McDermott
Will&Emery

Boston Brussels Chicago Düsseldorf London Los Angeles Miami Munich
New York Orange County Rome San Diego Silicon Valley Washington, D.C.

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

November 18, 2005

VIA EMAIL/EDOCKET

Ms. Debra Edwards
Director
Special Review and Reregistration Division
c/o Public Information and Records
Integrity Branch (7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Ethylene Oxide Risk Assessment; Notice of Availability; Reopening of Comment Period. Docket ID Number OPP-2005-0203

Dear Ms. Edwards:

These comments are submitted on behalf of our client, the American Spice Trade Association ("ASTA") in response to the subject Notice regarding the Ethylene Oxide Risk Assessment that was published in the Federal Register on October 19, 2005, 70 Fed. Reg. 60823-24.[1] Ethlyene Oxide ("ETO") is of critical importance to the spice industry. Therefore, any regulatory changes affecting the continued use and availability of this chemical for treatment with spice is of great interest to ASTA and its members.

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.

[1] ASTA appreciates the Agency reopening of the comment period on the Ethylene Oxide Risk Assessment. The original Notice of the Risk Assessment was published in the Federal Register on August 3, 2005. 70 Red. Reg. 44632-4. The additional time has been of assistance to ASTA in formulating these comments.

ASTA and its members believe the risk assessment that the Agency has performed for ETO and its metabolite ethylene chlorohydrin (ECH) should be significantly revised. The Agency has not considered the results of a study of the magnitude of the residues of ETO and ECH on spices that was recently submitted to it (MRID # 466253-01). As more fully described below, those data establish that through a change in fumigation practices, residue levels in treated spices were substantially reduced for both ETO and ECH. The Agency should consider these significantly reduced residue values in conducting its risk assessments of the chemical. It is believed that these data help substantiate that ETO can be used to treat spices in a manner that meets the safety provisions of Section 408 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 346a) as well as not presenting an unreasonable adverse effect to the environment, including man pursuant to the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 136 et seq.). In short, there is reliable information that demonstrates that the use of ETO on spices should be reregistered.[2]

I. The Use of ETO in the Spice Industry

The Agency has correctly estimated the annual use of ETO on spices. It is approximately 800,000 pounds annually. This is slightly less than ten percent of all of the ETO used for sterilization purposes annually in the United States. By far, most ETO sterilization is directed towards the treatment of medical and laboratory equipment.

In the spice industry, not all spices are sterilized, let alone sterilized with ETO. Use of a sterilant on spices typically depends on the level of pathogens in the spice lot. These levels are established on a customer by customer basis. In the spice industry, approximately 40% to 85% of the spice inventory of ASTA members may be treated during the course of a year. There are a variety of reasons supporting treatment. First and foremost, sterilization protects the public health. Many spices originate in developing countries where sanitation and commodity and food handling practices are not at the level established in the United States. Consequently, it is well recognized and acknowledged that raw spice may contain pathogens. These pathogens include *E.coli* and *Salmonella* which can cause severe illness and even death, particularly for those people who may be immuno-compromised. ETO is extremely effective in reducing bacterial loads, yeast and mold, coliforms and other pathogens. Because of its proven effectiveness against a wide array of pathogens, ETO is a key component used by the spice industry in protecting the food supply from environmental contamination as well as from intentional biological attack.[3] The United States has a limited number of tools to address

[2] ASTA also notes that substantial material comments have been submitted by the ETO registrants regarding, among other things, the manner in which the Agency has characterized the occupational risk to ETO and the appropriate model that should be used in determining the carcinogenic potential of the compound. ASTA concurs with a those substantive comments and requests that the Agency thoroughly consider those comments as it proceeds in the risk assessment process.

[3] EPA has recently approved the use of ETO as an emergency process to kill anthrax in the mail.

pathogens in the food supply. Tools such as ETO must be available to help assure the continued safety of the U.S. food supply.[4]

ETO is also used to address plant or animal pests that may find their way into spice packaging material. Consequently, treatment is necessary to protect U.S. agricultural crops and native vegetation from the introduction or dissemination of these plant or animal pests into the United States.

There is another reason why ETO is applied to treat spices. Spices are used because of their appearance and for the flavor they impart to a food product. The sterilization of spices with ETO generally has no significant effect on the appearance or flavor of the spice. Consequently, its use does not affect the continued merchantability of the treated spice product.

As the interest in assuring a safe food supply grows, the spice industry is seeing an increasing trend by customers to demand lower microbial loads in spices, particularly when these spices may be included in ready-to-eat foods. Therefore, we believe that sterilization of spices will increase over time.

II. Alternative treatment techniques are not as effective as ETO

There are several potential alternatives to ETO. These all have various shortcomings when compared to ETO. This is not to suggest that these alternatives do not have a valuable place in the arsenal of tools that the spice industry has to address pathogens. It simply reflects that, for a number of reasons, the preferred alternative currently is treatment with ETO. A review of these alternatives follows.

A. **Propylene Oxide.** Like ETO, propylene oxide is a fumigant sterilant. However, it is not as effective as ETO in achieving consistently very low microbial counts. Also, it is currently in the re-registration process at EPA. It is not known whether or under what conditions the chemical may ultimately be available to the spice industry after completion of the re-registration process.

B. **Irradiation.** Irradiation is a potential treatment technique for use on spices. However, there are certain drawbacks associated with this technique. There has been a reluctance on the part of the public to embrace this technology not only on spices but also for other food products, or at least that is the perception among many spice industry customers who refuse to accept any product that has been irradiated.

There are other issues associated with irradiation. From an economic perspective in comparison to ETO, irradiation involves an increased treatment cost, and increased transportation costs. It requires additional lead time, and generally it is impractical for a spice

[4] Treatment with ETO is the primary method recommended by FDA for reconditioning spices that have tested positive for a pathogen.

company to conduct this treatment at their own facility. Further, you can only treat a product once with irradiation. If re-treatment is necessary because of a high bacteria count or because of a re-infestation, irradiation cannot be used.

High doses of irradiation can alter the appearance of some spices. Also, there is not enough capacity of irradiation facilities to treat all spices. In some cases, operators of these facilities do not want to treat spices because of the potential impact on their operations such as spice aromas being picked up by other non-spice products in the treatment facility.

C. **Steam.** Steam sterilization works well for some spices, such as berries (black and white pepper) and seeds (celery, dill and fennel). However, there are product degradation issues primarily associated with leafy spices and paprika. Also steam sterilization is not generally commercially available within the Unites States.

III. Recently Submitted Data Demonstrate that ETO and ECH Residues Are Much Lower Than the Data EPA Has Relied On Its Risk Assessments

In conducting its risk assessments for ETO, it appears that the Agency relied heavily on the results of a magnitude of residue study of ETO and ECH in spices submitted to EPA in May 1994 (MRID #432180-01). Since that study was submitted, ASTA members were engaged in the ETO fumigation process improvement research and development program. This program has resulted in significant changes in treatment techniques that have dramatically reduced residues of ETO and ECH, improved worker safety, treatment efficiency and process reliability. The program's results are reflected in a new magnitude of residue study that was recently submitted to EPA (MRID # 466253-01). That study analyzed 15 representative whole spices and 14 representative ground spices for ETO and ECH residues. This new ETO fumigation process results in the reduction of the ETO residue for almost all spice matrices to below the limit of quantitation (LOQ) of 1 ppm within 72 hours of treatment. Further, substantial reductions in ECH residues have also been achieved. Table 1 compares the results of the 1994 study with the 2005 study.

Table 1

Magnitude of the Residue Reduction
With the
New ETO Fumigation Process

	Average ppm ETO			Average ppm ECH		
Spice	1994 Study	2005 Study [1]		1994 Study	2005 Study [2]	
	(Ug/mL)	(Ug/mL)		(Ug/mL)	(Ug/mL)	
Whole Black Pepper	217	<1.0	(0.138)	288	154	
Ground Black Pepper	729	6.10		1505	250	

Whole Red Pepper	758	<1.0	(0.090)	1611	231	
Ground Red Pepper	1072	1.1		1445	179	
Whole Cassia	747	5.64		124	25	
Ground Cassia	1482	4.4		208	<50	(41)
Whole Ginger	458	ND		259	<25	(14)
Ground Ginger	877	<1.0	(0.146)	1161	99	
Whole Turmeric	95	ND		126	51	
Ground Turmeric	357	<1.0	(0.125)	1595	125	
Whole Basil	402	<1.0	(0.119)	6060	1730	
Ground Basil	48	<1.0	(0.347)	5491	1088	
Whole Oregano	252	<1.0	(0.284)	1005	241	
Ground Oregano	783	ND		600	166	
Whole Sage	1063	<1.0	(0.218)	478	214	
Ground Sage	1313	ND		890	203*	
Whole Caraway	439	5.44		104	77	
Ground Caraway	2042	<1.0	(0.288)	355	78	
Whole Celery	276	<1.0	(0.579)	1015	299	
Ground Celerv	579	<1.0	(0.462)	2009	335	
Whole Coriander	399	3.06		618	844**	
Ground Coriander	2399	2.64		1164	67	
Whole Cumin	275	ND		716	128	
Ground Cumin	991	1.68		1372	181	
Whole Fennel	68	<1.0	(0.095)	1696	275	
Ground Fennel	1046	ND		2197	261	
Whole Nutmeg	760	20.5		298	<50	(22)
Ground Nutmeg	1345	1.73		255	66	
Whole Sesame Seed	221	1.71		<100	53	

[1] Values in parentheses are the actual calculated residues, which are below LOQ for ETO.

[2] Values in parentheses are below the ECH LOQ (indicated by < value) for the matrix.

* Control contained ca. 237 ppm ECH indicating pretreatment with ETO for this matrix.

** Control contained ca. 480 ppm ECH indicating pretreatment with ETO for this matrix. ND indicates no residue above LOD detected.

These results should be reviewed by the Agency and incorporated into the risk assessments that have been prepared. In doing so, it is believed that the risk profile for ETO including its metabolite ECH will be significantly revised.

IV. The Method Used to Apply ETO and the Personnel Protective Equipment Used by Workers Should Result In an Acceptable Worker Risk Assessment

ASTA believes it would be helpful to the Agency's consideration of the occupational exposure risk to ETO and its metabolites if the Agency considered how the chemical is applied and the steps taken by workers to handle the treated spices. ASTA notes that the Agency would like additional data in this regard, and ASTA would like to discuss further with the Agency those needs and the best method for addressing those needs. As noted above, the change in the manner in which ETO is applied results in virtually no ETO residues in the treated spices (see Table I). Further ECH in the spices is not volatile so exposure to this metabolite should not be a concern.

The actual application of ETO to spices involves the following:

The untreated spices are placed in a vacuum chamber by a fork lift operator. The chamber is sealed and a predetermined amount of the ETO is introduced. This amount depends on the size of the chamber and the amount of gas necessary to kill the pathogen in that size chamber.

The treated spice is held in the chamber for a set time. The gas is then evacuated and a number of air exchanges occur within the test chamber which reduces substantially ETO and ECH residues.

After the treatment has been completed, a worker will remove the treated spice. Historically, such worker would be wearing a canister mask. The industry routinely monitors the exposure of its workers to ETO. As the Agency has noted, there are various standards established applicable to exposure to ETO. *See e.g.,* 15 minute short term exposure limit of 5 ppm, and an 8 hour time-weighted average of 1ppm. With the new modified process, the exposures are well below these values. Consequently, ASTA believes that the Agency will ultimately determine that the occupational risk from exposure to ETO and its metabolites is acceptable.

V. Conclusion.

ASTA would reiterate its request to meet with the Agency to discuss the results of the new residue study, the concerns with some of the risk assessment methodologies used and results developed by the Agency in this instance as reflected herein, and the next steps to be taken in refining the current risk assessments. While this may slightly extend the time the Agency needs to make a final determination regarding the re-registration of ETO, given the significance of this chemical to the spice industry and to protecting the Nation's food supply from harmful

pathogens such as *E.coli* and *Salmonella*, exercising such care in the deliberative process is necessary and appropriate.

Thank you for your consideration of these comments.

Very truly yours,

Edward M. Ruckert

cc: ASTA ETO Members

WDC99 1164059-1.027734.0010