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Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Ethylene Oxide

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Approved By:

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Director, Special Review and
Reregistration Division

July 24, 2006
Date

Abstract

The Environmental Protection Agency (EPA) has concluded its tolerance reassessment for ethylene oxide (ETO) and has determined that with the exposure mitigation described in this document, there is a reasonable certainty that no harm to any population subgroup will result from exposure to ETO or its reaction products, ethylene chlorohydrin (ECH) and ethylene glycol (EG). Therefore, the four tolerances established for residues of ETO are now considered reassessed as safe under section 408(q) of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA).

This Tolerance Reassessment Decision (TRED) document considers dietary risk associated with pending requests for voluntary cancellation of use on basil from Honeywell - Fluorine Products NIC5 (Honeywell) and Balchem Corporation. In letters dated July 7, 2006, and July 10, 2006, respectively, both Balchem and Honeywell corporations have requested irrevocable voluntary termination of basil uses of its ethylene oxide products and requested label amendments. These requests will be approved pending the completion of a 30 day public comment period announced in the ***Federal Register***.

This TRED also considers the exposure mitigation achieved through use of sterilization methods which result in lower residues than the conventional method. The registrants have agreed to amend their labels to mandate use of such methods.

The Agency is issuing this TRED document for ETO as announced in a Notice of Availability published in the ***Federal Register***. The Agency is providing a 60-day comment period for stakeholders to respond to this risk management decision. If substantive information is received during the comment period that indicates a need to reconsider the decisions presented in this document, EPA may modify these decisions as appropriate through an amendment.

I. Introduction

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision for Ethylene Oxide." This document is also known as a Tolerance Reassessment Decision, or TRED. This TRED reassesses the tolerances associated with ETO and its reaction product ethylene chlorohydrin (ECH) to ensure the pesticide meets the standards of FQPA. No residues of ETO *per se* are expected on food at the time of consumption. Therefore, the dietary risk assessment focuses on the risks associated with ECH and another reaction product, ethylene glycol (EG).

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on the day before enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern, and that there is no common mechanism of toxicity with other pesticides, the tolerances are considered reassessed. Existing tolerances associated with ETO and its reaction products must be reassessed in accordance with FFDCA, as amended by FQPA.

This TRED will be followed by a Reregistration Eligibility Decision (RED) for ETO, scheduled for 2007. The RED will be prepared once the Agency's Office of Research and Development (ORD) completes its assessment of ETO carcinogenicity. Once the ORD carcinogenicity assessment is complete and publicly available, the results will be incorporated into the Office of Pesticide Programs' (OPP) risk assessment for ETO and a RED will be prepared. The RED will include an occupational assessment which is typically not included in a TRED. The RED will also address ETO's special review status. ETO was placed in special review in 1978 based on predicted developmental toxicity, mutagenicity, and neurotoxic effects in workers. In the early 1980s, the carcinogenicity of ETO emerged as an issue and was included as a special review concern. After the RED is finalized in 2007, the Agency intends to complete the special review for ETO later that year.

Readers should be aware that the current human health risk assessment reflects the following exposure mitigation outlined in chapter IV of this TRED and agreed to by the registrants.

Voluntary Deletion of the Following:

Use Pattern: Basil

Label Amendments:

Manufacturing and end-use label language to read:

Manufacturing and end use products will be amended to (1) prohibit use on basil, and (2) require the use of sterilization methods which have been demonstrated to result in residue levels which are lower than those that result from sterilization using conventional sterilization methods.

Specific label language is included in Section V of this document.

II. Background

ETO is a fumigant/sterilant used to sterilize medical or laboratory equipment, pharmaceuticals, and aseptic packaging (21 CFR §201), or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials, copra[1], dried vegetables and black walnuts (40 CFR §180), and artifacts, archival material or library objects. Sterilization/fumigation with ETO must be performed only in vacuum or gas-tight chambers designed for use with ETO. It is applied by commercial applicators only; there are no residential uses of ETO. Tolerances for residues of ETO and ECH in/on black walnuts, copra, whole spices and ground spices are established under 40 CFR §180.151.

Agency estimates of ETO usage indicate that a major use of ETO in the U.S. is commercial fumigation/sterilization. A majority of this fumigation is for sterilization of medical and laboratory items/equipment. A much smaller portion of ETO annual usage is for fumigation of herbs and spices. ETO treatment is the principal method used to reduce bacterial levels in spices/herbs and black walnuts. All other uses account for less than 1 percent of the total annual usage for pesticide purposes.

ETO residues decline rapidly after sterilization and are unlikely to be found in spices available for consumption. ECH and another reaction product, ethylene bromohydrin (EBH), have been shown to result from fumigation of foods with ETO due to ETO interaction with natural chlorides and bromides present in the crop. At high sterilization concentrations, ETO reacts with moisture to form another reaction product, ethylene glycol (EG), and, in the presence of sugars, glycol derivatives. Spice sterilization study data indicate persistent high levels of the reaction products ECH and EG in treated spices and herbs and walnuts. Therefore, toxicological

1 The tolerance and/or use in/on coconut copra will be proposed for revocation as the registrant is not supporting this use.

endpoints were selected for dietary exposure to these reaction products. However, no tolerances are required for EG because there is no acute toxicity endpoint and chronic dietary risk are well below EPA's level of concern. EBH residues are also found in treated commodities, but are minimal relative to ECH and therefore were not evaluated quantitatively in the risk assessment and no EHB tolerances are required.

III. ETO Risk Assessments

Please refer to Appendices B and C, respectively, for the Revised Acute Dietary Exposure Assessment for the Reregistration Eligibility Decision for ETO, dated June 21, 2006, and the Addendum to Revised Residue Chemistry Chapter for Ethylene Oxide Reregistration Eligibility Decision (RED) Document Issued July 12, 2006, for details on the risks associated with dietary exposure to ETO. These documents are also available in the public docket EPA-HQ-OPP-2005-0203, located on-line in the Federal Docket Management System (FDMS) http://www.regulations.gov.

IV. Regulatory Determinations

A. FQPA Assessment Supporting Tolerance Reassessment Decision

EPA has evaluated the dietary risks from the supported registered uses of ETO and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to ETO or its reaction products.

The Agency's dietary risk assessments incorporate both exposure to and toxicity of a given pesticide. Dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose predicted to result in no unreasonable adverse health effects to any human population subgroup, including sensitive members of such population subgroups. This level of concern is referred to as the population adjusted dose (PAD), which reflects the reference dose (RfD), either acute or chronic, adjusted to account for the FQPA safety factor.

Estimated risks that are less than 100% of the PAD are below EPA's level of concern. The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on any given day with no adverse health effects expected. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no adverse health effects expected.

The acute dietary exposure estimates for ETO food uses, which includes whole and ground spices (except basil), dried vegetables, and walnuts, for the general U.S. population and all population subgroups, occupy less than 100 percent of the aPAD. The highest acute exposures at the 99.9th percentile for ECH were for children 1 to 2 years old at 96 percent of the aPAD. This assessment concludes that for the commodities listed above, the acute dietary exposure estimates

for ECH are below the Agency's level of concern. An acute assessment for EG was not conducted because an acute RfD for EG was not established since effects were seen only at high doses (greater than 1,000 mg/kg/day) in oral studies including developmental toxicity studies.

The chronic dietary exposure estimates for both ECH and EG are below the Agency's level of concern for the general population and all population subgroups and occupy less than 100 percent of the cPAD. The highest estimated chronic exposures for ECH were for children 1 to 2 years old at 38 percent of the cPAD. The highest estimated chronic exposures for EG were for children 1 to 2 years old at 7 percent of the cPAD.

EPA has determined that risk from exposure to ETO and its reaction products is within its own "risk cup." In other words, EPA is able to conclude that the tolerances for ETO meet the FQPA safety standards. EPA has evaluated the dietary and drinking water risks from the supported registered uses of ETO and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to ETO and its reaction products. Because drinking water exposures are not expected, there are no residential uses, and the acute and chronic dietary exposure estimates for food are below the Agency's level of concern, the tolerances for ETO established at 40 CFR §180.151 are now considered reassessed under Section 408 (q) of FFDCA.

The Agency has also assessed potential risk to residential bystanders resulting from the commercial sterilization use of ETO. EPA's Office of Air and Radiation (OAR) conducted a residential risk assessment which estimated cancer as well as acute and chronic non-cancer risk to bystanders. The Agency concluded that potential cancer and non-cancer risks do not indicate any further regulatory action is necessary at this time.

B. Cumulative Assessment

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ETO and any other substances, and ETO does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that ETO has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

C. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity database for ETO, there were possible testicular effects (altered sperm counts and mobility) observed in a chronic monkey toxicity study. It should be noted that this study had many deficiencies and no other toxicological study involving ETO exhibited any potential endocrine disruption effects. Therefore, the Agency is confident that toxicity endpoints chosen for risk assessment purposes are protective of any potential endocrine disruption effects. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, ETO may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

D. Tolerance Reassessment Summary

Tolerances for residues of ETO under 40 CFR §180.151 in/on food commodities currently established and the proposed changes for ETO and ECH are summarized below.

(a) General. (1). Tolerances are established for the residues of the antimicrobial agent and insecticide ethylene oxide, when used as a post-harvest fumigant in or on the following food commodities:

Table1. Tolerance Reassessment Summary for Ethylene oxide

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.151 a(1)			
coconut, copra	50	revoke	should be revoked; treatment not used and registrant is not supporting this use
spices, whole	50	7	*[herbs and spices, group 19, dried (except basil)]*
walnut, black	50	50	*[walnut]*
Tolerances Listed Under 40 CFR §180.151 a(2)			
spices, processed	50	reassigned	Should be reassigned; ground spices included in *[herbs and spices, group 19, dried (except basil)]*
Tolerances to Be Proposed under 40 CFR 180.151 For Ethylene oxide			
vegetable, dried	none	7	

EPA will propose to remove all of section 151(a)(2) and replace with the following new section (a)(2):

Tolerances are established for residues of the ethylene oxide reaction product, 2-chloroethanol, commonly referred to as ethylene chlorohydrin, when ethylene oxide is used as a post-harvest fumigant in or on the following food commodities.

Table2. Tolerance Reassessment Summary for Ethylene oxide			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*[Correct Commodity Definition]***
Tolerances to Be Proposed under 40 CFR 180.151 For Ethylene Chlorohydrin			
herbs and spices, group 19, dried (except basil)	none	940	
vegetable, dried	none	940	

Codex Harmonization. There are no Codex Maximum Residue Levels (MRLs) for residues of ETO or ECH in/on spices/herbs. A Canadian MRL has been established for ECH at 1,500 ppm in/on spices. Canada does not have an MRL for ETO in spices/herbs. Since the U.S. residue data showed slightly lower levels of ECH, the Agency is proposing a 940 ppm tolerance. Consequently, the U.S. is not compatible with Canada in regards to ETO or ECH.

V. Data Requirements

These data requirements apply only to this TRED. Additional data requirements may be identified upon completion of the RED. EPA will issue a DCI in the near future for the studies listed below.

Product Chemistry Data Requirements. All pertinent data requirements are satisfied.

Toxicity Data Requirements. The database for ETO is found to be adequate and no additional studies are required for the parent compound. However, the following studies are identified as data gaps for the ETO reaction product ECH.

870.3700b	Developmental Toxicity (rabbits)
870.3800	Two-generation Reproduction Toxicity (rats)
870.4300	Chronic/Oncogenicity – Oral (rats and mice)
870.4100b	Chronic Toxicity – Oral (nonrodent)

Labeling Changes Summary Table [Appendix A]

In order to be consistent with the mitigation requirements outlined in the ETO TRED, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 1: Summary of Labeling Changes for Ethylene Oxide (ETO)

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	This product may only be used for formulation into a sterilant fumigation for the following pesticidal uses: to sterilize medical or laboratory items, pharmaceuticals, and aseptic packaging, or to reduce microbial load on cosmetics, whole and ground spices, ground vegetables or other seasoning materials excluding basil, and artifacts archival material or library items. "This product may not be used on or in any form of basil."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s). This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).@	Directions for Use

End Use Products		
Application Restrictions required for Risk Mitigation	Product labeling must be amended to remove all instructions for applications to Basil and the following statement must be added: "This product may not be used on or in any form of basil." Product labeling must be amended to restrict applications to use of the following type of equipment and methods: "After August 1, 2008, this product may only be applied to or on spices, dried vegetables or seasonings utilizing an ETO sterilization method that uses a single sterilization chamber to pre-condition and aerate with an alternating vacuum and aeration purging procedure. If you wish to employ an alternative method to that described below, you must contact the Environmental Protection Agency Office of Pesticide Programs for instruction on how to receive authorization." "Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then, introduce into the chamber a concentration of Ethylene Oxide not to exceed 500 mg/L, with a dwell time not to exceed 16 hours. Then evacuate the gas from the chamber using a sequence of not less than 16 steam washes (injections and evacuations) between 1.0 PSIA (28" Hg) and 2.0 PSIA (26"Hg) while maintaining a minimum chamber temperature of 120° F."	Directions for Use

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: June 21, 2006

SUBJECT: **Ethylene Oxide/Ethylene Chlorohydrin** Revised Acute Dietary Exposure Assessment for the Reregistration Eligibility Decision
PC Code: 042301
DP Barcode: D316677

REVIEWER: Becky Daiss, Environmental Health Scientist
Reregistration Branch 4
Health Effects Division (7509P)

THROUGH: Thurston Morton
Dietary Exposure Science Advisory Council (DESAC),
and
Susan Hummel, Branch Senior Scientist
Reregistration Branch 4
Health Effects Division (7509P)

TO: Susan Bartow, Chemical Review Manager
Special Review Branch
Special Review and Reregistration Division (7509P)

This document provides a revised acute probabilistic dietary risk assessment of exposures to ethylene chlorohydrin (ECH) resulting from use of ethylene oxide as a food fumigant using an improved fumigation process. This document updates the January 6, 2006 dietary assessment (B. Daiss, D325114). Only acute dietary exposures to ECH are assessed for this analysis because that scenario only produced risk estimates above EPA's level of concern based on a previous dietary assessment conducted for the Ethylene Oxide RED (B. Daiss, D313777, 3/30/05). This analysis incorporates ECH residue data from a recently conducted ethylene oxide fumigation study using the improved process which results in significantly reduced residues of ECH. The analysis has also been revised to exclude basil as a fumigated commodity based on comments submitted by McDermot, Will and Emmory regarding the registrant's intent to request deletion of basil from product labels.

Executive Summary

A refined acute dietary risk assessment of exposure to ethylene chlorohydrin was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. Residue data for this assessment was provided in 2001 ethylene oxide spice sterilization study submitted by the American Spice Trade Association (MRID 46635201). The submitted study describes a new ethylene oxide fumigation process that results in substantially reduced residues over those reported in the previously submitted magnitude of the residue study. For this assessment, it is assumed that basil is not fumigated with ethylene oxide based on the registrant's intent to request deletion of basil from the ethylene oxide product label. With the exception of basil, the entire distribution of fumigated commodity residues was used for the acute assessment. Maximum percent crop treated (sterilized) was used for the acute assessment.

Acute Dietary Exposure Results and Characterization

A refined probabilistic acute dietary exposure assessment was conducted for all supported ethylene oxide food uses except basil for the general U.S. population and various population subgroups. The assessment assumes commodities are treated with the improved fumigation process.

> This assessment concludes that for all supported commodities, except basil, the acute dietary exposure estimates for ethylene chlorohydrin are below HED's level of concern. The DEEM acute dietary exposure estimate at the 99.9th percentile for the highest exposed population subgroup, children 1-2 years of age, is 96% of the aPAD. A critical exposure contribution analysis for ethylene chlorohydrin indicates that marjoram and savory commodities account for the largest percentage of dietary risk for the general population as well as the highest exposed subgroup children 1-2 years old.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose below which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the special FQPA Safety Factor.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf ; or see SOP 99.6 (8/20/99).

II. Residue Information

The Biological and Economic Analysis Division (BEAD) provided a Quantitative Usage Analysis (QUA) for ethylene oxide (Attachment 1). Percent crop sterilized data were available and used for all treated commodities included in the dietary assessment. For the acute dietary analysis, the estimated maximum % crop sterilized with ethylene oxide was used when available. Available chemical specific data from cooking studies were used for cooked commodities.

Spices, herbs, and dried vegetables (garlic and onion) are treated as non-blended commodities for this assessment because sterilization occurs post-application and therefore blending of treated and non-treated spices, herbs, and dried vegetables is not likely to occur.

Existing and reassessed tolerances, assuming explicit deletion of basil from the product label, are provided in Table 1. These tolerances are based on residue data from a residue study in which the traditional sterilization process was used to treat spice/herb commodities. (J. Stokes, D325111, 1/25/06). If and when the improved ethylene oxide sterilization process as been fully adopted, as reflected in the product label, the tolerances may be reassessed and likely reduced based on the residue data from studies using the new process.

Table 1 - Tolerance Reassessment for Ethylene Oxide -- Tolerances Established Under 40 CFR §180.114

Commodity	Ethylene Oxide		Ethylene Chlorohydrin	
	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Current Tolerance (ppm)	Reassessed Tolerance (ppm)
spices/herbs (except basil)	50	50	--	2000
dried bulb vegetables	--	50	--	2000
Black walnut	50	50	--	50

Residue Data used for Acute Dietary Assessment:

Residues of Concern (residues included in dietary exposure analysis)

Residues of the ethylene oxide reaction product ethylene chlorohydrin only were included in this dietary assessment for spices/herbs, dried vegetable and walnuts. Ethylene chlorohydrin is considered a residue of concern for dietary exposure based on spice sterilization study residue data which shows that this compound is consistently present at high levels and that the residues persist.

Spice/Herb/Walnut Sterilization Study Data

Data from a 2001 ethylene oxide sterilization study were used to estimate residues of ethylene chlorohydrin in spices, herbs, walnuts, and dried vegetables (J. Stokes, D325111). This study was conducted in order to test the effect on ethylene oxide and ECH residue levels resulting from

recent improvements in the control of fumigation conditions that have been developed for the ethylene oxide sterilization process. Spice, herb, and walnut commodities were treated with ethylene oxide in commercial treatment chambers under conditions representative of the improved process and subsequently stored under conditions representative of actual handling practices in the spice industry. A total of 29 whole and ground spices and herbs were evaluated to represent three major categories of leaves, seeds and classical spices. Six whole and ground spices were also evaluated for residues resulting from repeated (two) treatments with ethylene oxide as representatives of the leaf, seed and classical spice categories. Spices were analyzed at three different post-treatment sampling intervals 0 time, 24 hours and 72 hours. Residue data from the 72 hour sampling interval was used in this dietary analysis. Based on information provided by the registrant, this data is assumed to be representative of residue levels likely to be found in treated spices.

HED assumes that herb and dried vegetable commodities identified as "fresh" in DEEM are not sterilized with ethylene oxide. Therefore, these commodities were excluded in this dietary analysis.

Residue Data Used for Acute Dietary Exposure Assessment

With the exception of the residue data for basil, all of residue data from the 2001 ASTA spice sterilization study have been used to assess acute dietary exposures to ethylene chlorohydrin. For individual commodities that are identified specifically in DEEM, commodity specific residue data were used if such data is provided in the ASTA residue study. For example, ASTA study residue data are provided for cinnamon and pepper and these spices are included as separate commodities in CSFII, therefore, cinnamon and pepper-specific residue data were included in a separate residue distribution file for these commodities. For commodities that are identified categorically in CSFII (e.g., "other spices/herbs"), study residue data from all of the spices and/or herbs provided for that category were used for the dietary assessment. For example, for the category "herbs other", all of the study data provided for specific herbs (i.e., oregano, sage) are used. Similarly, for herbs/spices that are identified specifically in CSFII but do not have corresponding commodity specific residue data from the sterilization study, all of the study residue data provided for specific spices and/or herbs were used to assess that commodity. For example, for the herb commodity chives, all of the study data provided for specific herbs (i.e., basil, oregano, sage) are used. Seeds are a subset of spices in CSFII. Therefore data from the sterilization study for spices and seeds were combined for spice and seed commodities in the dietary analysis. Study specific data for sesame seed which is identified as the food commodity category "other" were included in the residue distribution file for spices and seeds residue data. The ethylene oxide sterilization study provided no specific residue data for any commodities in the category of dried vegetables (e.g., garlic and onions). Therefore, all of the 72 hour residue data provided for all spice and herb commodities were included in the residue distribution file for dried onion and garlic commodities. Residues reported as non-detect were estimated at half the level of detection (LOD) for the acute dietary exposure assessment.

A drinking water exposure assessment was not conducted for this assessment because the Environment Fate and Effects Division expects that uses of ethylene oxide for indoor food and nonfood uses will result in insignificant exposure to drinking water resources.

Processing Factors

No processing factors (e.g., drying, baking) have been used because ethylene oxide spice sterilization is conducted post-processing.

Cooking Study

Cooking factors from a 1993 ^{14}C-ethylene oxide cooking study conducted by Agrisearch Inc., were used for the ethylene oxide dietary assessment. The cooking study was designed to determine the effect of cooking foods following addition of spices previously fumigated with ^{14}C-ethylene oxide. The identity and total quantity of ethylene oxide and its reaction products remaining in the foods after cooking was determined. Representative food types for the study (baked goods, biscuit; sauce, tomato sauce; and meat; frankfurter) were uniformly mixed with three representative spice types (leaves, seeds, and classical). The spices (9 total, 3 of each type) were fumigated with ^{14}C-ethylene oxide. The fumigated spice mixture was blended with the three representative food types for cooking (baked biscuit, boiled sauce, and fried frankfurter) and extracts were analyzed for quantitation of all observed radiocarbon materials. A more detailed description of the study is provided in the residue chemistry chapter (J. Stokes, D316652, 7/12/05). The study results demonstrated the magnitude and nature of the residue resulting from the cooked foods. The cooking factors determined for baked, boiled and fried foods were used for all EPA-defined food commodities specifically designated as baked, boiled, or fried in DEEM and Lifeline . Cooking factors were averaged for food forms designated as having undergone multiple methods of cooking i.e., baked/fried, baked/boiled, etc). Cooking factors for ethylene chlorohydrin residues are provided in Table 2.

Monitoring Data

No PDP or FDA monitoring data are available for ethylene oxide treated spices. Data used in the dietary analysis are provided in Tables 2 and 3.

Table 2. Data and Residue Estimates Used in Dietary Analyses

Commodity	Blended Status	Data Source	Max %CT	Process Factors	ECH Anticipated Residue Estimates
					Acute (Avg FT ppm)
Crop Group 19A: Herbs					
Chive	NB	Field Trials (ECH) 12 Samples 12 Detectable Residues	61	" "	RDF#3 Herbs (61% CT) TOTALZ=8 TOTALNZ=12

Table 2. Data and Residue Estimates Used in Dietary Analyses

Commodity	Blended Status	Data Source	Max %CT	Process Factors	ECH Anticipated Residue Estimates
					Acute (Avg FT ppm)
		MRID 46625301			
Coriander, leaves	NB	" "	" "	" "	" "
Coriander, leaves-babyfood	NB	" "	" "	" "	" "
Dillweed	NB	" "	" "	" "	" "
Herbs, other	NB	" "	" "	" "	" "
Lemongrass	NB	" "	" "	" "	" "
Marjoram	NB	" "	" "	" "	" "
Marjoram-babyfood	NB	" "	" "	" "	" "
Parsley, dried leaves	NB	" "	" "	" "	" "
Parsley, dried leaves-babyfood	NB	" "	" "	" "	" "
Savory	NB	" "	" "	" "	" "
Crop Group 19B: Spices					
Cinnamon	NB	Field Trials (ECH) 4 Samples 4 Detectable Residues MRID 46625301	45	NA	RDF#2 Cassia/Cinnamon (45% CT) TOTALZ=5 TOTALNZ=4
Cinnamon-babyfood	NB	" "	" "	" "	" "
Spices, other	NB	Field Trials (ECH) 44 Samples 42 Detectable Residues MRID 46625301	32	NA	RDF#6 Spices (32% CT) TOTALZ=94 TOTALNZ=44
Spices, other-babyfood	NB	" "	" "	" "	" "
Coriander, seed	NB	" "	12	" "	" "
Coriander, seed-babyfood	NB	" "	" "	" "	" "
Dill, seed	NB	" "	" "	" "	" "
Pepper, black and white	NB	Field Trials (ECH) 4 Samples 4 Detectable Residues MRID 46625301	31		RDF#5 Pepper (31% CT) TOTALZ=9 TOTALNZ=4
Pepper, black white-babyfood	NB	" "	" "	" "	" "
Crop Group 3: Bulb Vegetable					
Garlic, dried	NB	Field Trials (ECH) 56 Samples 56 Detectable Residues MRID 46625301	5		RDF#4 Onion/Garlic (5% CT) TOTALZ=1064 TOTALNZ=56
Garlic, dried-babyfood	NB	" "	" "	" "	" "

Table 2. Data and Residue Estimates Used in Dietary Analyses

Commodity	Blended Status	Data Source	Max %CT	Process Factors	ECH Anticipated Residue Estimates
					Acute (Avg FT ppm)
Onion, dry bulb, dried	NB	" "	" "	" "	" "
Onion, dry bulb, dried-babyfood	NB	" "	" "	" "	" "
Crop Group 14: Tree Nuts					
Walnut	NB	Field Trials (ECH) 3 Samples 3 Detectable Residues MRID 43218001	100	" "	RDF#7 Walnut (100 %CT) TOTALZ=0 TOTALNZ=3

* not blended (NB) – commodities are treated as non-blended commodities for this assessment because sterilization occurs post-application and therefore blending of treated and non-treated spices, herbs, and dried vegetables is not likely to occur.

Table 3. Cooking Factors for Ethylene Chlorohydrin Residues

Type	Factor	Used for	Source
Baking	0.19	All Baked Commodities	MRID 42755401
Boiling	0.75	All Boiled Commodities	MRID 42755401
Frying	0.002	All Fried Commodities	MRID 42755401

Cooking factors for commodities identified as baked or boiled, baked or fried etc., were averaged, e.g. CF for baked or fried commodities = 0.1

III Program and Consumption Information

Several reasonable peer-reviewed softwares have recently been emerging for modeling dietary exposure to pesticides. For a variety of technical, historical, and availability reasons, DEEM™ was the program generally used by EPA's Office of Pesticide Programs for conducting its dietary risk assessments. With the advent and current availability of a number of other exposure software programs, OPP, registrants, and other interested parties have available to them the option of selecting other peer-reviewed exposure software in conducting risk assessments for pesticides. Dietary exposure assessments may also be performed with other, similar programs, and if submitted, such results will be reviewed by EPA for acceptability and comparability to existing peer-reviewed software being used by OPP.

IIIa. DEEM-FCID™ Program and Consumption Information

The ethylene chlorohydrin acute dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using

publicly available recipe translation files developed jointly by USDA/ARS and EPA. For acute exposure assessment, consumption data are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

IV. Toxicological Information

HED evaluated the toxicology data base of ethylene chlorohydrin and selected doses and endpoints for acute dietary risk assessments. Acute toxicological endpoints for dietary exposure assessment for ethylene chlorohydrin have been selected from a developmental toxicity study in mice. Due to lack of developmental toxicity, reproduction toxicity and chronic combined carcinogenicity study in rats and mice for ethylene chlorohydrin, 10x data base uncertainty factor (UF_{DB}) is deemed necessary when estimating dietary risk for ethylene chlorohydrin.

Based on the analysis of data regarding pre- and/or post-natal susceptibility, the FQPA Safety factor is reduced from 10x to 1x for ethylene chlorohydrin. It is assumed that the exposure databases are complete and that risk assessment does not underestimate the potential risks for infants and children. Doses and toxicological endpoints selected for the acute and chronic dietary exposure scenarios are summarized in Table 4.

Table 4 Summary of Toxicological Doses and Endpoints for Ethylene oxide for Use in Human Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Ethylene Chlorohydrin			
Acute Dietary General	NOAEL= **100** mg/kg/day UF = **1000**	FQPA SF = **1X** **aPAD** = acute RfD	Developmental Toxicity Study – CD-1 Mice (Courtney et al., 1982)

Table 4 Summary of Toxicological Doses and Endpoints for Ethylene oxide for Use in Human Risk Assessments			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF* and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Population	**Acute RfD = 0.1** mg/kg/day	FQPA SF = **0.10** mg/kg/day	At 150 mg/kg/day, 75% mortality of maternal animals observed after 2-4 treatments (days) of dosing.

V. Results/Discussion

As stated above, for acute assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Table(s) 5-10 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years.

Results of Acute Dietary Exposure Analysis

The results of the DEEM acute dietary exposure analyses for commodities treated using the improved ethylene oxide fumigation process are reported in Table 5. This assessment concludes that for all supported commodities, except basil, the acute dietary 99.9th percentile exposure estimates for ethylene chlorohydrin are below HED's level of concern for the general U.S. population and several population subgroups. The DEEM acute dietary exposure estimates for the highest exposed population subgroup, children 1-2 years of age, is 96% of the aPAD. A more detailed discussion and characterization of the results is provided in Section VI.

Table 5. Ethylene Chlorohydrin DEEM Tier 3 Acute Dietary Exposure Analysis – New Process – No Basil							
Population Subgroup	aPAD (mg/kg/day)	95th %ile Exposure (mg/kg/day)	% aPAD. (95th %)	99th %ile Exposure (mg/kg/day)	% aPAD (99th %)	99.9th %ile Exposure (mg/kg/day)	% aPAD (99.9th %)
General U.S. Population	0.1	0.0029	3	0.0109	11	0.0362	36
All Infants (< 1 year old)	0.1	0.0002	<1	0.0110	11	0.0611	61
Children 1-2 years old	0.1	0.0116	12	0.0319	32	0.0960	96
Children 3-5 years old	0.1	0.0086	9	0.0260	26	0.0630	63
Children 6-12 years old	0.1	0.0047	5	0.0157	16	0.0375	38
Youth 13-19 years old	0.1	0.0030	3	0.0095	10	0.0312	31
Adults 20-49 years old	0.1	0.0026	3	0.0082	8	0.0246	25
Females 13-49 years old	0.1	0.0025	2	0.0079	8	0.0273	27
Adults 50+ years old	0.1	0.0020	2	0.0060	6	0.0201	20

VI. Characterization of Inputs/Outputs

In the course of conducting a refined dietary exposure analysis, decisions are made regarding the residue data used in the analysis (e.g., field trials, monitoring data, etc.), refinements incorporated in the analysis (such as percent crop treated and processing factors), and a variety of other issues which may be chemical- or crop-specific. A discussion of uncertainties regarding assumptions made for the refined acute dietary exposure analysis is provided below.

Data Limitations and Uncertainties

Residue Issues

Based on information provided by the registrants, the residue levels measured at 72 hours post treatment are likely to be representative of residues found in treated spices.

Translation of Residue Data

The residue data from the spice sterilization study have been used to assess acute dietary exposures to ethylene chlorohydrin. Date provided for the specific spice and herb commodities included in the study were assumed to be representative of all spices and herbs (i.e., including those for which no specific residue data were provided).

For individual commodities which are identified specifically in DEEM (i.e., individual commodities for which CSFII consumption data are available) commodity specific residue data were used. For example, study residue data are provided for pepper and pepper is included as a separate commodity in DEEM; therefore, pepper-specific residue data was included in a separate residue distribution file for that commodity. For commodities which are identified categorically in DEEM (e.g., other spices/herbs), ASTA study residue data from all of the spices and or herbs provided for that category are used for the dietary assessment. For example, for the category "herbs other", all of the study data provided for specific herbs (i.e., oregano, sage) were included in the residue distribution. Similarly, for herbs/spices that are identified specifically in CSFII but do not have corresponding commodity specific residue data from the sterilization study, all of the study residue data provided for specific spices and/or herbs were used to assess that commodity. For example, for the herb commodity chives, which is included as a separate commodity in DEEM, all of the study data provided for specific herbs (i.e., oregano, sage) were used. Seeds are a subset of spices in CSFII. Therefore data from the sterilization study for spices and seeds were combined for spice and seed commodities in the dietary analyses. Study specific data for sesame seed which is identified as the food commodity category "other" were included in the residue distribution file for spice commodities.

The ethylene oxide sterilization study provided no residue data for any commodities in the category of dried vegetables (i.e., garlic and onions). Therefore all of the residue data provided for all spice and herb commodities were used in the residue distribution file for dried onion and garlic commodities. ASTA defines spices as "any dried plant product used primarily for seasoning purposes". Included are tropical aromatics (pepper, cinnamon, cloves, etc.), leafy herbs (basil, oregano, marjoram, etc.), spice seeds (sesame, poppy, mustard, etc.) and dehydrated vegetables (onions, garlic, etc.). Blends such as curry, chili powders, poultry seasoning, etc. are part of the spice shelf, too. Only the dried vegetables, garlic and onion, were included in the dietary assessment. Whether, and if so, to what extent other dried vegetables and other seasonings not included in the assessment undergo ethylene oxide sterilization is uncertain. Exclusion of other dried vegetable commodities may result in an underestimation of dietary risk.

While use of different groupings of the available residue data may be justifiable, different arrangement of the data is unlikely to result in significantly different results.

As is standard practice for dietary assessments, residues reported as non-detect were estimated at half the LOD. The LOD was reported as 10 ppm.

Level of Refinement

Residue data incorporated into the probabilistic assessment were comprised of sterilization data for a subset of treated commodities. The commodities for which residue data are available were assumed to be representative of all treated commodities. Use of additional commodity specific data would improve the accuracy of the dietary assessment.

Incorporation of Monitoring Data

No PDP or FDA monitoring data are available for ethylene oxide treated spices. Data from a spice/herb/walnut sterilization study were used for the Tier 3 acute dietary analysis. Ethylene oxide sterilization is a post-harvest treatment, the sterilization study was conducted under representative spice/herb sterilization conditions, and residues of ethylene chlorohydrin and ethylene glycol did not show a consistent pattern of increase or decline indicating that concentrations may tend to stabilize after the initial reaction. Therefore it cannot be assumed that monitoring data would show significantly lower residues.

Processing Factors

Default Processing Factors

No processing factors have been used because ethylene oxide spice sterilization is conducted post-processing.

Cooking Study

Cooking factors from a 1993 ^{14}C-ethylene oxide cooking study conducted by Agrisearch Inc., were used for the ethylene oxide dietary assessment. The cooking factors determined for baked, boiled and fried foods were used for all EPA-defined food commodities specifically designated as baked, boiled, or fried in DEEM and Lifeline. Cooking factors were averaged for food forms designated as having undergone multiple methods of cooking i.e., baked/fried, baked/boiled, etc).

Adequacy of %CT data

Data on percent of domestic and imported spice, herb, dried vegetable and walnut commodities sterilized with ethylene oxide were provided by BEAD based on EPA data and American Spice Trade Association data from 1989, 1996. More recent and refined data were not available. For the acute dietary analysis, the estimated maximum % crop sterilized with ethylene oxide was used when available. Percent crop sterilized data was available and used for all treated commodities included in the dietary assessment.

Commodity specific percent crop sterilized data are used if such data are provided by BEAD and the commodity is included separately in DEEM/Lifeline (i.e., specific % sterilized data were used for pepper, cassia, and onion/garlic commodities). Specific % sterilized data was also used for seed commodities separately identified in DEEM/Lifeline. For all other commodities, percent sterilized data were used categorically for herb and spice commodities.

Significant Risk Contributors ("Risk Drivers")

A critical exposure contribution analysis for ethylene chlorohydrin indicates that marjoram, and savory commodities account for the largest percentage of dietary risk for the general population as well as the highest exposed population subgroup children 1-2 years old.

Sensitivity Analyses

No sensitivity analyses were performed because there were a number of commodities that contributed to the estimated risk (i.e., there was no single driver).

Additional Information for Risk Managers

Sterilization study and/or monitoring data for spices/herbs not included in the available study could be used to refine HED's risk estimates. Additionally, study/monitoring data for longer post-sterilization periods may be used to refine the dietary assessment. More complete and more refined % CT data could also be used to better estimate potential dietary risks.

VII. Conclusions

Refined dietary exposure analyses were performed for acute exposures to ethylene chlorohydrin using the DEEM model. When the residues associated with the improved ethylene oxide fumigation process are used and the commodity basil is excluded from the analysis, acute exposure estimates at the 99.9th percentile for ethylene chlorohydrin are below HED's level of concern for all population subgroups for dietary (food) exposures. For ethylene chlorohydrin, the DEEM model acute dietary exposure estimate for the highest exposed population subgroup, children 1-2 years of age, is 96% of the aPAD.

VIII. List of Attachments

1 - Percent Crop Treated Data from BEAD
2 - Acute DEEM Residue Input Files
3 - Acute DEEM Results Files
4 - DEEM Residue Distribution Files
5 - DEEM CEC Summary Files

Attachment 1 - Percent Crop Treated Data from BEAD

Ethylene Oxide Case #:2275 AI#:42301: Analyst: John Falkner 2001

EtO.wk4 EPA's QUANTITATIVE USAGE ANALYSIS Data years: 1988-94

Sites	Million lbs Available	Million lbs Treated	Percent Treated		Lb ai (000) Applied	
		Wtd Avg	Wtd Avg	Est Max	Est Avg	Est Max
Medical devices	-	-	-	-	6,000	6,560
Hospitals & Health Care facilities	-	-	-	-	720	800
Cosmetics	-	-	-	-	50	55
Beekeeping, Beehives, Equipment	-	-	-	-	-	1
Museums, Libraries	-	-	-	-	-	1
Black walnuts, processed	-	-	100%	-	-	-
Spices						
Domestic	108	33	30%			
Imported	597	193	32%			
Total Spices	705	226	32%	-	600	800
Type of Spice						
capsicum*	-	-	26%	31%		
cassia & cinnamon			32%	45%		
herbs*			60%	61%		
onion/garlic			4%	5%		
pepper-white & black			22%	31%		
paprika, imported			45%	51%		
roots-ginger, tumeric			35%	39%		
seeds*			7%	12%		
total					7370	8217

COLUMN HEADINGS
Wtd Avg = Weighted average--the most recent years are weighted more heavily.
Est Avg = Estimated average, which is estimated from available data.
Est Max = Estimated maximum, which is estimated from available data.
NOTES ON TABLE DATA
Calculations of the above numbers may not appear to agree because they are displayed as rounded:
A dash (-) indicates that information is NOT available in EPA sources or is insufficient to make an estimate.
*Spices
capsicum = red, chili, & cayenne peppers, domestic paprika.
herbs = basil, bay, cheervil, chives, cilantro, dill weed, oregano, marjoram, mint, parsley, rosemary, sage, savory, tarragon, thyme.
seeds = allspice, anise, annatto, caraway, cardamon, celery, cloves, coriander, cumin, dill, fennel, fenugreek, mace, mustard,nutmeg, poppy, sesame.
SOURCES: EPA data; American Spice Trade Association (1989, 1996)

Attachment 2 - Acute DEEM Residue File

```
U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID Acute analysis for ETO
Residue file name: C:\Documents and Settings\rdaiss\My Documents\RDAISS\DEEM-
FCID\ETO\etoacute-etoexpress-nobasil-6-8-06.R98
Analysis Date 06-09-2006            Residue file dated: 03-15-2006/14:16:33/8
Reference dose (aRfD) = 0.1 mg/kg bw/day
--------------------------------------------------------------------------------
RDL indices and parameters for Monte Carlo Analysis:
Index Dist Parameter #1           Param #2    Param #3    Comment
  #   Code
----- ---- -----------            ----------- ----------- ----------
  1     6   C:\rdaiss\ETO\basiletoexpress.rdf
  2     6   C:\rdaiss\ETO\cassiaetoexpress.rdf
  3     6   C:\rdaiss\ETO\herbsetoexpress2.rdf
  4     6   C:\rdaiss\ETO\onion-garlicetoexpress2.rdf
  5     6   C:\rdaiss\ETO\pepperetoexpress.rdf
  6     6   C:\rdaiss\ETO\spicesetoexpress.rdf
  7     6   C:\rdaiss\ETO\walnut.rdf

  EPA     Crop Food Name                          Def Res     Adj.Factors  RDL  Comment
  Code     Grp                                     (ppm)       #1     #2   Pntr
-------- ---- ------------------------------  ----------  ------ ------ ---  -------
19011030 19A  Chive
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                 0.000000   0.000  0.000
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                                 0.000000   0.000  0.000
                 211-Cooked; Fresh or N/S; Baked
                                                 0.000000   0.000  0.000
                 212-Cooked; Fresh or N/S; Boiled
                                                 0.000000   0.000  0.000
                 213-Cooked; Fresh or N/S; Fried
                                                 0.000000   0.000  0.000
                 221-Cooked; Frozen; Baked       1.000000   0.190  1.000   3
                 240-Cooked; Canned; Cook Meth N/S
                                                 1.000000   0.750  1.000   3
                 242-Cooked; Canned; Boiled      1.000000   0.750  1.000   3
19021050 19B  Cinnamon
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                 1.000000   1.000  1.000   2
                 130-Uncooked; Dried; Cook Meth N/S
                                                 1.000000   1.000  1.000   2
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                                 1.000000   0.310  1.000   2
                 211-Cooked; Fresh or N/S; Baked
                                                 1.000000   0.190  1.000   2
                 212-Cooked; Fresh or N/S; Boiled
                                                 1.000000   0.750  1.000   2
                 213-Cooked; Fresh or N/S; Fried
                                                 1.000000   0.002  1.000   2
                 214-Cooked; Fresh or N/S; Fried/baked
                                                 1.000000   0.100  1.000   2
                 215-Cooked; Fresh or N/S; Boiled/baked
                                                 1.000000   0.470  1.000   2
                 221-Cooked; Frozen; Baked       1.000000   0.190  1.000   2
                 230-Cooked; Dried; Cook Meth N/S
                                                 1.000000   0.190  1.000   2
                 232-Cooked; Dried; Boiled       1.000000   0.470  1.000   2
                 240-Cooked; Canned; Cook Meth N/S
                                                 1.000000   0.750  1.000   2
19021051 19B  Cinnamon-babyfood
                 211-Cooked; Fresh or N/S; Baked
                                                 1.000000   0.190  1.000   2
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                 230-Cooked; Dried; Cook Meth N/S
                                          1.000000   0.190  1.000   2
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   2
19011180 19A  Coriander, leaves
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 150-Uncooked; Cured etc; Cook Meth N/S
                                          1.000000   1.000  1.000   3
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 211-Cooked; Fresh or N/S; Baked
                                          0.000000   0.000  0.000
                 212-Cooked; Fresh or N/S; Boiled
                                          0.000000   0.000  0.000
                 213-Cooked; Fresh or N/S; Fried
                                          0.000000   0.000  0.000
                 221-Cooked; Frozen; Baked        1.000000   0.190  1.000   3
                 230-Cooked; Dried; Cook Meth N/S
                                          1.000000   0.190  1.000   3
                 232-Cooked; Dried; Boiled        1.000000   0.470  1.000   3
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   3
                 242-Cooked; Canned; Boiled       1.000000   0.750  1.000   3
                 250-Cooked; Cured etc; Cook Meth N/S
                                          1.000000   0.310  1.000   3
                 252-Cooked; Cured etc; Boiled    1.000000   0.750  1.000   3
                 253-Cooked; Cured etc; Fried     1.000000   0.002  1.000   3
19011181 19A  Coriander, leaves-babyfood        1.000000   1.000  1.000   3
19021190 19B  Coriander, seed
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                          1.000000   1.000  1.000   6
                 150-Uncooked; Cured etc; Cook Meth N/S
                                          1.000000   1.000  1.000   6
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 211-Cooked; Fresh or N/S; Baked
                                          0.000000   0.000  0.000
                 212-Cooked; Fresh or N/S; Boiled
                                          0.000000   0.000  0.000
                 213-Cooked; Fresh or N/S; Fried
                                          0.000000   0.000  0.000
                 214-Cooked; Fresh or N/S; Fried/baked
                                          0.000000   0.000  0.000
                 221-Cooked; Frozen; Baked        1.000000   0.190  1.000   6
                 230-Cooked; Dried; Cook Meth N/S
                                          1.000000   0.190  1.000   6
                 231-Cooked; Dried; Baked         1.000000   0.190  1.000   6
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   6
                 242-Cooked; Canned; Boiled       1.000000   0.750  1.000   6
                 250-Cooked; Cured etc; Cook Meth N/S
                                          1.000000   0.310  1.000   6
                 252-Cooked; Cured etc; Boiled    1.000000   0.750  1.000   6
                 253-Cooked; Cured etc; Fried     1.000000   0.002  1.000   6
19021191 19B  Coriander, seed-babyfood          1.000000   1.000  1.000   6
19021430 19B  Dill, seed
                 150-Uncooked; Cured etc; Cook Meth N/S
                                          1.000000   1.000  1.000   6
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 211-Cooked; Fresh or N/S; Baked
                                          0.000000   0.000  0.000
                 212-Cooked; Fresh or N/S; Boiled
                                          0.000000   0.000  0.000
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   6
19011440 19A  Dillweed
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                150-Uncooked: Cured etc; Cook Meth N/S
                                        1.000000   1.000  1.000   3
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                        0.000000   0.000  0.000
                211-Cooked; Fresh or N/S; Baked
                                        0.000000   0.000  0.000
                212-Cooked; Fresh or N/S; Boiled
                                        0.000000   0.000  0.000
                240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.750  1.000   3
03001650 3      Garlic, dried
                110-Uncooked; Fresh or N/S; Cook Meth N/S
                                        1.000000   1.000  1.000   4
                130-Uncooked; Dried; Cook Meth N/S
                                        1.000000   1.000  1.000   4
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                        0.000000   0.000  0.000
                211-Cooked; Fresh or N/S; Baked
                                        0.000000   0.000  0.000
                212-Cooked; Fresh or N/S; Boiled
                                        0.000000   0.000  0.000
                213-Cooked; Fresh or N/S; Fried
                                        0.000000   0.000  0.000
                214-Cooked; Fresh or N/S; Fried/baked
                                        0.000000   0.000  0.000
                215-Cooked; Fresh or N/S; Boiled/baked
                                        0.000000   0.000  0.000
                221-Cooked; Frozen; Baked       1.000000   0.190  1.000   4
                222-Cooked; Frozen; Boiled      1.000000   0.750  1.000   4
                230-Cooked; Dried; Cook Meth N/S
                                        1.000000   0.190  1.000   4
                232-Cooked; Dried; Boiled       1.000000   0.750  1.000   4
                233-Cooked; Dried; Fried        1.000000   0.002  1.000   4
                240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.750  1.000   4
                242-Cooked; Canned; Boiled      1.000000   0.750  1.000   4
                250-Cooked; Cured etc; Cook Meth N/S
                                        1.000000   0.310  1.000   4
03001651 3      Garlic, dried-babyfood
                240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.750  1.000   4
19011840 19A    Herbs, other
                110-Uncooked; Fresh or N/S; Cook Meth N/S
                                        1.000000   1.000  1.000   3
                150-Uncooked; Cured etc; Cook Meth N/S
                                        1.000000   1.000  1.000   3
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                        0.000000   0.000  0.000
                211-Cooked; Fresh or N/S; Baked
                                        0.000000   0.000  0.000
                212-Cooked; Fresh or N/S; Boiled
                                        0.000000   0.000  0.000
                213-Cooked; Fresh or N/S; Fried
                                        0.000000   0.000  0.000
                215-Cooked; Fresh or N/S; Boiled/baked
                                        0.000000   0.000  0.000
                221-Cooked; Frozen; Baked       1.000000   0.190  1.000   3
                230-Cooked; Dried; Cook Meth N/S
                                        1.000000   0.310  1.000   3
                232-Cooked; Dried; Boiled       1.000000   0.750  1.000   3
                233-Cooked; Dried; Fried        1.000000   0.002  1.000   3
                240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.220  1.000   3
                242-Cooked; Canned; Boiled      1.000000   0.220  1.000   3
                250-Cooked; Cured etc; Cook Meth N/S
                                        1.000000   0.310  1.000   3
                252-Cooked; Cured etc; Boiled   1.000000   0.750  1.000   3
                253-Cooked; Cured etc; Fried    1.000000   0.002  1.000   3
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19011841 19A  Herbs, other-babyfood
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   3
19012020 19A  Lemongrass                  1.000000   1.000  1.000   3
19012200 19A  Marjoram
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 130-Uncooked; Dried; Cook Meth N/S
                                          0.000000   0.000  0.000
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 211-Cooked; Fresh or N/S; Baked
                                          0.000000   0.000  0.000
                 212-Cooked; Fresh or N/S; Boiled
                                          0.000000   0.000  0.000
                 213-Cooked; Fresh or N/S; Fried
                                          0.000000   0.000  0.000
                 215-Cooked; Fresh or N/S; Boiled/baked
                                          0.000000   0.000  0.000
                 221-Cooked; Frozen; Baked       1.000000   0.190  1.000   3
                 232-Cooked; Dried; Boiled       1.000000   0.750  1.000   3
                 233-Cooked; Dried; Fried        1.000000   0.002  1.000   3
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   3
                 242-Cooked; Canned; Boiled      1.000000   0.750  1.000   3
19012201 19A  Marjoram-babyfood
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.310  1.000   3
03002380 3    Onion, dry bulb, dried
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 130-Uncooked; Dried; Cook Meth N/S
                                          1.000000   1.000  1.000   4
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 211-Cooked; Fresh or N/S; Baked
                                          0.000000   0.000  0.000
                 212-Cooked; Fresh or N/S; Boiled
                                          0.000000   0.000  0.000
                 213-Cooked; Fresh or N/S; Fried
                                          0.000000   0.000  0.000
                 214-Cooked; Fresh or N/S; Fried/baked
                                          0.000000   0.000  0.000
                 215-Cooked; Fresh or N/S: Boiled/baked
                                          0.000000   0.000  0.000
                 221-Cooked; Frozen; Baked       1.000000   0.190  1.000   4
                 222-Cooked; Frozen; Boiled      1.000000   0.750  1.000   4
                 230-Cooked; Dried; Cook Meth N/S
                                          1.000000   0.310  1.000   4
                 231-Cooked; Dried; Baked        1.000000   0.190  1.000   4
                 232-Cooked; Dried; Boiled       1.000000   0.750  1.000   4
                 233-Cooked; Dried; Fried        1.000000   0.002  1.000   4
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   4
                 242-Cooked; Canned; Boiled      1.000000   0.750  1.000   4
                 250-Cooked; Cured etc; Cook Meth N/S
                                          1.000000   0.310  1.000   4
03002381 3    Onion, dry bulb, dried-babyfood
                 211-Cooked; Fresh or N/S; Baked
                                          0.000000   0.000  0.000
                 240-Cooked; Canned; Cook Meth N/S
                                          1.000000   0.750  1.000   4
19012490 19A  Parsley, dried leaves
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.000000   0.000  0.000
                 211-Cooked; Fresh or N/S; Baked
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                                        0.000000   0.000  0.000
            212-Cooked; Fresh or N/S; Boiled
                                        0.000000   0.000  0.000
            213-Cooked; Fresh or N/S; Fried
                                        0.000000   0.000  0.000
            221-Cooked; Frozen; Baked   1.000000   0.190  1.000   3
            230-Cooked; Dried; Cook Meth N/S
                                        1.000000   0.310  1.000   3
            232-Cooked; Dried; Boiled   1.000000   0.750  1.000   3
            240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.750  1.000   3
            242-Cooked; Canned; Boiled  1.000000   0.750  1.000   3
19012491 19A  Parsley, dried leaves-babyfood
            211-Cooked; Fresh or N/S; Baked
                                        0.000000   0.000  0.000
            240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.750  1.000   3
19022740 19B  Pepper, black and white
            110-Uncooked; Fresh or N/S; Cook Meth N/S
                                        1.000000   1.000  1.000   5
            130-Uncooked; Dried; Cook Meth N/S
                                        1.000000   1.000  1.000   5
            150-Uncooked; Cured etc; Cook Meth N/S
                                        1.000000   1.000  1.000   5
            210-Cooked; Fresh or N/S; Cook Meth N/S
                                        1.000000   0.310  1.000   5
            211-Cooked; Fresh or N/S; Baked
                                        1.000000   0.190  1.000   5
            212-Cooked; Fresh or N/S; Boiled
                                        1.000000   0.750  1.000   5
            213-Cooked; Fresh or N/S; Fried
                                        1.000000   0.002  1.000   5
            214-Cooked; Fresh or N/S; Fried/baked
                                        1.000000   0.100  1.000   5
            215-Cooked; Fresh or N/S; Boiled/baked
                                        1.000000   0.470  1.000   5
            221-Cooked; Frozen; Baked   1.000000   0.190  1.000   5
            222-Cooked; Frozen; Boiled  1.000000   0.750  1.000   5
            230-Cooked; Dried; Cook Meth N/S
                                        1.000000   0.310  1.000   5
            231-Cooked; Dried; Baked    1.000000   0.190  1.000   5
            232-Cooked; Dried; Boiled   1.000000   0.750  1.000   5
            240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.750  1.000   5
            242-Cooked; Canned; Boiled  1.000000   0.750  1.000   5
            250-Cooked; Cured etc; Cook Meth N/S
                                        1.000000   0.310  1.000   5
            252-Cooked; Cured etc; Boiled 1.000000 0.750  1.000   5
            253-Cooked; Cured etc; Fried 1.000000  0.002  1.000   5
19022741 19B  Pepper, black and white-babyfood
            240-Cooked; Canned; Cook Meth N/S
                                        1.000000   0.310  1.000   5
19013340 19A  Savory
            110-Uncooked; Fresh or N/S; Cook Meth N/S
                                        0.000000   0.000  0.000
            130-Uncooked; Dried; Cook Meth N/S
                                        1.000000   1.000  1.000   3
            210-Cooked; Fresh or N/S; Cook Meth N/S
                                        0.000000   0.000  0.000
            211-Cooked; Fresh or N/S; Baked
                                        0.000000   0.000  0.000
            212-Cooked; Fresh or N/S; Boiled
                                        0.000000   0.000  0.000
            213-Cooked; Fresh or N/S; Fried
                                        0.000000   0.000  0.000
            215-Cooked; Fresh or N/S; Boiled/baked
                                        0.000000   0.000  0.000
            221-Cooked; Frozen; Baked   1.000000   0.190  1.000   3
```

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                233-Cooked; Dried; Fried          1.000000   0.002  1.000   3
                240-Cooked; Canned; Cook Meth N/S
                                                  1.000000   0.750  1.000   3
95003360 O    Sesame, seed
                110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                  0.000000   0.000  0.000
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                                  0.000000   0.000  0.000
                211-Cooked; Fresh or N/S; Baked
                                                  0.000000   0.000  0.000
                212-Cooked; Fresh or N/S; Boiled
                                                  0.000000   0.000  0.000
                213-Cooked; Fresh or N/S; Fried
                                                  0.000000   0.000  0.000
                230-Cooked; Dried; Cook Meth N/S
                                                  1.000000   0.310  1.000   6
                231-Cooked; Dried; Baked          1.000000   0.190  1.000   6
                232-Cooked; Dried; Boiled         1.000000   0.750  1.000   6
95003361 O    Sesame, seed-babyfood               1.000000   1.000  1.000   6
19023540 19B  Spices, other
                110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                  1.000000   1.000  1.000   6
                120-Uncooked; Frozen; Cook Meth N/S
                                                  1.000000   1.000  1.000   6
                130-Uncooked; Dried; Cook Meth N/S
                                                  1.000000   1.000  1.000   6
                150-Uncooked; Cured etc; Cook Meth N/S
                                                  1.000000   1.000  1.000   6
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                                  1.000000   0.310  1.000   6
                211-Cooked; Fresh or N/S; Baked
                                                  1.000000   0.190  1.000   6
                212-Cooked; Fresh or N/S; Boiled
                                                  1.000000   0.750  1.000   6
                213-Cooked; Fresh or N/S; Fried
                                                  1.000000   0.002  1.000   6
                214-Cooked; Fresh or N/S; Fried/baked
                                                  1.000000   0.100  1.000   6
                215-Cooked; Fresh or N/S; Boiled/baked
                                                  1.000000   0.470  1.000   6
                221-Cooked; Frozen; Baked         1.000000   0.190  1.000   6
                223-Cooked; Frozen; Fried         1.000000   0.002  1.000   6
                230-Cooked; Dried; Cook Meth N/S
                                                  1.000000   0.310  1.000   6
                231-Cooked; Dried; Baked          1.000000   0.190  1.000   6
                232-Cooked; Dried; Boiled         1.000000   0.750  1.000   6
                233-Cooked; Dried; Fried          1.000000   0.002  1.000   6
                240-Cooked; Canned; Cook Meth N/S
                                                  1.000000   0.750  1.000   6
                242-Cooked; Canned; Boiled        1.000000   0.750  1.000   6
                250-Cooked; Cured etc; Cook Meth N/S
                                                  1.000000   0.310  1.000   6
                252-Cooked; Cured etc; Boiled     1.000000   0.750  1.000   6
                253-Cooked; Cured etc; Fried      1.000000   0.002  1.000   6
19023541 19B  Spices, other-babyfood
                211-Cooked; Fresh or N/S; Baked
                                                  1.000000   0.190  1.000   6
                230-Cooked; Dried; Cook Meth N/S
                                                  1.000000   0.310  1.000   6
                240-Cooked; Canned; Cook Meth N/S
                                                  1.000000   0.750  1.000   6
14003910 14   Walnut
                110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                  1.000000   1.000  1.000   7
                130-Uncooked; Dried; Cook Meth N/S
                                                  1.000000   1.000  1.000   7
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                                  1.000000   0.310  1.000   7
                211-Cooked; Fresh or N/S; Baked
```

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                                    1.000000   0.190  1.000   7
221-Cooked; Frozen; Baked           1.000000   0.190  1.000   7
230-Cooked; Dried; Cook Meth N/S
                                    1.000000   0.190  1.000   7
240-Cooked; Canned; Cook Meth N/S
                                  1.000000   0.750  1.000   7
```

Attachment 3
Acute Results File

DEEM ETO Express - Results with Basil zeroed out

```
U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for ETO                                     (1994-98 data)
Residue file: etoacute-etoexpress-nobasil-8-8-06.R98
    Adjustment factor #2 used.
Analysis Date: 06-09-2006/13:18:37    Residue file dated: 06-09-2006/12:56:47/8
Daily totals for food and foodform consumption used.
MC iterations = 5000      MC list in residue file     MC seed = 1128
Run Comment: ""
==============================================================================
Summary calculations (per capita):
```

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
U.S. Population:	0.002861	2.86	0.010861	10.86	0.036162	36.16
All infants:	0.000239	0.24	0.011072	11.07	0.061052	61.05
Children 1-2 yrs:	0.011634	11.63	0.031869	31.87	0.096002	96.00
Children 3-5 yrs:	0.008580	8.58	0.025981	25.98	0.063025	63.02
Children 6-12 yrs:	0.004681	4.68	0.015666	15.67	0.037446	37.45
Youth 13-19 yrs:	0.002999	3.00	0.009485	9.48	0.031229	31.23
Adults 20-49 yrs:	0.002571	2.57	0.008193	8.19	0.024606	24.61
Adults 50+ yrs:	0.001897	1.90	0.006061	6.06	0.020094	20.09
Females 13-49 yrs:	0.002461	2.46	0.007909	7.91	0.027307	27.31

Attachment 4 RDF table

Spices(32% CT) TOTALZ=100 TOTALNZ=46 213 128 300 279 14 47 34 18 175 185 200 143 5 18 86 86 45 58 143 79 49 69 62 5 303 182 284 295 880 668 72 46 149 108 194 134 227 458 296 174 11 17 73 34 30 34	Herbs(61% CT) TOTALZ=5 TOTALNZ=8 195 292 208 128 207 327 334 242	Pepper (31% CT) TOTALZ=9 TOTALNZ=4 213 128 300 279 Cassia/Cinnamon (45% CT) TOTALZ=5 TOTALNZ=4 14 47 34 18 Walnut (100%CT) TOTALZ=0 TOTALNZ=3 50 50 50	Onion/Garlic (5% CT) TOTALZ=1024 TOTALNZ=54 213 128 300 279 14 47 34 18 175 185 200 143 5 18 86 86 45 58 143 79 49 69 62 5 303 182 284 295 880 668 72 46 149 108 194 134 227 458 296 174 11 17 73 34 30 34 195 292 208 128 207 327 334 242

Attachment 5 - Critical Exposure Contribution Analysis

Children 1-2 yrs
Low percentile for CEC records: 99.5 Exposure (mg/day) = 0.042827
High percentile for CEC records: 100 Exposure (mg/day) = 0.548699
Number of actual records in this interval: 3620
Critical foods/foodforms for this population (as derived from these records):
N=number of appearances in all records (including duplicates)
%=percent of total exposure for all records (including duplicates)

Food,	FF,	N ,	Percent,	Food Name
19012200,	240,	2272,	24.41%,	Marjoram-Cooked; Canned; Cook Meth N/S
19013340,	240,	2295,	24.17%,	Savory-Cooked; Canned; Cook Meth N/S
14003910,	130,	194,	13.01%,	Walnut-Uncooked; Dried; Cook Meth N/S
3002381,	240,	209,	7.03%,	Onion, dry bulb, dried-babyfood-Cooked; Canned; Cook Meth N/S
19011440,	240,	312,	5.68%,	Dillweed-Cooked; Canned; Cook Meth N/S
19011840,	240,	1646,	5.10%,	Herbs, other-Cooked; Canned; Cook Meth N/S
14003910,	211,	194,	3.44%,	Walnut-Cooked; Fresh or N/S; Baked
19021430,	240,	201,	2.82%,	Dill, seed-Cooked; Canned; Cook Meth N/S
19023540,	240,	159,	2.70%,	Spices, other-Cooked; Canned; Cook Meth N/S
19023540,	110,	72,	2.51%,	Spices, other-Uncooked; Fresh or N/S; Cook Meth N/S
19012490,	232,	122,	2.34%,	Parsley, dried leaves-Cooked; Dried; Boiled
3002380,	242,	49,	1.60%,	Onion, dry bulb, dried-Cooked; Canned; Boiled

U.S. Population
Low percentile for CEC records: 99.5 Exposure (mg/day) = 0.016494
High percentile for CEC records: 100 Exposure (mg/day) = 1.371348
Number of actual records in this interval: 87216
Critical foods/foodforms for this population (as derived from these records):
N=number of appearances in all records (including duplicates)
%=percent of total exposure for all records (including duplicates)

Food,	FF,	N ,	Percent,	Food Name
19012200,	240,	46701,	24.79%,	Marjoram-Cooked; Canned; Cook Meth N/S
19013340,	240,	46793,	24.78%,	Savory-Cooked; Canned; Cook Meth N/S
19023540,	240,	10602,	9.34%,	Spices, other-Cooked; Canned; Cook Meth N/S
19011440,	240,	10987,	8.07%,	Dillweed-Cooked; Canned; Cook Meth N/S
14003910,	130,	3505,	5.89%,	Walnut-Uncooked; Dried; Cook Meth N/S
19011840,	240,	37174,	5.81%,	Herbs, other-Cooked; Canned; Cook Meth N/S
3002381,	240,	1854,	3.69%,	Onion, dry bulb, dried-babyfood-Cooked; Canned; Cook Meth N/S
19021430,	240,	5538,	3.35%,	Dill, seed-Cooked; Canned; Cook Meth N/S
14003910,	211,	3751,	2.70%,	Walnut-Cooked; Fresh or N/S; Baked
19011180,	150,	375,	1.45%,	Coriander, leaves-Uncooked; Cured etc; Cook Meth N/S
19012490,	232,	1893,	1.07%,	Parsley, dried leaves-Cooked; Dried; Boiled

[Appendix C]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 12, 2006

MEMORANDUM

SUBJECT: Addendum to Revised Residue Chemistry Chapter For Ethylene Oxide Reregistration Eligibility Decision (RED) Document Issued July 12, 2005. New Tolerance Recommendations Based On Additional Residue Data In MRID 46625301.

DP Barcode: D330820
Chemical No. 042301
Reregistration Case No: 2275

FROM: Jerry B. Stokes, Chemist
Reregistration Branch 4
Health Effects Division [7509C]

THRU: Susan Hummel, Branch Senior Scientist
Reregistration Branch 4
Health Effects Division [7509C]

TO: Rebecca Daiss, Risk Assessor
Reregistration Branch 4
Health Effects Division [7509C]

Background

This memorandum is issued as an addendum to the Revised Residue Chemistry Chapter For Ethylene Oxide Reregistration Eligibility Decision (RED) Document Issued July 12, 2005. It does not supersede the previous document issued July 12, 2005. Tolerances for postharvest use of ETO on spices (whole) are established at 50 ppm on each (40 CFR §180.151). Although the current tolerance is expressed as" spices (whole) "and "ground spices", the historical use includes herbs (whole and ground) and dried vegetables (unspecified). A study (MRID

46625301) was conducted by the industry in order to test ETO and ECH residue levels resulting from an improved fumigation process referred to as "ETO Express" using a 20% ETO: 80% carbon dioxide formulation in the ETO sterilization of whole and ground spices and herbs.

"HED had previously recommended that the established 50 ppm tolerance (40 CFR 180.151) for ETO residues in spices and herbs remain unchanged at 50 ppm. However, this new steam process shows much lower residue levels after 72 hours. Therefore it is possible that the ETO tolerance could be lowered based **only if,** the registrants, with a label statement, restrict all US use of ETO to fumigate spices and herbs by this new process, and not allow any other treatment processes. Likewise the proposed tolerances for the residues of ECH in/on spices/herbs, dried (except basil), and basil could be adjusted downward **but only if** the new treatment method were used in all fumigations". (See memo of 01/25/06, J. Stokes).

Conclusions/Recommendations:

In response to HED's comment, according to SRRD, the industry **has now** stated to the Agency and to be documented in a "terms and conditions" letter forthcoming that all food commodity fumigations will be conducted only by the new procedure "ETO Express"as listed in MRID 46625301. They also have stated that basil will no longer be fumigated with any formulation of ETO (letters dated 07/07/2006, Honeywell International and 07/10/2006, ARC Specialty Products).

Therefore, HED has reevaluated the tolerances previously proposed in the January 2006 Revised Residue Chemistry Chapter. Thus, based on the results of HED's statistical tolerance generator for NAFTA-harmonized tolerances, HED finds that tolerances of 7 ppm ETO and 940 ppm ECH for spices/herbs fumigated with ETO are appropriate.

Note: Directions for use must be clearly defined on all labels that are allowed for the fumigation of spices and herbs (and seasoning materials). Labels of all ETO formulations that are used to sterilize commodities must include postharvest directions stating exposure time, temperature and percent humidity, amount of active ingredient ETO, aeration time in treatment chamber, additional storage conditions before treated commodities are released to market for consumption, and any other parameters (i.e., equipment type, capacity, that are necessary to insure consistency in each treatment). These parameters are needed so the established tolerances will always adequately cover potential residues of concern from ETO fumigation of spices and herbs. In addition, since ETO use will not be allowed for basil, then the label must prohibit application to basil and all seasoning materials that contain basil.

Detail Considerations:

860.1200 Directions for Use

The product used in this study was EPA # 36736-5 Sterilizing Gas 5 (20% ETO, 80% carbon dioxide, w/w). The sterilization of the spices and herbs was performed using a new process. The fumigation chamber was a commercial steel unit (1600 ft^3) fitted with a airtight steel door. The chamber was constructed with embedded steam jackets in all inside surfaces. All inside surfaces were heated by passage of steam through jackets to achieve the desired temperature. Chamber vacuum was produced with a large vacuum pump whose exhaust stream was connected to a gas scrubber system. Temperature and pressures were monitored during the process. Approximately 150 lb Sterilizing Gas 5 was delivered to the chamber during each treatment. The gas was injected manually at the appropriate time by the operator.

860.1340 Residue Analytical Methods - Plants

Method No. RA 10.3 "Determination of Ethylene Oxide Residues in Spices by Headspace Gas Chromatography". The Limit of Quantification (LOQ) was 1.0 ppm and the Limit of Detection was 0.25 ppm. Details of the method and method validation are discussed in MRID 46625301.

Method No. RA 12.2 "Determination of 2-Chloroethanol Residues in Spices".

The Limit of Detection was 10 ppm for 25 of the 29 spices and herbs, but several were listed at 25 ppm (3), with 1 undefined. Details of the method and method validation are discussed in MRID 46625301.

[Appendix C]

860.1520 Processed Food and Feed

A study (MRID 46625301) was conducted by the industry in order to test ETO and ECH residue levels resulting from an improved fumigation process referred to as "ETO Express" using a 20% ETO: 80% carbon dioxide formulation in the ETO sterilization of whole and ground spices and herbs.

"HED had previously recommended that the established 50 ppm tolerance (40 CFR 180.151) for ETO residues in spices and herbs remain unchanged at 50 ppm. However, this new steam process shows much lower residue levels even after 72 hours. Therefore it is possible that the ETO tolerance could be lowered based **only if,** the registrants, with a label statement, restrict all US use of ETO to fumigate spices and herbs by this new process, and not allow any other treatment processes. Likewise the proposed tolerances for the residues of ECH in/on spices/herbs, dried (except basil), and basil could be adjusted downward **but only if** the new treatment method were used in all fumigations". (See memo of 01/25/06, J. Stokes).

In response to HED's comment, according to SRRD, the industry **has now** stated to the Agency and to be documented in a "terms and conditions" letter forthcoming that all food commodity fumigations will be conducted only by the new procedure "ETO Express"as listed in MRID 46625301. They also have stated that basil will no longer be fumigated with any formulation of ETO (letters dated 07.07/2006, Honeywell International and 07/10/2006, ARC Specialty Products).

Therefore, HED has reevaluated the tolerances previously proposed in the January 2006 Revised Residue Chemistry Chapter. Thus, based on the results of HED's statistical tolerance generator for NAFTA-harmonized tolerances, HED finds that tolerances of 7 ppm ETO and 940 ppm ECH for spices/herbs fumigated with ETO are appropriate.

Data are not available for "vegetable, dried.". Therefore HED recommends that tolerances for ETO and ECH be established at the same levels as herbs and spices, 7 ppm and 940 ppm, respectively.

Tolerance Reassessments for Ethylene oxide

This was previously discussed in the Revised ETO RED (07/12/05). However, based on the results of HED's statistical tolerance generator for NAFTA-harmonized tolerances, HED finds that tolerances of 7 ppm ETO and 940 ppm ECH for spices/herbs fumigated with ETO are appropriate. In addition, other tolerances previously proposed are revised as shown in the following table.

[Appendix C]

180.151 Ethylene oxide; tolerances for residues.

(a) General. (1). Tolerances are established for the residues of the antimicrobial agent and insecticide ethylene oxide, when used as a postharvest fumigant in or on the following food commodities:

Table1. Tolerance Reassessment Summary for Ethylene oxide			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment//*Correct Commodity Definition/***
Tolerances Listed Under 40 CFR §180.151 a(1)			
coconut, copra	50	revoke	should be revoked; treatment not used
spices, whole	50	7	*[herbs and spices, group 19, dried (except basil)]*
walnut, black	50	50	*[walnut]*
Tolerances Listed Under 40 CFR §180.151 a(2)			
spices, ground	50		Should be revoked; ground spices included in *[herbs and spices, group 19, dried (except basil)]*
Tolerances to Be Proposed under 40 CFR 180.151 For Ethylene oxide			
vegetable, dried	none	7	

Remove all of Section (a)(2)

Add a new Section (a)(2):

Tolerances are established for residues of the ethylene oxide reaction product, 2-chloroethanol, commonly referred to as ethylene chlorohydrin, when ethylene oxide is used as a post-harvest fumigant in or on the following food commodities.

Table2. Tolerance Reassessment Summary for Ethylene oxide			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment//*Correct Commodity Definition]***
Tolerances to Be Proposed under 40 CFR 180.151 For Ethylene Chlorohydrin			
herbs and spices, group 19, dried (except basil)	none	940	
vegetable, dried	none	940	

[Appendix C]

Bibiliography

46625301 Wright, M. (2005) Magnitude of the Residue of Ethylene Oxide and Ethylene Chlorohydrin in/on Spices

Agency Memoranda Citations

Ethylene Oxide. Case 2275. Revised ETO RED. DP Barcode: D313774. July 12, 2006 J. Stokes

RDI: RRB4: S Hummel (July 12, 2006)
J. Stokes:PY1:10923:(703)305-7561:7509C

Attachment 1: Tolerance/MRL Harmonization Spreadsheet

[Appendix C]

Attachment 1:

This attachment contains the spreadsheet output from the Tolerance/MRL Harmonization Spreadsheet, which was developed by the NAFTA Tolerance/MRL Harmonization Workgroup that was charged with formulating a statistically-based, scientifically defensible methodology for establishing tolerances. The "MRL Summary" worksheet contains the results of various calculations performed automatically be the tolerance spreadsheet. The input to the spreadsheet is presented first, followed by a probability plot of the data. The recommended tolerance is highlighted on the output spreadsheet.

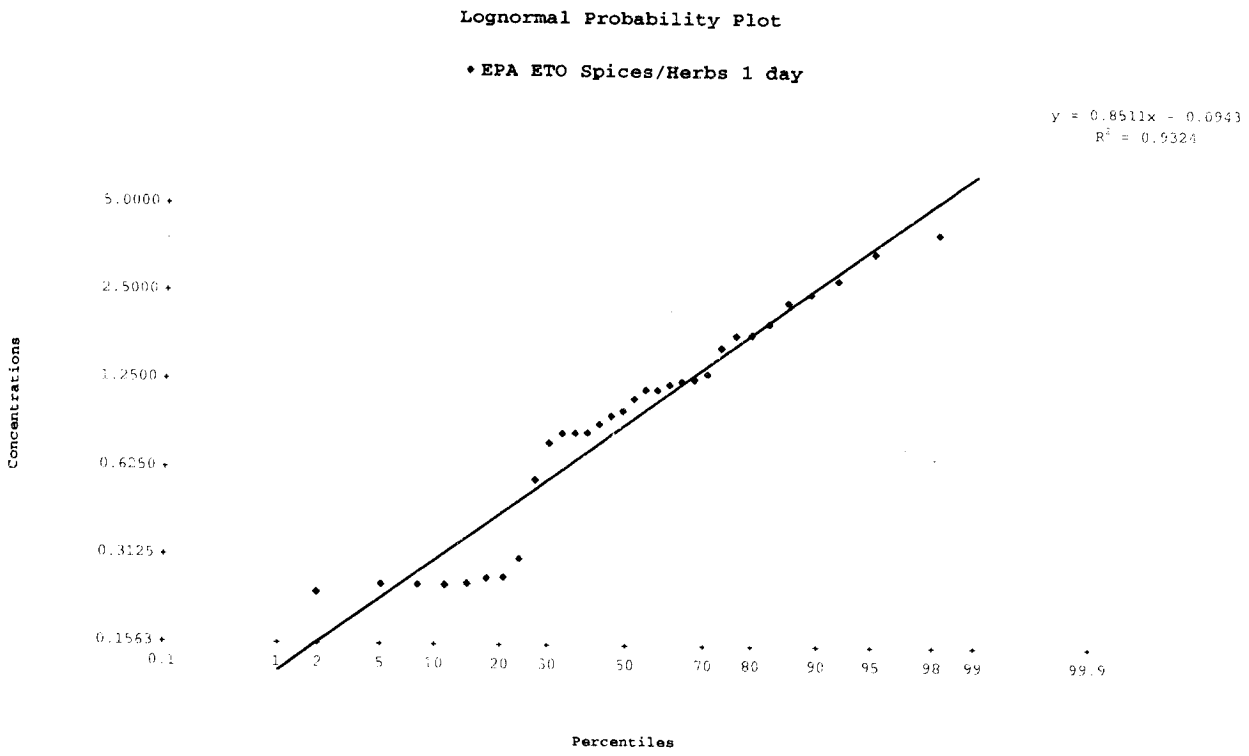
[Appendix C]

Regulator: EPA
Chemical: ETO
Crop: Spices/Herbs
PHI: 1 day
App. Rate:
Submitter:

Residues	LN(Residues)	Z-scores
2.530	0.93	1.21
4.090	1.41	2.07
3.500	1.25	1.64
1.260	0.23	0.36
1.180	0.17	0.12
1.280	0.25	0.44
2.360	0.86	1.07
2.000	0.69	0.94
2.820	1.04	1.40
1.340	0.29	0.53
1.230	0.21	0.28
1.180	0.17	0.20
0.839	-0.18	-0.28
0.900	-0.11	-0.20
0.774	-0.26	-0.53
1.650	0.50	0.62
1.830	0.60	0.82
1.820	0.60	0.72
0.834	-0.18	-0.44
0.836	-0.18	-0.36
0.578	-0.55	-0.62
0.309	-1.17	-0.72
0.253	-1.37	-1.07
1.000	0.00	-0.04
1.100	0.10	0.04
0.960	-0.04	-0.12
0.234	-1.45	-2.07
0.266	-1.32	-0.82
0.264	-1.33	-0.94
0.250	-1.39	-1.64
0.250	-1.39	-1.40
0.250	-1.39	-1.21

[Appendix C]

[Appendix C]


Lognormal Probability Plot
EPA ETO Spices/Herbs 1 day
y = 0.8511x - 0.0943
R² = 0.9324
5.0000
2.5000
1.2500
0.6250
0.3125
0.1563
0.1
Concentrations
1
2
5
10
20
30
50
70
80
90
95
98
99
99.9
Percentiles

Regulator:	EPA
Chemical:	ETO
Crop:	Spices/Herbs
PHI:	1 day
App. Rate:	
Submitter:	
n:	32
min:	0.23
max:	4.09
median;	1.05
average:	1.25

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	3.0 (3.5)	4.0 (4.5)	4.5 (--)
EU Method I Log Normal	4.0 **(7.0)**	**7.0** (13)	13 (--)
EU Method II Distribution-Free		4.0	
California Method $\mu + 3\sigma$		**4.5**	
UPLMedian95th		**6.0**	
Approximate Shapiro-Francia Normality Test Statistic		0.9324 p-value > 0.05 : Do not reject lognormality assumption	

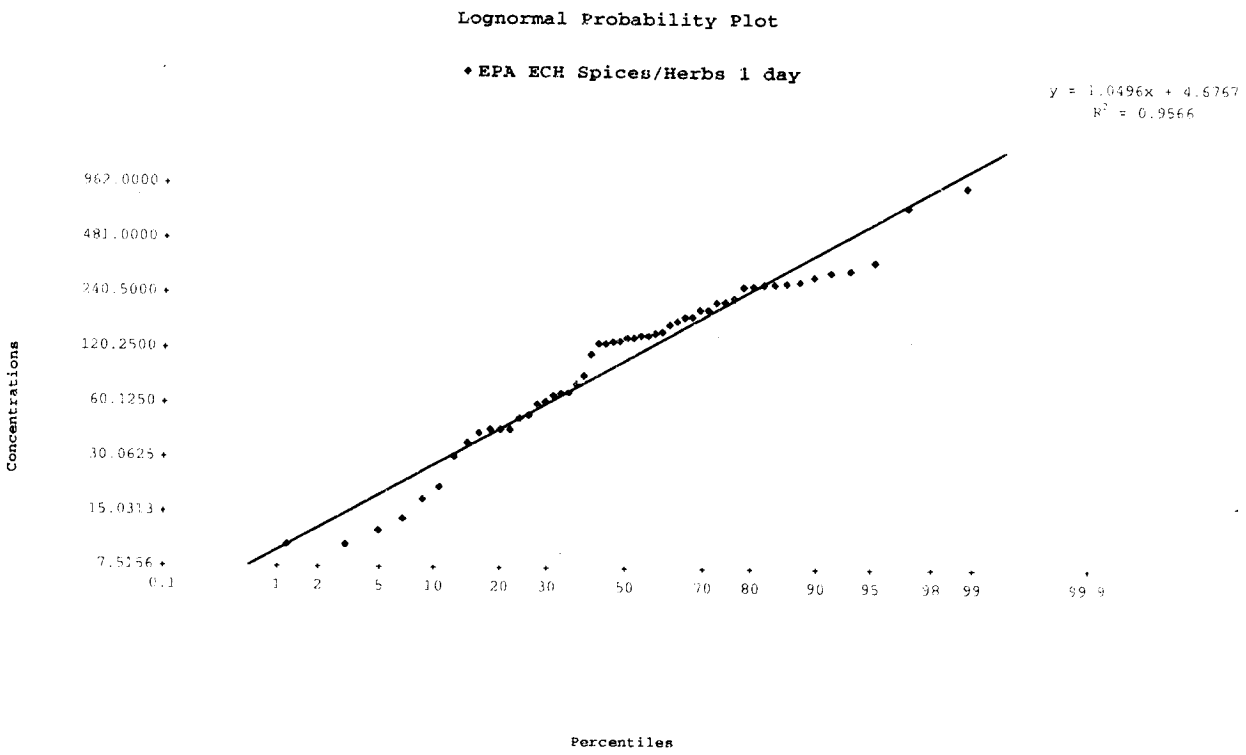
[Appendix C]

Regulator: EPA
Chemical: ECH
Crop: Spices/Herbs
PHI: 1 day
App. Rate:
Submitter:

Residues	LN(Residues)	Z-scores
167.000	5.12	0.29
185.000	5.22	0.44
270.000	5.60	0.78
289.000	5.67	1.15
115.000	4.74	-0.24
150.000	5.01	0.19
202.000	5.31	0.49
132.000	4.88	-0.19
21.000	3.04	-1.25
37.000	3.61	-1.07
53.000	3.97	-0.66
31.000	3.43	-1.15
79.000	4.37	-0.34
70.000	4.25	-0.44
132.000	4.88	-0.14
44.000	3.78	-0.91
153.000	5.03	0.24
184.000	5.21	0.39
283.000	5.65	1.07
146.000	4.98	0.09
146.000	4.98	0.14
223.000	5.41	0.66
279.000	5.63	0.99
306.000	5.72	1.25
233.000	5.45	0.72
44.000	3.78	-0.84
68.000	4.22	-0.49
63.000	4.14	-0.54
61.000	4.11	-0.60
324.000	5.78	1.36
222.000	5.40	0.60
278.000	5.63	0.91
333.000	5.81	1.49

962.000	6.87	2.27
745.000	6.61	1.87
71.000	4.26	-0.39
51.000	3.93	-0.72
135.000	4.91	-0.09
142.000	4.96	0.00
175.000	5.16	0.34
142.000	4.96	0.05
136.000	4.91	-0.05
371.000	5.92	1.65
202.000	5.31	0.54
273.000	5.61	0.84
14.000	2.64	-1.49
12.000	2.48	-1.65
88.000	4.48	-0.29
44.000	3.78	-0.78
18.000	2.89	-1.36
42.000	3.74	-0.99
10.000	2.30	-2.27
10.000	2.30	-1.87

[Appendix C]


Lognormal Probability Plot
EPA ECH Spices/Herbs 1 day
y = 1.0496x + 4.6767
R² = 0.9566
962.0000
481.0000
240.5000
120.2500
60.1250
30.0625
15.0313
7.5156
Concentrations
0.1
1
2
5
10
20
30
50
70
80
90
95
98
99
99.9
Percentiles

Regulator:	EPA
Chemical:	ECH
Crop:	Spices/Herbs
PHI:	1 day
App. Rate:	
Submitter:	
n:	53
min:	10.00
max:	962.00
median;	142.00
average:	169.17

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	450 (520)	570 (660)	700 (--)
EU Method I Log Normal	610 **(940)**	**1300** (2200)	2800 (--)
EU Method II Distribution-Free		460	
California Method $\mu + 3\sigma$		**680**	
UPLMedian95th		**730**	
Approximate Shapiro-Francia Normality Test Statistic		0.9566 p-value > 0.05 : Do not reject lognormality assumption	

Debra Edwards, Ph.D.
Director, Special Review and Reregistration Division
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

SUBJECT: [Registrant]'s Request for Voluntary Termination of Basil Uses of its Ethylene Oxide Products and Request for Label Amendments

Dear Ms. Edwards:

[Registrant] ([Registrant]), consistent with FIFRA section 6(f)(1)(A), hereby irrevocably requests voluntary termination of all basil uses of the ethylene oxide (ETO) products listed in the table shown below. [Registrant] requests that the Administrator waive the additional 180-day period under section 6(f)(1)(C)(ii). [Registrant] understands that the Administrator will provide for a 30-day public comment period following publication of this request in a Federal Register Notice. [Registrant] is including amendments to its affected registrations intended to effectuate the voluntary use terminations and associated label changes.

[Registrant]'s Registrations for ETO

Registration Number	Name	Status	Restricted Use Product	Percent Active Ingredient	Active Ingredient
					Ethylene Oxide
					Ethylene Oxide
					Ethylene Oxide

For the [Registration numbers] registrations listed above in the table, [Registrant] requests voluntary termination of ETO's use on basil. Specifically, [Registrant] requests that the following sentence be added in bold font at the end of the label use directions paragraph below, "**This product may not be used on or in any form of basil.**":

> [Product name] may be safely used only to sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, and reduce microbial load on cosmetics, and whole and ground spices. Items to be sterilized should be thoroughly cleaned of soil before being placed in any type of sterilizer.

[Registrant] requests provisions for sale, distribution, and use of existing stocks, as EPA defined that term at 56 Fed. Reg. 29362, as follows

> The registrant may sell and distribute existing stocks for one year from the date of this letter making the use termination request.

The product may be sold, distributed, and used by people other than the registrant until their stocks have been exhausted, provided that such sale, distribution, and use complies with the EPA-approved label and labeling of the product.

If you have any questions or comments about [Registrant]'s request, please contact [Registrant representative] at [phone number].

Sincerely,

[Registrant representative]

cc:

[Date]

Lois Rossi
Director, Reregistration Division
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

SUBJECT: [Registrant] - Request for Amended Registrations

Dear Ms. Rossi:

As per conversations between my company representatives and staff of the United States Environmental Protection Agency, [Registrant], submits this request for amendment of its registrations identified below to incorporate the below-stated terms and conditions. [Registrant] will submit all required registration amendment forms and revised labeling incorporating the deletions and additions set forth below by October 30, 2006.

[Registrant]'s Registrations for ETO:

Registration Number	Name	Status	Restricted Use Product	Percent Active Ingredient	Active Ingredient
					Ethylene Oxide
					Ethylene Oxide
					Ethylene Oxide

New Label Language to be Added:

For end use registrations, [list end use registration numbers] listed above in the table, [Registrant] requests that the following label language be added in bold:

"This product may not be used on or in any form of basil."

"After August 1, 2008, this product may only be applied to or on spices, dried vegetables or seasonings utilizing an ETO sterilization method that uses a single sterilization chamber to pre-condition and aerate with an alternating vacuum and aeration purging procedure. If you wish to employ an alternative method to that described below, you must contact the Environmental Protection Agency Office of Pesticide Programs for instruction on how to receive authorization."

"Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then; introduce into the chamber a concentration of Ethylene Oxide not to exceed 500 mg/L, with a dwell time not to exceed 16 hours. Then evacuate the gas from the chamber using a sequence of not less than 16 steam washes (injections and evacuations) between 1.0 PSIA (28" Hg) and 2.0 PSIA (26"Hg) while maintaining a minimum chamber temperature of 120° F."

For technical or manufacturing-use registrations, 67470-6 and 67470-7 listed above in the table, [Registrant] requests that the following label language be added in bold:

1. "Any product formulated from this product that is registered for use on spices, dried vegetables, or seasonings must include the following label language:

"This product may not be used on or in any form of basil."

"After August 1, 2008, this product may only be applied to or on spices, dried vegetables or seasonings utilizing an ETO sterilization method that uses a single sterilization chamber to pre-condition and aerate with an alternating vacuum and aeration purging procedure. If you wish to employ an alternative method to that described below, you must contact the registrant of this product for an identification of any alternative methods that are acceptable to the United States Environmental Protection Agency."

"Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then; introduce into the chamber a concentration of Ethylene Oxide not to exceed 500 mg/L, with a dwell time not to exceed 16 hours. Then evacuate the gas from the chamber using a sequence of not less than 16 steam washes (injections and evacuations) between 1.0 PSIA (28" Hg) and 2.0 PSIA (26"Hg) while maintaining a minimum chamber temperature of 120° F."

2. "Any product formulated from this product that is registered as a technical or manufacturing-use product must include the following label language:

"Any product formulated from this product that is registered for use on spices, dried vegetables, or seasonings must include the following label language:

"This product may not be used on or in any form of basil."

"After August 1, 2008, this product may only be applied to or on spices, dried vegetables or seasonings utilizing an ETO sterilization method that uses a single sterilization chamber to pre-condition and aerate with an alternating vacuum and aeration purging procedure. If you wish to employ an alternative method to that described below, you must contact the registrant of this product for an identification of any alternative methods that are acceptable to the United States Environmental Protection Agency."

"Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then; introduce into the chamber a concentration of Ethylene Oxide not to exceed 500 mg/L, with a dwell time not to exceed 16 hours. Then evacuate the gas from the chamber using a sequence of not less than 16 steam washes (injections and evacuations) between 1.0 PSIA (28" Hg) and 2.0 PSIA (26"Hg) while maintaining a minimum chamber temperature of 120° F."

[Registrant] notes that the label provision set forth above concerning basil reflects [Registrant]'s request for use termination in its [date] letter to the Agency.

Existing Stocks Provision:

[Registrant] understands that new technology relating to the reduction in residues for ETO and reaction products must be in use no later than August 1, 2008.

[Registrant] understands that amendments to the affected registrations and revised labels incorporating the additions and deletions set forth above must be submitted to the Registration Division by October 30, 2006 to the following:

Marshall Swindell
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Ave, N.W.
M/C 7505p
Washington DC, 20460

[Registrant] understands that, as of July 30, 2007, all new production of the products identified above must bear approved revised labels incorporating the additions and deletions set forth above.

[Registrant] understands that any person other than the registrant may continue to sell, distribute, or use its stocks of Ethylene Oxide affected products not bearing the new labeling until exhausted.

If you have any questions or comments about [Registrant]'s request, please contact [Registrant representative] at [phone number].

Sincerely,

[Registrant representative]