CODEX ALIMENTARIUS COMMISSION

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REVISED PROPOSED DRAFT ANNEXES TO THE CODE OF HYGIENIC PRACTICE FOR LOW- MOISTURE FOODS

(Prepared by Canada and the United States)

This CRD has been prepared by Canada and the United States (as Chair and Co-chair of the current working group). It reflects changes identified by country comments received to the latest eWG report (CX/FH 15/47/7). It could be used as the working document for the discussion on Agenda Item 6 of the Provisional Agenda.

ANNEX I

EXAMPLES OF MICROBIOLOGICAL CRITERIA FOR LOW-MOISTURE FOODS

1. While the safety of foods is principally achieved through the implementation of control measures, ~~M~~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.

2. Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997).

3. 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].

4. 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 ~~security~~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 ~~food safety~~microbiological criteria for low-moisture food products

5. Low-moisture foods include many different types of 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 ~~food safety~~microbiological criterion is not needed for a low-moisture food that will undergo wet blending and a heat treatment that will eliminate *Salmonella*. The following microbiological criteria can be used for a low-moisture food when the potential for the risk either 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.

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. [1]

[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.[2]

[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]

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.

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.

[1] International Commission on Microbiological Specifications for Foods (ICMSF). 2011. Microorganisms in foods 8. Use of data for assessing process control and product acceptance. Table A3 page 362. Springer, New York, USA.

[2] Performance calculated with the ICMSF spreadsheet (icmsf.org) following the procedure as decribed by M. van Schothorst, M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole. 2009. Relating microbiological criteria to food safety objectives and performance objectives. Food Control 20: 967-979.

ANNEX II

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

1. 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.

2. 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.

3. 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. At a minimum, sampling should involve non-food contact surfaces that are in close proximity to food and food contact surfaces.

4. 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.

5. 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. ~~specialized nutritional products for the treatment of moderate and severely acute malnutrition~~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 ~~monitoring program~~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 AROMATIC HERBS

INTRODUCTION

1. Dried, fragrant, aromatic or pungent, edible plant substances, in the whole, broken or ground form, e.g. spices and dried aromatic herbs, impart flavour, aroma or colour when added to food. Spices and dried aromatic 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.

2. The production, processing, and packing of spices and dried aromatic herbs is very complex. For example, source plants for spices and dried aromatic 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 aromatic 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 aromatic herbs is also highly complex and can span long periods of time and include a wide range of establishments. For example, spices and dried aromatic 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 aromatic 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 aromatic herbs are prepared for different purposes.

3. The safety of spices and dried aromatic 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 aromatic 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 aromatic herbs. The complex supply chain for spices and dried aromatic 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.

4. The safety of spices and dried aromatic 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 aromatic herbs.

SECTION I - OBJECTIVES

5. 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 aromatic herbs from primary production to consumer use. Particular attention is given to minimizing microbial hazards.

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

6. This Annex applies to spices and dried aromatic herbs - whole, broken, ground or blended. Spices and dried aromatic 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 aromatic 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

7. This Annex follows the format of the *General Principles of Food Hygiene* (CAC/RCP 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* (CAC/RCP 53-2003) and the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

8. 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 aromatic 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

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

Spices and Dried Aromatic Herbs – dried plants or parts of plants (roots, rhizomes, bulbs, leaves, bark, flowers, fruits, and seeds)~~components or mixtures of dried plants~~ 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 aromatic herbs to eliminate or reduce microbial contaminants to an acceptable level.

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

SECTION III - PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE

10. Source plants for spices and dried aromatic 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

11. 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

12. 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

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

14. Spices and dried aromatic 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

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

16. Plants or parts of plants used for the preparation of spices and dried aromatic 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.

17. 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.

18. 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 aromatic 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.

19. 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

20. 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 aromatic 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.

21. When packing spices and dried aromatic 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 aromatic herbs to prevent liquid ink from contaminating the contents and increasing the moisture in the spices and dried aromatic herbs. It is recommended that paper tags be used instead of liquid ink for marking.

22. 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

23. 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.

24. Premises and rooms should be designed with a means of dust control, since spices and dried aromatic 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

25. 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.

26. 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

27. Facilities for the storage of spices and dried aromatic herbs should be designed and constructed to prevent high humidity or other conditions that could result in ~~high~~ moisture levels in product that would support the growth of moulds.~~Spices and dried aromatic herbs are susceptible to mould contamination and/or growth if storage conditions are not appropriate. Spices and dried aromatic herbs should be stored in an environment with humidity that does not result in product moisture that can support the growth of moulds.~~

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

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

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Specific process steps

5.2.1.1 Mechanical Drying

29. Plants or parts of plants used for the preparation of spices and dried aromatic 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.

30. Mechanical drying methods should be used instead of natural (open) air drying, where possible, to limit exposure of spices and dried aromatic 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.

31. 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.

5.2.1.2. Cleaning of spices and dried aromatic herbs

32. Spices and dried aromatic 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.

33. 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.

5.2.1.3 Microbial Reduction Treatments

34. 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 aromatic 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* (CAC/GL 69-2008). Commonly used methods involve the application of steam, fumigation or radiation. Where spices and dried aromatic herbs are irradiated, refer to the *Code of Practice for Radiation Processing of Food* (CAC/RCP 19-1979) and the *General Standard for Irradiated Foods* (CODEX STAN 106-1983).

35. 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.

36. 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.

37. 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.

38. 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.

5.2.2 Microbiological and other specifications

39. Refer to the *General Principles of Food Hygiene* and the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997).

40. 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 aromatic herb and the conditions under which the product was produced.

41. 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 aromatic herbs have been prepared, packed or held under unsanitary conditions;
- Not contain chemical residues resulting from the treatment of spices and dried aromatic 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.

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

5.2.3 Microbiological cross-contamination

43. Effective measures should be taken to prevent cross-contamination of uncontaminated spices and dried aromatic 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 aromatic herbs that have undergone a microbial reduction treatment should be processed and stored separately from untreated spices and dried aromatic herbs. Equipment should not be used for both treated and untreated products without adequate cleaning and disinfection before use with treated products.

5.2.4 Physical and chemical contamination

44. Appropriate ~~machines~~ 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 ~~diameters~~ may be used to obtain the size required for each product and to remove foreign matter.

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

46. Magnets/metal detectors should be used to ~~detect~~ separate ~~and separate~~ ferrous ~~from~~ 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 metals to be extracted~~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 aromatic herbs should be arranged in a fine layer to facilitate this operation.

47. 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

48. Spices and dried aromatic 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 aromatic 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 aromatic herbs showing signs of pest damage or mould growth because of the potential for them to contain mycotoxins such as aflatoxins.

49. 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.

50. Spices and dried aromatic herbs and blends of these are often manufactured without a step that would inactivate pathogens. Spices and dried aromatic 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 aromatic 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 aromatic herbs are not known, verification activities such as inspection and testing should be increased.

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

5.4 PACKAGING

52. Non-porous bags/containers should be used to protect the spices and dried aromatic herbs from contamination and the introduction of moisture, insects and rodents. In particular, the reabsorption of ambient moisture ~~in humid tropical climates~~ 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.

53. Spices and dried aromatic 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.

54. 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

55. Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-69) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003).

5.8 RECALL PROCEDURES

56. 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* (CAC/GL 60-2006).

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

6.2 CLEANING PROGRAMMES

57. 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.

58. Dry cleaning is the preferred means of cleaning establishments handling spices and dried aromatic 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.

59. 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 aromatic 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.

60. 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 ~~and then by thorough drying~~. 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

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

6.4 WASTE MANAGEMENT

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

6.5 MONITORING EFFECTIVENESS

63. Verification of ~~sanitation~~ 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

64. Refer to the *Code of Practice for the Packaging and Transport of Fresh Fruit and Vegetables* (CAC/RCP 44-1995). In addition, bulk transport of spices and dried aromatic 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 ~~germination and~~the growth of moulds ~~spores~~ and pathogenic bacteria.

8.1 GENERAL

65. Spices and dried aromatic 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 aromatic 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 aromatic 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 aromatic herbs that have been spilled are vulnerable to contamination and should not be used as food.

ANNEX IV

ANNEX ON DRIED/DEHYDRATED FRUITS AND VEGETABLES INCLUDING EDIBLE FUNGI

SECTION II – SCOPE, USE AND DEFINITIONS

2.1 SCOPE

1. This Annex applies to fruits and vegetables dried by natural or artificial means or a combination of both, including freeze dried. The fruit or vegetable may be sliced, cubed, diced, granulated, or in other sub-divided form, or left whole prior to dehydration.

2. Tree nuts are excluded from the scope of this annex.

2.2 USE

3. Refer to the *General* Principles *of Food Hygiene* (CAC/RCP 1-1969).

SECTION III - PRIMARY PRODUCTION

4. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003).

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

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

4.2 PREMISES AND ROOMS

4.2.1 Design and layout

6. Where practicable, adequate measures should be implemented to keep the moisture as low as possible in the establishments. Cutting sheds in which fruit is pitted, cut or otherwise prepared and spread on trays for drying should preferably be closed buildings with screened windows that do not permit access by rodents, insects, or birds. Where cutting is done in open sheds, adequate precautions should be taken to protect against insect, rodent and bird contamination or harbourage.

4.3 EQUIPMENT

4.3.1 General

7. Equipment used for drying should be so constructed and operated that the product cannot be adversely affected by the drying medium.

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

8. Refer to the *General Principles of Food Hygiene* and the *Code of Hygienic Practice for Fresh Fruits and Vegetables.*

9. Methods of preservation or treatment of the finished product should be such as to kill any insects or mites remaining after processing and to result in protection against contamination, deterioration, or development of a public health hazard. The finished product should be of such moisture content that it can be distributed and held under any normally foreseeable conditions without significant deterioration by decay, mould, enzymatic changes, or other causes.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

5.2.2.1 Drying

10. Fruits and vegetables may be dried naturally, e.g. air dried, or mechanically, provided adequate measures are taken to prevent contamination of the raw material during the process. ~~Where fruits or vegetables are dried by the sun in drying yards, such yards should be recognized as food processing yards. Such yards should as far as possible comply with such of the provisions of Section IV of the *General Principles of Food Hygiene.*~~

11. For additional information relevant to drying, refer to Sections 3.3.3 and 5.2.1.1 in the Annex III on Spices and Dried Aromatic Herbs.

~~11.~~12. ~~10.~~ The finished product should be of such moisture content that it can be held in the localities of origin and distribution under any normally foreseeable conditions for those localities without significant deterioration by mould, enzymatic changes, or other causes.

ANNEX V

ANNEX FOR DESICCATED COCONUT

SECTION II – SCOPE, USE AND DEFINITIONS

2.1 SCOPE

1. This annex applies to desiccated coconut, the dried product prepared for human consumption without requiring further processing which is obtained by shredding or otherwise comminuting the pared kernel of coconuts, the fruit of the palm, *Cocos nucifera L~~Cocosnucifera~~*.

2.2 USE

2. Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

2.3 DEFINITIONS

Coconuts ~~– coconuts consist of an outer skin (green or brown when harvested) enclosing a thick fibrous coating or husk; inside the husk is a woody shell which encloses the kernel and which is separated from it by a brown skin. The pared kernel consists of a solid white layer enclosing an aqueous liquid known as coconut water~~ The fruit of the coconut palm *Cocos nucifera*; a large hard shelled seed lined with a white edible meat and containing a milky liquid.~~.~~

Coconut meat - white solid layer of the kernel.

Dehusking- the removal of the husk, leaving the shell intact.

Hatcheting- the removal of the shell.

Paring - the removal of the brown skin around the kernel.

Retting - to prepare for further processing by soaking which facilitates separation of fibers from the woody parts of the stem.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.2 PREMISES AND ROOMS

4.2.1 Design and layout

3. The husk, if it is not removed in the growing area, should be removed in a place separate from the factory. Deshusked nuts should be received into the premises~~factory buildings~~, and the ~~processes~~ operations of hatcheting, paring, and washing of the coconut meat should be carried out in a separate section from the subsequent ~~processes~~operations. There should be no direct access from the hatcheting, paring, and washing sections to the other sections.

4. The ~~sections~~ premises should be so arranged that the coconut passes from the hatcheting, paring, and washing ~~sections~~ areas through to the packing room without retracing its path or passing through an area used for ancillary activities. Precautions should be taken to prevent contamination of ~~shredding,~~ desiccating, shredding,and packing sections of the factory with dust.

5. Husk pits for the retting of husks should be located such that they do not serve as a source of contamination of wells from which water is drawn for use in the plant.

SECTION V - CONTROL OF OPERATION

6. Desiccators used for the coconut meat should not be used for the drying of coconut parings.

7. Refer to the *General Principles of Food Hygiene* and the *Code of Hygienic Practice for Fresh Fruits and Vegetables.*

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

8. Inspection and sorting. At the paring and washing stage, all kernels should be inspected and any unfit, including germinated kernels, rejected.

Processing. ~~After washing and before shredding, t~~The coconut meat should be subjected to an effective ~~process~~ treatment to eliminate pathogenic organisms from the surface of the meat, such as direct steam or immersion in an adequate quantity of boiling water for a time sufficient to eliminate microbial pathogens from the surface.

Handling. After this ~~process~~operation, the coconut meat should not be manually handled in any way, but mechanical devices, or containers and scoops or rakes or other implements constructed of impervious materials, should be used to minimize contamination.

Desiccating. Shredded coconut should be dried in a current of clean hot air free from chemical contamination until the moisture content reaches a safe level for storage. There should be thin layering of shredded coconut on the desiccator trays, and effective methods for the breaking up of the mat should be used. After drying, the desiccated coconut should be cooled before packaging.

5.4 PACKAGING

9. Packaging should be done in a separate clean room. Mechanical rams or vibrators may be used to minimize manual handling of the desiccated coconut.

ANNEX VI

ANNEX FOR GROUNDNUTS (PEANUTS)

SECTION II – SCOPE, USE AND DEFINITIONS

2.1 SCOPE

1. This Annex applies to groundnuts, also known as peanuts, monkey nuts or earth nuts (*Arachishypogaea*L). It covers all types and forms of raw, dried groundnuts (peanuts) in-shell and shelled.

2.2 USE

~~1.~~**2.** Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Code of Practice for the Prevention and Reduction of Aflatoxins in Peanuts* (CAC/RCP 55-2004).

SECTION V - CONTROL OF OPERATION

5.2 KEY ASPECTS OF HYGIENE CONTROLS

5.2.2 Specific Process Steps

~~2.~~3. The shelled groundnuts should be continuously inspected to determine whether the plant equipment or any other appropriate process, is performing properly and the groundnuts are free of foreign material, damage and contamination. Any equipment adjustments indicated by the inspection should be made promptly.

~~3.~~4. ~~Once t~~Where the shelled groundnuts are ~~size~~ graded, additional de-stoning should be done in order to remove small light stones, dirt balls and other foreign material which could not be removed in the farm stock de-stoners. Special care should be taken to avoid overloading size grading equipment.

5. The water activity of in-shell and shelled groundnuts (peanuts) should be low enough to prevent growth of microorganisms normal to the nut harvesting, processing and storage environment (e.g. an a_w of 0.70 or less at 25°C (77°F).

Inspection and Sorting

6. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials Experience has shown that aflatoxin is most frequently associated with mouldy, discoloured, shrivelled, insect damaged or otherwise damaged groundnuts. Mould contaminated groundnuts may exhibit some of the following characteristics:

(a) Darker skin colouring before and/or after roasting.

(b) Darker flesh (after blanching) before and/or after roasting.

(c) Resistance to splitting and/or blanching.

~~4.~~7. To remove mould-contaminated nuts effectively, sorting should be performed before and after blanching and roasting. Where splitting is part of the processing operation, nuts that resist splitting should be removed. The effectiveness of sorting techniques should be checked by regular aflatoxin analyses of the sorted groundnuts stream or of the finished product, or both. This should be done frequently enough to give assurance that the product is completely acceptable.

5.3 INCOMING MATERIAL REQUIREMENTS

5.3.1 Storage

~~5.~~8. Area with new concrete floors or walls should not be used for storage until it is absolutely certain that the new concrete is well-cured and free of excess water. For the first year it is safest to use an approved plastic cover spread over the entire new concrete floor as a moisture barrier prior to use for groundnuts. However, other means of protecting the groundnuts against moisture from "sweating" of concrete can be used, such as stacking of containers on pallets. The plastic can be removed when the warehouse is emptied. This system will protect against moulding of the groundnuts due to sweating of new concrete.