CODEX ALIMENTARIUS
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CODE OF HYGIENIC PRACTICE FOR LOW-MOISTURE FOODS

CXC 75-2015

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1. INTRODUCTION

There are many different types of products that fall under the grouping of low-moisture foods. Since 2001, there have been a number of outbreaks associated with the consumption of low-moisture foods, which has raised concerns regarding the safety of these products. The primary pathogens of concern that are associated with low-moisture foods to date, include *Salmonella* spp. and *Bacillus cereus.* However, most outbreak-related illnesses associated with low-moisture foods have been caused by *Salmonella* spp. and, for this reason, the Code of Hygienic Practice focuses on controls for *Salmonella* spp.

The water activity (a_w) of low-moisture foods is often well below 0.85 and foodborne pathogens such as *Salmonella* cannot multiply under these conditions. Even though pathogen growth is prevented in these products, the cells can remain viable for extended periods of time. For *Salmonella* spp., the infectious dose is thought to be very low, as demonstrated by the small numbers of cells per serving recovered from low-moisture foods implicated in outbreaks. Furthermore, there is evidence that the composition of a food (especially, high fat content) may protect *Salmonella* against the acidic conditions of the stomach, potentially increasing the likelihood of illness from consuming low numbers of the organism. Pathogens such as *Salmonella* can be difficult to control in a low-moisture food operation environment, because they can persist for prolonged periods of time in the dry state and in low-moisture products. Microorganisms are more heat tolerant in food matrices at reduced water activity.

Investigations from *Salmonella* outbreaks indicate that the safety of low-moisture foods depends fundamentally on the control of *Salmonella* in the food operation environment. Maintaining good hygienic practices, hygienic design of equipment, proactive maintenance programmes, control of incoming materials, and effective ingredient control in the low-moisture food establishment, will help prevent the contamination of low-moisture foods with pathogens. Special attention should be paid to those products that are exposed to the processing environment following a pathogen reduction step, products that are not subjected to a pathogen reduction step, and products for which ingredients are added after a pathogen reduction step.

SECTION I - OBJECTIVES

This Code addresses Good Manufacturing Practices (GMPs) and Good Hygienic Practices (GHPs) that will help control microbial hazards associated with all stages of the manufacturing of low-moisture foods. Particular attention is given to minimize *Salmonella* spp., which is currently considered the primary pathogen of concern in these products. These GMPs and GHPs, if adhered to, should also be effective in preventing the risk from other pathogens that may be of concern.

SECTION II - SCOPE, USE AND DEFINITIONS

2.1 Scope

This Code covers GMPs/GHPs for the manufacturing of low-moisture foods for human consumption. This Code applies to, dried fruits and vegetables (e.g. desiccated coconut), cereal-based products (e.g. breakfast cereals), peanut and other nut butters, dry protein products[1] (e.g. dried dairy products and soy protein), confections (e.g. chocolate and cocoa), snacks (e.g. spice-seasoned chips/crisps), tree nuts, seeds for consumption (e.g. sesame seeds and sesame seed paste), spices and dried culinary herbs, and specialized lipid based nutritional products[2] for the treatment of moderate and severely acute malnutrition[3]. Milled grain products such as flour may be within the scope when used in foods that would not be subject to a microbial inactivation step.

2.2 Use

This Code follows the format of the *General Principles of Food Hygiene* (CXC 1-1969) and should be used in conjunction with it, as well as with other applicable codes such as the *Code of Hygienic Practice for Dried Fruits* (CXC 3-1969), *Code of Hygienic Practice for Desiccated Coconut* (CXC 4-1971), *Code of Hygienic Practice for Dehydrated Fruits and Vegetables including Edible Fungi* (CXC 5-1971), *Code of Hygienic Practice for Tree Nuts* (CXC 6-1972), and *Code of Hygienic Practice for Groundnuts (Peanuts)* (CXC 22-1979). When designing and implementing food safety control systems for products according to the provisions of commodity specific Codes of Hygienic Practices (e.g. *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004)) the recommended practices and measures of this Code should be taken into consideration.

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[1] Report of an FAO/WHO Consultation Process: Ranking of Low Moisture Foods in Support of Microbiological Risk Management (to be published).

[2] Specialized lipid based nutritional products can be categorized as ready-to-use supplementary foods (RUSF) for the treatment of moderate acute malnutrition and ready-to-use therapeutic foods (RUTF) for the treatment of severely acute malnutrition.

[3] Although the provisions of this Code could be applied in the production of powdered infant formula, this product is excluded from the scope, given the specific vulnerable group of consumers. These products are currently appropriately addressed in the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008).

The provisions in this document should be applied as appropriate, with consideration of the diversity of ingredients, processes, and control measures of the products and various degrees of risk involved in producing low-moisture foods.

2.3 Definitions

Refer to definitions in the *General Principles of Food Hygiene* and other applicable codes (see section 2.2 of this code for the list of additional applicable codes). In addition, the following terms have the meaning stated:

Controlled wet cleaning – the removal of soil, including food residues, dirt, grease or other objectionable matter using a limited amount of water and detergents and controlling the spread of the water used.

Dry cleaning – the removal of soil, including food residues, dirt, grease or other objectionable matter by actions such as wiping, sweeping, brushing, scraping, or vacuuming the residues without the use of water and detergents.

Harbourage site – a site in the environment or on equipment (e.g. cracks, holes, junctions) that enables the accumulation of residues (e.g. food debris, dust, and water) potentially permitting the growth and/or survival of microorganisms such as *Salmonella*.

Low-moisture foods – foods that have a water activity (a_w) of 0.85 or below.

Wet cleaning – the removal of soil, including food residues, dirt, grease or other objectionable matter using water and detergents.

SECTION III - PRIMARY PRODUCTION

Raw materials and ingredients used to manufacture low-moisture foods vary substantially. They are produced under different conditions and using various production methods and technologies. Therefore, microbial hazards vary significantly from one type of product to another and detailed discussions of the primary production methods of each raw material and ingredient is beyond the scope of this document. In each primary production area, it is necessary to consider practices that promote the production of safe food. Refer to the *General Principles of Food Hygiene* and other applicable codes.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

Refer to the *General Principles of Food Hygiene*.

4.2 Premises and rooms

Refer to the *General Principles of Food Hygiene*.

4.2.1 *Design and layout*

Proper hygienic design, zoning and layout of premises and rooms are essential to ensure that entry of pathogens into the establishment is controlled (e.g. minimizing the potential for entry and, in the case of entry, preventing the pathogen from becoming established in the environment). For example, if a pathogen such as *Salmonella* is introduced into the establishment, proper design and layout can prevent the transfer to areas where processed products are exposed to the environment prior to packaging. In establishments processing and packing low-moisture foods, dry processing areas should be designed to exclude moisture from the environment to the extent possible, in order to prevent growth and minimize the likelihood of a pathogen becoming established in the environment.

Raw material handling, pre-processing and other areas (e.g. maintenance areas, waste areas, and toilet facilities) should be separated from post-processing handling areas. Additionally, physical separation within the low-moisture food establishment based on specific hygiene requirements will help minimize pathogen transfer from one area to another. Where an establishment uses a pathogen reduction step, the area following that step should be physically separated from other parts of the operation in order to implement different hygiene measures based on the type of production and the risk for pathogen introduction. In some establishments the design may include a transitional area in order to enhance hygiene measures prior to the area with the most stringent hygiene measures. This last approach should be considered for food intended specifically for consumers more susceptible to illness from foodborne pathogens, to facilitate the implementation of enhanced controls.

Separation of one hygiene area from another and the control of dust can be achieved using physical barriers, such as walls, doors, split conveyers, etc. Alternatively, separation of areas and control of dust can also be achieved by the appropriate design of ventilation systems and airflow.

Limiting the introduction and use of water is one of the primary means to control pathogens in low-moisture food establishments. In the low-moisture food establishment, there may be areas that only require dry cleaning and other areas where water is appropriately used. It is important that the layout and the hygienic design of the establishment ensure that areas intended for dry cleaning remain in a dry state and receive only dry cleaning and disinfection. If these sites are intended to be wet cleaned even occasionally, then the hygienic design should accommodate water while preventing the establishment of microbial harbourage sites. To limit the introduction of water in the processing areas requiring stringent hygiene controls, hand washing and footbath (if used) stations should be located outside, at the entrance of this area, and, to the extent possible, water distribution systems (e.g. piping) should be located outside the high hygiene area. Additionally, the infrastructure (e.g. ventilation, physical structure) should be designed to prevent entry of unwanted water from the surrounding processing area, as a result of processing activities or from cleaning and disinfecting activities or from outside the establishment.

4.2.2 *Internal structures and fittings*

Overhead structures should be designed to minimize the accumulation of dust and dry materials, especially when they are directly above exposed products.

Internal structures and fittings should be designed to eliminate cavities that could serve as microbial harbourage sites.

In operations where condensate may form or where humidity is high, adequate control measures, such as drip pans or a ventilation system to remove environment humidity, should be in place to prevent condensate from contaminating products or creating conditions that allow the proliferation of pathogens such as *Salmonella* within the production environment.

Entry and exit doors from basic (general) hygiene areas to areas of more stringent hygiene control should be tightly fitted and, if necessary, equipped with self-closing devices.

4.3 Equipment

Refer to the *General Principles of Food Hygiene*.

4.3.1 *General*

Proper hygienic equipment design is essential to prevent contamination of the product with a pathogen from the processing environment and to ensure that if a pathogen such as *Salmonella* is introduced, it remains transient and does not become established in areas of the equipment that could serve as a source of product contamination. Equipment should be designed to facilitate cleaning with little or no water and, when controlled wet cleaning is required, to allow thorough drying before reusing the equipment for low-moisture foods. Alternatively, equipment should be designed for easy disassembly such that parts can be removed from the stringent hygiene area for wet cleaning in a separate location outside the area. The equipment design should be as simple as possible with a minimum number of parts, and to the extent possible, all parts should be accessible for inspection and cleaning. If water is required for washing, the equipment should be designed to accommodate water and should ensure rapid and complete drying to prevent microbial growth and the establishment of microbial harbourage sites. Furthermore, the equipment design should minimize the build-up of food residues and the creation of microbial harbourage sites. Particular attention should be given to the design of equipment located in areas that require the most stringent hygiene controls.

A written document should be developed for equipment acceptance, as well as for cleaning, disinfecting and drying of equipment prior to allowing entry into the processing area. This is particularly important for used equipment, which may have been contaminated during its prior use.

In order to minimize the potential for harbourage sites, hollow areas of equipment should be eliminated whenever possible or permanently sealed.

Push buttons, valve handles, switches and touch screens should be designed to ensure product and other residues (including liquid) do not penetrate or accumulate and become a harbourage site.

4.4 Facilities

Refer to the *General Principles of Food Hygiene*.

The integrity of the facilities should be inspected on a regular basis for problems such as the presence of bird nests or roosting sites, roof leaks, etc. Problems should be corrected as soon as they are detected to ensure a sound structure of the facility.

4.4.2 *Drainage and waste disposal*

Since limiting water is one of the primary means to control pathogens such as *Salmonella* in a low-moisture food establishment, the areas requiring stringent hygiene controls should ideally not have drains. However, if drains are present, the floors should be properly sloped for effective drainage and to allow for rapid drying and kept dry under normal conditions. The drains should be designed to prevent backflow, especially if drains are connected to areas with less stringent hygiene requirements. Additionally, when drains are present, these should be sealed during dry processing operations. When water is used in other areas such as the basic hygiene area, water drainage must ensure rapid drying.

4.4.3 *Cleaning*

Areas where low-moisture foods are handled and manufactured should be designed and constructed in such way as to facilitate dry cleaning and the avoidance of water. Non-fixed equipment should be cleaned outside of the area needing more stringent hygiene control.

4.4.6 *Air quality and ventilation*

Exhaust vents should be inspected to ensure they are hygienically designed, so as to prevent condensate formation and accumulation around the vent exit and to prevent water dripping back into the facility. It should be ensured that exhaust ducts are of sanitary design, are cleanable, and that reverse air flow does not occur.

Where necessary, prevention of the ingress of dust, as well as the movement of dust from one area to another, should be prevented or minimized using air filters and by maintaining a positive air pressure in the areas requiring more stringent hygiene control relative to other areas in the establishment. The type of filters installed in the air handling units may vary from simple dust filters to high efficiency filters, depending on the product and the intended use and consumer. Filters should be inspected and maintained to prevent them from becoming harbourage sites for pathogens.

Attention should be given to the location of the air intake for the establishment in relation to sources of contamination e.g. if the air intake is too close to the surface of the roof, contaminants from bird faeces can be drawn into the operation. Air filters should be considered for use on air intakes.

Where air is used in the facility, in the equipment or in processing lines for specific purposes such as for cooling or transportation of products, direct contact with the product is possible and the air should be dried and filtered to exclude microorganisms and moisture, where appropriate.

SECTION V - CONTROL OF OPERATION

5.1 Control of food hazards

Refer to the *General Principles of Food Hygiene*.

Different hygiene requirements should be implemented based on the degree of hygiene control required in the different areas, or zones, such as the pre-processing raw material handling area and the post-processing and finished product handling area. More stringent hygiene controls should be applied in areas where products that have received a pathogen reduction treatment or that are in their final ready-to-eat state are exposed to the environment of the facilities**.**

Since food particles and dust are normally expected to be present in some processing areas, adequate nutrients are always available to microorganisms. However, microbial growth cannot occur if the low-moisture food establishment is maintained in a dry state. Processing and packing areas for low-moisture foods are typically at ambient temperature. This facilitates maintaining dry conditions, but if moisture is present, growth of microorganisms can occur rapidly. Control measures should be in place to minimize the use of water in the entire low-moisture food establishment. During operation, dry conditions should be maintained in processing areas requiring the most stringent hygienic controls, e.g. after the product has received a pathogen reduction treatment. Some low-moisture food establishments use processing steps that involve the addition of moisture, e.g. blanching almonds in a hot water bath to remove the skin, steam treatments for pathogen reduction. Where water is used, measures should be taken to ensure that it does not enter the dry processing areas of the establishment. Conditions leading to the formation of condensate should be eliminated or minimized to the greatest extent possible. Problems may arise not only when water is visible, but also once an area that has become wet has dried. *Salmonella* is tolerant to drying and can be found in spots where standing water has dried out.

Uncontrolled moisture (e.g. leaking roofs, leaking pipes, condensate, improper cleaning) is a major contributor to the presence of pathogens in low-moisture foods because it provides the moisture necessary for multiplication of the pathogen in ambient temperature rooms. This increases the likelihood of product contamination of multiple lots of product over time. In the case of an unusual event in a low-moisture production area, such as a roof leak, a faulty sprinkler, leaking water or steam valves or a drain backup that introduces water in the processing area of the establishment, efforts should be made to remove water immediately from the dry areas, in order to keep the plant environment as dry as possible. A thorough review and assessment of the situation should be made, evaluating the need for increased sampling and testing of product and the environment and appropriate corrective actions. The continuation of production should be assessed with regard to any negative impact on product safety, in which case, production should be stopped. With respect to a roof or other water leak, the leak should be fixed and the affected area cleaned, disinfected and completely dried and clean dry conditions verified through visual inspection. If any product is affected at the time of the event, it should be disposed of appropriately. This could include reconditioning. Environmental samples should be taken to verify the effectiveness of the cleaning and disinfection in the area unintentionally contaminated with water.

5.2 Key aspects of hygiene control systems

Refer to the *General Principles of Food Hygiene*.

5.2.2 *Specific process steps*

Whenever feasible, low-moisture foods or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. The degree of heat resistance may also vary based on specific ingredients. For additional information on validation, refer to the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008). Additionally, refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).

Commonly used microbial reduction treatments for low-moisture foods or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. irradiation, antimicrobial fumigation) control measures. Where foods are irradiated, refer to the *Code of Practice for Radiation Processing of Food* (CXC 19-1979) and the *General Standard for Irradiated Foods* (CXS 106-1983).

The need for microbial challenge studies to support the validation should be determined. The following should be considered when choosing and validating a pathogen reduction step (control measure) for low-moisture foods and their raw materials:

- The necessary target level of pathogen reduction should be determined considering the expected level of the target pathogen in the food prior to the microbial reduction treatment.
- The control measure (thermal or non-thermal) should be validated appropriately for the type of low-moisture food and be capable of achieving the necessary target level of pathogen reduction at the operational scale of the in-plant process.
- If microbial challenge studies are needed, appropriate strains of microorganisms (pathogen or surrogate) should be identified. For laboratory studies, a pathogen such as *Salmonella* should be used, but an appropriate surrogate would be necessary for in-plant validation studies. A surrogate organism should be selected based on data specific to the low-moisture food of interest that demonstrate resistance traits equivalent to the pathogen of concern when exposed to the control measure of interest.
- The associated critical limits for the in-plant process to meet its assigned target level of pathogen reduction should be determined.

Once the necessary pathogen reduction step of the in-plant process has been appropriately validated, suitable monitoring and verification activities should be conducted by the establishment to demonstrate that the process continues to meet the critical limits during operation. When monitoring of control measures or verification results demonstrate deviations, appropriate corrective actions should be taken.

5.2.3 *Microbiological and other specifications*

Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21- 1997).

In view of the limited information end-product testing provides in terms of the effectiveness of the hygiene control measures, an environmental monitoring program should be considered to verify effectiveness of the sanitation control measures in the low-moisture food establishment.

If there is reason to suspect a product may have been contaminated (e.g. a leaking roof over an area where dry product is exposed to the environment), a thorough review and assessment of the situation should be made evaluating the need for increased sampling and testing of product and the environment and appropriate corrective actions, including, where necessary, processing of product using a validated control measure. The finished product should not be released until adequate investigation has shown that it complies with appropriate specifications.

5.2.4 *Microbiological cross-contamination*

The most stringent hygienic practices should be in place following a pathogen reduction step to prevent recontamination during subsequent manufacturing and packaging.

The traffic (e.g. movement of personnel and materials) between one hygiene area and another should be controlled to minimize the potential for pathogen contamination. The following should be considered for an area requiring a higher degree of hygienic control:

- Traffic into the area should be minimized and strictly controlled.
- Personnel should follow established hygiene procedures prior to entering the area, e.g. changing or covering shoes, washing and drying hands.
- Dedicated workers and equipment, including utensils and cleaning tools, should be assigned to this area.
- Ingredients that are mixed into a finished product without a subsequent pathogen reduction step should comply with section 5.3.
- Air should flow from the areas requiring most stringent hygiene to those with more basic hygiene, where appropriate.

5.3 Incoming material requirements

Refer to the *General Principles of Food Hygiene*.

A supplier approval and verification program should be developed for sensitive ingredients. Sensitive ingredients are ingredients that have tested positive for pathogens, such as *Salmonella,* in the past or have been implicated in past outbreaks or are used to make products that are intended for consumers more susceptible to illness from foodborne pathogens. The supplier approval and verification program should be developed to assess the adequacy of control measures implemented for pathogens such as *Salmonella*. The supplier's food safety program should be evaluated and audited with respect to the recommendations outlined in this document before approval. Periodic raw material and/or ingredient testing should be conducted upon receipt to verify supplier control. For sensitive ingredients that will be added to the finished product without a further pathogen reduction step, the most stringent controls may be necessary.

Additionally, within the low-moisture food establishment, sensitive ingredients should be held under adequate hygiene conditions to avoid recontamination. Where feasible, sensitive ingredients should be stored in a segregated area. Where required, certain sensitive ingredients should be stored under controlled temperature and moisture conditions. Before sensitive ingredients are brought into an area that requires a high degree of hygiene control, procedures should be in place to minimize cross-contamination from packaging materials or containers used to transport the ingredients, from handling or from other sources of contamination.

5.4 Packaging

Refer to the *General Principles of Food Hygiene*.

5.5 Water

Refer to the *General Principles of Food Hygiene*.

5.5.4 *In temperature-controlled equipment*

Preventive maintenance should be in place to identify and correct microfractures in jacketed temperature-controlled equipment such as holding or mixing tanks that are double-walled and filled with water to control temperature in the processing of chocolate, peanut butter, etc. Nevertheless, potable water should be used for jacketed temperature-controlled equipment, to prevent contamination of product being held or processed in the equipment in the event of microfractures in the equipment that could allow traces of contaminated water to leak inside.

5.6 Management and supervision

Refer to the *General Principles of Food Hygiene*.

Managers and supervisors should have knowledge of the primary pathogen of concern (e.g. *Salmonella*) in their low-moisture food, as well as an understanding of the procedures necessary for control of this pathogen. Managers and supervisors should also have an understanding of the procedures to follow when environmental or finished product sampling results are non-compliant.

5.7 Documentation and records

Refer to the *General* Principles *of Food Hygiene*.

5.8 Recall procedures

Refer to the *General Principles of Food Hygiene*.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 Maintenance and cleaning

Refer to the *General Principles of Food Hygiene*.

6.1.1 *General*

Processing of low-moisture foods will result in dust accumulation on conveyors, walls, equipment and other surfaces. Product accumulation (e.g. on walls, ceilings, conveyor belts, lids and walls of batch tanks or mixing tanks, the bottom of a bucket elevator), which may become a source of contamination, should be removed in a timely manner. This is particularly important for products that have the ability to attract and hold water, or products that are in an environment of high humidity leading to moisture absorption and localized condensation.

When construction in the low-moisture food establishment is done as part of maintenance activities, control measures should be in place to prevent potential release of pathogens, such as *Salmonella*, from hidden harbourage sites. The following should be considered during construction activities:

- The construction area should be isolated from the processing area.
- Dust should be prevented, minimized, or effectively captured and controlled.
- Traffic patterns into and out of the construction area should be controlled.
- Negative air pressure should be maintained in the construction area.
- Cleaning procedures in the processing areas should be intensified to minimize the spread of dust or contaminants from the construction zone.
- Care should be taken when wet cleaning within the construction area to ensure that water does not create conditions that allow the proliferation of pathogens such as *Salmonella* within the production environment.

Similar procedures may be necessary during other maintenance activities such as dismantling or re-positioning of equipment.

6.1.2 *Cleaning procedures and methods*

There are three types of cleaning methods in a low-moisture food establishment: dry cleaning, controlled wet cleaning, and wet cleaning. The type of cleaning practices to be used in different hygiene areas should be specified. Dry cleaning should be used as the routine cleaning practice for the area that requires the most stringent hygiene control (e.g. after any pathogen reduction treatment or a product with no pathogen reduction treatment). In the area requiring the most stringent hygiene controls, there may be circumstances where controlled wet cleaning will need to be used (e.g. in response to a situation in which environmental or product contamination has been established). In those cases, documented procedures should be in place. Wet cleaning should only be used in non-critical, non-process areas of the establishment (e.g. maintenance areas, waste areas and toilet facilities).

6.1.2.1 *Dry cleaning and disinfection*

The objective of dry cleaning is to remove product residues without the use of water by using tools or cleaning aids that do not involve the application of water or other aqueous solutions. Where appropriate, dry abrasives can be an effective method of removing persistent product residues on equipment or surfaces without introducing water. Hot food grade oil is sometimes used to flush the interior of equipment used to handle pumpable low-moisture products such as peanut butter or chocolate. However, research has shown that hot oil may not be completely effective in removing *Salmonella* from contaminated processing equipment.

The following should be considered when establishing appropriate dry cleaning procedures:

- Designated trained personnel should be responsible for dry cleaning procedures.
- Dry cleaning tools should be cleanable, durable, without loose parts, designed for the purpose and dedicated for the area.
- A designated area should be provided to store cleaning tools not in use.
- Compressed air can be used for dry cleaning in special situations (e.g. to dislodge dust from inaccessible points), but when compressed air is used, it should be dried and filtered to exclude microorganisms and moisture prior to use.
- Separate tools should be provided for the dry cleaning of floors. Tools and vacuums that are used for cleaning food contact surfaces should not be used to clean non-food contact surfaces. Well-designed portable vacuum cleaners or similar tools are recommended to remove residues.
- If possible, vacuum cleaners should be dedicated to specific areas, so that vacuumed material can be tested as part of an environmental monitoring program.
- Dry cleaning tools (e.g. brooms, dry cloth) as well as vacuum cleaners should be well maintained so they do not become carriers of contamination. Vacuum cleaners should be cleaned and disinfected in a designated area, so as not to become a source of contamination.
- Where filters are part of dry cleaning tools, they should be properly maintained on a regular basis and replaced when necessary.
- Alcohol-based disinfectants provide a means to disinfect equipment with a very minimal introduction of water, but water should be avoided as much as possible.
- Cleaning and disinfection programs should be monitored for their effectiveness and verified by visual observations and, where applicable, environmental monitoring.

6.1.2.2 *Controlled wet cleaning*

The following should be considered when establishing appropriate controlled wet cleaning procedures:

- As much product residue as possible should be removed by dry cleaning.
- Only the minimum amount of water needed should be used.
- Procedures should be in place to collect water to prevent water spreading on the floor or to other non-wet cleaned areas.
- Water aerosols should be avoided and high pressure water application should not be used.
- When possible, parts of equipment should be removed and wet cleaning conducted in a room dedicated to cleaning.
- Equipment and areas should be disinfected following the controlled wet cleaning.
- Complete drying of all areas and components involved (e.g. equipment parts, floor) should be done after controlled wet cleaning.
- Controlled wet cleaning should be monitored and verified by visual observation that the area is dry and by environmental monitoring.
- If necessary, production should be stopped while controlled wet cleaning is taking place and only restarted once the area is dry.

6.1.2.3 *Wet cleaning*

The following should be considered when wet cleaning is used:

- The amount of water should be minimized and its use should be limited to specific areas where possible.
- Excessive use of water and high pressure hoses should be avoided.
- Care should be taken to prevent tracking water into areas intended to remain dry.
- Complete drying of all areas should be done after wet cleaning.

6.2 Cleaning programmes

Refer to the *General Principles of Food Hygiene*.

In some establishments, where there is a potential for the presence of cracks or other harbourage sites that may be difficult to eliminate even with regular maintenance, using a dry cleaning method is particularly important. By keeping the sites dry (i.e. using the dry cleaning method), even if food residues or dust enter such a site, potential problems can be minimized. Once water enters a harbourage site, microbial growth can occur and the potential risk of contamination of the environment and of the product is increased.

6.3 Pest control systems

Refer to the *General Principles of Food Hygiene*.

6.4 Waste management

Refer to the *General Principles of Food Hygiene*.

6.5 Monitoring effectiveness

Refer to the *General Principles of Food Hygiene*.

Establishments should put in place an environmental monitoring program for products with known risk for pathogens such as *Salmonella* (e.g. nuts and nut products, dry protein products). Sampling and testing of the environment, including swabs and samples of dust and product residue, is a critical activity to verify the effectiveness of pathogen control measures within the establishment. The main target organism for environmental monitoring should be *Salmonella*. However, it may be advantageous to also include Enterobacteriaceae (EB) as an indicator of process hygiene. The presence of high levels of EB is a good indication of conditions that may support the presence and potential for growth of *Salmonella*. However, testing for EB alone is not sufficient, since even low levels of EB do not guarantee the absence of *Salmonella*.

When pathogens such as *Salmonella* or process hygiene indicator microorganisms such as EB are detected in the environment of the establishment and their levels exceed “decision criteria” as established by the food business operator, appropriate measures should be taken to investigate the source of contamination and to eliminate or control the microorganisms in the environment.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

Refer to the *General Principles of Food Hygiene*.

SECTION VIII - TRANSPORTATION

Refer to the *General Principles of Food Hygiene*.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the *General Principles of* Food Hygiene.

SECTION X - TRAINING

10.1 Awareness and responsibilities

Refer to the *General Principles of Food Hygiene*.

10.2 Training programmes

Refer to the *General Principles of Food Hygiene*.

The training program should educate employees on the proper hygienic practices to follow in order to minimize the entry or the spread of pathogens, such as *Salmonella,* in the low-moisture food establishment. Adherence to traffic pattern control measures should also be included in the training. Since *Salmonella* can be difficult to control in a food operation environment because it can persist for a prolonged period of time in the dry state and in low-moisture products, the employees should understand the importance of following proper hygienic practices and the importance of avoiding the introduction of water. Such training should include personnel who enter the area on a temporary basis (e.g. maintenance workers, contractors).

10.3 Instruction and supervision

Refer to the *General Principles of Food Hygiene*.

10.4 Refresher training

Refer to the *General Principles of Food Hygiene*.

ANNEX I

EXAMPLES OF MICROBIOLOGICAL CRITERIA FOR LOW-MOISTURE FOODS WHEN DEEMED APPROPRIATE IN ACCORDANCE WITH THE *PRINCIPLES AND GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA RELATED TO FOODS* (CXG 21-1997)

While the safety of foods is principally achieved through the implementation of control measures, microbiological testing can be a useful tool to evaluate and verify the effectiveness of food safety and food hygiene practices, provide information about process control, and even a specific product lot, when sampling plans and methodology are properly designed and performed. The intended use of information obtained (e.g. evaluating the effectiveness of process hygiene, evaluating the risk posed by a particular hazard) can aid in determining what microorganisms are most appropriate to test for. Test methods validated for the intended use should be selected. Consideration should be given to ensure proper design of a microbiological testing program. Trend analysis of testing data should be undertaken to evaluate the effectiveness of food safety control systems.

Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

Where appropriate, specifications for pathogenic microorganisms, such as *Salmonella* spp., should be established that take into account subsequent processing steps, the end use of the low moisture food, the conditions under which the product was produced, as well as the intended population, especially when such a population may be more susceptible to foodborne infection.

When used properly and combined with validated process controls, testing can provide actionable information that helps to assure the safety of the products produced. Testing cannot guarantee the safety of the product. Microbiological testing alone is limited in its application and may convey a false sense of confidence in the safety of the food due to the statistical limitations of sampling plans, particularly when the hazard presents an unacceptable risk at low concentrations and has a low and variable prevalence. Microorganisms are not homogeneously distributed throughout food and testing may fail to detect organisms present in a lot.

Example of microbiological criteria for low-moisture food products

Low-moisture foods include many different types of products. Microbiological testing is not appropriate for all low-moisture food products. Therefore, conditions under which food is expected to be handled, treated, and consumed after sampling should be considered when establishing a microbiological criterion. For example, a microbiological criterion is not needed for a low-moisture food that will undergo wet blending and a heat treatment that will eliminate *Salmonella*. The *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997) should be followed in determining whether a microbiological criterion for *Salmonella* would be deemed necessary and would contribute to the protection of public health.

The following microbiological criteria can be used for a low-moisture food when deemed necessary for verification of *Salmonella* control. The criteria are based on whether the potential for the risk decreases (e.g. cooking reduces the number of *Salmonella*), remains the same (the number of *Salmonella* changes very little), or increases (e.g. potential growth, such as use of the low-moisture food as an ingredient in a high moisture food) between the time of sampling and when the food is consumed or when the food targets a population that is highly susceptible to foodborne infection (e.g. the young, the elderly, and the immuno compromised). The sampling plan may be adjusted based on product specific data, e.g. a history of data indicating a process is operating consistently. Ongoing process control verification testing, which can use a “moving window approach” can also reduce the amount of testing. Finally, the need for testing can be minimized when product safety is addressed by raw material controls and by the design and implementation of process controls, with ongoing documentation demonstrating that the appropriate procedures have been followed.

Example Microbiological Criteria that May be Appropriate for Low-Moisture Foods If Such Criteria are Deemed Necessary[g,h]					
Microorganism/Target population	**Likely change to level of hazard/risk**	**n**	**c**	**m**	**Class Plan**
Salmonella/ Intended for consumption by general population	Reduce risk[a]	5	0	0/25 g	2
	No change in risk[b]	10	0	0/25 g	2
	May increase risk[c]	20	0	0/25 g	2
Salmonella/ Intended for consumption by highly susceptible populations	Reduce risk[d]	15	0	0/25 g	2
	No change in risk[e]	30	0	0/25 g	2
	May increase risk[f]	60	0	0/25 g	2

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class sampling plan; m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality.

[a] The sampling plan performance is the geometric mean concentration (grams containing one cell) at which the sampling plan will reject a lot with 95% confidence. The geometric mean concentration detected is 1 cfu in 49 g of product if the within lot standard deviation is assumed to be 0.5 log cfu/g. The geometric mean concentration detected is 1 cfu in 55 g of product if the within lot standard deviation is assumed to be 0.8 log cfu/g. [4]

[b] The sampling plan performance is the geometric mean concentration (grams containing one cell) at which the sampling plan will reject a lot with 95% confidence. The geometric mean concentration detected is 1 cfu in 120 g of product if the within lot standard deviation is assumed to be 0.5 log cfu/g. The geometric mean concentration detected is 1 cfu in 180 g of product if the within lot standard deviation is assumed to be 0.8 log cfu/g.[1]

[c] The sampling plan performance is the geometric mean concentration (grams containing one cell) at which the sampling plan will reject a lot with 95% confidence. The geometric mean concentration detected is 1 cfu in 270 g of product if the within lot standard deviation is assumed to be 0.5 log cfu/g. The geometric mean concentration detected is 1 cfu in 490 g of product if the within lot standard deviation is assumed to be 0.8 log cfu/g.[1]

[d] The sampling plan performance is the geometric mean concentration (grams containing one cell) at which the sampling plan will reject a lot with 95% confidence. The geometric mean concentration detected is 1 cfu in 200 g of product if the within lot standard deviation is assumed to be 0.5 log cfu/g. The geometric mean concentration detected is 1 cfu in 330 g of product if the within lot standard deviation is assumed to be 0.8 log cfu/g.[4]

[e] The sampling plan performance is the geometric mean concentration (grams containing one cell) at which the sampling plan will reject a lot with 95% confidence. The geometric mean concentration detected is 1 cfu in 430g of product if the within lot standard deviation is assumed to be 0.5 log cfu/g. The geometric mean concentration detected is 1 cfu in 850g of product if the within lot standard deviation is assumed to be 0.8 log cfu/g.[1]

[f] The sampling plan performance is the geometric mean concentration (grams containing one cell) at which the sampling plan will reject a lot with 95% confidence. The geometric mean concentration detected is 1 cfu in 910 g of product if the within lot standard deviation is assumed to be 0.5 log cfu/g. The geometric mean concentration detected is 1 cfu in 2000 g of product if the within lot standard deviation is assumed to be 0.8 log cfu/g.[1]

[g] The methods to be employed should be the most recent version of ISO 6579, or other validated methods that provide equivalent sensitivity, reproducibility, and reliability.

[h] The criterion above is applied with the underlying assumption that the history of the lot is unknown, and the criterion is being used on a lot-by-lot basis. In those instances where the history of the product is known (e.g. the product is produced under a fully documented HACCP system), alternate sampling criteria involving between-lot process control testing may be feasible (e.g. the “moving window” approach). The typical action to be taken when there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption; (2) recall the product if it has been released for human consumption and (3) determine and correct the root cause of the failure.

[4] FAO/WHO.2016. Risk Manager’s Guide to the Statistical Aspects of Microbiological Criteria Related to Foods Microbiological Risk Assessment Series VOL 24, available at ftp://ftp.fao.org/codex/meetings/CCFH/CCFH46/FAO%20MC%20draft%20140814a.pdf

ANNEX II

GUIDANCE FOR THE ESTABLISHMENT OF ENVIRONMENTAL MONITORING PROGRAMMES FOR *SALMONELLA* SPP. AND OTHER ENTEROBACTERIACEAE IN LOW-MOISTURE FOOD PROCESSING AREAS

Manufacturers of low-moisture foods should consider the potential risk to consumers in the event their products contain *Salmonella* when they are released for distribution. Environmental monitoring in low-moisture food processing environments is a useful means of verifying effectiveness of hygiene controls applied and of detecting potential harbourage sites for pathogens. It also generates information about the processing environment, allowing corrective actions to be taken in a timely manner.

Environmental monitoring should be conducted under normal operating conditions. The appropriate sampling approach should depend on the purpose of sampling (i.e. what is to be verified) and the significance of the environment in terms of the likelihood of contaminating end products. Examples of areas where environmental monitoring should be used include post-lethality areas, packing lines and other areas immediately surrounding where ready-to-eat foods are exposed to the environment.

Environmental monitoring sampling sites should be prioritized according to the likelihood of contamination of processing lines and the impact on product in case of contamination.

The sampling approach may be adjusted according to the previous findings and, where appropriate, should include sampling from additional locations and/or from finished product, as part of corrective actions for non-conforming environmental results. Sampling plans should also be modified appropriately when facility and equipment modifications occur.

A number of factors (a - g) should be considered when developing the sampling program to ensure its effectiveness:

(a) Target organisms

i. Most microorganisms present in the processing environment are transient and are eliminated by the cleaning procedures in place. However, some may find a harbourage site within the environment unless appropriate care is taken to prevent this.

ii. *Salmonella* can survive desiccation for long periods of time and can persist in the dry environment of low-moisture food establishments. Therefore, where end products may be contaminated with *Salmonella* from the environment, as a minimum, environmental monitoring should be targeted at *Salmonella*. As *Salmonella* may occur in low numbers, environmental monitoring is often combined with monitoring of the family Enterobacteriaceae (EB), which includes *Salmonella*, as this group shows similar resistance to drying and is more common in processing facilities. Consequently, the monitoring of EB in the environment may provide an early indication that the conditions necessary for *Salmonella* colonisation may exist, and hence provide an earlier indication of potential problems. Testing of EB can also be used to verify the effectiveness of cleaning procedures.

(b) Sampling locations, number of samples and timing

i. The number of samples will vary with the complexity of the process and processing lines and the intended use of the food (e.g. ready-to-eat foods vs. ingredients for further processing).

ii. Preferential locations for sampling should focus on areas where harbourage or entry leading to contamination is likely to occur, especially difficult to access sites, and where product is exposed to the environment. Greater emphasis should be placed on sampling areas after a pathogen reduction step, if one is used for the food. Information on appropriate locations can be found in the published literature and should be based on process experience and expertise, or on historical data gathered through plant surveys. Sampling locations should be reviewed on a regular basis and additional ones may need to be included in the program, depending on special situations such as major maintenance or construction activities or where there is observed indication of poor hygiene.

iii. It is important to conduct environmental sampling, particularly for *Salmonella*, after several hours of production in order to detect microorganisms transferred from harbourage sites. There should be adequate sampling of all manufacturing shifts and production periods within these shifts. Additional samples for EB testing just prior to start-up are good indices of the effectiveness of cleaning operations.

(c) Frequency of sampling

i. The frequency of environmental sampling should be based primarily on factors such as the characteristics of the products and of the area sampled, and the amount of production. It should be defined based on existing data on the presence of relevant microorganisms in the areas submitted to such a monitoring program. In the absence of such information, sufficient suitable data should be generated to correctly define the appropriate frequency. Such data should be collected over sufficiently long periods of time so as to provide representative and reliable information on the prevalence and occurrence of *Salmonella*.

ii. The frequency of the environmental sampling should be adjusted according to the findings and their significance in terms of the risk of contamination. In particular, the detection of pathogens in the finished product should lead to increased environmental and investigational sampling to identify the contamination sources. The frequency should also be increased in situations where an increased risk of contamination can be expected, e.g. in the case of maintenance or construction activities, a contamination event, or following wet cleaning activities.

(d) Sampling tools and techniques

It is important to choose and adapt the type of sampling tools and techniques to the type of surface and sampling locations. For example, scraping of residues from surfaces or collection of residues from vacuum cleaners may provide useful samples, and moistened sponges may be appropriate for large surfaces. Sampling tools and techniques may need to be validated to demonstrate effective recovery of the target organisms. In areas requiring stringent hygiene controls, wipes and sponges should be slightly moistened (not wet or dripping) to collect as much residue as possible. After sampling, care should be taken to ensure the area is completely dry after the sampling.

(e) Analytical methods

The analytical methods used to analyse environmental samples should be suitable for the detection of the target organisms. Special focus should be paid to the characteristics of food matrices in order to adapt the preparation of food samples where food residues are tested. Considering the characteristics of environmental samples, it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately. Under certain circumstances, it may be possible to composite (pool) certain samples but if this is done then the sensitivity of the microbiological testing method should not be reduced. However, in the case of positive findings, additional testing will be necessary to determine the location of the positive sample.

(f) Data management

The monitoring program should include a system to record the data and to facilitate their evaluation, e.g. performing trend analyses. A continual review of the data is important to revise and adjust monitoring programs and take actions to manage contamination.

(g) Actions in case of non-conforming results

i. The purpose of the monitoring program is to find target organisms, if present in the environment. Decision criteria and responses based on these monitoring programs should be articulated when establishing the program. The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of contamination), to intensified cleaning, to source tracing (increased frequency and number of samples for environmental testing), to review of hygienic practices, holding and testing of product, up to product disposition. In the case of persistent contamination, the identification of the strain (e.g. molecular subtyping) could be helpful for taking appropriate corrective actions.

ii. In general, manufacturers should expect to find EB in the processing environment. Therefore, an appropriate action plan should be designed and established to adequately respond where decision criteria are exceeded. Decision criteria can be based upon individual results as well as on trends. A review of hygiene procedures and controls should be considered when criteria are exceeded. The manufacturer should address each non-conforming result of *Salmonella* and evaluate changes and/or patterns in the trends of EB counts; the type of action will depend upon the likelihood of contaminating the product with *Salmonella* and/or other pathogens of concern.

ANNEX III

ANNEX ON SPICES AND DRIED CULINARY HERBS

INTRODUCTION

Dried, fragrant, aromatic or pungent, edible plant substances, in the whole, broken or ground form, e.g. spices and dried culinary herbs, impart flavour, aroma or colour when added to food. Spices and dried culinary herbs may include many parts of the plant, such as aril, bark, berries, buds, bulbs, leaves, rhizomes, roots, seeds, stigmas, pods, resins, fruits, or plant tops.

The production, processing, and packing of spices and dried culinary herbs are very complex. For example, source plants for spices and dried culinary herbs are grown in a wide range of countries and on many types of farms, e.g. from very small farms to, in rare instances, large farms. Agricultural practices for growing source plants for spices and dried culinary herbs also vary tremendously from virtually no mechanization to highly mechanized practices. Drying of source plants may be performed mechanically (for rapid drying) or naturally (e.g. slower drying under the sun for several days). The distribution and processing chain for spices and dried culinary herbs is also highly complex and can span long periods of time and include a wide range of establishments. For example, spices and dried culinary herbs grown on small farms may pass through multiple stages of collection and consolidation before reaching a spice processor and packer or a food manufacturer. Dried product processing generally involves cleaning (e.g. culling, sorting to remove debris), grading, sometimes soaking, slicing, drying, and on occasion grinding/cracking. Some spices and dried culinary herbs are also treated to mitigate microbial contamination, typically by steam treatment, gas treatment (e.g. ethylene oxide), or irradiation. Processing and packing/repacking may also take place in multiple locations over long periods of time, since spices and dried culinary herbs are prepared for different purposes.

The safety of spices and dried culinary herbs products depends on maintaining good hygienic practices along the food chain during primary production, processing, packing, retail, and at the point of consumption. Sporeforming bacteria, including pathogens such as *Bacillus cereus*, *Clostridium perfringens*, and *Clostridium botulinum*, as well as non-sporeforming vegetative cells of microorganisms such as *Escherichia coli, Staphylococcus aureus*, and *Salmonella* spp. have been found in spices and dried culinary herbs. There have been a number of outbreaks of illness associated with spice and seasoning consumption, with most being caused by *Salmonella* spp. that have raised concerns regarding the safety of spices and dried culinary herbs. The complex supply chain for spices and dried culinary herbs makes it difficult to identify the points in the food chain where contamination occurs, but evidence has demonstrated that contamination can occur throughout the food chain if proper practices are not followed.

The safety of spices and dried culinary herbs can also be affected by mycotoxin-producing moulds, e.g. those producing aflatoxin (such as *Aspergillus flavus* or *Aspergillus parasiticus*) or ochratoxin A (such as *Aspergillus ochraceus, Aspergillus carbonarius,* or *Penicillium verrucosum*). Chemical hazards such as heavy metals and pesticides, as well as physical contaminants such as stones, glass, wire, extraneous matter and other objectionable material, may also be present in spices and dried culinary herbs.

SECTION I - OBJECTIVES

This Annex addresses Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs) and Good Hygienic Practices (GHPs) that will help minimize contamination, including microbial, chemical and physical hazards, associated with all stages of the production of spices and dried culinary herbs from primary production to consumer use. Particular attention is given to minimizing microbial hazards.

SECTION II - SCOPE, USE AND DEFINITION

2.1 Scope

This Annex applies to spices and dried culinary herbs - whole, broken, ground or blended. Spices and dried culinary herbs may include the dried aril (e.g. the mace of nutmeg), bark (e.g. cinnamon), berries (e.g. black pepper), buds (e.g. clove), bulbs (e.g. dried garlic), leaves (e.g. dried basil), rhizomes (e.g. ginger, turmeric), seeds (e.g. mustard), stigmas (e.g. saffron), pods (e.g. vanilla), resins (e.g. asafoetida), fruits (e.g. dried chilli) or plant tops (e.g. dried chives). It covers the minimum requirements of hygiene for growing, harvesting and post-harvest practices (e.g. curing, bleaching, blanching, cutting, drying, cleaning, grading, packing, transportation and storage, including disinfestation and fumigation) processing establishment, processing technology and practices (e.g. grinding, blending, freezing and freeze-drying, treatments to reduce the microbial load) packaging and storage of processed products. For spices and culinary herbs collected from the wild, only the measures for handling and post-harvest activities (i.e. from section 3.3.2 onward) apply.

2.2 Use

This Annex follows the format of the *General Principles of Food Hygiene* (CXC 1-1969) and should be used in conjunction with it and other applicable codes such as the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

This Annex is a recommendation to which producers in different countries should adhere as far as possible taking into account the local conditions while ensuring the safety of their products in all circumstances. Flexibility in the application of certain requirements of the primary production of spices and dried culinary herbs can be exercised, where necessary, provided that the product will be subjected to control measures sufficient to obtain a safe product.

2.3 Definitions

Refer to definitions in the *General Principles of Food Hygiene* (CXC 1–1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003). In addition, the following expressions have the meaning stated:

Spices and Dried Culinary Herbs – dried plants or parts of plants (roots, rhizomes, bulbs, leaves, bark, flowers, fruits, and seeds) used in foods for flavouring, colouring, and imparting aroma. This term equally applies to whole, broken, ground and blended forms.

Disinfest – to eliminate harmful, threatening, or obnoxious pests, e.g. vermin

Microbial Reduction Treatment – process applied to spices and dried culinary herbs to eliminate or reduce microbial contaminants to an acceptable level.

Source Plant –plant (non-dried) from which the spice or dried culinary herb is derived.

SECTION III - PRIMARY PRODUCTION

3.1 Environmental Hygiene

Source plants for spices and dried culinary herbs should be protected, to the extent practicable, from contamination by human, animal, domestic, industrial and agricultural wastes which may be present at levels likely to be a risk to health.

3.3 Handling, Storage and Transport

Each source plant should be harvested using a method suitable for the plant part to be harvested in order to minimize damage and the introduction of contaminants. Plant matter that is damaged or other plant waste material should be disposed of properly and removed from the growing/harvest area in order to minimize the potential for it to serve as a source of mycotoxin-producing moulds or pathogenic bacteria. If possible, only the amount that can be processed in a timely manner should be picked in order to minimize growth of mycotoxin-producing moulds and pathogenic bacteria prior to processing. When the amount harvested exceeds processing capabilities, the excess should be stored under appropriate conditions.

3.3.1 *Prevention of cross-contamination*

Specific control methods should be implemented to minimize the risk of cross-contamination from microorganisms associated with harvesting methods. The following should be considered:

- Where appropriate, the soil under the plant should be covered with a clean sheet of plastic or clean plant material such as straw during picking/harvesting to avoid contamination by dirt or plant matter that has fallen prior to harvesting. Plastic that will be reused should be easy to clean and disinfected. Plant material should be used only once.
- Source plant material that has fallen to the ground should be disposed of properly if it cannot be made safe by further processing.

3.3.2 *Storage and transport from the growing/harvest area to the packing establishment*

Spices and dried culinary herbs should be kept in areas where contact with water or moisture is minimized.

Spices and dried culinary herbs should be stored on raised platforms or hung under a non-leaking roof in a cool dry place. The storage location should prevent access, to the extent practicable, by rodents or other animals and birds and should be isolated from areas of excessive human or equipment traffic.

3.3.3 *Drying*

3.3.3.1 *Natural Drying*

Refer to the *Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes* (CXC 68-2009) with regard to the location of the drying area.

Plants or parts of plants used for the preparation of spices and dried culinary herbs may be dried naturally, e.g. air dried, provided adequate measures are taken to prevent contamination of the raw material during the process. The drying time depends on the environmental conditions surrounding the product, i.e. temperature, relative humidity, and air velocity.

If dried naturally, plants or parts of plants should be dried on clean, elevated racks, clean concrete floors, or clean mats or tarps or by hanging under a non-leaking roof and not on the bare ground or in direct contact with the soil. Pathways should be made in the drying area to prevent anyone from walking on the crop. The drying plant material should be raked/turned frequently to limit mould growth.

Concrete floors or slabs poured specifically for drying source plants should be subject to an appropriate cleaning program and, where appropriate, disinfected. New concrete slabs should be used for drying only when it is absolutely certain that the new concrete is well-cured and free of excess water. A suitable plastic cover spread over the entire new concrete slabs can be used as a moisture barrier; however, the sheet should be completely flat to prevent the pooling of water. Suitable precautions should be taken, where practicable, to protect the spices and dried culinary herbs from contamination and damage by domestic animals, rodents, birds, mites, insects or other objectionable substances during drying, handling and storage. If drying outdoors, drying platforms should be placed under a roof/tarp free of tears, holes or frayed material that will prevent rewetting by rainfall and contamination from birds overhead.

Drying time should be reduced as much as possible by using optimal drying conditions (e.g. temperature, humidity and ventilation) to avoid fungal growth and toxin production. The thickness layer of the drying source plant material should be considered in order to consistently achieve a safe moisture level.

3.3.3.2 *Mechanical Drying (see Section 5.2.1.1)*

3.3.4 *Packing in the growing/harvest area*

Packing activities can occur in the growing/harvest area. Such packing operations should include the same sanitary practices, where practical, as packing spices and dried culinary herbs in establishments or modified as needed to minimize risks. To prevent germination and growth of spores, the products must be dried to a safe moisture level prior to packing.

When packing spices and dried culinary herbs in the growing/harvest area for transport, storage, or for further sale, new bags/containers should be used to prevent the potential for microbial, physical and chemical contamination. When bags/containers are marked, food-grade ink should be used to minimize the potential for contamination with ink. When bags/containers have an open structure, such as jute bags, the bag/container should not be marked when filled with spices and dried culinary herbs to prevent liquid ink from contaminating the contents and increasing the moisture in the spices and dried culinary herbs. It is recommended that paper tags be used instead of liquid ink for marking.

Removal of discarded plant material should be done on a regular basis in order to avoid accumulation that would promote the presence of pests.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.2 Premises and rooms

Where practicable, buildings and facilities should be designed to provide separation, by partition, location or other effective means, between operations that could result in cross-contamination. They should be designed to facilitate hygienic operations according to the one-way flow direction, without backtracking, from the arrival of the raw materials at the premises to the finished product, and should provide for appropriate temperature and humidity conditions for the process and the product.

Premises and rooms should be designed with a means of dust control, since spices and dried culinary herbs are likely to generate particulate matter that can be carried to other parts of the room or premises by air currents.

4.3 Equipment

Equipment should be installed so as to allow access for cleaning and to minimize transfer of dust particles to other pieces of equipment or to the environment.

The risk of contamination from equipment should be assessed and controlled. Wherever possible, forklifts, utensils, and maintenance tools for the finished product and packaging areas should be different from those used in the “raw” material area (e.g. prior to the microbial reduction treatment).

4.4 Facilities

4.4.8 Storage

Facilities for the storage of spices and dried culinary herbs should be designed and constructed to prevent high humidity or other conditions that could result in moisture levels in product that would support the growth of moulds.

SECTION V - CONTROL OF OPERATION

5.1 Control of food hazards

Measures should be taken at each step in the food chain to minimize the potential for contamination of spices and dried culinary herbs by microbial pathogens (including mycotoxin-producing moulds), chemical contaminants and other contaminants not intentionally added to food such as excreta, rodent hair, and insect fragments, which may compromise food safety or suitability.

5.2 Key aspects of hygiene control systems

5.2.2 *Specific process steps*

5.2.2.1 *Mechanical Drying*

Plants or parts of plants used for the preparation of spices and dried culinary herbs may be dried mechanically (e.g. forced air drying), provided adequate measures are taken to prevent contamination of the raw material during the process. To prevent the growth of microorganisms, especially mycotoxin- producing moulds, a safe moisture level should be achieved as rapidly as possible.

Mechanical drying methods should be used instead of natural (open) air drying, where possible, to limit exposure of spices and dried culinary herbs to environmental contaminants and to prevent growth of moulds. If hot air drying is used, the air should be free of contaminants and precautions should be made to prevent combustion gases from contacting the plant material or stored plant material in the area.

Drying time should be reduced as much as possible by using optimal drying conditions to avoid fungal growth and toxin production. The thickness layer of the drying source plant should be considered in order to consistently achieve a safe moisture level.

5.2.2.2 *Cleaning of spices and dried culinary herbs*

Spices and dried culinary herbs should be cleaned properly (e.g. culled and sorted) to remove physical hazards (such as the presence of animal and plant debris, metal and other foreign material) through manual sorting or the use of detectors, such as metal detectors. Raw materials should be trimmed to remove any damaged, rotten or mouldy material.

Debris from culling and sorting should be periodically collected and stored away from the drying, processing and packaging areas to avoid cross-contamination and attracting pests.

5.2.2.3 *Microbial Reduction Treatments*

In order to control microbiological contamination, appropriate methods of treatment may be used in accordance with the regulations set by the competent authority. When necessary to reduce risk, spices and dried culinary herbs should be treated with a validated microbial reduction treatment prior to reaching the consumer in order to inactivate pathogens such as *Salmonella*. For additional information on validation, refer to the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008). Commonly used methods involve the application of steam, fumigation or radiation. Where spices and dried culinary herbs are irradiated, refer to the *Code of Practice for Radiation Processing of Food* (CXC 19-1979) and the *General Standard for Irradiated Foods* (CXS 106-1983).

Factors that should be controlled when using steam include exposure time and temperature. The process should ensure that all of the product achieves the desired temperature for the full length of time required. A drying step may be necessary to remove added moisture.

Factors that should be controlled when using irradiation include radiation dose and the size and shape of the package, as well as the penetrability of the packaging material to the type of radiation used. The process should ensure that all of the product is exposed to the minimum dose of radiation needed to provide the intended effect.

Factors that should be controlled when using fumigation treatments such as ethylene oxide or propylene oxide include product initial temperature, chamber temperature, chemical concentration, exposure time, vacuum and/or pressure, density of the product, and gas permeability of the packaging material. The process should ensure that all product is directly exposed to the gas for the full length of time required.

For pathogen inactivation treatments the adequacy of the selected control measure (thermal or non- thermal) and associated critical limits for processing should be determined, considering the increased heat resistance reported for *Salmonella* at low water activities and the increased resistance of spores to most microbial reduction treatments. In some cases, challenge studies may be needed to support validation. Once the lethality of the process is validated by scientific data, the establishment should periodically verify that the process continues to meet the critical limits during operation and the process criteria intended to achieve microbiocidal effects in the establishment.

5.2.3 *Microbiological and other specifications*

Refer to the General Principles of Food Hygiene and the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997).

Where appropriate, specifications for pathogenic and toxigenic microorganisms, chemical residues, foreign material, and decomposition should be established that take into account subsequent processing steps, the end use of the spice or dried culinary herb and the conditions under which the product was produced.

When tested by appropriate methods of sampling and examination, the products should:

- Be free from pathogenic and toxigenic microorganisms in levels that may present a risk to health; and should comply with the provisions for food additives;
- Not contain any substances originating from microorganisms, particularly mycotoxins, in amounts that exceed the tolerances or criteria established by the Codex Alimentarius Commission or, where these do not exist, by the competent authority;
- Not contain levels of insect, bird or rodent contamination that indicate that spices and dried culinary herbs have been prepared, packed or held under unsanitary conditions;
- Not contain chemical residues resulting from the treatment of spices and dried culinary herbs in excess of levels established by the Codex Alimentarius Commission or, where these do not exist, by the competent authority;
- Comply with the provisions for contaminants, and with maximum levels for pesticide residues established by the Codex Alimentarius Commission or, where these do not exist, by the competent authority.

Verification activities should include, as necessary, appropriate environmental and/or product testing. (Refer to Annex I and Annex II).

5.2.4 *Microbiological cross-contamination*

Effective measures should be taken to prevent cross-contamination of uncontaminated spices and dried culinary herbs by direct or indirect contact with potentially contaminated material at all stages of the processing. Raw products that may present a potential hazard should be processed in separate rooms, or in areas physically separate from those where end-products are being prepared. Spices and dried culinary herbs that have undergone a microbial reduction treatment should be processed and stored separately from untreated spices and dried culinary herbs. Equipment should not be used for both treated and untreated products without adequate cleaning and disinfection before use with treated products.

5.2.5 *Physical and chemical contamination*

Appropriate tools and methods should be used to remove physical hazards such as pebbles or heavier stones. To separate foreign matter from the product, air tables or gravity separators can be used for particles of the same size and different density. Sieves of different mesh may be used to obtain the size required for each product and to remove foreign matter.

Regardless of the type of separator used, the following parameters should be considered:, density, weight and size of particle, air speed, inclination of the sieve plate, vibration, etc. for the highest effectiveness of the procedure.

Magnets/metal detectors should be used to separate ferrous and non-ferrous/metallic matter from product or detect it in the product and remove the contaminated product. For good extraction, magnets should be as close as possible to the product. Magnets work more efficiently when product flows freely. If needed, more than one magnet should be placed in the line. Magnets should be cleaned frequently. Equipment should be designed in such a way as to prevent metals extracted by magnets from being swept by the flow of product. Spices and dried culinary herbs should be arranged in a fine layer to facilitate this operation.

In all cases, particles identified by the metal detector should be removed and records kept of how much and what type of foreign matter was collected and when it was cleaned. This data should be used in determining how the metals or foreign matter got there in order to implement appropriate corrective measures.

5.3 Incoming material requirements

Spices and dried culinary herbs or their source plants should not be accepted by the establishment if they are known to contain contaminants which will not be reduced to acceptable levels by normal processing procedures, sorting or preparation. Precautions should be taken to minimize the potential for contamination of the establishment and other products from incoming materials that may be contaminated. Plants, parts of plants, spices and dried culinary herbs suspected of being contaminated with animal or human faecal material should be rejected for human consumption. Special precautions should be taken to reject spices and dried culinary herbs showing signs of pest damage or mould growth because of the potential for them to contain mycotoxins such as aflatoxins.

Raw materials should be inspected and sorted prior to processing (foreign matter, odour and appearance, visible mould contamination). Laboratory tests, e.g. for moulds or pathogens such as *Salmonella*, should be conducted when necessary.

Spices and dried culinary herbs and blends of these are often manufactured without a step that would inactivate pathogens. Spices and dried culinary herbs should be obtained from approved suppliers. An approved supplier is one that can provide a high degree of assurance that appropriate controls in accordance with this Code have been implemented to minimize the possibility that chemical, physical and microbiological contamination occurs in the ingredient. Because of the diversity of production practices for spices and dried culinary herbs, it is important to understand the controls in place for production of the incoming material. When the control measures used to produce the spices and dried culinary herbs are not known, verification activities such as inspection and testing should be increased.

Consideration should be given to a program for testing spices and dried culinary herbs to be used without a lethality step for relevant pathogens, e.g. *Salmonella*. Spices and dried culinary herbs in which *Salmonella* is detected should not be used unless they are subjected to an effective microbial reduction treatment.

5.4 Packaging

Non-porous bags/containers should be used to protect the spices and dried culinary herbs from contamination and the introduction of moisture, insects and rodents. In particular, the reabsorption of ambient moisture should be prevented. Contamination should be prevented by the use of liners where appropriate. It is recommended that new bags or containers be used for food contact packaging. If reusable bags/containers are used, they should be properly cleaned and disinfected before use. All bags/containers should be in good condition and particular attention paid to the potential for loose bag fibres that can become potential contaminants. Secondary containment bags/containers providing additional protection can be reused but should not have been previously used to hold non-food materials such as chemicals or animal feed.

Spices and dried culinary herbs, e.g. dried chilli peppers, should not be sprayed with water to prevent breakage during packing. This may result in growth of moulds and microbial pathogens, if present.

Finished products may be packed in gas tight containers preferably under inert gases like nitrogen or under vacuum in order to retard possible mould growth.

5.7 Documentation and records

Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

5.8 Recall procedures

Records should identify the source (or lot number) of incoming raw materials and link the source or lot to the lots of outgoing products to facilitate traceability/product tracing. Reference should also be made to *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CXG 60-2006).

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

6.2 Cleaning programmes

A cleaning and disinfection schedule should be established to ensure that all areas of the establishment are appropriately cleaned and that special attention is given to critical areas including equipment and materials. The air handling system should be included in the cleaning and disinfection schedule. The cleaning and disinfection schedule should describe whether to use wet or dry cleaning. The presence of water in the dry processing environment can result from improper use of water during cleaning.

Dry cleaning is the preferred means of cleaning establishments handling spices and dried culinary herbs, since the use of water can enhance the probability of contamination from pathogens such as *Salmonella.* Dry cleaning should collect, remove and dispose of residues without redistributing them or cross-contaminating the environment.

Dry cleaning is especially important in older establishments in which, in spite of regular maintenance, there may be a potential for the presence of cracks or other harbourage sites that may be difficult to eliminate. Even if residues of spices and dried culinary herbs enter such a site, potential problems can be minimized if the residues and the sites are dry and kept dry. Once water enters the harbourage site, microbial growth can occur and the potential risk of contamination to the environment and eventually to the product is increased.

Wet cleaning may be appropriate in certain circumstances, e.g. when *Salmonella* has been detected in the environment. Wet cleaning should be followed by disinfection with preferably an alcohol-based disinfectant that will rapidly evaporate after contact. Suitable, alternative disinfectants that are not alcohol-based may be used where appropriate. Wet cleaning should be followed by thorough drying.

6.3 Pest control systems

Drains should be trapped or otherwise equipped with appropriate means to prevent entry of pests from drainage systems.

6.4 Waste management

Care should be taken to prevent access to waste by pests.

6.5 Monitoring effectiveness

Verification of hygienic control measures should include an environmental monitoring program that has been designed to identify pathogens such as *Salmonella* in the processing areas. (Refer to Annex II.)

SECTION VIII – TRANSPORTATION

Refer to the *Code of Practice for the Packaging and Transport of Fresh Fruit and Vegetables* (CXC 44-1995). In addition, bulk transport of spices and dried culinary herbs, such as by ship or rail, should be well ventilated with dry air to prevent moisture condensation, e.g. resulting from respiration and when the vehicle moves from a warmer to a cooler region or from day to night. Prior to bulk transport, the products must be dried to a safe moisture level to prevent the growth of moulds and pathogenic bacteria.

8.1 General

Spices and dried culinary herbs should be stored and transported under conditions that maintain the integrity of the container and the product within it. Vehicles should be clean, dry, and free from infestation. Spices and dried culinary herbs should be loaded, transported, and unloaded in a manner that protects them from any damage, contamination or water. Care should be taken to prevent condensation when unloading spices and dried culinary herbs from a refrigerated vehicle or while taking out of a cold storage. In warm, humid weather, the products should be allowed to reach ambient temperature before exposure to external conditions. Spices and dried culinary herbs that have been spilled are vulnerable to contamination and should not be used as food.