Appendix B

QUESTIONS TO ASK WHEN CONDUCTING A HAZARD ANALYSIS

For each of the following 12 sections listed below, there are a useful questions that will help identify hazards connected with incoming materials and process steps at a facility.

- 1.0 INGREDIENTS
- 2.0 INTRINSIC FACTORS
- 3.0 FOOD PROCESSING STEPS
- 4.0 MICROBIOLOGICAL PROFILE OF INGREDIENTS OR FOOD
- 5.0 FACILITY DESIGN
- 6.0 EQUIPMENT
- 7.0 PACKAGING
- 8.0 SANITATION
- 9.0 WORKER HEALTH, HYGIENE AND TRAINING
- 10.0 CONDITIONS OF STORAGE (FROM PACKAGING THROUGH TO THE END USER)
- **11.0 INTENDED CONSUMER USE**
- **12.0 INTENDED CONSUMER**

1.0 INGREDIENTS

- 1. Does the food or ingredient contain any:
 - a. Microbiological hazards (e.g. Salmonella, Staphylococcus aureus);
 - b. Chemical hazards
 (e.g. aflatoxin, antibiotic or pesticide residues); or
 - c. Physical hazards (e.g. stones, glass, metal)?
- 2. Are ice and steam used in formulating or in handling the food?
 - a. Is it made from potable water (water fit for human consumption)?
- 3. Does the geographical region or the supplier play a role in the hazards associated with the ingredients?

2.0 INTRINSIC FACTORS

Intrinsic factors are any chemical or physical characteristics that affect the microbial or chemical stability of the food, either during or after processing. These physical or chemical characteristics prevent the growth of bacteria to high levels. They also suppress toxin production.

Intrinsic factors can include:

- Acidity;
- Types of acidifying agents;
- Salt concentration;
- Carbohydrate type and concentration;
- Water activity (available free water); and
- Types of preservatives used.
- 1. What hazards could result if the chemical or physical requirements of the food are not met?
- 2. During processing or before the finished-product state, is there a likelihood of microbial growth that might contribute to the presence of toxins, or high levels of bacteria, resulting in unsafe food?

- 3. Does the finished product support the survival or growth of pathogens or toxin production in last stages of food handling, storage or consumption?
- 4. Can you compare your product to one that is already on the market? What hazards are associated with the existing product?

3.0 FOOD PROCESSING STEPS

- Is there one step that is effective in killing pathogens? Does this step destroy vegetative and spore forms of the pathogen?
 If so, this will be the critical control point for biological hazards.
- Is recontamination likely (usually through packaging or product handling) once the product is dealt with by the critical process? If so, what hazards (biological, chemical or physical) could result in recontamination of the product?

4.0 MICROBIOLOGICAL PROFILE OF INGREDIENTS OR FOOD

- 1. What are the usual associated pathogens or spoilage bacteria in the ingredient/food?
- 2. What is the likelihood of a pathogen being present in the ingredient/food before and during processing?
- 3. What is the severity of the pathogen presence in the ingredient/ food before and during processing?
- 4. How does the ingredient/food's microbial profile change over time? How does it change:
 - Before consumption?
 - During normal shelf life?
 - During other conditions?

- 5. Is there a hazard from a change in the food's microbial profile over its normal storage? Could this affect the safety of the ingredient/food?
- 6. What is the likelihood of a pathogen being present in the food when it's consumed?
- 7. What is the severity of pathogen presence in the food when it is consumed?

5.0 FACILITY DESIGN

- 1. Are there concerns associated with facility layout with possible contact between raw materials and the finished products (e.g. cross-contamination)?
- 2. Are employee flow or equipment location possible sources of recontamination?
- 3. If producing ready-to-eat (RTE) foods, is there a risk of cross-contamination?
- 4. Is there a possibility of recontamination with pathogens? By what pathogens?
- 5. What hazards should be considered as possible contaminants of finished products?
- 6. In areas where finished product is handled, is positive air pressure needed for product safety?

6.0 EQUIPMENT

- 1. Is the equipment designed to deliver the necessary treatment (e.g. time and temperature) in order to produce safe food?
- 2. Is the equipment designed for the volume of food that is being processed?

- 3. Does the equipment operate without breakdowns? If it does breakdown, do alarms alert the operator?
- 4. Does the installation of the equipment allow for sanitation and ease of maintenance?
- 5. Does the design of the equipment allow for easy cleaning and sanitizing?
- 6. How likely is contamination from the equipment? Is there a chance of physical hazards (e.g. metal fragments, shavings), and/or chemical hazards (e.g. oils and lubricants)?
- 7. Does the use of the following pieces of equipment reduce the likelihood and severity of biological, chemical or physical hazards in food?
 - a. Metal detectors
 - What are the metal hazards associated with the ingredients and the processing facility (ferrous, non-ferrous, stainless steel)?
 - Is the metal detector designed and calibrated for the product characteristics?
 - b. Magnets
 - Is the magnet design effective for the process parameters?
 - c. Sifters
 - Is the sifter regularly maintained?
 - Is it the appropriate opening size?
 - d. Filters
 - Is the filter design effective for the process/product? Is it working well?
 - Are the filters regularly maintained?

- e. Screens
 - Are screens regularly maintained?
 - Is it the appropriate opening size?
- f. Thermometers
 - Is the thermometer designed to be used for the process parameters?
 - Is it calibrated?
- g. Bone removal devices
 - Is the bone detector designed for the process parameters?
- 8. Does normal equipment wear-and-tear contribute to the increased likelihood and severity of a physical hazard in the finished product?
- 9. Does equipment design allow for safe production of allergen and non-allergen containing ingredients? Also, does it allow for easy and effective cleaning and sanitizing? If not, what controls are needed to control these chemical hazards?

7.0 PACKAGING

- 1. Does the packaging affect the growth of bacteria and/or toxin formation?
- 2. Does the package include instructions on how to maintain product safety?
- 3. Are there clear and important instructions for the consumer to follow to ensure safe food preparation?
- 4. Is the packaging material resistant to damage? Or is it protective enough to minimize any packaging damage that might allow microbial contamination or possibly microbial growth?
- 5. Are there features to clearly indicate, or prevent, product tampering?
- 6. Is each package clearly labeled to allow for product tracking or recall?

- 7. What is the likelihood that a product will not be labeled with ALL necessary information? As a result of this, could it allow an allergenic product to get to consumers (without their knowledge of the allergen)?
- 8. Is the label correct for the actual packaged product? Does the label clearly identify the presence of allergens and ingredients?

8.0 SANITATION

- 1. Can sanitation procedures affect the safety of the food?
- 2. Are the facility and equipment designed for easy cleaning and sanitization?
- 3. Can the sanitation program be delivered effectively? Can it react to situations where ongoing sanitation is needed?

9.0 WORKER HEALTH, HYGIENE AND TRAINING

- 1. Can employee health or personal hygiene practices impact the safety of the food being processed?
- 2. Do employees understand the process and the factors they must control to ensure preparation of safe foods?
- 3. Will the employees tell management about any problem that could impact food safety?

10.0 CONDITIONS OF STORAGE - FROM PACKAGING THROUGH TO THE END USER

- 1. What is the likelihood that the food will be temperature abused during transport and storage (exposed to temperatures above the desired temperature)? What is the likelihood of this leading to unsafe food? What is the severity of this hazard?
- 2. What is the likelihood that the food will be exposed to hazards (biological, chemical and/or physical) during transport or storage? And will this contribute to contamination?

11.0 INTENDED CONSUMER USE

- 1. What is the likelihood that the consumer will not heat the product enough if heating is required? What are the risks of such an action, or lack of action?
- 2. What are the risks if the product is consumed past its listed shelf life?
- 3. If leftovers result, what is the likelihood that the product will become unsafe? How severe are the consequences of this?

12.0 INTENDED CONSUMER

- 1. What consumer is the food intended for? Is it intended for:
 - a. General public (healthy population);
 - b. Infants;
 - c. Children;
 - d. Elderly; and/or
 - e. Immuno-compromised individuals?
- 2. What is the likelihood that the food intended for the general public is consumed by someone more inclined to illness (infants, immuno-compromised, the elderly)?

- 3. Where will the food be prepared for consumption?
 - a. Consumer's home;
 - b. Food service;
 - c. Restaurant; or
 - d. Institution (e.g. hospital)?