

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



OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

July 12, 2005

MEMORANDUM

SUBJECT: Revised Residue Chemistry Chapter For Ethylene Oxide Reregistration Eligibility Decision (RED) Document per Registrant's Error Corrections.

DP Barcode: D316652
Chemical No. 042301
Reregistration Case No: 2275

FROM: Jerry B. Stokes, Chemist
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THRU: Susan Hummel, Branch Senior Scientist
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Background

Ethylene oxide (ETO) is used as a postharvest fumigant on spices and black walnut. Spices become contaminated because they are grown in warm, humid climates that favor the proliferation of microorganisms and may be harvested, handled, packed, and stored under unsanitary conditions. ETO reduces the microbial load and kills pathogens while minimally affecting the sensory qualities of the spices. Spice blends that contain salt are not treated with ETO because of reaction of chloride ion with ETO to form ethylene chlorohydrin (ECH). Also, any bromide ion present in the material to be fumigated will react with ETO to form ethylene bromohydrin (EBH). Black walnut are treated to kill coliform bacteria and any pathogens that may be present in black walnut.

Ethylene oxide is a FIFRA 88 List B reregistration pesticide. A FIFRA 88 Phase VI Data Call-In was issued by the Agency in October 1989 which cited numerous

deficiencies in the product and residue chemistry databases. Additional product and residue chemistry data received since 1989 have been reviewed by the Agency. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of ETO. Product chemistry is not assessed by HED for List B, C, or D pesticides.

Tolerances for postharvest use of ETO on spices (whole) and black walnut are established at 50 ppm on each (40 CFR §180.151). Although the tolerance states only spices (whole), the historical use includes spices (ground) and herbs (whole and ground) and dried vegetables (unspecified).

Residue Chemistry Deficiencies/Comments

1. Directions for use must be clearly defined on all labels that are allowed for the fumigation of spices and black walnut. Labels of all ETO formulations that are used to treat herbs and spices, and black walnut 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 spices and black walnut 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 (See Nature of Residues in Plants, this memo) from ETO fumigation of spices/herbs and black walnut. Labels must clearly define terms “spices” and “other seasoning materials”.
2. The qualitative nature of ETO residues in plants is adequately understood. The HED Metabolism Committee determined that the residues of concern in plants are ETO, ECH and EBH. The committee has determined that ethylene glycol (ETG) is not a residue of concern. While the MARC concluded that both ECH and EBH are residues of concern, the ETO Risk Assessment Team now concludes that the residue levels of EBH are insignificant compared to the residue levels of ECH, and thus it is sufficient to regulate only residues of ECH.
3. Residue data are adequate to support the fumigant uses on spices and herbs (as defined by the Agency’s crop groups) and black walnut. Residue data support the established and proposed tolerances outlined in the following comment # 4.
4. The existing 50 ppm ETO tolerance should be clearly defined in regard to what is included in term “spices”; the ETO tolerance is based on residue data collected 2 weeks after treatment. Magnitude of the residue studies found minimal EBH levels in spices and black walnut. Therefore, HED suggests that a tolerance be established based on ECH residue levels which should cover any expected ethylene bromohydrin residues. A 2000 ppm tolerance should be established for residues of ECH in/on spices and herbs (dried) (except basil), and a 5000 ppm tolerance should be established in/on basil (dried) based on residues

at 2 month sampling. The existing 50 ppm ETO tolerance for black walnut is adequate based on 2- week residue data. Tolerances in/on black walnut for residues of ECH or EBH (LOQ <100 ppm) are not proposed because of minimal residue levels.

5. According to the registrants, items such as dried onion, dried garlic, and other dehydrated vegetables are included in American Spice Trade Association (ASTA) definition of spices (see this memo). As these foods are in other crops groups as defined by the Agency, tolerances should be established on these items. Since residue data are not available for ECH residues in/on dried vegetables, tolerances for ECH residues could be based on the 5000 ppm basil tolerance in lieu of additional residue data.
6. Analytical methodology should be tested in the Agency laboratory. The need for independent method trial will be determined by Agency laboratory. The registrant should submit multiresidue methodology for ETO and ECH.
7. The tolerance and/or use in/on coconut copra should be revoked. The registrant is not supporting the use.
8. The three cooking methods with ETO treated spices showed various degrees of reduction for ETO (98%) and ECH (20-97%). Some ETG was formed in the spice on the fumigation process, while additional amounts of ETG increased due to ETO reaction with water in the cooking process. Based on the fairly stable nature of ECH, probably little is formed from the reaction of ECH with water. The high percentages of volatile residues trapped in each cooking process were not identified other than total ¹⁴C ppm extracted. Due to the co-distilling properties of both ECH and ETG with water these were probably removed in the heating processes and captured in the traps. Under normal treatment of spices there is an aeration time and during this period most of ETO (<0.5 ppm remaining) would be degassed. Therefore, high levels of ETO residues would not be present in food prior to cooking. Even in uncooked foods, the levels of ETO would be <0.5 ppm. Under this assumption, without initial conversion of ETO to ETG, the levels of ETG would be less than observed in this study.
9. Cooking studies indicate that 93-99% of the ETO, ECH, and EBH residues were converted to ETG upon cooking/baking of black walnut (0.03% ETO, 6.1% ECH, and 6.7% EBH).
10. Analytical reference standards for ETO and ECH must be submitted to the EPA National Pesticide Standards Repository.

PRODUCT CHEMISTRY:

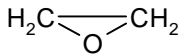
Table 1. Ethylene oxide Nomenclature	
Chemical structure	
Common name	Ethylene oxide
Molecular Formula	C ₂ H ₄ O
Molecular Weight	44.053
IUPAC name	oxirane
CAS name	oxirane
CAS #	75-21-8
PC Code	042301
Current Food/Feed Site Registration	whole spices, black walnut

TABLE 2. Physicochemical Properties of Ethylene oxide		
Parameter	Value	Reference (MRID)
Boiling point/range	10.4 C	43053201
pH at 25 C	NA	
Density at 25 C	gas at 25 C	
Water solubility at 25 C	Miscible in water.	43053201
Solvent solubility at 25 C	Soluble in ethanol, and ether. Solubility in dioctyl phthalate at 40 °C, 217mg/g.	43053201
Vapor pressure at 20 C	1.4 bar; gas at room temperature	43053201
Dissociation constant, pK _a	Not applicable	
Octanol/water partition coefficient at 25 C	K _{ow} = -0.26 to -0.30	43053201
Stability	Reduces silver nitrate, polymerized in the presence of magnesium and calcium. Unstable to sunlight, metal and metal ions. Reaction rate increases with temperature.	43053201
UV/visible absorption spectrum	Not available	

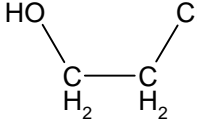
Table 3. Ethylene Chlorohydrin Nomenclature	
Chemical structure	
Common name	Ethylene chlorohydrin
Molecular Formula	C ₂ H ₅ ClO
Molecular Weight	80.154
IUPAC name	2-Chloroethanol
CAS name	2-Chloroethanol
CAS #	107-7-3
PC Code	none
Current Food/Feed Site Registration	None. Reaction product formed in whole and ground spices/herbs, and black walnut when fumigated with ETO

TABLE 4. Physicochemical Properties of Ethylene Chlorohydrin	
Parameter	Value
Boiling point/range	129.7 C
pH at 25 C	NA
Density at 20 C, g/cm ³	1.2015- 1.2025
Water solubility at 25 C	miscible
Solvent solubility at 25 C	NA
Vapor pressure at 20 C	5 mm
Dissociation constant, pK _a	NA
Octanol/water partition coefficient at 25 C	log POW -0.06
Stability	NA
UV/visible absorption spectrum	NA

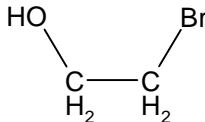
Table 5. Ethylene Bromohydrin Nomenclature	
Chemical structure	
Common name	Ethylene bromohydrin
Molecular Formula	CH ₂ OHCH ₂ Br
Molecular Weight	124.95
IUPAC name	2-Bromoethanol
CAS name	2-Bromoethanol
CAS #	540-51-2
PC Code	none
Current Food/Feed Site Registration	None. Reaction product formed in whole and ground spices/herbs, and black walnut when fumigated with ETO

TABLE 6. Physicochemical Properties of Ethylene Bromohydrin	
Parameter	Value
Boiling point/range	149-150 C
pH at 25 C	NA
Density at 20 C	1.494
Water solubility at 25 C	miscible
Solvent solubility at 25 C	NA
Vapor pressure at 20 C	NA
Dissociation constant, pK _a	NA
Octanol/water partition coefficient at 25 C	NA
Stability	NA
UV/visible absorption spectrum	NA

RESIDUE CHARACTERIZATION

General Discussion on Residue Chemistry of Ethylene oxide

860.1200 Directions for Use

Product List

A search of the OPPIN conducted 01/05/05 identified products Listed in Table 4 registered under PC Code 042301. Only those products listing spices and/or black walnut are included.

EPA Reg. No.	Formulation	% AI	Registrant	Product Name
7182-1	gas	100	3M Health Care	Steri-Gas
10330-16	gas	10	Praxair, Inc.	Carboxide
10330-18	gas	20	Praxair, Inc.	Medifume 20%
10330-21	gas	8.5	Praxair, Inc.	Medifume 8.5%
36736-2	gas	100	Balchem Corporation	Ethylene Oxide
36736-3	gas	80	“	Sterilizing Gas 3
36736-4	gas	10	“	Sterilizing Gas 4
36736-5	gas	20	“	Sterilizing Gas 5
36736-6	gas	12	“	Sterilizing Gas 6
36736-7	gas	8.5	“	Sterilizing Gas 8
36736-8	gas	100	“	Ethylene Oxide MUP
67470-1	gas	20	Allied Signal, Inc.	Oxyfume 20
67470-3	gas	12	Allied Signal, Inc.	Oxyfume 12
67470-4	gas	8.5	Allied Signal, Inc.	Carboxide
67470-6	gas	100	Allied Signal, Inc.	Ethylene Oxide
67470-7	gas	100	Allied Signal, Inc.	Ethylene Oxide 100R
69340-2	gas	97	Andersen Products	Anprolene (AN79)
69340-4	gas	89	Andersen Products	Anprolene (AN1004)
70009-1	gas	100	Cosmed Group, Inc.	Ethylene oxide

Other products listed:

SLN NC-950002: Used as a sterilant for beekeeping equipment to control foulbrood disease. Product used is 8.5% Ethylene Oxide and Carbon Dioxide Sterilant Gas, EPA Reg. No. 11491-8 and available only to NC Department of Agriculture regulatory personnel). Some **SEC 18s** are listed in OPPIN, but details are not available.

Use Pattern

Formulations, containing the active ingredient, ETO may be used as a postharvest fumigant for spices (whole or ground) and black walnut.

Specific directions for treatment of spices and black walnut are not listed on any label of the active labels. A similar phrase is present on each label: “ This may be used only to sterilize medical or laboratory items, pharmaceuticals, aseptic packaging (See 21 CFR 201.1 (d)(5), or to reduce microbial load on cosmetics, **whole and ground spices or other seasoning materials (See 40 CFR 180.151)** and artifacts, archival materials or library objects”.

NOTE: Labels of all ETO formulations that are used to treat spices and black walnut 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 dried spices and herbs and black walnut 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 data are needed so the established tolerances will always adequately cover potential residues of concern (See Nature of Residues in Plants, this memo) from ETO fumigation of spices/herbs and black walnut. Labels must clearly define terms “spices” and “other seasoning materials”). According to the registrants, items such as dried onions, dried garlic, and dehydrated vegetables are included in ASTA definition of spices (see below). As these foods are in other crops groups as defined by the Agency, tolerances may have to be established on these items. Need for additional residue data or translation of data will be assessed upon review of requested label directions

NOTE: With respect to copra, EPA received responses to a DCI issued 5/5/86. Respondents in their letters (Union Carbide & Balchem Corporation, 8/8/86 and Pennsylvania Engineering Company, 8/12/86) stated that they could not find any evidence that copra is currently fumigated with ETO. Therefore, the established ETO tolerance on copra could be revoked if the use no longer exists.

Additional Information:

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 also part of the spice shelf.

The FDA defines spices similarly, except that they do not include the dehydrated vegetables in the label definition of "spices". Any form of dehydrated vegetable product must be labeled separately. Such color contributing spices as paprika, turmeric and saffron must either be labeled separately or as "spice coloring". The Department of Agriculture (meat and poultry products labeling) has nearly the same requirements as the FDA, except that colorant spices and mustard must always be listed separately while onion powder and garlic powder may be listed as "flavors". All other forms of dehydrated vegetables must be listed separately by name.

Historically, (according to ASTA) "spices" referred to the tropical aromatics only, while "herbs" meant specifically the leaves and seeds of certain temperate-zone plants. While those distinctions are still used, "spice" has come also to mean the whole family of dried plant seasonings, including spices, herbs, blends and dehydrated vegetables.

860.1300 Nature of the Residue - Plants

The qualitative nature of ETO residues in plants is adequately understood. The HED Metabolism Committee has determined that the residue of concern in plants is the residues of ETO, ECH and EBH (L. C. Cheng, 01/27/95 and 05/16/95). The committee has determined that ETG is not a residue of concern. While the MARC concluded that both ECH and EBH are residues of concern, the ETO Risk Assessment Team now concludes that the residue levels of EBH are insignificant compared to the residue levels of ECH, and thus it is sufficient to regulate only residues of ECH.

MRID 42455401

Carbon-14 uniformly labeled in the ethylene carbon atoms of ETO was used in the residue identification study. The spices used for this study included nine representative herbs and spices: basil, oregano, sage, celery, nutmeg, black pepper, cassia/ cinnamon, capsicum/red pepper (all ground), and whole sesame seed. For the residue identification study, fumigation was conducted in a glass chamber (200 mL) with spice packages (gas permeable 4 x 4 inch paper sacks prepared from large commercial sacks (double paper with plastic liner). Each sack held about 1-3 grams of spice.

Duplicate samples of spices (1 to 3 g) were treated with 0.4 to 0.7 g ETO-14C at 100 F for 8 hours, followed by 6 to 8 vacuum flushes, and the treated spices aerated in the chamber with the stopcocks in the open position at room temperature for another 10 to 14 hours. These benchtop conditions are comparable to those used commercially (800 mg/L at 110-130 F for 10 hours, then 8 air washes, and followed by 10 hours of out-of-chamber aeration.

A portion of each fumigated spice sample was oxidized to determine the initial TRR (total radioactive residue). Less than 10% of the TRR's remained unextracted after

solvent extractions. The average material balance for all spices was 97%. Extracts of various fractions were analyzed by HPLC equipped with a Ramona carbon-14 detector and a UV detector set at 200 nm. The residue components were identified by comparing the retention times of known standards (ETO, ECH, EBH, and ETG).

An unknown component present at 10% TRR or more was found in several spices. This unknown was determined to be a conjugate of ETG by treatment with concentrated sulfuric acid. Thus, the residues in spices and herbs after ETO fumigation include ETO, ECH, EBH, and ETG (free and conjugated).

HED Metabolism Committee Conclusion: 02/28/1995

The Committee concluded that until additional toxicology data are available, then the tolerance expression should include **ETO, ECH and EBH** because of measurable levels of halohydrins present in treated spices and herbs and black walnut, and that the initial dietary risk estimate should be based on ETO levels measured soon after fumigation and aeration according to commercial practices. **ETG** was not considered of toxicological concern. This should yield a conservative ETO dietary risk assessment since spices and herbs and black walnut are normally not consumed right after treatment.

Based on current information from the spice industry trade practices **HED concludes** that residue values measured at 2 weeks after treatment should be used for setting the tolerance level, and the residue data 2 month and after levels in estimating dietary exposure to ETO and ECH only.

860.1300 Nature of the Residue - Livestock

Based on the post harvest fumigant use of ETO only on spices and black walnut, livestock are not exposed to ETO or ECH residues either in any feedstuffs, or from dermal treatments. Data are not required.

860.1340 Residue Analytical Methods - Plants

Early methodology: Equivalency Study (MRID 42143101)

Sample analysis was performed at McCormick & Co., Inc., Hunt Valley, MD. The title of the method used is "Gas Chromatographic Determination of Ethylene Oxide and its Reaction Products in Spices", Analytical Method No. ETO-001, American Spice Trade Association (12/16/91). A spice sample (2-10 grams) is extracted with water (in a shaker), and the mixture is centrifuged. The supernatant is cleaned up on a silica gel solid phase extraction (SPE) column and then analyzed by GC using a flame ionization detector. n-Butanol is added as an internal standard. ETO, ECH, EBH, and ETG are detectable by this method. For each spice matrix, two controls and 6 fortified samples (duplicate tests at 50, 500 or 1000, and 2000 or 8000 ppm) were analyzed. Results of the recoveries for the method validation study, fortification study during

sample analysis and stability study were highly variable. LOQ and LOD were not defined in this study.

Analytical Method (MRID No. 43218002)

The title of the report is "Analytical Method Validation Study for Determination of Residues in Spices and Black Walnuts: Ethylene Oxide, Ethylene Chlorohydrin, Ethylene Bromohydrin, and Ethylene Glycol" (P. G. Hoffman, R. Slesinski, and M. Kovacs, 4/29/94, Project ID ETO 92-01). The study was conducted at McCormick & Company, Inc., Hunt Valley, MD. Experiments were initiated on 12/9/92 and completed on 10/20/93.

Three separate methods were developed for the determination of residues of ETO, ECH/EBH, and ETG. The method validation study was conducted to demonstrate the reliability of these methods for measuring residues of ETO, ECH, EBH, and ETG in spices and black walnut.

The registrant defined the limit of quantitation (LOQ) of the analytical method of each analyte as the lowest fortification level which yielded reproducible mean recoveries in the range of 60-120% for ETO, 70-120% for ECH and ETG, and 70-142% for EBH. LOQ's were initially estimated based upon visual inspection of chromatograms of control versus fortified control samples. These initial levels were raised if acceptable recoveries had not been obtained. Standard solutions of ETO, ECH, EBH and ETG used for solvent standard curves and fortification of control samples were prepared by taking serial dilutions from a stock standard solution.

Method No. RA 10.2 "Determination of Ethylene Oxide Residues in Spices by Headspace Gas Chromatography", 2/26/93. A sample is prepared by weighing into a headspace vial gram quantities of spice or black walnut and octanol (100 μ L with or without ETO added). For samples of large particle size, blending or hammering is performed. The vial is capped with a crimp-sealed, teflon-lined rubber septum. Sample vials are then placed in the automated headspace carousel for analysis. The GC is connected to a flame ionization detector.

Method No. RA 12.1 "Determination of 2-Chloroethanol and 2-Bromoethanol Residues in Spices and Related Products", 2/26/93. Two to 4 grams of the sample are weighed into a centrifuge tube. An appropriate volume of a standard solution of ECH or EBH dissolved in water is added for a spike sample. Deionized water (40 mL) containing an internal standard of 10 ppm 1-butanol is then added. The sample is shaken on a mechanical shaker and then centrifuged if necessary for 10 minutes at 2000 rpm. An aliquot (3 mL) is pipetted onto an Extrelut QE clean-up column and eluted with ethyl acetate. The eluate is concentrated before analysis on GC. Detection is by flame ionization.

Method No. RA 24.0 "Determination of Ethylene Glycol Residues in Spices and Related Products", 7/12/93. Two to four grams of the sample are weighed into a

centrifuge tube. An appropriate volume of a standard solution of ETG dissolved in water is added for a spike sample. The sample is extracted with 40 mL of deionized water. An aliquot is removed, concentrated, and diluted with acetone. The resulting solution is filtered through a disposable nylon filter before injection into the gas chromatograph equipped with a flame ionization detector.

Recoveries in herbs, spices and black walnut were in general in the range of 60-120% for ETO when fortified at 0.5 ppm, 70-120% for ECH and EBH when fortified at 25 ppm, and 70-142% for ETG when fortified at 100 ppm. For the black walnut only, recoveries were 93-117% for ETO when fortified at 0.5 ppm, 76-91% for ECH when fortified at 25 ppm, 120-132% for EBH when fortified at 25 ppm, and 70-82% for ETG when fortified at 100 ppm. The overall recoveries for herbs, spices and black walnut are considered acceptable in view of the numerous natural components present in herbs and spices.

The methodologies are adequate for the current use. However the methods should be tested in the Agency laboratory.

860.1340 Residue Analytical Methods - Livestock Commodities

Based on the post harvest fumigant use of ETO only on spices and black walnut, livestock are not exposed to ETO or ECH residues either in any feedstuffs, or from dermal treatments. Data are not required.

860.1360 Multiresidue Methods

Multiresidue methods are needed for ETO and ECH. Registrant should submit data.

860.1380 Storage Stability

For storage stability (5 F), extracts were fortified with 1000 ppm of ETG, and analyzed at 0 day, 1 month, 2 months, 4 months, and 6.5 months. Results obtained from ground black pepper, ground oregano, whole sesame seed, and ground turmeric indicate ETG is stable (79% to 101%) for at least 6.5 months under frozen storage. Storage stability was not determined for ECH. Data from the Equivalency Study indicated that ECH residues were relatively stable for at least 30 days. No storage stability studies were conducted for ETO. Most analyses of ETO were conducted within 24 hours of sampling. For those that were not, an additional data point for either a few days before or after the target analysis interval is available. For those samples taken near the end of the analysis when the values of ETO approached the LOQ (0.5 ppm), the analyses were repeated at a subsequent interval to verify the previous result.

860.1400 Water, Fish, and Irrigated Crops

ETO is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

860.1460 Food Handling

ETO is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

ETO is presently not registered for direct use on food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

860.1500 Crop Field Trials

ETO is not used on fresh spices or fresh herbs; the existing use is a postharvest treatment of the corresponding dried commodities. Therefore, no residue chemistry data are required for field crops of fresh spices or herbs under this guideline topic. Likewise, since the treatment of black walnut involves shelled pieces, data is only required on processed black walnut. These commodities will be discussed under 860.1520. Processed Food and Feed.

860.1520 Processed Food and Feed

MRID 42143101

Although an equivalency study was not required in the 10/10/89 Data Call-In Notice, a study was initiated by American Spice Trade Association (ASTA). It was designed to determine the impact of sterilization parameters such as treatment (dwell) time, chamber temperature, and humidity on residue levels of ETO and its reaction products in spices, and to define the worst case sterilization conditions under which the highest residue levels in spice would occur. Three major categories of spices were selected for the study: basil, whole and ground, representing the herbs and leaves; pepper, whole and ground, representing the classical spices; and celery seed, whole and ground, and whole sesame seed, representing the seeds. These spices were chosen because they are typically treated with ETO prior to consumption, their volume in commerce is relatively high, and the oil content in these spices is quite different. Results are presented in submitted data package. Data from this study was used to design trials for adequate data collection for tolerance setting purposes.

OTHER

For the residue/persistence study, spices and herbs and black walnut were fumigated according to commercial practices. Treatment concentration for spices and herbs was 800 mg/L at 110-130 F for 10 hours. Eight air washes passed through the chamber before the treated spices and herbs were aerated outside the chamber for 10 hours. The chamber was under a partial initial vacuum (26-28 inches Hg) after which steam was introduced for 20-30 minutes. Spices and herbs were stored in typical commercial gas

permeable bags in 40 to 60 lb units. All spices and herbs including controls were fumigated with methyl bromide to eliminate potential insect infestation upon receipt

Black walnut were treated at 275 mg/L (10% ETO in 90% carbon dioxide) at 75 F for 40 hours with ambient humidity and partial vacuum (15 inch Hg). Four air washes passed through the chamber and treated black walnut were left in chamber for 2 more hours. The report did not state whether black walnut had been treated with methyl bromide.

Initial levels of ETO, ECH, EBH, and ETG in general are higher in ground spices and herbs than those in their whole form, with minor exceptions such as basil. The level of ETO in whole and ground spices and herbs and black walnut drop off sharply within the first two weeks after treatment (including degassing and out-of-chamber aeration). There is no consistent trend of decline for ECH from the initial levels among spices and herbs and these levels tend to stabilize after two weeks or one month. Most of the treated spices and herbs contain about 100 ppm or less EBH throughout the analysis period, with the exception of whole and ground nutmeg which may contain up to 300 ppm EBH at the 1 month interval. Levels of ETG in various treated spices and herbs seem to have stabilized by the 2 week to 1 month period. It is not surprising to find much higher levels of ECH, EBH, and ETG in treated spices and herbs since these three compounds are much less volatile and less reactive than ETO.

Levels of ETO in treated black walnut decline to 1-3 ppm at the 2 week interval. Levels of ECH, EBH and ETG are substantially lower in treated black walnut (generally <100 ppm in each), even immediately after treatment.

Untreated spices and herbs and black walnut contained nondetectable or low levels (3 ppm) of ETO, nondetectable level or low level (27 ppm, 1 sample) of ECH. Most spices and herbs and black walnut control samples contained EBH (36 to 55 ppm) since herbs and spices had been treated with methyl bromide. For ETG, practically all untreated herbs and spices contained measurable amounts of up to 275 ppm (in basil control samples); untreated black walnut contained 17- 42 ppm. The levels of ETO, ECH, EBH, and ETG in treated herbs and spices following ETO treatment are too high to be attributable to background.

MRID 43218001 and 43218002

SPICES:

Residues trials using similar parameters as in the above study showed that initial levels of ETO, ECH, EBH, and ETG are generally higher in ground herbs and spices than those in their whole form, with minor exceptions such as basil. The level of ETO in whole and ground spices and herbs drop off sharply within the first two weeks after treatment (and including degassing and out-of-chamber aeration). There is no consistent trend of decline of ECH from the initial levels among spices and herbs and these levels tend to stabilize after the first two weeks. Most of the treated herbs/ spices contain about 100 ppm or less EBH throughout the analysis period, with the exception of whole and ground

nutmeg which may contain up to 300 ppm EBH at the 1 month interval. Levels of ETG in various treated spices and herbs seem to have stabilized during the 2 week to 1 month period. It is not surprising to find much higher levels of ECH, EBH, and ETG in treated spices and herbs since these three compounds are much less volatile and much less reactive than ETO. Levels of ECH in treated spices and herbs obtained in this study are in accord with those high levels reported by spice companies in 1968 and FDA in 1983. The present study corroborates the results from previously conducted residue identification study (using ^{14}C ETO) and Equivalency Study (using cold ETO) in which high levels of ETO, ECH, EBH and ETG were found in herbs and spices under very similar treatment parameters.

TABLE 8. SUMMARY OF ETHYLENE OXIDE/ETHYLENE CHLOROHYDRIN/ETHYLENE BROMOHYDRIN/ETHYLENE GLYCOL RESIDUES IN SPICES/HERBS (mean: ave of 2 analyses, same sample)

Commodity	# of Treatments	ETO Residues, ppm (mean)			ECH Residues, ppm, (mean)			EBH Residues, ppm, (mean)			ETG Residues, ppm, (mean)		
		0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo
SPICES/HERBS													
Classical													
black pepper (w)	1	318	7	<0.5	150	337	191	<100	<100	<100	<100	130	<100
black pepper (w)	2	116	27	<0.5	425	408	283	<100	<100	<100	253	162	143
black pepper (g)	1	569	21	0.9	1216	1390	1358	<100	<100	<100	562	687	759
black pepper (g)	2	889	16	1	1793	1984	1984	<100	<100	<100	771	1132	1121
capsicum (w)	1	731	5	<0.5	1416	1610	495	<100	<100	<100	961	697	943
capsicum (w)	2	785	43	<0.5	1805	1570	1132	<100	<100	<100	1551	1006	2240
capsicum (g)	1	710	37	<0.5	1294	1431	1094	112	101	<100	1374	735	1004
capsicum (g)	2	1434	27	<0.5	1595	1733	1178	112	<100	<100	1033	3711	1582
cassia (w)	1	747	17	<0.5	124	116	221	<100	<100	<100	513	703	656
cassia (g)	1	1482	4	<0.5	208	292	216	<100	<100	<100	966	672	674
ginger (w)	1	458	0.9	<0.5	259	466	114	<100	<100	<100	312	591	121
ginger (g)	1	877	<0.5	<0.5	1161	292	1308	<100	<100	<100	1344	1473	1965
turmeric (w)	1	95	<0.5	<0.5	126	<100	102	<100	<100	<100	<100	<100	<100
turmeric (g)	1	357	<0.5	<0.5	1595	1754	1688	<100	<100	<100	810	812	773
Leafy													
basil (w)	1	393	25	1	5869	5205	1459	305	206	103	1275	--	1494
basil (w)	2	411	17	1	6250	5067	2318	210	198	<100	1690	2023	1994
basil (g)	1	59	<0.5	<0.5	4707	3405	3649	370	150	<100	973	950	1246
basil (g)	2	36	3	2	6275	4543	4645	244	115	<100	1282	1629	1335

TABLE 8. SUMMARY OF ETHYLENE OXIDE/ETHYLENE CHLOROHYDRIN/ETHYLENE BROMOHYDRIN/ETHYLENE GLYCOL RESIDUES IN SPICES/HERBS (mean: ave of 2 analyses, same sample)													
Commodity	# of Treatments	ETO Residues, ppm (mean)			ECH Residues, ppm, (mean)			EBH Residues, ppm, (mean)			ETG Residues, ppm, (mean)		
		0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo
oregano (w)	1	252	25	<0.5	1005	492	285	<100	<100	<100	2349	1346	1155
oregano (g)	1	783	0.9	<0.5	600	821	854	<100	<100	<100	892	864	958
sage (w)	1	1063	12	<0.5	478	389	585	<100	<100	<100	511	581	588
sage (g)	1	1313	0.6	<0.5	890	1070	902	<100	<100	<100	1030	1155	5104
Seeds													
caraway (w)	1	439	<0.5	<0.5	104	<100	<100	<100	<100	<100	247	228	220
caraway (g)	1	2042	2	<0.5	355	419	438	<100	<100	<100	851	1117	1359
celery (w)	1	253	6	<0.5	856	768	608	<100	<100	<100	262	258	241
celery (w)	2	298	6	<0.5	1174	1071	626	<100	<100	<100	496	456	365
celery (g)	1	438	2	<1.0	1618	1697	868	<100	112	<100	570	727	723
celery (g)	2	720	1	<1.0	2400	1733	944	125	<100	<100	992	942	920
coriander (w)	1	399	7	1	618	637	870	<100	<100	<100	230	278	353
coriander (g)	1	2399	21	<0.5	1164	2066	944	<100	<100	<100	695	715	1079
cumin (w)	1	273	16	1	716	1127	735	<100	<100	<100	188	755	546
cumin (w)	2	277	4	<0.5	1696	1272	604	<100	<100	<100	940	655	530
cumin (g)	1	981	12	<0.5	893	1035	702	<100	<100	<100	511	778	730
cumin (g)	2	1000	3	<0.5	1850	1308	1026	<100	<100	<100	1197	1281	1171
fennel (w)	1	68	1	<0.5	1409	384	166	<100	<100	<100	696	345	419
fennel (g)	1	1046	1	<0.5	2197	2110	1638	109	<100	<100	1036	1000	917
nutmeg (w)	1	658	16	<0.5	241	249	197	296	340	200	564	602	676
nutmeg (w)	2	862	20	<0.5	355	387	226	317	324	138	118	1226	994
nutmeg (g)	1	1948	8	<0.5	257	241	281	325	189	173	1281	1845	1809

TABLE 8. SUMMARY OF ETHYLENE OXIDE/ETHYLENE CHLOROHYDRIN/ETHYLENE BROMOXYDRIN/ETHYLENE GLYCOL RESIDUES IN SPICES/HERBS (mean: ave of 2 analyses, same sample)													
Commodity	# of Treatments	ETO Residues, ppm (mean)			ECH Residues, ppm, (mean)			EBH Residues, ppm, (mean)			ETG Residues, ppm, (mean)		
		0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo
nutmeg (g)	2	741	7	<0.5	253	542	381	220	371	159	2323	2502	2544
sesame (w)	1	221	6	<0.5	<100	<100	11354	<100	<100	<100	1320	106	116
Average (27 samples, 1 treatment)		737	8.8	0.58	1090	1038	761	132	117	106	880	471	925
Average (41samples) (1and 2 treatments)		706	10.5	0.63	1402	1261	1189	138	127	106	858	594	1019

SUMMARY OF ETHYLENE OXIDE/ETHYLENE CHLOROHYDRIN/ETHYLENE BROMOXYDRIN/ETHYLENE GLYCOL RESIDUES IN BLACK WALNUT (mean: ave of 2 analyses, same sample)													
Commodity	# of Treatments	ETO Residues, ppm (mean)			ECH Residues, ppm, (mean)			EBH Residues, ppm, (mean)			ETG Residues, ppm, (mean)		
		0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo	0 day	2 wk	2 mo
BLACK WALNUT													
Ice cream pieces	1	517	3	<0.5	<100	<100	<100	<100	<100	<100	<100	<100	107
Large fancy	1	318	1	<0.5	<100	<100	<100	<100	<100	<100	<100	<100	<100
Medium fancy	1	457	2	<0.5	<100	<100	<100	<100	<100	<100	<100	<100	<100

High Residue Levels After 1 and 2 ETO Treatments	
2 Week High	2 Month High
SPICES/HERBS	
ETO (capsium, whole), 2 treatments: 43	ETO (basil, ground), 2 treatments: 2
ECH (basil, whole), 1 treatment: 5205	ECH (basil, ground), 2 treatments: 4645
EBH (nutmeg, ground), 2 treatments: 371	EBH (nutmeg, whole), 1 treatment: 200
ETG (capsium, ground), 2 treatments: 3711	ETG (sage, ground), 1 treatments: 5104
BLACK WALNUT	
ETO, 1 treatment: 3	ETO, 1 treatment: <0.5
ECH, 1 treatment: <100	ECH, 1 treatment: <100
EBH, 1 treatment: <100	EBH, 1 treatment: <100
ETG, 1 treatment: <100	ETG, 1 treatments: 107

Conclusions:

Spices/Herbs

The ETO residue data clearly show a rapid decline of ETO residues in spices and herbs in a 2 week post-treatment period. At the end of a 2 months post-treatment period, the residues are <0.5 for all but several spice/herb samples. However, ECH appears to persist in the spices and herbs even after the 2 months. Samples were continually analyzed from day 0 (following fumigation period and aeration time), days 3, 6-9, 14-15, 28-30, 56-58, 112-119, and 180-202. During this time, the amounts of ECH in most spice/herb samples showed sporadic residues (high to low, then back to high) not really declining over time. This sporadic data behavior could be attributed to sampling techniques, or perhaps experimental design of data collection. Several ways of analyzing the data were evaluated, i.e., averaging all residue values for each sample from day 0 to 2 months, or from day 0 to 4-6 months. With many spices/herbs the ECH residues at 4-6 months did not differ much from those at day 0. In fact some appear to be higher at the 4-6 month sampling time frame. Based on the highest values observed, a tolerance of 5000 ppm might be needed for basil. Based on the residues observed in some of the other treated spices/herbs, this would be quite high, and would greatly over estimate the real ECH residues that might exist in all treated spices/herbs. Presently Canadian has a 1500 ppm limit on ECH residues in spices. Taking the average for all spices after 1 treatment (27 spice/herb samples, whole and ground) and the average for after 1 and 2 treatments (41 samples, whole and ground) at the 2 week and 2 month periods, all averages fall below this 1500 ppm value. EBH residues were <100 ppm (LOQ) in most samples. While the MARC concluded that both ECH and EBH are residues of concern, the ETO Risk Assessment Team now concludes that the residue levels of EBH are insignificant compared to the residue levels of ECH, and thus it is sufficient to regulate only residues of ECH.

Therefore, HED recommends that a 2000 ppm tolerance for the residues of ECH in/on spices/herbs, dried (except basil). A 5000 ppm tolerance for the residues of ECH should be established in/on basil (dried) based on the 2 month sampling.

In addition, the present 50 ppm tolerance for ETO residues in spices should remain at this level based on the numerous two digits level residues (12-43 ppm) observed from residue data after 2 weeks. Spices and herbs can be moving in commerce after 2 weeks, however, we would expect a 2 month holding time to be typical. No tolerances will be needed for ETG or EBH.

Black walnut:

The above residue data showed that levels of ETO in treated black walnut decline to 1-3 ppm 2 weeks after treatment. Levels of ECH, EBH and ETG are substantially lower in treated black walnut (generally <100 ppm each), even immediately after treatment.

However previous HED comments stated that it takes about 8 days or more for the majority of treated black walnut to reach the customer. The fumigation data on black walnut (L. Cheng, 3/28/96) showed 32-70 (ave. 41) ppm ETO, <100 ppm ECH and <100 ppm EBH one week after ETO treatment. Cooking studies indicate that 93-99% of these residues were converted to ETG upon baking/cooking (0.03% ETO, 6.1% ECH, and 6.7% EBH left on black walnut).

ETO residue data in the later study (MRIDs 43218001 and 43218002) clearly show a rapid decline of ETO residues in black walnut in a 2 week period. At the end of a 2 months period, the residues are <0.5 for all samples. Residue levels for both ECH and EBH values were at LOQ (<100 ppm). However, as the previous HED review showed higher residues in a 1-week period after treatment, then **the existing ETO tolerance for black walnut should remain at 50 ppm. Tolerances for the residues of ECH or EBH will not be needed because of minimal levels (LOQ<100 ppm). No tolerance will be needed for ETG.**

MRID 42755401

A cooking study (frying, baking and boiling) was also submitted using a variety of ETO-fumigated spices and herbs. This study was designed to determine the effect of cooking foods following addition of spices and herbs previously fumigated with carbon-14 ETO. The identity and total quantity of ETO and its "metabolites" in foods before and after cooking were determined. The study was performed at Agrisearch Incorporated, Frederick, MD (Project No. 3002).

Test spices and herbs arrived in sealed plastic bottles from Baltimore Quality Assurance, Inc. These included whole and ground basil, whole oregano, whole sage (dried leaves), ground celery, whole sesame, ground nutmeg (seeds), ground black pepper, ground cassia, and ground red pepper (classical). Equal weight of the nine representative spices and herbs were placed in miniature paper sacks that were made from commercial gas permeable three-ply, 50-pound weight Kraft paper lined with one-ply polyethylene. The spices and herbs were treated with radiolabeled ETO in a laboratory bench top fumigation chamber previously described in the Residue Identification Study (L. Cheng, 11/6/92). One chamber outlet valve was connected to two traps containing 2N sulfuric acid joined in series. Treatment (incubator) temperature was at 100 F for 8 hours. Following the fumigation period, a series of vacuum flushes (6 to 8) through the acid traps was conducted. The chamber stopcocks were left open to allow air through the treated spices and herbs at room temperature overnight (10 to 14 hours). Residues in treated spices and herbs before cooking were determined.

Recipes from various cookbooks were consulted to obtain a herb or spice to food ratio sufficient to yield measurable and identifiable residues in the foods after cooking. For baking, a pre-packaged biscuit mix was obtained from the local grocery. It contained no spices but included all other ingredients for rising and browning during the baking process. The dry biscuit mix was blended by hand swirling with treated spice mixture (9 herbs/ spices) and water was added to it. The prepared mixture was scraped into a cake and then baked for 30 to 45 minutes. For frying,

emulsified frankfurter meat that contained no spice but was of the same consistency and production type as that was used for hot dogs and sold in commerce was used. The meat was blended with treated spice mixture in a beaker with hand stirring and then fried for 10 minutes. For boiling, a pre-packaged tomato sauce that contained an unspecified "spice" was purchased from a local grocery. Treated spice mixture was added and boiled for 5 minutes. An aliquot of the prepared biscuit, meat and tomato sauce were removed for combustion.

Each method of cooking required a different heat source. An Erlenmeyer flask served as the utensil. Baking was conducted in an oven set at 375 to 400 F, frying was accomplished on a hot plate preheated at 375 to 400 F, and boiling was via a heating mantle. In each case the cooking flask was attached to a series of volatiles traps: duplicate 2N sulfuric acid traps, and a single 1N potassium hydroxide trap. The cooking process was conducted under partial vacuum and repeated once. Levels of radioactivity volatilized into the acid and base traps and rinse ranged from 27% to 56%.

After cooking, the foods were extracted with distilled and deionized water twice, followed by 1M sulfuric acid/acetonitrile 20:1 (v/v) and 2M sulfuric acid. Portions of the cooked food were also combusted to determine the residual radiocarbon left after cooking. High performance liquid chromatography was used to analyze the extractable residue in foods using either a UV detector (200 nm) or a radioactivity monitor.

A comparison of residue reduction and distribution in spice mixture before and after cooking are showed the following table:

Sample	Total initial residue, ppm	Total cooked residue, ppm	Percent initial extracted and identified					% Non-extractable\ conjugated	% Volatile	Total % accounted for
			ETO	ETC	EBH	ETG	Total			
Spice mixture	2985	NA	24	29	<1	30	83	11	NA	94
Baking	134	82	<1	9	<1	40	49	6	51	106
Boiling	168	167	<1	22	<1	40	62	14	29	105
Frying	14	14	<1	<1	<1	41	41	8	50	99

Using the following formula:
$$\frac{(\% \text{ initial extracted/identified in cooked item})(\text{total cooked residue in ppm})}{(\% \text{ initial extracted/identified in spice mixture}) (\text{total initial residue in uncooked item})}$$
 = cooking reduction factor,

the values for each cooking method was calculated.

Cooking Factors				
Cooking method	ETO	ECH	EBH	ETG
Baking (375-400 F, 30-45 min)	0.02	0.2	Not calculated, beginning residue minute	0.8
Boiling (212 F, 5 min)	0.004	0.8	Not calculated, beginning residue minute	1.3
Frying (375-400 F, 10 min)	0.04	0.03	Not calculated, beginning residue minute	1.4

Summary: The three cooking methods showed various degrees of reduction for ETO and ECH. Some ETG was formed in the spice on the fumigation process, while additional amounts of ETG increased due to ETO reaction with water in the cooking process. Based on the fairly stable nature of ECH, probably little is formed for reaction of ECH with water. The high percentages of volatile residues trapped in each cooking process were not identified other than total 14C ppm extracted. Due to the co-distilling properties of both ECH and ETG with water these were probably removed in the heating processes and captured in the traps. Under normal treatment of spices there is a aeration time and during this period most of ETO (<0.5 ppm remaining) would be degassed. Therefore, high level of ETO residues would not be present in food prior to cooking. Even in uncooked foods the levels of ETO would be <0.5 ppm. Under this assumption, without initial ETO to convert to ETG, the levels of ETG would be less than observed in this study.

SURVEY (DP D230199)

The American Spice Trade Association, Inc (ASTA), submitted the results of a trade practices survey conducted in 1995-96 to provide additional benefits and use information for ETO on spices. HED requested this information in order to aid in the estimation of anticipated residues

and in the determination of appropriate tolerance levels in spices. The submission also responded to the specific questions raised by EPA.

The survey elicited response from 15 spice companies which together accounted for about 70% of the sales volume of ASTA members. It also included the participation of the largest contract treatment company which oversees 3 treatment facilities. These companies represented the retail, food service, and industrial segments of the spice market. One aspect of the survey was to collect information for use in estimating the times between fumigation and processing/shipping, and the shelf-life of spices before consumption. ASTA concluded that based on the survey results 21% of the total pounds of imported and domestic spices were treated with ETO or some other method (such as propylene oxide, steam, irradiation), and the vast majority of ETO fumigation was done in the United States. About 70% of the treated spices were fumigated with ETO. The available data indicate that spices are shipped to a distribution warehouse for at least 2 weeks, but usually 16 weeks, after ETO treatment, and these spices are not immediately available for consumption. Based on the time reported between treatment of spice and processing, processing of spices and shipment to distribution warehouses, ASTA estimated the shortest interval between ETO treatment and consumption to be 2 months, and typically much longer. The use of import data to estimate the percent crop treated does not account for the percent of spices that are imported for non-food purposes, or the total pounds lost due to the removal of foreign matter (or off-grade material), and production/processing waste. This implies that consumption factors based on spice import data may be an overestimate of spice ingestion.

There are two basic channels of trade on spices. In one path, imported spices may be treated either at a contract sterilization facility before receipt or in-house upon receipt at the plant. The treated spices may then be cleaned, ground, blended, and packaged before being shipped to a distributor or warehouse. Alternatively, spices may be processed first (cleaning, etc), fumigated in-house or at a contract facility, and stored in warehouses or shipped to industrial distributors.

The turnover rate of spices in the consumer markets was determined. The study was conducted with the following assumptions: 1) larger stores turn over spices faster than smaller ones and stores in larger metropolitan areas faster than smaller areas, 2) geographic representation modeling after the four Census regions is valid, and 3) the number of stores sampled in each region is proportional to the total sales volume. Spices collected and analyzed included capsicum (red pepper), paprika, cumin, oregano, black pepper, basil, white pepper, thyme leaves, mustard seed, marjoram leaves, celery seed, and ground cinnamon from several name brands. The study focused on the date codes that appeared on spice containers. The difference between the date codes and the day of sampling indicates the shelf-life of spices before consumption. A range of shelf-life representing from 30 days to 120 days and beyond resulted. The survey also concluded uncooked vs. cooked uses of spices in foods." Uncooked" category included snacks, salad dressings, and cold salads). An average of 75% of spices are cooked before consumption.

860.1650 Submittal of Analytical Reference Standard

Analytical reference standards for ETO and ECH must be submitted to the EPA National Pesticide Standards Repository.

860.1850 Confined Accumulation in Rotational Crops

ETO is presently not registered for direct use on growing food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

860.1900 Field Accumulation in Rotational Crops

ETO is presently not registered for direct use on growing food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

Table 6. Residue Chemistry Science Assessment for Reregistration of Ethylene oxide (PC Code 042301).			
GLN Data Requirements	Current Tolerances (ppm) [§180.151]	Additional Data Needed?	MRID Nos. ¹
860.1200: Directions for Use	N/A = Not Applicable	Yes ²	42143101, 43218001, 43218002
860.1300: Nature of the Residue - Plants	NA	No	424555401
860.1300: Nature of the Residue - Animals	NA	NA	
860.1340: Residue Analytical Method			
- Plant Commodities	50	No	42143101, 43218001, 43218002
- Animal Commodities	NA	NA	
860.1360: Multiresidue Method	NA	Yes ³	
860.1380: Storage Stability Data			
- Plant Commodities	NA	No	42143101, 43218001, 43218002
- Animal Commodities	NA	NA	
860.1400: Magnitude of the Residue - Water, Fish, and Irrigated Crops	NA	NA	
860.1460: Magnitude of the Residue - Food Handling	NA	NA	
860.1480: Magnitude of the Residue - Meat, Milk, Poultry, Eggs			
- Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	NA	NA	
- Milk	NA	NA	
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	NA	NA	
860.1500: Crop Field Trials			
	NA	NA	
860.1520: Processed Food/Feed			
- Spices/Black walnut	50	No	42143101, 43218001, 43218002, 42755401
860.1650: Submission of Analytical Standards	50	Yes ⁴	
860.1850: Confined Accumulation in Rotational Crops	NA	NA	
860.1900: Field Accumulation in Rotational Crops	NA	NA	

1 MRIDs are defined in bibliography.

2 Directions for use must be clearly defined on all labels that are allowed for fumigation of spices and black walnut. Labels of all ETO formulations that are used to treat herbs and spices, and black walnut 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 spices and black walnut are released to market for consumption, and any other parameters (i.e., equipment type, capacity, that are necessary to insure consistency in each treatment. Labels must clearly define terms “spices” and “other seasoning materials”).

3 Multiresidue data must be submitted for ETO and ECH.

4 Analytical reference standards for ETO, ECH, and EBH must be submitted to the EPA National Pesticide Standards Repository.

TOLERANCE REASSESSMENT SUMMARY

Tolerance Reassessments for Ethylene oxide

The residues to be regulated are ETO and ECH.

Table 7. Tolerance Reassessment Summary for Ethylene oxide.				
Commodity	Current Tolerance (ppm)	Range of Residues (ppm)	Tolerance Reassessment (ppm)	Comment/[Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.151:				
Coconut, copra	50	--	--	Should be revoked ; treatment not used
spices, whole	50	<0.5 - 43	50	spices and herbs, dried
walnut, black	50	32-70	50	residue data support current level
Tolerances to Be Proposed under 40 CFR 180.151 For Ethylene Chlorohydrin:				
spices/herbs, dried	none	<100- 5205	2000	
basil, dried	none	1459-4645	5000	
dried onion and garlic	none	none given	5000 ¹	
dehydrated vegetables	none	none given	5000 ¹	

1 Tolerance based on data given for basil. Data were not given for dried onion, garlic, or other dried vegetables.

Codex/International Harmonization

There are no Codex MRLs for residues of ETO or ECH in/on spices/herbs or walnuts. Therefore, there are no compatibility problems with respect to U.S. tolerances. A Canadian MRL has been established for ECH at 1500 ppm in/on spices. Canada does not have an MRL for ETO in spices/herbs or walnuts. Since the US residue data showed slightly higher levels of ECH, and we have proposed a 2000 ppm tolerance. Consequently, we are not compatible with Canada in regards to parent ETO or ECH. No Mexican MRLs have been established for ETO or ECH in/on spices/herbs or walnuts.

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MRID

Citation Reference

-
- | MRID | Citation Reference |
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