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Edward M. Ruckert
Attorney at Law
eruckert@mwe.com
202.756.8214

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VIA E-MAIL AND U.S. MAIL

Debra Edwards, Ph.D.
Director, Special Review and Reregistration Division
c/o Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
U.S. Environmental Protection Agency, Room S-4400
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: **Comments of the American Spice Trade Association ("ASTA") Concerning the Proposal to Change the Tolerance for Ethylene Oxide, Docket No. EPA-HQ-OPP-2008-0834**

Dear Dr. Edwards:

On December 31, 2008, a notice of proposed rulemaking was published in the Federal Register which among other things, would change the tolerance for ethylene oxide ("EO"). *73 Fed. Reg. 80317-32.* The proposal included changes to the expression of the commodities subject to the tolerance for EO, the level of this tolerance and the level of ethylene chlorohydrin ("ECH") the specific reaction product being added to the tolerance expression.

Our client, the American Spice Trade Association (ASTA), is a trade association that represents the U.S. spice industry. It was founded in 1907 and represents the interests of approximately 175 members including companies that grow, dehydrate, and process spices. ASTA's members include U.S.-based agents, brokers, and importers, and companies based outside of the U.S. that grow spices and ship them to the U.S. and other companies associated with the U.S. spice industry. ASTA members manufacture and market the majority of spices sold in the U.S. at retail and to food processors.

EO is a critical fumigant used to prevent the spread of a variety of pests including microbial organisms which are injurious to human health. EO is the most significant tool available to the U.S. spice industry to prevent not only the introduction and dissemination of plant pests in spices but also extremely dangerous human microbial contaminants such as *salmonella*, *e-coli*, etc. Without EO, our nation would face a significant increase in actual risk from these dangerous pathogens. Consequently, ASTA's members are very interested in the continued availability of EO for use in treating spices and in assuring that residues in treated spices are within required tolerances.

ASTA members have reviewed the subject proposed rule and have several comments regarding the proposal. First, the description of the treated commodities that would be subject to the tolerance expression is too limited. Specifically, the Agency proposes to replace the current references to "whole spices" and "ground spices" in *40 CFR 180.151(a)* with "Herb and spice, group 19, dried, except basil" and "vegetable, dried". *Id at 80329.* ASTA and its members believe that the proposed tolerance expression may not be as comprehensive as the existing tolerance expression. We are not objecting to the exclusion of basil from the tolerance expression. It is recognized that sufficient data have not be developed to date that would allow the Agency to include basil in the revised tolerance expression.

Attached is the ASTA spice list. With the exception of basil, each of the other listed spices may be treated today with EO in accordance with the current label requirements. Consequently, ASTA and its members strongly believe that the tolerance expression should address all potentially treated commodities. ASTA would request that the Agency review the ASTA "spice list" and where necessary, modify the tolerance expression to include all of those spices. Again, it is understood that basil, at this time, would not be included in the tolerance expression.

Second, as the Agency has acknowledged, a new process for applying the EO was introduced into the spice industry. This treatment process is specified on the EO product label. In most cases, the ASTA members have been able to make the necessary changes resulting in treated product being within the proposed tolerance. This is particularly true for treatment of whole spices. However, in some limited circumstances involving treating certain ground (processed) spices, there has been some difficulty in meeting the proposed tolerance value for the reaction product ECH. There is no problem meeting the current tolerance for EO in effect. Some of ASTA's members need some additional brief time to help assure that the tolerance proposal can be met in all circumstances. During that time they will be examining the treatment application to see what additional steps need to be taken to assure that all treated commodities meet the proposed tolerance. Based on the foregoing, it is requested that the finalization in the tolerance expression not be made effective before August 31, 2009.

ASTA and its members appreciate the opportunity to comment on the proposed rule. EO's continued availability is of vital interest to our members and helping to assure the continued safety of our nation's food supply.

Very truly yours,

Edward M Ruckert

Edward M. Ruckert
Counsel to the American Spice Trade Association

cc: Cheryl Deem
Joanne Cashin

AMERICAN SPICE TRADE ASSOCIATION, INC.
SPICE LIST

Spices

ASTA recommends that for the purpose of complying with FDA food labeling regulations (21 CFR Sec. 101.22), the following items may be declared in a product's ingredient statement either individually by its common or usual name or included under the term "spice" as permitted in 21 CFR Sec. 101.22(h). The spices on this list, and their derivatives (e.g. extracts and oleoresins), are considered by FDA to be generally recognized as safe (GRAS), or approved food additives (See 21 CFR Secs. 172.510, 182.10, and 182.20).

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Allspice (Pimento)	Berry	Pimenta officinalis
Anise Seed	Seed	Pimpinella anisum
Star Anise	Fruit	Illicium verum Hook
Balm (lemon balm)	Leaf	Melissa officinalis L.
Basil Leaves (Sweet)	Leaf	Ocimum basilicum
Bay Leaves (Laurel Leaves)	Leaf	Laurus nobilis
Black Caraway (Russian Caraway Black Cumin)	Seed	Nigella sativa
Camomile, English or Roman	Flower	Anthemis nobilis L.
Camomile, German or Hungarian	Flower	Matricaria chamomilla L.
Capsicums	Fruit	Capsicum spp.
Caraway Seed	Seed	Carum carvi Maton.
Cardamom[1]	Fruit	Elettaria cardamomum
Cassia/Cinnamon	Bark	Cinnamomum spp.
Celery Seed	Seed	Apium graveolens
Chervil	Leaf	Anthriscus cerefolium
Chives	Leaf	Allium schoenoprasum
Cilantro (Coriander Leaf)	Leaf	Coriandrum sativum
Cinnamon/Cassia	Bark	Cinnamomum spp.
Cloves	Bud	Syzygium aromaticum
Coriander Seed	Seed	Coriandrum sativum
Cumin Seed (Cummin)	Seed	Cuminum cyminum
Dill Seed	Seed	Anethum graveolens/Anethum sowa
Dill Weed	Leaf	Anethum graveolens/Anethum sowa
Fennel Seed	Seed	Foeniculum vulgare
Fenugreek Seed (Foenugreek Seed)	Seed	Trigonella foenum-graecum
Ginger	Root	Zingiber officinale
Horseradish	Root	Armoracia lapathfolia Gilib.
Juniper	Berry	Juniperus communis
Lavender	Flower	Lavandula officinalis Chaix.
Mace	Aril	Myristica fragrans
Marjoram Leaves	Leaf	Majorana hortensis Moench
Mustard Seed	Seed	Brassica juncea/B. hirta/B. nigra
Nutmeg	Seed	Myristica fragrans
Oregano Leaves	Leaf	Origanum vulgare/Lippia spp.

Paprika	Fruit	Capsicum spp.
Parsley (Dehydrated Parsley, Parsley Flakes)	Leaf	Petroselinum crispum
Black Pepper	Berry	Piper nigrum
White Pepper	Berry	Piper nigrum
Green Peppercorns	Berry	Piper nigrum
Pink Peppercorns	Berry	Schinus terebinthifolius
Peppermint Leaves (Peppermint Flakes)	Leaf	Mentha piperita
Poppy Seed	Seed	Papaver somniferum
Rosemary Leaves	Leaf	Rosmarinus officinalis
Sage Leaves	Leaf	Salvia officinalis/Salvia triloba
Savory Leaves	Leaf	Satureia montana/Satureia hortensis
Sesame Seed[1]	Seed	Sesamum indicum
Spearmint Leaves (Spearmint Flakes)	Leaf	Mentha spicata
Tarragon Leaves	Leaf	Artemisia dracunculus
Thyme Leaves	Leaf	Thymus vulgaris/Thymus serpyllum/Thymus satureioides
Vanilla Bean	Fruit	Vanilla planifolia/Vanilla tahitensis Moore

Dehydrated Vegetables Used As Spices

Because, in addition to their use as spices (e.g. granulated or powdered onion and garlic), these items are traditionally regarded as foods, they shall be declared by common or usual name consistent with 21 CFR Sec. 101.22(a)(2):

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Garlic	Bulb	Allium sativum
Onion	Bulb	Allium cepa

Spices Used As Color Additives

Consistent with 21 CFR Sec. 101.22(a)(2), the following spices, which can be used to impart color as well as flavor, shall be declared as "spice and coloring" or declared individually by common or usual name:

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Annatto Seed	Seed	Bixa orellana
Paprika	Fruit	Capsicum spp.
Saffron	Stigma	Crocus sativus
Turmeric	Root	Curcuma longa

FOOTNOTE:
[1]Must be listed by specific form (i.e., natural or hulled).

Revised January 22, 2004
Approved by ASTA Board of Directors/Government Relations Committee March 2004