spent irrigation water should be stored under refrigeration pending completion of the analysis.

Sprouts

Total of five (5) sample units of 200g of sprouts should be collected. For each sample unit, one 25 g sample unit should be analysed for the presence of *E. coli* O157:H7 and one 25 g sample unit should be analysed for the presence of *Salmonella* spp. Unused portions of the sprout sample units should be stored under refrigeration pending completion of the analysis.

When Pathogens of Microbial Concern are Detected

When spent irrigation water or sprout samples are found to be positive for *Salmonella* spp. or *E. coli* O157:H7, this is considered to be a health risk and in violation of Sections 4 & 7 of the *Food and Drugs Act*. The sprout manufacturer should notify the CFIA immediately.

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