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Circular No: 8/2021

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Sub: Guidelines on preventing Ethylene Oxide (ETO) contamination in spices exported to EU-reg

Ref: Spices Board Circular No:18/2020 dated 2nd December, 2020 on Potential risk due to presence of Ethylene Oxide in export consignments intended to the European Union (EU)- reg

Spices Board has received RASFF alerts from the European Union (EU) for presence of Ethylene Oxide (ETO) in spices exported from India to the EU.

The Board after detailed deliberations with the Indian spice industry has prepared a set of guidelines on preventing Ethylene Oxide (ETO) contamination in spices exported to EU, which is attached as Annexure I.

All exporters of spices and spice products are advised to follow the guidelines and to exercise due diligence, to ensure absence of ETO residues in spices and spice products exported from India to the EU.

Director (MKTG)

To
All Exporters of Spices and Spice Products

(Issued from File No: MKT-RASFF/0001/2021)

(Hindi Version follows)



Annexure - I

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 non-explosive 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.

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 placed as Appendix-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 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 shall be recorded for taking necessary steps to avoid future recurrence. Adequate precautions shall be taken while procuring from such sources.
- Exporters shall identify ETO as a hazard and incorporate critical control points for ETO in their hazard analysis critical control points (HACCP) plan.
- Exporters, as a monitoring measure, shall include voluntary testing of ETO during raw material procurement and on final product intended to be exported to EU.
- Exporters shall ensure that transporters, storage houses, packaging material suppliers, cold storage etc. does not use ETO during any processes.
- ETO treated products (if any) 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 shall be demarcated and adequate measures shall 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.
- to EU 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:

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, herbs and their source plants shall 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 shall be taken to minimize the chances for cross-contamination of the establishment and other products from incoming materials that may be contaminated.
- Plants & plant parts, used as spices and herbs, if suspected of being contaminated with any filthy material, shall be rejected.
- Special precautions shall be taken to reject spices and herbs showing signs of pest damage/infestation or mould growth, so as to eliminate the potential hazard of mycotoxins such as aflatoxins.
- Raw materials shall 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*, shall be conducted when necessary.



- Because of the diversity of production practices for spices and herbs, it is important to understand the controls in place for production of the incoming material. Spices and herbs shall 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.
- If the control measures used to produce the spices and herbs are not known, verification activities such as inspection and testing shall be increased. Consideration shall be given to a program for testing spices and herbs.

b) Measures to prevent microbiological cross-contamination

- Effective measures shall be taken to prevent cross-contamination of spices and herbs by direct or indirect contact with potentially contaminated material at all stages of the processing. Raw products that may present a potential hazard shall be processed in separate rooms, or in areas physically separate from those where end-products are being prepared/stored.
- Spices and herbs that have undergone a microbial reduction treatment shall be processed and stored separately from untreated spices and herbs.
- Customs Bonded warehouses/ external storage areas shall also comply with the requirement of having separate storage spaces for ETO treated and non-treated materials to avoid cross contamination. As far as possible, it shall be ensured that products intended for export to the EU shall be stored separately, without proximity to export items intended to non-EU countries.
- The equipment which have been used to handle treated products shall be adequately cleaned and disinfected after use. Care shall be taken to avoid use of equipment to handle both treated and untreated products, without adequate cleaning and disinfection.

c) Packaging

- Non-porous bags/containers shall be used to protect the spices and herbs from contamination, occurrence of moisture and infestation of insects and rodents. In particular, the re-absorption of ambient moisture shall be prevented. Contamination shall 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 shall be in good condition and particular attention shall be paid to avoid loose bag fibers that can become potential contaminants.
- Spices and herbs, e.g. dried chilli peppers, shall not be sprayed with water to prevent breakage during packing. This may result in growth of moulds and microbial pathogens.
- 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

- While moving the commodity into or out of the warehouse, adequate care shall be taken to ensure protection from any of the external adverse environmental factors like rain, high temperature, humidity etc. During transportation, attention shall be given to avoid exposure to water/moisture and to ensure that pests or debris do not penetrate into the commodity.
- Regular checks shall be made to ensure that the transporting vehicle is covered, that there are no rips in the covers and no leaks on the undersides of vehicle which could allow water from the road to get into the vehicle.
- Vehicles used for transportation must be clean, dry, odour-free and free from infestation, which helps to prevent cross contamination from previously transported products.
- Bags shall preferably be placed on pallets to avoid contact with the floor. The pallets and frames used for transportation shall be hygienic and dry.
- Spices absorb moisture quickly if the bags get wet, resulting in considerable increase in moisture content. For products that require a long period for transportation, temperature and humidity shall be monitored, where appropriate.
- Fully ventilated containers are preferable for transporting 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.
- Care shall be taken not to damage the dry-bags packed with spices, and any spillages shall be cleaned immediately.



- Ample space shall be maintained between bags and the roof of the vehicle. Use of the saddle stow method, which minimizes side contact and maximizes airflow between the bags, is recommended.
- While transporting spices and herbs in bulk (E.g. by ship or rail), care shall be taken to ensure adequate ventilation, so as to prevent moisture condensation, resulting from respiration, movement of vehicle from a warmer to a cooler region or from day to night etc
- Prior to bulk transport, the products must be dried to a safe moisture level to prevent the growth of mould and pathogens.

5. Sample handling and testing:

- Adequate care shall be taken while handling samples for testing so as to eliminate the possibility of cross contamination from gloves, sampling equipment etc.
- Appropriate 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 using GC-MS/MS¹.

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https://www.eurl-pesticides.eu/docs/public/tmp/it_article.asp?LabID=200&CntID=1164&Theme_ID=1&Pdf=False&Lang=EN



Appendix I

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	
0810010	Anise	
0810020	Black caraway	
0810030	Celery seed (Lovage seed)	
0810040	Coriander seed	
0810050	Cumin seed	
0810060	Dill seed	0.1
0810070	Fennel seed	
0820000	(ii) Fruits and berries	
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)	0.1
0820070	Vanilla pods	
0820080	Tamarind	
0820990	Others	
0830000	(iii) Bark	
0830010	Cinnamon (Cassia)	
0830990	Others	0.1
0840000	(iv) Roots or rhizome	
0840010	Liquorice	
0840020	Ginger *	0.1
0840030	Turmeric (Curcuma)	
0840040	Horseradish	
0840990	Others	
0850000	(v) Buds	
0850010	Cloves	
0850020	Capers	0.1
0850990	Others	
0860000	(vi) Flower stigma	
0860010	Saffron	0.1
0860990	Others	

*Although the EU Regulation 2015/868 cites the limit for Ginger as 0.1 mg/kg, it has been observed that RASFF alerts have been issued against an MRL of 0.02 mg/kg . This discrepancy has been taken up with DG SANTE, EU and an official clarification is awaited.



0870000	(vii) Anil	
0870010	Mace	0.1
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