Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

FOOD SAFETY PRACTICES GUIDANCE FOR SPROUT MANUFACTURERS

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Canada

PREFACE

Sprouts continue to be a popular choice for Canadians as a low calorie, nutritious food. However many recent outbreaks of food-related illness have been traced back to sprouts contaminated with harmful bacteria, including *Salmonella* spp. and *E. coli* O157:H7. The traditional procedures for sprouting seeds for human consumption cannot guarantee the absence of these bacterial pathogens, but the risk can be significantly reduced through strict adherence to good manufacturing practices, especially where the principles of Hazard Analysis Critical Control Points (HACCP) are applied to the process.

The *Code of Practice for the Hygienic Production of Sprouted Seeds*, developed with the sprout industry's input in 2001, and amended in February 2007, continues to be the current Canadian regulatory guideline used to assess sprout manufacturers' compliance with Canada's *Food and Drugs Act* and *Regulations.* In an effort to further reduce the risk posed by the consumption of raw sprouts and to assist processors wanting to adopt the HACCP approach, CFIA has developed the *Food Safety Practices Guidance for Sprout Manufacturers* (FSPGSM) document. This guide incorporates Chapters 4 to 10 of the *Code of Practice for the Hygienic Production of Sprouted Seeds*, as well as Chapters 1 to 8 of the *General Principles of Food Hygiene, Composition and Labelling* (GPFHCL),[1] in addition to other reference material, as a suggested prerequisite program. The FSPGSM provides guidance on potential hazards and controls related to a HACCP approach, and is also designed to address other factors that affect product integrity, including composition, compliance with standards and labeling requirements. It was developed by CFIA with input from a number of interested parties, including the Canadian sprout industry, Health Canada and provincial government representatives, and is being offered to manufacturers as a food safety resource.

HACCP is a systematic approach that assesses each step in a food manufacturing process for potential hazards and identifies controls to prevent their occurrence. HACCP is recognized by regulators, industry and academia as the most reliable food safety approach available to the food industry. Prior to the application of HACCP, a firm should be operating in accordance with Good Manufacturing Practices (GMPs) and food safety legislation and the guidance of a person trained in HACCP. The GMPs (prerequisite programs) serve as the building blocks upon which a HACCP plan is built.

A HACCP system is developed following a careful review and analysis of the unique processing facility in which it is to be implemented. Chapter 1 of the *Food Safety Practices Guidance for Sprout Manufacturers* document primarily provides guidance related to hazard analysis and control of the manufacturing process, while Chapters 2 to 8 provide guidance related to a generic prerequisite program. The intent is that processors wishing to develop their own HACCP program can modify or adapt this generic guide to fit their particular facility and operation.

[1] The General Principles of Food Hygiene, Composition and Labelling (GPFHCL) refers to the CFIA Code of Practice - General Principles of Food Hygiene, Composition and Labelling, First Edition, April 2006.

It is hoped that this document will complement existing references and the initiatives of other agencies, to make it easier for sprout processors to adopt HACCP and ultimately produce the safest possible product.

SCOPE

This guidance document has been developed for the manufacturing of sprouts that are grown in water: mung bean sprouts, alfalfa sprouts, onion sprouts, etc. It applies to products that are packaged (any format and material) and sold in Canada.

HAZARD SUMMARY FOR SPROUTS GROWN IN WATER

The following table summarizes potential hazards associated with sprout production and suggests possible control measures. The manufacturer is responsible for identifying hazards specific to the operation and determining how each hazard can be controlled. For additional information, refer to the specific sections of the *Food Safety Practices Guidance for Sprout Manufacturers* (FSPGSM) listed in the Reference column.

PROCESS STEP	POTENTIAL HAZARDS	CONTROL MEASURES	REFERENCE IN FSPGSM
Incoming Materials / Receiving (seeds, packaging materials, and chemicals)	- Pathogenic bacteria in seeds (e.g., *Salmonella* and *E. coli* O157:H7). - Pesticide residues in seeds. - Allergen contamination in seeds (e.g., soy, wheat, sesame seeds). – Extraneous materials (e.g. stones, glass, metal). - See also *All Process Steps* in the last row.	- Obtain a guarantee from the suppliers that the seeds, packaging materials and chemicals meet the establishment's purchase specifications (e.g., the supplier provides a Letter of Guarantee). - Check incoming materials against predetermined screening criteria when received (e.g., Good Agricultural Practices [GAP], Certificate of Analysis). - At receiving, inspect condition of all incoming materials and confirm purchase specifications are met. Do not use materials that do not meet specifications. - Test incoming seeds.	1.4
Storage of Incoming Material	- Growth of pathogenic microorganisms and mould. - Contamination due to improperly stored chemicals (e.g., cleaning product, fertilizers). - Cross-contamination by allergens (e.g., soy, wheat, sesame seeds). - See also *All Process Steps* in the last row.	- Keep storage area dry to reduce the risk of mould and bacteria growth. - Store chemicals in separate location from seeds and packaging material. - Store allergens separately from all non-allergenic ingredients and materials.	6.2
Sorting and Weighing	- See *All Process Steps* in the last row.		1.6.2
Initial Rinse	- Contamination by pathogenic microorganisms and/or chemicals in the water. - Inadequate rinse fails to lower the bacterial count. - See also *All Process Steps* in the last row.	- Monitor and/or test water to ensure it is acceptable (potable). Change water accordingly. - Monitor and/or test that rinsing is done correctly. - Include an antimicrobial treatment step in the process.	3.4 1.8 1.8

PROCESS STEP	POTENTIAL HAZARDS	CONTROL MEASURES	REFERENCE IN FSPGSM
Antimicrobial Treatment	- Contamination by pathogenic microorganisms and/or chemicals in the water. - Inadequate reduction of pathogenic microorganisms due to inadequate antimicrobial treatment. - Chemical residue on final product from use of unapproved antimicrobial treatment. - See also*All Process Steps* in the last row.	- Monitor and/or test water to ensure it is acceptable (potable). - Test spent irrigation water for pathogens 48 hours after initial seed soaking. - Use antimicrobial products at appropriate level and monitor or test. - Use only antimicrobial treatments that are approved for use on food.	3.4 1.11 1.8 1.8
Rinse after Antimicrobial Treatment	- Contamination by pathogenic microorganisms and/or chemicals in the water. - Excessive antimicrobial residue on final product. - See also *All Process Steps* in the last row.	- Monitor and/or test water to ensure it is acceptable (potable). - Effective rinsing procedure is in place and is monitored and/or tested.	3.4 1.8
Pre-germination Soak and Rinse	- Contamination by pathogenic microorganisms and/or chemicals in the water. - Growth of bacteria in standing water. - See also *All Process Steps* in the last row.	- Monitor and/or test water to ensure it is acceptable (potable). - Minimize soak time in standing water and/or add antimicrobial to water.	3.4 1.8
Germination	- Contamination by pathogenic microorganisms and/or chemicals in the irrigation water. - Growth of bacteria due to warm room and water temperature. - Potential chemical residue from inappropriate or excess chemical/fertilizer use. - See also *All Process Steps* in the last row.	- Monitor and/or test water to ensure it is acceptable (potable). - Test spent irrigation water for pathogens 48 hours after initial seed soaking. - Use only chemicals that are approved for use on food. Use at appropriate level and monitor or test.	3.4 1.11 1.1

PROCESS STEP	POTENTIAL HAZARDS	CONTROL MEASURES	REFERENCE IN FSPGSM
Harvesting	- High bacterial count on sprouts related to warm and wet germination conditions. - See also *All Process Steps* in the last row.	- Rinsing and rapid chilling of the sprouts at harvest.	1.8
Final Rinse and Cooling /Dehulling	- Contamination by pathogenic microorganisms and/or chemicals in the water. - High bacterial count related to warm room and water conditions. - See also *All Process Steps* in the last row.	- Monitor and/or test water to ensure it is acceptable (potable). - Rinse harvested sprouts thoroughly with cold potable water and transfer to refrigerated storage without unnecessary delay.	3.4 1.8
Removal of Water/ Draining	- See *All Process Steps* in the last row.		1.8
Bulk Cooling	- Growth of pathogenic microorganisms due to inadequate cooling. - See also *All Process Steps* in the last row.	- Ensure rapid cooling of bulk packed sprouts.	1.8
Packaging/ Labelling/ Coding	- Undeclared allergen in finished product. - Growth of pathogenic microorganisms related to improper label instructions on product storage and shelf life. - See also *All Process Steps* in the last row.	- Adequate separation of allergens and non-allergens during processing steps, storage and packaging. - Monitor labels on product (e.g., labelling of potential allergenic ingredients, correct label applied to product, all information provided (e.g., list of ingredients, shelf life/lot number) is complete, accurate and legible.	1.6, 1.9, 6.2 1.2, 1.9
Storage of Finished Product	- Growth of pathogenic microorganisms due to inadequate cooling. - Bacterial or chemical cross-contamination from improperly stored items (e.g. other goods or food allergens stored with sprouts). - See also *All Process Steps* in the last row.	- Control temperature and storage practices in sprout storage cooler to minimize growth of pathogenic microorganisms. - Adequate separation of chemicals, seeds and finished products. - Adequate separation of allergens and non-allergen products during storage.	6.2

PROCESS STEP	POTENTIAL HAZARDS	CONTROL MEASURES	REFERENCE IN FSPGSM
Shipping/ Distribution	- Contamination by pathogenic microorganisms, hazardous extraneous matter and/or chemicals due to unsanitary carriers, improper distribution temperatures and/or damaged packaging. - See also *All Process Steps* in the last row.	- Monitor carriers during loading to ensure transportation conditions meet the establishment's requirements.	6.1
****All Process Steps****	- Contamination with pathogenic microorganisms, chemicals and extraneous material due to employee error as a result of lack of training and/or failure to understand the importance of following written standard operating procedures (SOPs) and/or good manufacturing practices (GMPs).	- Provide employees with training in standard operating procedures (SOPs) and/or good manufacturing practices (GMPs) appropriate to their position and the work being done.	5.2
	- Contamination by pathogenic microorganisms, chemicals and/or extraneous matter due to unsanitary handling practices.	- Provide employee training in proper hygiene and correct handling procedures. - Monitor employee practices.	5.1, 5.2
	- Contamination by pathogenic microorganisms, extraneous matter (e.g., screws from equipment) and/or chemicals (including lubricants) due to improper equipment design, installation and maintenance.	- Use equipment that has been properly designed and installed for use in a food establishment. Maintain equipment appropriately to ensure functioning effectively. Ensure food contact surfaces are food grade and equipment is designed and positioned to prevent contamination of product.	2.1
	- Contamination by pathogenic microorganisms and/or chemicals due to improper cleaning and sanitizing of equipment and facilities.	- Monitor procedures and verify the effectiveness of the sanitation program.	4.1
	- Contamination by pathogenic microorganisms carried in the air or the result of condensation.	- Control and monitor airflow and the ventilation system to minimize risk of product contamination.	3.2
	- Cross-contamination by pathogenic microorganisms due to improper plant layout (e.g., inadequate separation of operations).	- Separate non-compatible operations through building and process design.	3.2
	- Cross–contamination by pathogenic microorganisms due to improper movement of employees or visitors between process steps.	- Control employee and visitor movement within plant.	5.1
	- Contamination by pathogenic microorganisms due to the presence of rodents, birds or insects.	- Monitor the effectiveness of the pest control program.	4.2

USING THE GUIDANCE DOCUMENT

Each section of this "Food Safety Practices Guidance" document describes specific GMPs and includes the following:

- a "Principle Statement" found in a box at the beginning of the section;
- when necessary, a "Rationale," and
- anticipated Outcomes.

Principle Statement

Principle statements are outcome-based generic statements of objectives similar to those found in the Codex Alimentarius code. They are intended to capture the intent of the guideline, while allowing flexibility in addressing specific products or processes.

Rationale

Rationales are included only when required to explain the "principle statement." They are included in several chapters of the Food Safety Practices Guidance document (Control of Operation, Equipment, Records and Complaint Handling and Recalls) to explain the nature of the concern or potential hazard(s) and the need for control.

Anticipated Outcomes

The "Anticipated Outcomes" in the Food Safety Practices Guidance document are intended to guide the industry by describing the factors influencing the objective underpinning the principle statement. The CFIA recognizes that there may be "alternative means" of meeting the intent of the principle statement other than those described in the guidance. For example, these "alternative means" may include a specific process step that will be used to control an associated food safety risk or meet a regulatory requirement.

CHAPTER 1

CHAPTER 1: CONTROL OF OPERATION

1.1 PRODUCT FORMULATION AND COMPOSITION

1.1.1 Availability and Accuracy of Product Formulae

Current written formulae are available for each sprout product.

Rationale
Formulae provide information aimed at ensuring the production of a consistent product and to avoid potential hazards (e.g., adding unlisted ingredients which could cause allergic reactions).

Anticipated Outcomes

- Current written formulae are available for each multi-component product.
- The formulae contain all details of the formulation as follows:
  - identification of all ingredients, food additives and/or processing aids (e.g., brand/supplier, concentration, type, common name); and
  - amounts of all ingredients (when a mix of different types of sprouts are used).
- Products are formulated to ensure accurate nutrition declarations where required (see 1.1.3 Compositional Requirements for further details).

1.1.2 Identification of Critical Processing Factors in Product Formulation

This section does not apply to sprouts.

1.1.3 Compositional Requirements

The nutrient content of the food is controlled to meet declared label values (when present*) and applicable requirements found in the *Food and Drugs Act* and *Regulations*. Foods for which nutrient content claims and health claims are made meet the compositional requirements of the *Food and Drug Regulations* [Division 24, B.01.503, and B.01.600].

* Fruits and vegetables, including sprouts, are exempt from nutrition labelling requirements, unless the package bears a claim. Manufacturers may provide a Nutrition Facts table **voluntarily, but if they do so,** they must then meet all the nutrition labelling requirements.

Rationale
Inaccurate nutrition information, nutrient content claims and health claims may pose a health risk for people making food choices based on the nutrient content of the food.

Anticipated Outcomes

- The manufacturer has control over the formulation to ensure that all nutrient content declarations are met.

NOTE: The following documents provide further guidance on composition and labelling issues. They are available on the CFIA Web site at: http://www.inspection.gc.ca/english/fssa/labeti/nutrition-pagee.shtml**.**
i. The *Evaluation Standard for Nutrition Labelling* addresses, in detail, the requirements of the Nutrition Facts table and the factors involved in determining nutrient content and producing a product with a consistent nutrient profile. This document may be found within the Nutrition Labelling Toolkit.
ii. The *2003 Guide to Food Labelling and Advertising* provides detailed guidance on the requirements for nutrient content and diet-related health claims.
iii. The Nutritional Labelling Compliance Test constitutes the CFIA methodology for assessing the accuracy of nutrition labelling and claims.

1.1.4 Food Additives

Food additives are controlled to meet the requirements of the *Food and Drugs Act* and *Regulations*.

Rationale
Inadequate control of food additives and/or processing aids could result in chemical or biological hazards.

Anticipated Outcomes

- Chemicals can be considered food additives, processing aids, or food contaminants depending on their nature and/or their use (e.g., growth regulators, plant nutrients, fertilizers, pH adjusters for water and/or antimicrobial agents) and the amount of residual chemical in the final product.
- The manufacturer ensures that all food additives used are permitted for use in the particular food and meet the requirements of the *Food and Drug Regulations* [Division 16] and other applicable regulations.
- The manufacturer has chemical specifications (e.g., composition and concentration) for all food additives and/or processing aids and ensures that all specifications are met.
- Where there are no specifications in the *Food and Drugs Act* and *Regulations*, the manufacturer requires that all food additives and/or processing aids meet Food Chemical Codex (FCC) grade specifications or equivalent (e.g., specification sheets, clear identification of the grade on the additive package or blanket guarantees).
- The manufacturer ensures that processing aids are used at levels in accordance with Good Manufacturing Practices (as per label instructions) and can demonstrate through calculations that food additives are permitted within the maximum level specified in the *Food and Drug Regulations*.

NOTE: Processing aids are substances that are added to a food for a technological effect during processing and that are not present in the finished food product or are present at insignificant and non-functional levels. Note that food additives are not processing aids.

1.2 LABELLING AND NET QUANTITY

1.2.1 Labelling / 1.2.2 Net Quantity

The manufacturer has controls in place to ensure that the labels are complete and accurate, and meet the requirements of the *Food and Drugs Act* and *Regulations*, the *Consumer Packaging and Labelling Act* and *Regulations* and the *Weights and Measures Act* and *Regulations*, where applicable.

Rationale
Mandatory information (where applicable) on food labels allows consumers to make informed choices by providing:

- basic product information (i.e., common name, list of ingredients in the case of mixed varieties of sprouts, net quantity, durable life date, and name and address of the manufacturer);
- Nutrition Facts table (where applicable); and
- other product information (e.g., instructions for safe storage, handling or safe use of the product).

NOTE: "Mandatory Information" is determined, in part, by the regulatory requirements specific to the commodity in question.

NOTE: Pre-packaged sprouts are labelled with clear instructions to enable the next person in the food chain to handle, display, store or use the product safely.

Refer to Chapter 2 (Basic Labelling Requirements) and Chapters 5 to 8 (nutrition labelling and claims) of the *2003 Guide to Food Labelling and Advertising* for further details.
http://www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml

Anticipated Outcomes

- The manufacturer has procedures in place to ensure that all mandatory information is properly declared on food labels in accordance with Canadian food labelling legislation, and that all label claims are accurate and not misleading.
- Each container of sprouts is labelled with a Best Before date.
- Sprouts are labelled with the statement "**Keep Refrigerated**." Refrigeration means exposure to a temperature of 4°C or less, but does not mean frozen.

1.3 PROCESS DESIGN

1.3.1 Process Design

The manufacturer demonstrates that foods do not develop any safety hazards (biological, physical or chemical) as a result of process design.

Rationale
Written scientific evidence is necessary to demonstrate that each process adequately ensures the safety of the product. An inadequate process could result in unintentional incorporation of ingredients, such as undeclared allergens like soy, sesame and/or wheat, or in lack of control of pathogenic organisms, toxins and other hazards.

Anticipated Outcomes

- A written description of the process(es), including procedures, is available upon request.
- Each process is established using accepted scientific methods. Details of actual experimental methods are available.
- All **critical control points (CCPs)** for each product, including the critical limits for each CCP, are identified, tested, evaluated and validated in the development of the process. See the following Process Flow Diagram for a generic process flow and potential CCPs. For further information regarding CCP rationale see the CFIA's *HACCP Generic Model for Sprouts Grown in Water*.
- Any changes to the product formulation or the process are assessed to ensure there is no impact on the safety or composition of the product.

See Section 7.2.1 for expected Process Design Records.

A **Hazard Analysis and Critical Control Point (HACCP)** system is a prevention-based food safety system designed to prevent, reduce to acceptable levels, or eliminate the biological, chemical, and physical hazards associated with food production. One strength of HACCP is its proactive approach to food safety that consists in preventing food contamination rather than trying to identify and control contamination after it has occurred. Sprout manufacturers may control food hazards through a system based on Hazard Analysis and Critical Control Point (HACCP) principles. They may:

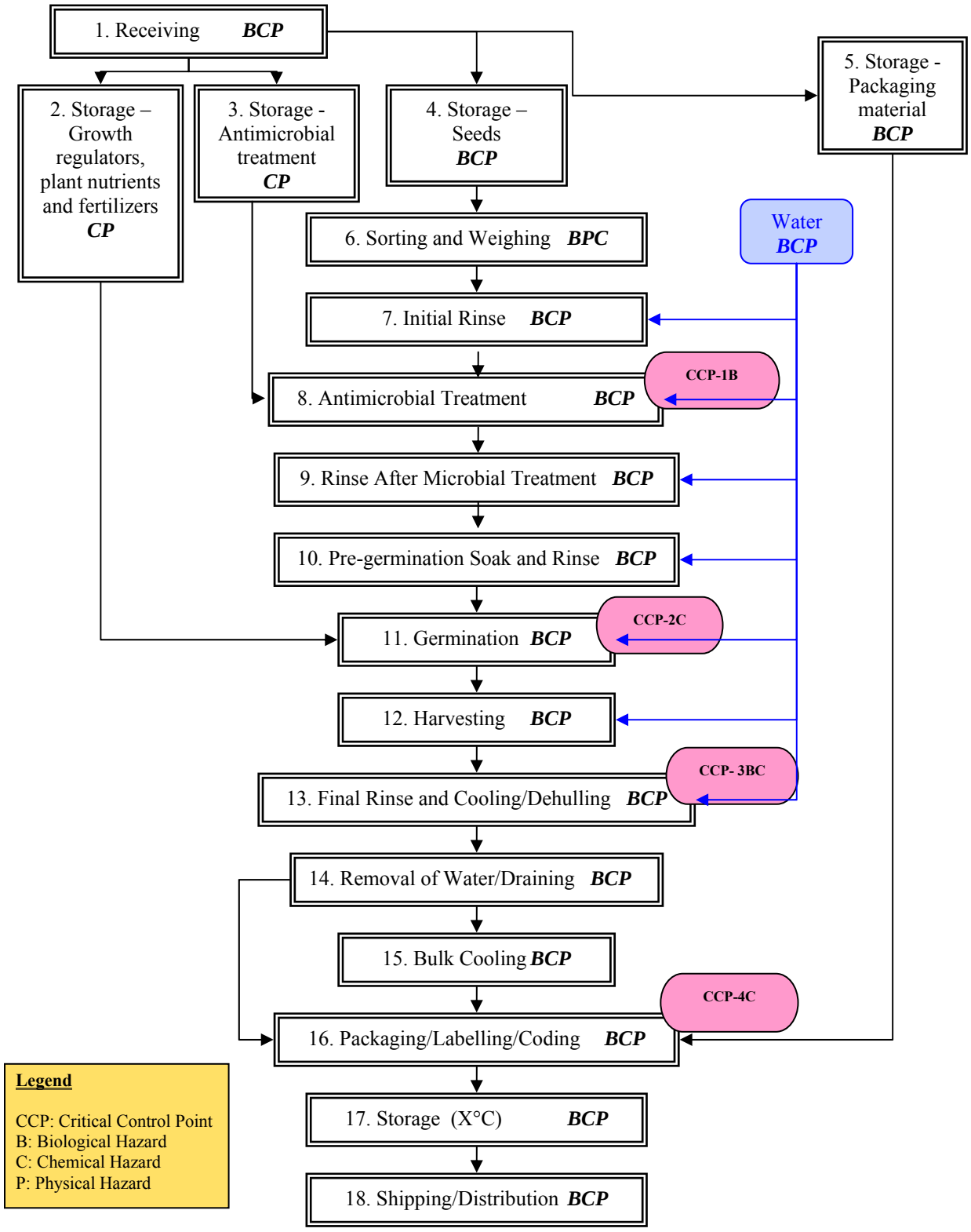
- identify hazards potentially associated with sprouts and the sprouting process;
- identify any steps in their operations that are critical for controlling the safety of sprouts;
- implement effective control procedures at those steps by establishing critical limits;
- monitor control procedures to ensure their continuing effectiveness;
- have procedures in place for dealing with deviations from the critical limits;
- verify control procedures periodically and whenever the operations change; and
- maintain records as specified in Chapter 7 of this Guidance document.

A 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.

The HACCP team at each establishment is responsible for validation of the HACCP system, that is, first validating the hazards that exist in the facility and then validating that the standards for the prerequisite programs (GMPs) and the standards for the critical limits of the critical control point(s) are able to control the hazards. A validation should also to be conducted whenever new procedures, policies or control measures are introduced. If scientific studies and/or government regulations exist in relation to the standard or critical limit, the facility may quote this information as the validation. If not, the facility conducts a validation study to validate the control measure through testing. Once the initial validation is completed during development of the HACCP system, the facility conducts a validation of control measures at least once yearly. This yearly validation reviews all of the standards of the prerequisite programs (GMPs), as well as the critical limits of the critical control points, to ensure that these control measures continue to be effective in controlling the identified hazards.

For additional information on how to build a HACCP system, see Appendix C (Hazard Analysis And Critical Control Point (HACCP) Summary) of this Guidance document, the *HACCP Generic Model for Sprouts Grown in Water* and the *Food Safety Enhancement Program Manual*: (http://www.inspection.gc.ca/english/fssa/polstrat/haccp/manue/tablee.shtml).

Generic Process Flow Diagram identifying suggested Critical Control Points (CCPs) for Sprouts Grown in Water. See the *HACCP Generic Model for Sprouts Grown in Water* for more details.



NOTE: While the generic model identifies antimicrobial treatment as a critical control point (CCP) for addressing the risk of pathogen contamination, seed purchase specifications (requiring pathogen-free seed, seed produced under GAP, etc.) and/or the testing of seed at receiving play a significant role in reducing the risk related to contamination of finished product. The testing of sprout irrigation water at 48 hours is also considered important.

1.4 INCOMING MATERIAL CONTROL

NOTE: Control of incoming materials (Receiving) could be included in Chapter 6 – Transportation and Storage, provided that all of the anticipated outcomes for sections 1.4.1 and 1.4.2 are achieved.

1.4.1 Incoming Seeds and Other Non-Packaging Inputs

The manufacturer controls incoming seeds and other non-packaging inputs so that foods are not exposed to safety hazards (biological, physical and chemical), and so they remain both safe and correctly labelled.

Rationale
Prevention of health hazards begins with control of incoming seed and other non-packaging inputs. Inadequate incoming product controls, such as a lack of appropriate product testing and sorting, or a failure to verify labels, could result in the sale of contaminated product or misrepresented product. Specifications provide standards against which the manufacturer can assess the acceptability of the components necessary for the production of the finished product.

NOTE: The degree of control exercised is appropriate to the level of risk posed by the ingredient to the safety of the food.

Anticipated Outcomes

NOTE: As the variety of seeds used in the edible sprout industry expands, manufacturers need to ensure that all types chosen are acceptable for human consumption (i.e., have a history of safe use as food and do not contain naturally occurring or added toxic compounds).

- Sprout manufacturer has specifications that seeds were produced under *Good Agricultural Practices* (GAP) (e.g., provide evidence that the product was grown according to Appendix B Seed Production – Good Agricultural Practices) and seeds are free of microbial pathogens (i.e., *Salmonella* spp. and *E .coli* O157:H7). Seed producers should provide certificates of analysis.
- Sprout manufacturer has specifications to avoid presence of undeclared allergens (e.g., soy, sesame, wheat) and acquires a letter of agreement from each supplier to indicate that all specifications are met.
- Sprout manufacturer has certificates of analysis for microbial pathogens of concern (i.e., *Salmonella* spp. and *E. coli* O157:H7) from seed producers or distributors for each incoming lot. If certificates of analysis are not provided by seed producers or distributors or if sampling and analyses have not been done according to Section 3.10 of Appendix B Seed Production – Good Agricultural Practices, sprout manufacturers

analyse the seed lots for the presence of microbial pathogens of concern according to Section 3.10 of the Appendix B.
NOTE: It is important for sprout manufacturers to be aware that negative results do not guarantee pathogen free seeds because of analytical and sampling limitations.

- Statistically valid sampling methods are used.
NOTE: It is important to use random sampling techniques, sufficient sample sizes and subsample numbers to represent the lot as best as possible.
- Where seed lots are analysed for the presence of microbial pathogens of concern, the seed lots are not be used until the analytical results are available. Seed lots for which positive results are obtained are not used for sprout production.
- The sprout manufacturer maintains a documented history of seed suppliers' adherence to specifications (e.g., analytical results, GAP records, etc.).
- Each bag of seeds is labelled with the name of the seed producer or distributor, the lot number and the country of origin. The same information should be available for all components of seed blends.
- Each bag or container of seeds and incoming material is examined for physical damage (e.g., holes made by rodents), signs of contamination (e.g., stains, bird droppings and rodent activity including faeces and urine), insects, mould, lubricants from field equipment) and foreign material (e.g., stones, wood, metal, glass) upon arrival. Contaminated or potentially contaminated seeds are not to be used for sprout manufacture.

NOTE: Section 1.1.4 of this document provides guidance for assessing specifications for food additives and/or processing aids.

See Section 7.2.2 for expected incoming material control records.

Non-Conforming Ingredients

- When ingredients fail to meet specifications that impact food safety, the manufacturer investigates and identifies the root cause. The manufacturer initiates corrective action by determining whether food safety is compromised and by taking the necessary actions. See Section 1.10 - Deviations and Corrective Action and Section 7.2.5 - Deviations and Corrective Action Records**.**

1.4.2 Packaging Materials

The manufacturer controls incoming packaging materials to meet the requirements of Division 23 of the *Food and Drugs Regulations*, such that no biological, physical or chemical hazards result in the food.

Rationale
Controls are necessary to ensure that packaging materials meet the manufacturer's specifications. Inadequate controls could result in the use of containers that may contaminate the product, or may permit physical, chemical or biological contamination of the product.

Anticipated Outcomes

- Packaging design and materials provide adequate protection for sprouts to minimize contamination, prevent damage, and accommodate proper labelling.
- Packaging materials are new, clean and non toxic and pose no threat to the safety and suitability of sprouts under the specified conditions of storage and use.
- Packaging material appears in the *Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency, or the packaging supplier can provide a "Letter of no objection" from Health Canada.
- Each lot of packaging material is examined for physical damage, signs of contamination (e.g., stains, bird droppings, rodent activity [e.g., faeces, urine], and insects) and foreign material (e.g., wood, metal, glass) at receiving. Contaminated or potentially contaminated packaging material is not to be used for sprout manufacture.

NOTE: The *Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products* is available on the CFIA Web site, http://www.inspection.gc.ca/english/fssa/reference/refere.shtml

See Section 7.2.2 for expected Incoming Material Control Records.

1.5 PACKAGING CONTROL

1.5.1 Packaging

Handling and use of packaging is controlled to prevent product contamination.

Rationale
Inadequate control of packaging steps may result in the use of damaged, defective or contaminated packaging, which may lead to contamination of the product.

Anticipated Outcomes

- The manufacturer has an effective system in place to prevent the use of contaminated, damaged or defective containers (e.g., receiving and storage controls, visual examination prior to use).
- Only packaging materials required for immediate use are kept in the packaging or filling area.
- Packing is done under hygienic conditions that preclude the introduction of contamination into the product.
- Containers are used only for their intended purpose.

1.6 PRODUCT PREPARATION

1.6.1 Control of Preparation and Composition

Factors significant to food safety are controlled during preparation to minimize physical, chemical and biological hazards, and to ensure accuracy of composition.

Rationale
Inadequate control of factors associated with product preparation could result in inadequate processing or the presence of undeclared allergens (e.g., soy, sesame, wheat). The product may violate permissible levels of food additives.

Anticipated Outcomes

- The manufacturer has controls in place to prevent hazards associated with the preparation of the product. Areas significant to food safety are outlined below:

Allergens
The manufacturer has controls in place to prevent the presence of undeclared allergens. Allergens are ingredients that can elicit an allergic response in sensitive individuals. Areas that may require control include

- cross-contamination or carry-over;
- inappropriate use of rework;
- ingredient changes, substitutions or additions;
- incorrect labels;
- incorrect or incomplete list of ingredients; and
- unknown ingredients (e.g., seeds purchased from a new supplier and without specifications).

NOTE: The CFIA website (http://www.inspection.gc.ca/english/fssa/labeti/allerg/allerge.shtml) provides extensive information and guidance for the food industry regarding food allergens, including Canada's list of priority allergens, guidance on the labelling of allergens in food, a guidance tool for managing allergen risk, the *Letter to Food Manufacturers, Importers, Distributors and Retailers on Declaration of Food Allergens – Pre-Packaged Foods*, and the *Letter to Food Manufacturers and Importers in Canada – Precautionary Labelling for Allergens in Pre-packaged Foods.*

Food Additives
The manufacturer has controls in place to ensure that the food additives that are used are permitted, and are used within allowable levels. Specifically, controls ensure

- clear identification of additives;
- accurate measurement;
- adequate blending for homogeneity; and
- checks against unauthorized substitution.

See Section 7.2.3 for expected Product Preparation Records.

1.6.2 Cleaning/Sorting Contamination Control

Seeds are cleaned, receive antimicrobial treatment and are rinsed in such a manner as to reduce biological, physical and chemical contamination and to prevent contamination of the finished product.

Rationale
Adequate cleaning and antimicrobial treatment of seeds is necessary to prevent, reduce or remove contamination with biological, chemical and/or physical hazards. Initial rinsing before the antimicrobial treatment removes dirt and increases the efficiency of the antimicrobial treatment. Seeds should undergo an antimicrobial treatment to reduce the potential for contamination by pathogenic microorganisms.

Anticipated Outcomes

The manufacturer controls the following hazards (where applicable):

Biological hazards

- Sorting controls - visual inspection to prevent use of noticeably damaged seeds.
- Control by initial rinse - increase efficiency of antimicrobial treatment.
- Antimicrobial treatment of seeds, i.e., minimum 3 log reduction of the microbial pathogens of concern (*Salmonella* spp. and *E. coli* O157:H7).

Chemical hazards

- Sorting controls – visual inspection to prevent use of noticeably damaged seeds (e.g., staining or discolouration on seeds from lubricants or industrial chemicals).
- Control by rinsing – initial rinse to remove chemical contaminant from seeds.

Physical hazards

- Extraneous matter controls – visual inspection, sifting, sorting/cleaning by water, e.g., removal of stones, pebbles, wood, metal, glass.

Refer to the CFIA's *Database for Hazard Identification* for more hazard information.

Refer to Section 1.8.1 (Processing Controls) for details on initial Rinse, antimicrobial treatment and rinse after antimicrobial treatment.

1.7 PRODUCT CODING CONTROL

1.7.1 Product Coding

Pre-packaged sprouts are identified with code marks or lot numbers on the label or container to allow the identification of product in the event of a recall.

Rationale

Coding control permits products to be traced through the distribution chain and could provide manufacturing details.

NOTE: Coding is not a mandatory labelling requirement (for sprouts); however, this practice is recommended under Section 8.2.1 (Recall Procedure) to enhance the effectiveness of a recall.

Anticipated Outcomes

- The manufacturer ensures that pre-packaged sprout products are permanently marked with a legible code or lot identification on the label, the package or the container.
- The coding system identifies where the product was manufactured (facility, line, etc.) and when (shift, day, month, year, etc.).
- The exact meaning of all code marks used is available from the manufacturer.
- Where used, case codes are legible and correspond to the identifying marks on the product within.

1.8 PROCESS CONTROL

1.8.1 Processing Controls (Cleaning and sorting process: Initial rinse, Antimicrobial treatment for seeds, Rinse after antimicrobial treatment and Germination and harvesting process: Pre-germination soak and rinse, Germination, Harvesting, Final rinse and cooling/ dehulling and Bulk cooling).

All processing factors are controlled to ensure the safety of the product.

Rationale
Inadequate control of processing factors could result in biological, chemical or physical hazards.

Anticipated Outcomes

- The manufacturer evaluates the process and identifies all factors that have an impact on the safety of the final product.
- The manufacturer ensures all appropriate processing factors are controlled within acceptable limits.
- The manufacturer monitors factors significant to food safety at a scheduled frequency.

The typical **cleaning and sorting process** involves the following:

► ***Initial rinse***

- Seeds are rinsed and agitated in large volumes of potable water. The process is repeated with potable water until most of the dirt is removed and the rinse water remains clear.

- The rinsing process is carried out in such a way to maximize surface contact with water (e.g., use large buckets of water and sieves).

► ***Antimicrobial treatment for seeds***

NOTE: If seeds for sprouting have been grown under GAP and stored and transported in closed containers, the likelihood of the seeds being contaminated with pathogenic bacteria is minimized but not eliminated. Seeds should undergo an antimicrobial treatment to reduce the presence of viable of 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.

NOTE: **What does Log mean?**

"Log" = Logarithm = "power of ten"

1 Log = 10^1 = 10 = ten times
2 Log = 10^2 = 100 = 100 times
3 Log = 10^3 = 1000 = 1000 times
4 Log = 10^4 = 10,000 = 10,000 times

****

When expressed as Log Reduction with respect to microbial counts or population numbers:

Given an initial bacterial count of 1,000 bacteria per gram in a product:

- One Log (1 Log) Reduction would decrease the bacteria population to 100 per gram. (a reduction of 90%)
- Two Log (2 Log) Reduction would decrease the bacteria population to 10 per gram. (a reduction of 99%)
- Three Log (3 Log) Reduction would decrease the bacteria population to 1 per gram. (a reduction of 99.9%)

When a 3-Log Reduction is required, it is anticipated that immediately before the treatment, the initial (starting) count of the organism of concern (i.e. *Salmonella*), if present, will be well below 1,000 per gram, resulting in a final theoretical count well below 1 per gram.

Depending on the food commodity and the microorganism of concern, government or industry standards may require different hazard reduction levels, i.e. a 3 Log Reduction in certain cases (i.e. sprouts) or a 12 Log Reduction in others (i.e. low acid canned food).

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

- A fresh solution of antimicrobial treatment is used for each sprout lot:
- Seeds are well agitated in large volumes of antimicrobial treatment solution to maximize surface contact. At least five times the volume of antimicrobial treatment solution for the amount of seeds is used (e.g., for each 5 kg of seeds, at least 25 litres of antimicrobial treatment solution is used).
- Antimicrobial treatment products are appropriate for use on foods.
- The duration of the treatment and the concentration of the antimicrobial treatment solution used are accurately measured and recorded.
- Strict measures are in place to prevent re-contamination of seeds after the antimicrobial treatment.

Warning: Chemical treatments can 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.

► ***Rinse after antimicrobial treatment***

- The seeds are thoroughly rinsed with potable water after the antimicrobial treatment. Rinsing with potable water is repeated an adequate number of times to reduce the level of the antimicrobial treatment solution in order to meet GMP levels. The GMP level is the amount of the antimicrobial treatment solution required to achieve the intended purpose.

NOTE: Antimicrobial treatment residues are to be removed in the Final Rinse step.

The typical **germination and harvesting process** involves:

► ***Pre-germination soak and rinse***

When a pre-germination soak is used, the sprout manufacturer performs the following:
- All containers used for soaking are sanitized prior to use.
- Seeds are soaked in water for a short period to minimize microbial growth.
- This step may also include an additional antimicrobial treatment.
- After soaking, seeds are rinsed thoroughly with potable water.

► ***Germination***

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

- Only potable water is used.

NOTE: If recirculated water is used, proper water treatments are in place to maintain the potability of the water. Monitoring systems are in place to ensure the adequacy of the treatment.

- The spent irrigation water is collected after 48 hours of germination and analysed for the presence of microbial pathogens.
  See Section 1.11.1, Verification Procedures, for further information.

NOTE: When growth regulators, plant nutrients, fertilizers and pH adjusters for water are added at this step, they must be mixed and added to the seeds as per the label directions to ensure appropriate use.

► ***Harvesting***

All equipment is cleaned and sanitized before each new batch.

- Harvesting is done with cleaned and sanitized tools dedicated for this use.
- There are no unnecessary delays between harvesting and final rinse and/or cooling.

► ***Final rinse and cooling/dehulling***

NOTE: 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. In addition, the final rinse will reduce the antimicrobial treatment level to safe levels (e.g., for chlorine - *Guidelines for Canadian Drinking Water Quality*).

NOTE: Refer to the *Guidelines for Canadian Drinking Water Quality*, published by Health Canada: *http://www.hc-sc.gc.ca/ewh-semt/water-eau/drink-potab/guide/index_e.html*

When the final rinse is carried out, the following procedures are followed:

- Sprouts are rinsed in cold potable water.
- Water is changed as needed (e.g., between lots or batches) to prevent cross-contamination.
- Rinsing is sufficient to remove antimicrobial treatment solution, plant nutrients, growth regulators and fertilizers on sprouts.
- Where applicable, sprouts are drained using a sanitized food-grade centrifugal dryer.

► ***Bulk cooling***

- Sprouts are placed in a cool room to further lower the temperature.
- Sprouts are placed in small, shallow containers to allow for rapid cooling and to minimize the potential growth of pathogens.
- There are no unnecessary delays prior to packaging.

See Section 7.2.4 for expected Process Control Records.

1.9 LABELLING CONTROL

1.9.1 Prevention of Mislabelling

The manufacturer has controls in place to prevent mislabelling.

Rationale
Control of labelling is important to ensure that the correct label is applied to each product. Use of incorrect labels could mislead the consumer and could pose a potential health hazard to segments of the population with allergies (to wheat, soy, sulphites, etc.).

Anticipated Outcomes

The manufacturer has procedures in place to ensure that the correct label is applied to the correct product. Typical controls are listed below:

- Product types are effectively separated during change-overs (e.g., appropriate breaks between products, visual inspection to ensure products are not mixed prior to labelling);
- Different product labels or pre-labelled packaging are effectively separated, and the number of product label types is kept to a minimum;
- During storage, care is taken to prevent mixing of individual labels or bundles of labels (e.g., labels are stored in separate boxes, no labels are loose and unused labels are returned to the correct boxes); and
- Procedures are in place to ensure the product being supplied or added to the labelling operation corresponds to the labels in use (e.g., on-line checks to ensure that products are correctly labelled).

NOTE: The CFIA website (http://www.inspection.gc.ca/english/fssa/labeti/allerg/allerge.shtml) provides extensive information and guidance to the food industry regarding food allergens, including Canada's list of priority allergens, guidance on the labelling of allergens in food, a guidance tool for managing allergen risk, the *Letter to Food Manufacturers, Importers, Distributors and Retailers on Declaration of Food Allergens – Pre-Packaged Foods*; and the *Letter to Food Manufacturers and Importers in Canada – Precautionary Labelling for Allergens in Pre-packaged Foods.*

1.10 DEVIATIONS AND CORRECTIVE ACTION

1.10.1 Deviation Control

When critical limits or limits of acceptability are exceeded or defects occur which could affect product safety or composition, procedures are in place to identify, isolate and evaluate products.

Rationale
Deviations from critical limits, limits of acceptability and procedures, or the occurrence of defects, may affect the safety of the product. Inadequate deviation procedures or non-adherence to procedures could result in the sale of unsafe product or misrepresented product.

NOTE: Deviation procedures apply to **all** sections of this guidance, where appropriate.

Anticipated Outcomes

The manufacturer has a pre-determined and documented deviation procedure designed to identify deviations in either the product and/or the procedures, isolate defective products and take appropriate corrective actions.

Identification of Deviation
- The manufacturer has a system in place to identify deviations when they occur.

Isolation of Affected Product
- The manufacturer has effective procedures in place to isolate, clearly mark and control all product manufactured during the deviation period.
    - All unsatisfactory product is isolated back to the point where the process was last in control. This could be beyond the last satisfactory record.
    - Isolated product is clearly marked (e.g., firmly attached tags contain the following information: hold number, product, the amount, the date held, the reason for the hold, and the name of the person holding the product).
    - The manufacturer maintains control of the product from the hold date to the date of final disposition or until other actions are required following product evaluation.

Evaluation of Affected Product
- Product evaluation is conducted by a qualified person.
- Action on affected product (e.g., returning unused ingredients/materials to the supplier, sorting of suspect lots, re-processing, disposal) is conducted in an appropriate manner by adequately trained personnel.
- Evaluation is adequate to detect potential health hazards, or to identify misrepresentation. For example:
    - sampling is adequate to identify the extent of the problem;
    - the tests are appropriate;
    - the judgement is based on sound science; and

- the product is not released until the evaluation has determined that no health hazard exists and that the product is in compliance with appropriate legislation.

See the *HACCP Generic Model for Sprouts Grown in Water* for suggested deviation procedures and corrective actions.

1.10.2 Corrective Action

Corrective action taken following any deviation is effective to rectify and to prevent recurrence of the deviation.

Rationale
Corrective action procedures are necessary to determine the cause of the problem and to take action to prevent recurrence. It is essential to follow up any corrective action with monitoring and reassessment to ensure that the correction has been effective.

Anticipated Outcomes

- As part of the deviation procedure, the manufacturer has a set of documented corrective actions that include
  - an investigation to determine the cause of the deviation;
  - preventative measures taken to prevent recurrence of the deviation; and
  - verification by the manufacturer of the effectiveness of the corrective action taken.

See Section 7.2.5 for expected Deviations and Corrective Action Records.

See the *HACCP Generic Model for Sprouts Grown in Water* for suggested deviation procedures and corrective actions.

1.11 VERIFICATION OF PRODUCT SAFETY

1.11.1 Verification Procedures (Including testing for spent irrigation water)

The manufacturer uses supplementary methods of evaluation to verify the conformance and effectiveness of controls affecting product safety.

Rationale
The purpose of verification is to assess the conformance and effectiveness of existing controls in preventing health hazards and to indicate areas where improvements are required.

NOTE: Verification applies to all sections of this guidance, where appropriate.

Anticipated Outcomes

- The manufacturer verifies the conformance and effectiveness of controls affecting product safety.
- Individuals or organizations responsible for verification are identified. These individuals or organizations are suitably qualified.
- The verification frequency and methods are appropriated to the hazards associated with the product and process.

- Methods of verification may include the following:

    - review all specifications for incoming ingredients and materials as well as letters of agreement at an adequate frequency and/or whenever any changes are made;
    - develop 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 is 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;

      NOTE: The criteria set out in the Health Canada's Guidance for Industry: *Sample Collection and Testing for Sprouts and Spent Irrigation Water* (December 2006) should be used by sprout manufacturers as a basis for establishing a sampling program. See Appendix A, Guidance for Industry: *Sample Collection and Testing for Sprouts and Spent Irrigation Water* for details.

      Refer to Health Canada's *Compendium of Analytical Methods* for microbiological guidelines and analysis for seeds, sprouts and irrigation water (http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index_e.html)

    - ensure that employees are adhering to sampling programs if applicable;
    - on-site assessment of the monitoring procedures (e.g., GMPs and critical control points);
    - review of records for completeness;
    - review of deviation record to ensure that appropriate corrective actions are taken and recorded in the event of a deficiency;
    - independent external or internal audits; and
    - analysis of consumer complaint trends.

See Section 7.2.6 for expected Verification Records.

CHAPTERS 2 TO 8

CHAPTER 2: EQUIPMENT

2.1 GENERAL EQUIPMENT

2.1.1 Design, Construction and Installation

All equipment and utensils are designed, constructed and installed to function as intended, to permit effective cleaning and sanitation and to prevent contamination of sprouts.

Anticipated Outcomes

- Equipment is designed, constructed and installed to ensure that
  - the process is capable of delivering the required results;
  - it can be adequately and easily cleaned, sanitized, maintained and inspected to prevent contamination of the product during operations;
  - contamination of the product during operation is prevented (e.g., location of lubricant reservoirs); and
  - proper drainage is permitted and, where appropriate, equipment is connected directly to drains. Where applicable, drains are fitted with backflow preventers.

2.1.2 Food Contact Surfaces

Food contact surfaces are constructed of appropriate materials and are maintained in a manner to prevent contamination of sprouts.

Anticipated Outcomes

- Food contact surfaces of equipment, containers and utensils coming in contact with sprouts are smooth, non-corrosive, non-absorbent, non-toxic, free from pitting, cracks or crevices, and able to withstand repeated cleaning and sanitation.
- Where plastic containers (tubs, boxes, totes, etc.) are used to handle seeds and sprouts, the manufacturer ensures that they are constructed of approved materials (see next point).
- When coatings, paints, chemicals, lubricants and other materials are used for food contact surfaces or utilized on equipment where there is a possibility of contact with food, **either**
  - the substances are listed in the *Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency, **or**
  - the manufacturer has a "Letter of no objection" from Health Canada.

  NOTE: The Reference Listing is on the CFIA Web site, http://www.inspection.gc.ca/english/fssa/reference/refere.shtml
- Equipment and utensils used to handle inedible material are not used to handle edible material.

2.1.3 Equipment Maintenance and Calibration Program

An effective maintenance and calibration program is in place to ensure that equipment performs consistently as intended and prevents contamination of the product.

Anticipated Outcomes

- The manufacturer has an effective written preventative maintenance and calibration program to ensure that equipment that may impact on food safety functions as intended. This includes
    - a list of equipment requiring regular maintenance; and
    - the maintenance procedures and frequencies (e.g., equipment inspection instructions, a schedule of adjustments and part replacements based on the equipment manufacturer's manual or equivalent, or based on operating conditions that could affect the condition of the equipment).
- The manufacturer establishes written protocols, including calibration methods and frequencies, for equipment monitoring and/or controlling devices that may impact on food safety.
- Equipment is maintained in a manner which ensures that there is no potential for the development of physical or chemical hazards (e.g., hazards resulting from inappropriate repairs, flaking paint and rust, excessive lubrication).
- Maintenance and calibration of equipment is done by appropriately trained personnel.
- The preventative maintenance and calibration programs and written protocol are adhered to.

See Section 7.3.1 for expected Equipment/Instrumentation Maintenance and Calibration Records.

2.1.4 Instrumentation Maintenance and Calibration Program

Instrumentation is designed, constructed, installed, calibrated and maintained such that the equipment is capable of delivering the required process, thereby ensuring product safety.

Rationale
Improper design, installation, calibration or maintenance of instruments can lead to inadequate processing of the product, or to misuse of food additives.

Anticipated Outcomes

- The manufacturer has an effective written preventative maintenance and calibration program to ensure that instrumentation which may impact on food safety functions as intended. This includes
    - a list of instrumentation requiring regular maintenance and calibration; and
    - the maintenance and calibration procedures and frequencies.

- Instruments which control factors that may have an impact on food safety are designed, installed, constructed, calibrated and maintained as necessary to ensure that they function as intended.
- Maintenance and calibration of instruments is done by appropriately trained personnel.
- The preventative maintenance and calibration programs and written protocol are adhered to.

The following are some examples of instrumentation that may be required to control factors significant to the process:

Temperature measuring devices

- Temperature measuring/recording devices are installed, calibrated and maintained as necessary to ensure accuracy.

Timing Devices

- Timing devices are verified upon installation, and thereafter annually (or more frequently as necessary to ensure accuracy).
- Any official timing device is located so that it can be easily and accurately read by the operators.

Metal Detectors

- Metal detection equipment is designed, constructed, installed, calibrated and maintained in accordance with the equipment manufacturer's manual, to ensure effective removal of metals. This may include adjustment for product effect, selection of target metal and size, timing of the reject mechanism and suitability for environmental conditions.

Other Instrumentation

- Other specialized instrumentation necessary for the control of factors significant to food safety is in place and calibrated as necessary (e.g., chorine injectors, chlorine concentration test equipment, pH meters).

NOTE: The manufacturer should initiate corrective actions as per Section 1.10, Deviations and Corrective Action, when a critical limit or a limit of acceptability are exceeded or whenever products could have been affected and found not to meet specifications.

See Section 7.3.1 for expected Equipment/Instrumentation Maintenance and Calibration Records

CHAPTER 3: PREMISES

3.1 BUILDING EXTERIOR

3.1.1 Outside Property and Buildings

Buildings and surrounding areas are designed, constructed and maintained in a manner which prevents conditions that may result in the contamination of food.

Anticipated Outcomes

Grounds, Roadways and Drainage

- The surrounding land is maintained to control sources of contamination such as debris and pest harbourage areas.
- The building is not located in close proximity to any environmental contaminants.
- Roadways are properly graded, compacted, dust-proofed and drained.
- The surrounding property is adequately drained.

Exterior Building Structure

- The building exterior is designed, constructed and maintained to prevent entry of contaminants and pests. For example, the exterior has no unprotected openings; air intakes are appropriately located; and the roof, walls and foundation are maintained to prevent leakage.

3.2 BUILDING INTERIOR

3.2.1 Design, Construction and Maintenance

Building interiors and structures are designed, constructed and maintained so as to prevent conditions that may result in the contamination of food.

Anticipated Outcomes

Floors, Walls, Ceilings

- Floors, walls and ceilings are constructed of materials that are durable, impervious, smooth, cleanable, and suitable for the production conditions in the area (i.e., materials will not result in the contamination of the environment or food).
- Where appropriate, wall, floor and ceiling joints are sealed and angles are coved to prevent contamination and facilitate cleaning.
- Floors, walls and ceilings are composed of materials that will not result in the contamination of the environment or food.
- Floors are sufficiently sloped to permit liquids to drain to trapped outlets.
- Ceilings, overhead structures, stairs and elevators are designed, constructed and maintained to prevent contamination.

NOTE: Construction materials are listed in the *Reference Listing of Accepted Construction materials, Packaging Materials and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency, **or** the manufacturer has a "letter of no objection" from Health Canada.
The Reference Listing is on the CFIA Web site:
http://www.inspection.gc.ca/english/fssa/reference/refere.shtml

Windows and Doors

- Windows are sealed or equipped with close fitting screens.
- Where there is a likelihood of breakage of glass windows that could result in the contamination of food, the windows are constructed of alternative materials or are adequately protected.
- Doors have smooth, non-absorbent surfaces and are close fitting and self-closing where appropriate.

Process Flow Separation

Building interiors and structures permit good hygienic practices, including protection against cross-contamination between and during operations. Examples:

- Storage, antimicrobial treatment of seeds, germination and packaging areas are physically separated from each other to prevent cross-contamination between incompatible operations;
- The internal design and layout are designed to facilitate good hygienic practices during production, including protection against cross-contamination between operations and during cleaning and sanitation of utensils and equipment. There is regulated flow in the process, from the arrival of the raw material at the premises to the finished product;
- Where mobile equipment (such as hand trucks or forklifts) moves between incompatible areas, measures are taken to sanitize the wheels (floor foamers, sanitizer sprays, etc.) to minimize cross-contamination; and
- Where food processing operations other than sprouts exist at the same facility, there is adequate separation to prevent potential hazards associated with cross-contamination (e.g., biological, chemical, allergens).

3.2.2 Lighting

Lighting is adequate for the activity being conducted. Where appropriate, light bulbs and fixtures are protected to prevent contamination of food or packaging material.

Anticipated Outcomes

- Lighting is appropriate such that the intended production or inspection activity can be effectively conducted. The lighting does not alter food colour and is not less than the following:
    - 540 lux (50 foot candles) in inspection areas;
    - 220 lux (20 foot candles) in work areas; and
    - 110 lux (10 foot candles) in other areas.

Inspection areas are defined as any point where the food product or container is visually inspected or instruments are monitored.

NOTE: These intensities may vary when used to control the growth of sprouts.

- Light bulbs and fixtures located in areas where there is exposed food or packaging material are of a safety type or are protected to prevent contamination of food or packaging material in case of breakage.

3.2.3 Ventilation

Adequate ventilation is provided to prevent excessive condensation and dust, and to minimize entry of contaminated air.

Anticipated Outcomes

- Ventilation provides sufficient air exchange to prevent unacceptable accumulations of condensation or dust and to minimize entry of contaminated air.
- Ventilation systems are constructed to avoid airflow from contaminated areas to clean areas and designed to be adequately maintained and cleaned.
- Ventilation openings are equipped with close fitting screens or filters, as appropriate, to prevent the intake of contaminated air.
- Filters (e.g., filters for intake air and compressed air) are cleaned or replaced at least as often as the manufacturer specifies, or more frequently if a problem is indicated, such as evidence of filter fouling or perforation.

3.2.4 Waste Disposal

Sewage, effluent and waste storage and disposal systems are designed, constructed and maintained to prevent contamination.

Anticipated Outcomes

- Drainage and sewage systems are equipped with appropriate traps and vents.
- Establishments are designed and constructed so that there is no cross-connection between the sewage system and any other waste effluent system in the establishment.
- Effluent or sewage lines do not pass directly over or through production areas unless they are controlled to prevent contamination.
- Adequate facilities and equipment are provided and maintained for the storage of waste and inedible material prior to their removal from the establishment. These facilities are designed to prevent contamination.
- Containers used for waste are clearly identified and leakproof and, where appropriate, they are covered.
- Waste is removed and containers are cleaned and sanitized at an appropriate frequency to minimize the potential of contamination. Waste is not allowed to accumulate in seed and sprout handling and storage areas or the adjoining environment.

3.3 SANITARY FACILITIES

3.3.1 Employee Facilities

Employee facilities are designed, constructed and maintained to permit effective employee hygiene and to prevent contamination.

Anticipated Outcomes

- Handwashing and hand sanitizing stations are located at all entrances and throughout the sprouting and packaging rooms. Stations are properly maintained and, where appropriate, have trapped waste pipes to drains.
- Boot-sanitizing troughs or mats are at all entrances to post-seed disinfection areas. Sanitizer chemical levels are specified by the label and measured as necessary to maintain the specified levels.
- Washrooms, lunchrooms and change rooms are adequately ventilated and maintained in a clean condition They are separate from and do not lead directly into food processing areas.
- Facilities provide adequate means of hygienically washing and drying hands and include wash basins, soap, hand sanitizer, sanitary hand-drying supplies or devices and a supply of hot and cold water (or suitably controlled temperature) adjacent to toilets.
- Toilet facilities are maintained in a sanitary condition and in good repair at all times.
- Toilet facilities are designed to allow hygienic removal of waste and are segregated from production packaging and storage areas to avoid contamination of food or premises.
- Handwashing notices are posted in conspicuous places adjacent to the toilet facilities, so that personnel will see them when returning to work.

3.3.2 Equipment Cleaning and Sanitizing Facilities

Facilities for cleaning and sanitizing equipment are adequately designed, constructed and maintained to prevent contamination.

Anticipated Outcomes

- Facilities are constructed of corrosion-resistant materials which are capable of being easily cleaned, and are provided with potable water at temperatures appropriate for the cleaning chemicals used.
- Equipment cleaning and sanitizing facilities are adequately separated from food storage, processing and packaging areas, to prevent contamination.

3.4 WATER/ICE/STEAM QUALITY

3.4.1 Water and Ice

The potability of hot and cold water is controlled to prevent contamination.

NOTE: See the *Guidelines for Canadian Drinking Water Quality*, published by Health Canada:
http://www.hc-sc.gc.ca/ewh-semt/water-eau/drink-potab/guide/index_e.html

Anticipated Outcomes

- Potable water meets the requirements of Health Canada's Guidelines for Canadian Drinking Water Quality and any applicable provincial and municipal requirements. Water is analysed by the manufacturer with a frequency adequate to confirm its potability. For microbial analysis, water from municipal water is analysed semi-annually and water from other sources is analysed on a monthly basis. For chemical analysis, water from non-municipal sources is analysed at the initial start-up of the well, as a minimum.
- Sprout manufacturers have contingency plans in place to deal with provincial/municipal orders to boil water and unsatisfactory water analyses results.
- There are no cross-connections between potable and non-potable water supplies and all hoses, taps and other similar sources of potential contamination are designed to prevent backflow or back-siphonage.
- Where it is necessary to store water, storage facilities are adequately designed, constructed and maintained to prevent contamination (e.g., covered).
- Water treatment chemicals, where used, are listed in the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency, **or** the manufacturer has a "letter of no objection" from Health Canada. The Reference Listing is on the CFIA Web site: http://www.inspection.gc.ca/english/fssa/reference/refere.shtml
  The chemical treatment is monitored and controlled to deliver the desired concentration and to prevent contamination.
- Recirculated water is treated, monitored and maintained as appropriate to the intended purpose. Recirculated water has a separate distribution system, which is clearly identified.
- In areas for food processing, handling, packaging and storage, water temperatures and pressures are adequate for all operational and clean-up needs.
- Ice used in direct contact with food is made from potable water and is protected from contamination. Ice purchased by the manufacturer is treated as an incoming ingredient and is assessed under item 1.4.1 Incoming Seeds and Other Non-Packaging Inputs.

See Section 7.4.1 for expected Water/Ice/Steam Quality Records.

3.4.2 Steam

The potability of steam which is in direct contact with food or food contact surfaces is controlled to prevent product contamination. Steam supply is adequate to meet operational requirements.

NOTE: Where steam is not in direct contact with food or food contact surfaces, this section is considered to be not applicable.

Anticipated Outcomes

- Boiler treatment chemicals used are listed in the *Reference Listing of Accepted Construction Materials, Packaging Materials, and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency, **or** the manufacturer has a "letter of no objection" from Health Canada. The Reference Listing is on the CFIA Web site, http://www.inspection.gc.ca/english/fssa/reference/refere.shtml.
- Boiler feedwater is tested regularly and the chemical treatment is controlled to prevent contamination.
- The steam supply is generated from potable water and is adequate to meet operational requirements.
- Traps are provided as necessary to ensure adequate condensate removal and elimination of foreign materials.

See Section 7.4.1 for expected Water/Ice/Steam Quality Records.

CHAPTER 4: SANITATION AND PEST CONTROL

4.1 SANITATION

4.1.1 Sanitation Program

An effective sanitation program for equipment and premises is in place to prevent contamination of food.

Anticipated Outcomes

- The manufacturer has a written cleaning and sanitation program for all equipment which includes:
  - the identification of the responsible person;
  - the frequency of the activity;
  - the chemicals and concentrations used;
  - the temperature requirements;
  - the procedures for cleaning and sanitizing, as follows:
    i) identify lines, equipment and utensils;
    ii) outline disassembly/reassembly instructions as required for cleaning and inspection;
    iii) identify areas on equipment requiring special attention;
    iv) outline the method of cleaning, sanitizing and rinsing.
  - the type and frequency of inspection to verify the effectiveness of the program.
- The manufacturer has a written cleaning and sanitation program for premises (production and storage areas) which specifies areas to be cleaned, the method of cleaning, the person responsible and the frequency of the activity. Special sanitation and housekeeping procedures required during production are specified within the document (e.g., removal of product residues during breaks).
- Chemicals are used in accordance with the manufacturer's instructions and are listed in the *Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency, **or** the manufacturer has a "letter of no objection" from Health Canada. The Reference Listing is on the CFIA Web site: http://www.inspection.gc.ca/english/fssa/reference/refere.shtml
- Cleaning and sanitizing equipment is designed for its intended use and is properly maintained.
- The sanitation program is carried out in a manner that does not contaminate food or packaging materials during, or subsequent to, cleaning and sanitizing (e.g., no contamination by aerosols or chemical residues).
- Effectiveness of the sanitation program is monitored and verified (e.g., by a pre-operational inspection of premises and equipment or, where appropriate, by microbiological sampling) and where necessary, the program is adjusted accordingly.
- The sanitation program is adjusted as necessary to incorporate new cleaning procedures (e.g., new equipment, new chemicals, etc.).
- The sanitation program may be used to provide control over cross-contamination issues associated with the production of non-allergenic and allergenic products.

- Operations begin only after sanitation requirements have been met.

See Section 7.5.1 for expected Sanitation Records.

Example of cleaning and sanitizing steps within processing areas

Cleaning and sanitizing steps

1. Remove heavy debris from floors with brooms or shovels and dry clean processing equipment, if needed.
2. Pre-rinse the equipment with potable water.
3. Clean remaining debris from floor.
4. Rinse floor and drains with potable water using a low pressure hose.
5. Use dedicated brushes to scrub floor and drains with an effective cleaner, applying potable water as needed.*
6. Foam and scrub the equipment with an effective cleaner and scrub using dedicated brushes.
7. Thoroughly rinse the equipment, floors, and drains with potable water using a low pressure hose.
8. Remove excess water from floors.
9. Sanitize (according to manufacturer directions) the equipment and floors.**

* Minimize splashing during the cleaning of floor drains by using an appropriate brush, such as a brush ¼ inch smaller than the diameter of the drain opening, or a splash guard.
**Work from top down for cleaning and sanitizing activities. Some equipment may need to be disassembled before cleaning and sanitizing and then reassembled.

4.2 PEST CONTROL

4.2.1 Pest Control Program

Effective pest control programs are in place to prevent entry of pests, to detect and eliminate pests and to prevent the contamination of food.

Anticipated Outcomes

- There is an effective written pest control program for the premises and equipment that includes
    - the identification of the person to whom the manufacturer assigned responsibility for pest control;
    - where applicable, the name of the pest control company or the name of the person contracted for the pest control program;
    - the list of chemicals used, the concentration, the location where they were applied, and the method and frequency of application;
    - a map of trap locations; and
    - the type and frequency of inspection carried out to verify the effectiveness of the program.
- Pesticides used are registered under the *Pest Control Products Act* and *Regulations* and are listed in the *Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency. Pesticides are used in accordance with the label instructions. The Reference Listing can be found on the CFIA Web site: http://www.inspection.gc.ca/english/fssa/reference/peste.shtml.
- Chemical treatment of equipment, premises or ingredients to control pests is conducted in a manner to ensure that the maximum residue limit of the *Food and Drugs Act* and *Regulations* is not exceeded (e.g., the number of fumigation treatments per lot is limited).
- Poisonous rodenticides are not used in food processing or storage areas.
- Birds, insects, reptiles, rodents and other animals are excluded from establishments.

See Section 7.5.2 for expected Pest Control Records.

CHAPTER 5: PERSONNEL

5.1 HYGIENE AND HEALTH REQUIREMENTS

5.1.1 Cleanliness and Conduct

All persons entering food handling areas maintain an appropriate degree of personal cleanliness and take the appropriate precautions to prevent the contamination of food.

Anticipated Outcomes

- All persons wash their hands upon entering food handling areas, before starting work, after handling contaminated materials (e.g., picking objects off the floor, handling garbage, cleaning chemicals or raw incoming materials), after breaks and after using toilet facilities or blowing their nose. Where necessary to minimize microbiological contamination, employees use disinfectant hand dips.
- Protective clothing, hair covering, footwear and/or gloves, appropriate to the operation in which the employee is engaged, are worn and maintained in a sanitary manner (e.g., employees in production areas wear effective hair coverings). Protective clothing (e.g., coats, aprons) stay in the germination or packaging areas when the employee leaves these areas (e.g., before breaks).
- Disposable gloves are changed whenever contamination is a possibility.
- Any behaviour which could result in contamination of food, such as eating, use of tobacco or chewing gum, or unhygienic practices such as spitting are prohibited in food handling areas.
- All persons entering food handling areas remove jewellery and other objects which may fall into or otherwise contaminate food. Jewellery which cannot be removed, including wedding bands and medical alerts, is covered.
- Personal effects and street clothing are not kept in food handling areas and are stored in a manner to prevent contamination.
- Access of personnel and visitors is controlled to prevent contamination. The traffic pattern of employees prevents cross-contamination of the product (For example, the employees avoid going back and forth to various stages of production. The employees do 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.).
- Responsibility for ensuring that all personnel comply with the requirements of this section is specifically allocated to competent supervisory personnel.

5.1.2 Communicable Diseases and Injuries

No person who is known to be infected with a disease likely to be transmitted through food, or who has open cuts or wounds, is permitted to work in food handling areas where there is a likelihood of the person directly or indirectly contaminating the food.

Anticipated Outcomes

- The manufacturer has a policy, and enforces the policy, to prevent personnel from working in food handling areas if they are known to be suffering from a disease, or are known to be carriers of a disease transmissible through food.
- The manufacturer requires that employees advise management when they are suffering from a communicable disease likely to be transmitted through food. Conditions that are to be reported include
    - jaundice;
    - diarrhoea;
    - vomiting;
    - fever;
    - sore throat with fever; and
    - discharges from the ear, eye or nose.
- Employees having open cuts or wounds do not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering (e.g., rubber gloves).

5.2 TRAINING

5.2.1 General Food Hygiene Training

Food handlers are trained in personal hygiene and hygienic handling of food, and they understand the precautions necessary to prevent the contamination of sprouts.

Anticipated Outcomes

- The manufacturer has a written training program for employees and maintains appropriate records.
- Appropriate training in personal hygiene and hygienic handling of food is provided to all food handlers at the beginning of their employment.
- This food hygiene training is reinforced and updated at appropriate intervals, and each time the food handler changes duties.

5.2.2 Technical Training

To ensure food safety, personnel are trained such that they have adequate technical knowledge and understanding of the operation(s) or process(es) for which they are responsible.

Anticipated Outcomes

Training is appropriate to the complexity of the manufacturing process and the tasks assigned. Examples are listed below.

- Personnel are trained to understand the importance of the critical factors for which they are responsible; the critical limits and/or company standards; the procedures for monitoring; the action to be taken if the limits or standards are not met; and the records to be kept.
- Personnel and supervisors are trained to have adequate technical knowledge and understanding of the operations or processes for which they are responsible.
- Managers and supervisors for sprout manufacturing have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks in order to take the appropriate action necessary to remedy deficiencies.
- All employees, including maintenance and customer services employees, are trained to implement allergen controls.
- Personnel responsible for the maintenance and calibration of equipment impacting on food safety have been appropriately trained to identify deficiencies that could affect product safety, and to take the appropriate corrective action (e.g., in-house repairs, contract repairs). Individuals performing maintenance on specific equipment are appropriately trained.
- Personnel and supervisors responsible for the sanitation program are appropriately trained to understand the principles and methods required for effective cleaning and sanitizing.
- Personnel and supervisors responsible for water treatment and water safety monitoring are appropriately trained to understand the principles and methods and are competent in applying procedures designed to protect the safety of food.
- Personnel who handle potentially hazardous chemicals are instructed in safe handling and disposal techniques.
- Additional training is provided as necessary to keep knowledge of equipment and processing technology current.
- Periodic assessments of the effectiveness of training and instruction programs are made as well as routine supervision and checks to ensure that procedures are being carried out effectively.

CHAPTER 6: TRANSPORTATION AND STORAGE

NOTE: If control of incoming materials (Receiving) is included in this chapter, all of the anticipated outcomes for sections 1.4.1 and 1.4.2 should be achieved.

6.1 TRANSPORTATION

6.1.1 Food Carriers

Carriers used by the manufacturer are designed, constructed, maintained, cleaned and utilized in a manner that prevents food contamination and minimizes microbial growth.

Anticipated Outcomes

- The manufacturer verifies that carriers are suitable for the transportation of food. For example,
  - Carriers are inspected by the manufacturer prior to loading and upon receipt of products to ensure they are free from contamination and suitable for the transportation of food;
  - The manufacturer can demonstrate that the carrier has an adequate cleaning and sanitizing program in place.
- Sprouts are transported in a manner designed to protect against biological (microbial), chemical and physical contamination from untreated seeds, other raw foods (e.g., raw meat), dust and fumes, etc.
- Where the same carriers are used for food and non-food loads (e.g., dual use), procedures are in place to restrict the type of non-food loads to those that do not pose a risk to food loads being carried in the same shipment, or to subsequent food loads (after an acceptable clean-out).
- Carriers are loaded, arranged and unloaded in manner that prevents damage and/or contamination of the food.

6.1.2 Temperature Controls

Sprouts are transported in a manner designed to prevent temperature abuse that could result in deterioration of the product and affect its safety.

Anticipated Outcomes

- Sprouts are maintained at 4˚C or less during transport to minimize microbial growth. The temperature is monitored and recorded for each shipment.

  NOTE: For certain types of sprouts, excessively low temperatures could result in chilling injury or necrosis leading to faster deterioration of the final product.

6.2 STORAGE

6.2.1 Incoming Materials Storage

Storage and handling of incoming ingredients and packaging materials is controlled to prevent damage and contamination.

Anticipated Outcomes

- Incoming materials, seeds and packaging materials are handled and stored in a manner that prevents damage and/or contamination (including cross-contamination with allergens). For example, the storage area for seeds is clean, dry, protected against pests and separate from the rest of the facility. It is not used to store equipment, chemicals or personal items. Seeds are stored off the floor, away from walls and in proper storage conditions to prevent mould and bacterial growth and facilitate pest control inspection.
- Seed rotation is controlled to prevent deterioration and spoilage.
- Seeds are not stored near packaging material or finished product.
- Open bags are stored in closed containers or otherwise protected from contamination.

6.2.2 Non-Food Chemicals – Receiving and Storage

Non-food chemicals are received and stored in a manner that prevents contamination of food, packaging materials and food contact surfaces.

Anticipated Outcomes

- Non-food chemicals are received and stored in a dry, well-ventilated area.
- Non-food chemicals are stored in designated areas ensuring that there is no possibility for cross-contamination of food or food contact surfaces.
- Where required for ongoing use in food handling areas, these chemicals are stored in a manner that prevents contamination of food, food contact surfaces and packaging materials.
- Non-food chemicals are stored and mixed in clean, correctly labelled containers.
- Non-food chemicals are dispensed and handled only by authorized and properly trained personnel.

6.2.3 Finished Product Storage

Sprouts are stored under conditions that minimize microbial growth, and they are handled to prevent damage and contamination.

Anticipated Outcomes

- Sprouts are stored at 4 ˚C or less to minimize microbial growth. A thermometer is installed and the storage room temperature is monitored daily.
- Sprouts are stored and handled under conditions that minimize deterioration and prevent contamination, e.g., minimal time between harvest and refrigeration of sprouts and adequate air circulation.
- Sprout rotation is controlled to minimize deterioration and prevent spoilage that could present a health hazard, e.g., product exceeding shelf life.
- Returned defective or suspect product is clearly identified and isolated in a designated area for appropriate disposition.
- Sprouts are stored and handled in a manner that minimizes damage, e.g., control of stacking heights and forklift damage.

NOTE: For certain types of sprouts, excessively low temperatures can result in chilling injury or necrosis leading to faster deterioration of the final product.

CHAPTER 7: RECORDS

7.1 GENERAL RECORDS

7.1.1 General Record Requirements

Information is recorded in a manner that represents an accurate history of the product or process. Records are retained for the required period of time.

Anticipated Outcomes

- Records include controls, limits, monitoring results and subsequent follow-up documents. Records include seed sources and lot numbers, water analysis results, sanitation checks, pest control monitoring, sprout lot codes, sprout and spent irrigation analysis results, production volumes, storage temperature monitoring, product distribution and consumer complaints.
- Records are legible, permanent and accurately reflect the actual events, conditions or activities.
- Errors or changes are identified so that the original record remains clear (e.g., strike out with a single stroke and initial the correction/change).
- Each entry on a record is made by the responsible person at the time that the specific event occurred. The completed records are signed and dated by the responsible person.
- Critical control point records are signed by a qualified individual designated by management. All other records are reviewed at an appropriate frequency to provide an early indication of potentially serious deficiencies.
- Records are retained for at least one year after the Best Before date on the label or container.
- Records are maintained and are available upon request.

7.2 RECORDS ON CONTROL OF OPERATION

7.2.1 Process Design Records

Records are available to demonstrate the adequacy of procedures and methods used in process development.

Rationale
Records are necessary to verify that factors significant to food safety, including critical control points, are adequate in order to produce a safe product.

Anticipated Outcomes

- Records are available upon request to verify that reliable procedures have been followed in designing the process.

7.2.2 Incoming Material Control Records

The manufacturer keeps records that demonstrate the adequacy of incoming materials control.

Rationale
Records are necessary to verify the manufacturer's control over biological, physical and/or chemical hazards.

Anticipated Outcomes

The minimum record requirements for the monitoring of incoming materials are as follows:

- History of seed suppliers' adherence to specifications, GAP records and analytical results, seed producer/distributor, country of origin, lot number.
- Seed certification records of being pathogen-free.
- Data on antimicrobial agents and food chemicals (e.g., food additives).
- Information confirming acceptability of packaging material

Non-Conforming Incoming Materials
- The manufacturer has records to
  - identify the material;
  - identify the deficiency; and
  - specify the preventative and corrective action taken.

7.2.3 Product Preparation Records

Records for factors significant to food safety are maintained and are available on request.

Rationale
Records are necessary to verify that factors significant to food safety during preparation are controlled.

Anticipated Outcomes

- The manufacturer has records that demonstrate control of product preparation through adherence to factors significant to food safety where applicable.

7.2.4 Process Control Record

Written records that adequately reflect the control of critical control points and/or factors significant to food safety during processing are available upon request.

Rationale
Records are necessary to verify the safety of the process.

Anticipated Outcomes

- The manufacturer has records that demonstrate control of critical control points and/or factors significant to food safety during processing.
- The records of the antimicrobial treatment process include the date, product (including type of seed used), lot, treatment used (including the duration of treatment and the concentration of antimicrobial treatment solution), reference of process, person responsible and microbiological test results.
- Deviations are noted on the records by the operator during the process, not after the fact.

NOTE: Minimum information required on records may vary depending on the type of process.

7.2.5 Deviations and Corrective Action Records

Records are available to demonstrate the control of deviations and the effectiveness of corrective actions taken.

Rationale
Records are required to verify that the manufacturer has control of deviations and that corrective action has been effective.

Deviation/Hold

Deviation records include information such as

- product and code;
- date when the product was manufactured, held, released or destroyed;
- description of deviation and reason for the hold;
- amount of product held, e.g., back to the point where the process was last in control;
- results of evaluation/sort, e.g., amount analysed, analysis report of the number and nature of defects;
- disposition of held product, e.g., amount sorted, destroyed or returned to the supplier, employee sales, distress or salvage, reconditioning, and retail sales;
- signature of personnel responsible for hold and evaluation; and
- signed authorization for disposition.

Corrective Action

Corrective action records include information such as

- cause of deviation identified;
- corrective action taken to correct deficiency;
- follow-up/assessment of effectiveness of corrective action;
- Preventative measures taken to prevent recurrence of the deviation;
- date corrective action was taken and verified; and
- signature of person responsible.

7.2.6 Verification Records

Records are available to demonstrate the adequacy of verification procedures.

Rationale
Records show the results of verification and confirm the conformance and effectiveness of manufacturing controls.

Anticipated Outcomes

- Verification records include sprout and spent irrigation analysis results.
- Records of verification include the methods utilized, the date, the individuals/organizations responsible, the results/findings and the action taken (corrective action when a deviation is found).

7.3 RECORDS ON EQUIPMENT

7.3.1 Equipment/Instrumentation Maintenance and Calibration Records

Records are available to demonstrate adherence to the maintenance and calibration program for equipment and instrumentation that may impact on food safety.

Rationale
Records permit verification of the effectiveness of the equipment/instrumentation maintenance and calibration program.

Anticipated Outcomes

- In **Maintenance Records** for equipment and/or instrumentation that may impact on food safety, the manufacturer typically includes an identification of the equipment and/or instrumentation, the maintenance activity, the date of maintenance, the person responsible and the reason for the activity.
- In **Calibration Records** for critical equipment and/or instrumentation that may impact on food safety, the manufacturer typically includes an identification of the equipment and/or instrumentation, the date of calibration, the person responsible, the calibration results and corrective actions.

7.4 RECORDS ON PREMISES

7.4.1 Water/Ice/Steam Quality Records

Written records that adequately reflect control of water, ice and steam quality and treatment are available upon request.

Anticipated Outcomes

- The manufacturer has records available upon request to demonstrate the adequacy of the microbiological and/or chemical safety of the water, ice and steam supply as outlined below.

Water Potability Records	***Water Treatment Records***	***Boiler Feedwater Treatment Records***
- water source	- method of treatment	- method of treatment
- sample site	- sample site	- analytical results
- analytical results	- analytical results	- analyst
- analyst	- analyst	- date
- date	- date	

7.5 RECORDS ON SANITATION AND PEST CONTROL

7.5.1 Sanitation Records

Records are available to demonstrate the effectiveness of the sanitation program.

Anticipated Outcomes

- The records of sanitation activities include the date, the person responsible, the findings, the corrective action taken, and the microbiological test results where appropriate.

7.5.2 Pest Control Records

Records are available to demonstrate the effectiveness of the pest control program.

Anticipated Outcomes

- Minimum pest control records include
  - the results of the inspection programs (e.g., the findings in traps, the location of insect infestations) and the corrective action taken;
  - a record of pest control activities (e.g., the pesticide used, the method and location of application, the dates of fumigation); and
  - the date and the person responsible.

7.6 RECORDS ON COMPLAINT HANDLING AND RECALLS

7.6.1 Complaint Records

Records of product complaints, investigation findings and action taken are available upon request.

Rationale
Records provide verification that the appropriate action was taken within a reasonable time frame.

Anticipated Outcomes

- The establishment maintains detailed records of consumer complaints received and of the subsequent investigation, including corrective action taken. Complaint records include the information listed below.

Consumer Information
- The manufacturer's records contain, at a minimum:
    - the name, address and telephone number of the complainant, and the date the complaint was received;
    - details of the complaint and/or illness;
    - the product's name, code and size; and
    - the retail outlet where the product was purchased.

Investigation
- The manufacturer's records contain, at a minimum:
    - the name of person responsible for the investigation;
    - the action taken (concerning the product and/or the process) as a result of the investigation;
    - the corrective action taken to prevent a recurrence; and
    - a follow-up/assessment of the effectiveness of the corrective action.

7.6.2 Distribution Records

Product distribution records are available to enable the manufacturer to recall any lot of food in a timely fashion.

Anticipated Outcomes

- Distribution records contain sufficient information to permit traceability to a particular code or lot number. The following minimum information is required for distribution records:
    - the product identification and size;
    - the lot number or code;
    - the quantity; and
    - name and type of the account, (e.g. manufacturer, distributor, retailer) addresses, and phone numbers of recipients.

CHAPTER 8: COMPLAINT HANDLING AND RECALLS

8.1 COMPLAINT HANDLING

8.1.1 Product Complaints

The establishment has an effective system for handling and investigating complaints.

Rationale
Product complaints are an important indicator of possible deficiencies in manufacturing controls and/or deficiencies in the distribution handling system. When the complaint handling system itself is deficient, it could result in failure to identify and eliminate risks.

Anticipated Outcomes

- The manufacturer has a system to handle and investigate product complaints which identifies the person or persons responsible for receiving, evaluating, categorizing and/or investigating complaints.
- Complaints are accurately categorized according to safety, composition and other regulatory concerns.
- Potentially serious complaints are forwarded immediately to appropriate personnel for action.
- Safety and contamination complaints are investigated by appropriately trained technical personnel.
- Examination of the complainant's specimen, the retail product or other product of the same code is conducted on complaints related to food safety.
- Complaints pertaining to composition, fraud and other regulatory concerns are investigated in an effective manner.
- The depth of the investigation is appropriate to the risk and similar complaint trends.
- Appropriate corrective action is taken for deviations identified during the investigation.

See Section 7.6.1 for expected Complaint Records.

8.2 RECALLS

8.2.1 Recall Procedure

The sprout manufacturer establishes a written procedure to permit the complete, rapid recall of any lot of sprouts from the market.

Anticipated Outcomes

- A written procedure is in place to enable the recall of any lot of product and provide detailed information to assist in the investigation of any identified produce contamination.
  NOTE: In some instances your firm may be required to recall a product because of the use of a raw ingredient or packaging material which has been determined to be unsafe. By linking raw ingredient lot codes to the finished product code, your firm will be able to identify which of your finished products need to be recalled.
- The written procedure identifies the person or persons responsible (e.g., recall coordinators) and the roles and responsibilities of those who coordinate and implement a recall.
- The procedure specifies methods to identify, locate and control recalled product, and includes a requirement to investigate other products that may be affected by the hazard and should be included in the recall.
- The procedure emphasizes that the recall be monitored to assess its effectiveness (e.g., an "effectiveness check" is conducted to the appropriate level of distribution specified in the recall notice).
- The Canadian Food Inspection Agency is immediately notified in the region where the manufacturer is located. This notification includes the following:
  - the amount of product produced, the amount in inventory and the amount distributed;
  - the name, size, code or lot numbers of the food recalled;
  - the area in which the product was distributed (e.g., local, national, international); and
  - the reason for the recall.

See Section 7.6.2 for expected Distribution Records.

NOTE: For additional information on developing a recall plan, please refer to the following CFIA Web site:
http://www.inspection.gc.ca/english/fssa/recarapp/rap/mgguide.shtml#1.0.

8.2.2 Recall Capability

Recall procedures are tested periodically to verify the manufacturer's capability to rapidly identify and remove product from the market.

Anticipated Outcomes

- The manufacturer demonstrates the capability to provide accurate information on a timely basis, to ensure that all affected product can be rapidly identified and removed from the marketplace. For example
  - the manufacturer conducts periodic testing (internal simulations) to verify the capability of the procedure to rapidly identify and control a code lot of potentially affected product, and to reconcile the amount of product produced with the amount in inventory and the amount in distribution; and

- the manufacturer identifies and corrects any deficiencies in the recall procedure.

GLOSSARY

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

Adverse food reaction - a general term that can be applied to a clinically abnormal response to an exposure to a food or a food component.

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

Allergens - any substance capable of producing an abnormal immune response in sensitive individuals.

Capability - a standardized evaluation of the inherent capability of equipment to consistently perform a specified function under actual operating conditions after significant causes of variation have been eliminated.

Certification - with reference to this document, certification refers to the guarantee a supplier (vendor) provides to a manufacturer that the material meets the manufacturers specifications, e.g., certificate of analysis. This may include periodic monitoring to verify adherence to specifications and audits to validate the status of the supplier certification program.

Change control - the control that a manufacturer maintains over any changes to the formula, ingredients, equipment, packaging, thermal processing and manufacturing process to ensure the safety of the finished product is not directly or indirectly affected.

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.

Control - means that an operation performs consistently within pre-determined limits based on process capability, meets process requirements, provides a mechanism to maintain the stability of the process and consistently results in a safe product.

Corrective action - the actions to be taken when the results of any monitoring indicates a loss of control. In addition, this term refers to any action taken to bring the process into control and to deal with any affected product when critical limits or other criteria are not met. The action should be prompt and appropriate to the seriousness of the deficiency.

Critical Control point (CCP) - a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit - a value which separates acceptability from unacceptability (for a critical control point).

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

Deterioration - for the purposes of this document, deterioration can be used interchangeably with spoilage; however, deterioration can also apply to non-food products such as packaging materials. For non-food items, deterioration is a physical or chemical change in the material that may adversely affect the safety of the food.

Deviation - failure to meet the critical limits for a critical control point or failure to meet the limits of acceptability for factors significant to food safety.

Deviation procedure - a pre-determined and documented set of corrective actions (immediate and preventive) which are implemented when a deviation occurs.

Documents - for the purposes of this document, documents refer to written formulae, procedures or specifications used by or required of a manufacturer.

Equipment that may impact on food safety - equipment that performs a function whose impact on the process is such that a food safety hazard could be prevented, eliminated or reduced to acceptable levels.

Factors significant to food safety - means any property, characteristic, condition, aspect, or other parameter, a variation of which may affect the safety of the product or the process.

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) - the general practices used in the planting, growing, harvesting, sorting, packing, storage and transportation of seeds which will reduce and minimize the risks of biological, chemical and physical contamination.

Hazard - the potential to cause harm. A biological, chemical or physical property that may cause an unacceptable consumer health risk.

Hazard Analysis Critical Control Points (HACCP) - a systematic approach to identifying and assessing hazards and risks associated with a food operation and defining the means of their control.

Inspection areas - (definition with respect to lighting requirements), inspection areas are defined as any point where food products or containers are visually inspected or instruments are monitored.

Limit of acceptability – a value that separates acceptability from unacceptability (for factors significant to food safety).

Lot - means the amount of product of a specific container size, product style and code produced by a food establishment during a specified period of time.

Master formula - the master formula is the official formula referenced by a manufacturer for a given product.

Microorganisms - include yeasts, moulds, bacteria, viruses and parasites. When used as an adjective the term “microbial” is used.

Monitoring - a planned sequence of observations or measurements to assess whether a CCP (or other activity) is under control.

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

Recall (noun) - denotes the process of recalling the affected product and encompasses all tiers of the affected product distribution system.

Recall (verb) - means for a firm to remove from further sale or use, or to correct, a marketed product that contravenes legislation administered and/or enforced by CFIA.

Recall, Periodic testing - internal activities conducted periodically to verify the capability of the manufacturer to rapidly identify and control a given lot of product. These activities do not necessarily require that the manufacturer contact customers.

Records - observations and measurements recorded by a manufacturer to determine adherence to critical limits, limits of acceptability or other specified requirements (for a critical control point or for factors significant to food safety).

Refrigeration - means exposure to a temperature of 4°C or less, but does not mean frozen.

Risk - an estimate of the likelihood of occurrence of a hazard.

Sanitizing - the application of heat or chemical treatments to destroy or substantially reduce the number of microorganisms present 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 practices, on the same land and harvested during the same period).

Spoilage - a process whereby food is rendered unacceptable through microbiological or chemical reaction.

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 antimicrobial treatment 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.

Validation - the obtaining of evidence showing that control measures are capable of being consistently effective. Validation is performed when new control measures or a new food safety control system is designed, or when changes indicate the need for revalidation, in order to confirm that the control measures or food safety control systems, when implemented as intended, are capable of controlling the hazard to the appropriate level and that this level of control can be achieved consistently.

Vendor - for the purpose of this document, vendor is equivalent to supplier.

Verification – examination of the accuracy, correctness or effectiveness of validated processes or process controls through testing, investigation or comparison against a standard.

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APPENDIX A: GUIDANCE ON SAMPLE COLLECTION AND TESTING OF THE SPENT IRRIGATION WATER AND SPROUTS[1]

Microbial testing of spent irrigation water is considered to be one of the most practical and acceptable testing techniques currently available.[2] 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 microbial pathogens of 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 121^0C (250^0F) for 30 minutes in an autoclave, prior to use. Heat-resistant, dry materials may be sterilized in a dry-heat oven at 140^0C (284^0F) 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

[1] Based on Health Canada's Policy Document entitled "Guidance for Industry: Sample Collection and Testing for Sprouts and Spent Irrigation Water," (December 2006).
[2] Based on Health Canada's Policy Document entitled "Policy on Managing Health Risk Associated with the Consumption of Sprouted Seeds and Beans," (December 2006).

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 4^0C (32 to 40^0F). 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 *E. coli* O157:H7). These methods are described in the Health Canada (HC) Compendium of Analytical Methods:
http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index_e.html

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 200 g 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.

APPENDIX B: SEED PRODUCTION – GOOD AGRICULTURAL PRACTICES

Section 3 of the *Code of Practice for the Hygienic Production of Sprouted Seeds*, February 2007, published by the Canadian Food Inspection Agency, outlines several steps in the production of seeds where the application of GAP is aimed at preventing microbial pathogen contamination of seeds.

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 spout 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 (e.g., 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.

APPENDIX C: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SUMMARY

The HACCP Generic Model and the Food Safety Practices Guidance Document were developed by the Canadian Food Inspection Agency (CFIA) in an effort to reduce the health risks posed by the consumption of higher risk foods (e.g. sprouts, RTE fresh-cut vegetables, spices, etc).

HACCP (Hazard Analysis Critical Control Point) is recognized as the most respected food processing concept in the world for enhancing the production of safe food. The HACCP approach involves a review of each step of the food manufacturing process, from start to finish, in order to identify every possible hazard or source of contamination. Hazards can be biological (e.g., pathogens), chemical (e.g., pesticides, allergens) or physical (e.g., extraneous material). For each identified hazard or source of contamination, a reliable control or procedure is put into place to ensure the contamination does not occur or is controlled to an acceptable level.

A HACCP system is built on an establishment's existing food safety program. The standard operating procedures developed and written by the firm can be Good Manufacturing Practices (GMPs) or an adopted food safety code. In many HACCP guideline documents, these GMPs are referred to as "Prerequisite Programs," which represent the foundation of the HACCP Plan. The GMPs must be equivalent to the international Codex Alimentarius General Principles of Food Hygiene to ensure adequate control exists over the environment in which the food processing is taking place.

It is generally recognized that in adopting the HACCP approach, a food processing establishment needs to carry out the following five preliminary tasks:

1. Assemble a HACCP team with the expertise and knowledge to develop the HACCP Plan.
2. Thoroughly describe the product and its intended use (e.g., common name, important product characteristic, shelf life, labelling instructions, etc).
3. List all product ingredients and incoming materials that come in contact with the product or are used in preparing the product.
4. Develop an accurate and detailed Process Flow Diagram (from raw material receiving to finished product shipping) and Plant Schematic/Blue Print showing product and traffic flow.
5. Verify the Process Flow Diagram and Plant Schematic on-site.

After completing the preliminary tasks, the HACCP team develops the HACCP Plan by applying the seven Principles of HACCP to each food category processed.

Principle 1
Conduct a hazard analysis (HA) from the receiving of raw materials to the use of the finished product by the consumer.

Note: Information on food hazards (e.g., biological, chemical and physical hazards) can be obtained from CFIA's *Reference Database for Hazard Identification*, scientific publications, and industry associations.

Principle 2
Apply the HACCP decision tree to determine Critical Control Points (CCPs).

Principle 3
Establish Critical Limits, i.e., criteria that define acceptability and unacceptability of food product.

Principle 4
Establish monitoring procedures to ensure that the critical limits are being met.

Principle 5
Establish deviation procedures when monitoring at a CCP indicates a deviation from an established critical limit.

Principle 6
Establish Procedures for Verification to confirm the company's conformance to the HACCP Plan and to confirm the effectiveness of the HACCP Plan

Principle 7
Establish documentation and records, including the HACCP Plan details, processing records, as well as HACCP related monitoring and verification records.

The HACCP Generic Model, developed following the CFIA's Food Safety Enhancement Program (FSEP) approach, includes all of these 7 principles. It provides information to be used by the firm in developing a plant-specific HACCP plan. The generic model includes an example of a process flow diagram and identifies possible food safety hazards associated with each step in the process. Using the Codex Alimentarius decision tree the generic model determines the points in the process where Good Manufacturing Practices (GMPs) in place at the facility do not control the potential hazard (critical control points). For each of the critical control points in the process, the generic model provides examples of procedures to be implemented in order to ensure that the hazard is controlled (monitoring procedures), procedures to be implemented when monitoring determines that the hazard is no longer controlled and a possible food safety hazard could exist (deviation procedures), and procedures to be implemented to ensure that both the monitoring procedures and the deviation procedures are being followed and are effective in controlling the identified hazards (verification procedures). It is hoped the HACCP Generic Model will provide guidance and information to manufacturers in developing their own HACCP plan. Each processor must create its own process flow diagram according to its specific practices and procedures. As well, hazards and how they are controlled as described in the generic model, will need to be changed where necessary to reflect a processors' unique flow diagram and or product characteristics.

Additional information on developing a HACCP Plan can be found in the FSEP Manual on the CFIA Web site:
http://www.inspection.gc.ca/english/fssa/polstrat/haccp/manue/tablee.shtml

The Food Safety Practices Guidance Document includes a proposed good manufacturing practices (GMPs) guide that could serve as a "prerequisite program." As mentioned above, by implementing GMPs the manufacturer could control many of the hazards identified for each step in the process. The document also includes information on process controls. Both the Generic Model and the Guidance document are intended to be tools for industry's voluntary use in creating a food safety control system.

APPENDIX D: SOIL-GROWN SPROUTS

CFIA's *HACCP Generic Model for Sprouts Grown in Water* and its *Food Safety Practices Guidance for Sprout Manufacturers* document, although specifically focussed on sprouts that are grown in water, should also be useful for processors of soil-grown sprouts interested in developing a HACCP Plan.

Processors of soil-grown sprouts are encouraged to follow the *Code of Practice for the Hygienic Production of Sprouted Seeds* and all other available codes, including the guidance provided in the *Code of Hygienic Practices for Fresh Fruits and Vegetables*, Codex Alimentarius Commission CAC/RCP 53 -2003.
www.codexalimentarius.net/download/standards/10200/cxp_053e.pdf

The following guidance, which comes from the ***Code of Hygienic Practices for Fresh Fruits and Vegetables***, Codex Alimentarius Commission, is appropriate for soil-grown sprouts.

3.2 Primary production of fresh fruits and vegetables

3.2.1 Agricultural inputs (any incoming materials used for the primary production of fresh fruits and vegetables) should not contain microbial or chemical contaminants at levels that may adversely affect the safety of fresh fruits and vegetables.

Subsection 3.2.1 includes water for irrigation, harvesting, fertilizers, pest control and other agricultural chemicals, hydroponic water; manure, biosolids and other natural fertilizers; soil; agricultural chemicals; and biological controls.

3.2.1.3 Soil
Soil should be evaluated for hazards. If the evaluation concludes that such hazards are at levels that may compromise the safety of crops, control measures should be implemented to reduce the hazards to acceptable levels. If this cannot be achieved by available control measures, growers should not use soils for primary production.

3.2.2 Indoor facilities associated with growing and harvesting
For operations where fresh fruits and vegetables are grown indoors (greenhouses, hydroponic culture, etc.) suitable premises should be used.

3.2.2.1 Location, design and layout
Premises and structures should be located, designed and constructed to avoid contaminating fresh fruits and vegetables and harbouring pests such as insects, rodents and birds.
Where appropriate, internal design and layout should permit compliance with good hygienic practices for the primary production of fresh fruits and vegetables indoors, including protection against cross-contamination between and during operations. Each

establishment should be evaluated individually in order to identify specific hygienic requirements for each product.

"**Annex For Sprout Production**"

The ***Code of Hygienic Practices for Fresh Fruits and Vegetables*** contains an Annex that provides additional specific guidance for sprout production. With respect to soil-grown sprouts, Section 5 - Control of Operation (Subsection 5.2.2.6) states as follows: Where necessary and when used, soils or other matrices should be treated (e.g., pasteurized to achieve a high degree of microbial reduction.).