Draft Guidelines on preventing Ethylene Oxide (ETO) contamination in Spices Exports to EU

1. Background:

Ethylene oxide (ETO) is a flammable, colorless gas at temperatures above 51.3 F (10.7 C). When used directly in the gaseous form or in nonexplosive gaseous mixtures with nitrogen or carbon dioxide, ETO serves as a disinfectant, fumigant, sterilizing agent, and insecticide. The major use of ETO is the sterilization of medical equipment. ETO is also used to reduce the microbial contamination in post harvest stage in plant products including spices, 2-Chloroethanol or ECH is the degraded product of ETO. US have established tolerance levels for residues of ETO in food materials, when used as a post-harvest sterilizing agent in Spices as 7 mg/kg and for ECH as 940 mg/kg. Canada also have set maximum residue levels (MRLs) for ETO at 7 mg/kg and ECH at 940 mg/kg. Codex Standards do not have MRLs for ETO and ECH for foods.

ETO has also been reported to be produced from natural sources. In certain plants, ethylene (a natural plant growth regulator) is degraded to ethylene oxide. It is also a product of ethylene catabolism in certain microorganisms. ETO is also generated from water logged soil, manure, and sewage sludge. Quantitative estimates of production from these natural sources are not studied much, but emissions are expected to be negligible.

2. EU regulation on ETO:

The current EU legislation regulating residues of ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide) is Commission Regulation (EU) 2015/868, which sets the MRL (Maximum Residue Level) for the sum of ETO and ECH in herbs and spices. The use of ETO for the sterilization of foodstuffs within the EU as well as the import of foodstuffs containing residues of ETO and ECH above the MRLs into the EU is illegal. Applications of biocidal products containing ethylene oxide are allowed for disinfection in the EU, but without food contact.

The MRLs of ETO for spices & herbs have been specified in the Commission regulation (EU) 2015/868 of 26 May 2015 which is attached as Annex-1.

3. Preventive measures for ETO contamination

- Exporters of Spices to EU shall not use ETO as sterilizing agent to reduce microbial contamination in spices consignments intended for export to EU.

- Exporters are advised to check and test their raw materials, processing aids and finished goods for ETO contamination. On instances of ETO detection, exporters shall not export the products to EU. Root cause analysis for its occurrence and preventive measures to be followed should be recorded for future compliance. Frequency of raw material check should be increased for such supply and suppliers.

- Exporters shall included ETO as a hazard in their hazard analysis critical control points (HACCP).

- Exporters shall include voluntary testing of ETO during raw material procurement and on final product intend to be exported to EU as a monitoring measure.

- Exporters shall ensure that transporters, storage houses, packaging material suppliers, cold storage etc. shall not use ETO during any processes.

- ETO treated products intended for destinations other than EU shall be separately processed, stored & transported at all times to prevent cross contamination.

- Exporters of organic spices to EU shall follow the guidelines/ advisories on prevention of ETO contamination in organic products issued by APEDA / Organic Certification Bodies under NPOP.

- In case the exporters have their own ETO sterilization unit, areas where ETO is used should be demarcated and adequate measures should be taken to prevent the cross-contamination with spices intended for export to EU. Food Safety/ HACCP Plan shall be established and implemented to control the cross-contamination of spices and spice products. Spice unit shall monitor the ETO /its residue in spices and spices products and keep records.

- Awareness training on not to use ETO sterilization for EU exports shall be imparted to all the stakeholders including raw material suppliers/Traders/processors.

4. **Alternate methods of sterilization**

Exporters of spices to EU are encouraged to use alternate methods of sterilization as suitable.

a) Steam Sterilization
b) Irradiation (not applicable to organic products under NPOP)
c) any other suitable methods

5. Guidance on microbial load reduction

Manufacture exporters of Spices are advised to adhere to the following guidelines in processing of spices to reduce / eliminate microbial contamination in spices.

a) Codex General Principles of Food Hygiene (CXC-1-1969)
b) Code of Hygienic Practices for Low Moisture Foods (CAC/RCP 75-2015)
c) Requirements of Schedule IV of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations 2011.

a) 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 & plant parts, used as spices and dried culinary herbs, if suspected of being contaminated with any filthy material should be rejected.

- Special precautions should be taken to reject spices and dried culinary herbs showing signs of pest damage/infestation or mould growth because of the potential hazard from them to contain mycotoxins such as aflatoxins.

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

- 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 have been implemented to minimize the possibility of chemical, physical and microbiological contamination.

- 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 .

b) Measures to prevent 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.

c) 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 re-absorption 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. All bags/containers should be in good condition and particular attention paid to the potential for loose bag fibers that can become potential contaminants.

- 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 microbial growth.

d) Transportation

- When the commodity is moved into or out of the warehouse, ensure that it is protected from any of the external adverse environmental factors like rain, high temperature, humidity etc. During transportation, attention should be given to avoid re-entry of water/moisture into the commodity and to ensure that pests or debris cannot penetrate into the commodity.

- Regular checks should be made to ensure that the truck is covered and that there are no rips in the covers and no leaks on the undersides of trucks which could allow water from the road to get into the truck. Check from the inside by closing all doors and looking for holes where daylight is visible.

- Trucks must be clean, dry and odour-free which helps to prevent cross contamination from previously transported products.

- The pallets or wooden floors of transport containers should be hygienic and dry. For products that require a long period of transportation, temperature and humidity should be monitored, where appropriate. Spices absorb moisture quickly if the bags get wet and as a result the moisture content increases considerably.

- Bags should preferably be placed on a layer of pallets to avoid contact with the floor where condensation from the ceiling and walls may gather.

- If available, fully ventilated containers are preferable for spices in bags, especially if shipped from a high humidity region. Desiccant boxes filled with calcium chloride can absorb around 100% of their own weight in moisture and may be used for added protection.

- It is important that care is taken not to damage these dry-bags and any spillages should be cleaned up immediately.

- It is important to maintain ample space between bags and the roof of the containers or transportation devices. Use of the saddle stow method, which minimizes side contact and maximizes airflow between the bags, is recommended.

- 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.

- 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.

5.Sample testing:

Suitable testing methods shall be employed for testing of ETO in spices.

e.g Based on EURL-SRM: Analysis of Ethylene Oxide and its Metabolite 2-Chloroethanol by the QuOil or the QuEChERS Method and GC-MS/MS.

Annex 1

MRLs of ETO for spices & herbs specified in the Commission regulation (EU) 2015/868

Code number	**Groups and examples of individual products to which the MRLs apply**	**Ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide) mg/kg**
0800000 SPICES		
0810000	(i) Seeds	0.1
0810010	Anise	
0810020	Black caraway	
0810030	Celery seed (Lovage seed)	
0810040	Coriander seed	
0810050	Cumin seed	
0810060	Dill seed	
0810070	Fennel seed	
0820000	(ii) Fruits and berries	0.1
0820010	Allspice	
0820020	Sichuan pepper (Anise pepper, Japan pepper	
0820030	Caraway	
0820040	Cardamom	
0820050	Juniper berries	
0820060	Pepper, black, green and white (Long pepper, pink pepper)	
0820070	Vanilla pods	
0820080	Tamarind	
0820990	Others	
0830000	(iii) Bark	0.1
0830010	Cinnamon (Cassia)	
0830990	Others	
0840000	(iv) Roots or rhizome	0.1
0840010	Liquorice	
0840020	Ginger	
0840030	Turmeric (Curcuma)	
0840040	Horseradish	

0840990	Others	
0850000	(v) Buds	0.1
0850010	Cloves	
0850020	Capers	
0850990	Others	
0860000	(vi) Flower stigma	0.1
0860010	Saffron	
0860990	Others	
0870000	(vii) Aril	0.1
0870010	Mace	
0870990	Others	
0231020	Peppers (Chilli peppers)	0.02
0220010	Garlic	0.02
0256030	Celery leaves	0.05
0256040	Parsley	0.05
0256050	Sage	0.05
0256060	Rosemary	0.05
0256070	Thyme (Marjoram, oregano)	0.05
0256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0.05
0256090	Bay leaves	0.05
0256100	Tarragon (Hyssop)	0.05
0401080	Mustard seed	0.05
0163050	Pomegranate	0.02