

# The Future of Ethylene Oxide Use on Spices

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Edward M. Ruckert  
McDermott Will & Emery  
September 24, 2008

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# Ethylene Oxide - Overview

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- I. Background
- II. Current Situation
- III. Future Actions
- IV. Concluding Remarks

# I. Background

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- Tolerance Reassessment and Risk Management Decision (TRED) for Ethylene Oxide (ETO)
  - Issued July 2006
  - Review of all food uses of ETO for compliance with the Food Quality Protection Act (FQPA) of 1996
  - Tolerances for ETO and its reaction product ethylene chlorohydrin (ECH) were reassessed as “safe” after certain risk mitigation measures were implemented

# I. Background (cont'd)

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- Re-registration Eligibility Decision (RED) for ETO
  - Comprehensive review of ETO
  - Issued March 2008
  - Builds on 2006 TRED for ETO
  - Risk/Benefit decision
  - Focus on potential risks to workers
  - Agency heavily scrutinizes benefits of use of ETO

# I. Background (cont'd)

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- Re-registration Eligibility Decision (RED) for ETO (cont'd)
  - Impact of other countries of the World banning ETO use on spices
  - A EPA Worker Study – Critical
  
- RED Decision of EPA
  - Use on spices re-registered
  - Additional protective measures for workers in sterilizing facilities to reduce potential risk (e.g., employee safety and training)
  - Additional data needed for ECH

## II. Current Situation

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- Data Call-In (DCI)
  - Issued to registrant November 2007
  - To maintain use in spices, EPA requires multi-generation reproduction study in rats and developmental studies in rats and rabbits involving ECH
  - Initial response to EPA provided on February 2008– Waiver request
  - May 2008 – Waiver request denied

## II. Current Situation (cont'd)

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- Alternative Approach Being Developed by ASTA with the Assistance of the Registrant
  - Dr. Laura Plunkett of Integrative Biostrategies, LLC
    - Toxicologist and Pharmacologist
  - Involves examination of all available developmental and reproductive toxicity data for ETO and ECH
  - Pharmacokinetic approach to the data involving a weight of the evidence approach including consideration of various routes of exposure etc.
  - We anticipate meeting with EPA in October 2008 to revisit Dr. Plunkett's approach

## III. Future Actions

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- Press EPA to accept approach on DCI request
- If successful, then submit Dr. Plunkett's paper and dialogue with the Agency
- If unsuccessful, then two issues need to be addressed:
  - Cost of the studies
  - Registrant permission to do them
- Tolerance Action:
  - ETO residues in herbs and spices (Crop Group 19): 7 ppm
  - ECH residues in herbs and spices (Crop Group 19): 940 ppm
- Future agency review of ETO