METHYL BROMIDE, PROPOSED AMBIENT AIR LEVEL RECOMMENDATION

COMMENTS AND CONCERNS RE NORTH CAROLINA DEPARTMENT OF ENVIRONMENTAL QUALITY (NC DEQ'S)PROPOSED RISK ANALYSIS AND AMBIENT AIR LEVEL (AAL) RECOMMENDATION FOR METHYL BROMIDE (FEB 22, 2019)

NC DEQ Secretaries' Science Advisory Board Meeting
April 1, 2019

ECOLAB

CO-PRESENTORS

JEFF MARSHALL, PE
VICE PRESIDENT, SCS ENGINEERS

SCS ENGINEERS
Environmental Consultants and Contractors

ALISON MARWITZ, JD
SENIOR REGULATORY SPECIALIST II, PEST ELIMINATION DIVISION, ECOLAB INC.

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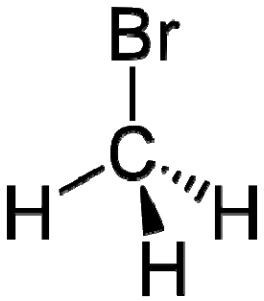
Overview

- Detailed comments submitted by Ecolab Inc.
- Presentation Discussion Points
  - Current Methyl Bromide Regulations
  - Concerns with Use of Chronic Toxicity Standard for an Acute Exposure Standard
  - Compliance with the Proposed AAL Cannot be Demonstrated Using Real-time Methyl Bromide Monitoring Equipment



Existing Methyl Bromide Regulations & Programs

- Primary North Carolina and Federal Agencies and Programs
  - U.S. Environmental Protection Agency (USEPA), Pesticide Program under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  - The U.S. Department of Agriculture's (USDA) Invasive Species Control Program – Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) Division
  - N.C. Department of Agriculture and Consumer Services (NC DA&CS), pesticide applicator licensing and certification program
- Additional Federal Agencies and Programs
  - U.S. Department of Transportation, Occupational Safety and Health Agency & National Institute for Occupational Safety and Health, U.S. Food and Drug Administration, Food Quality Protection Act, Department of Homeland Security, etc…

USEPA FIFRA Pesticide Regulation: History

- Pesticide regulation pre-dates USEPA, originated by USDA ~1947 in response to original FIFRA
- Methyl bromide introduced 1932, first registered in 1961
- FIFRA required re-registration of all pesticides first registered before November 1, 1984
- Methyl bromide re-registration initiated in 1990s and completed in 2016
- Expanded FIFRA label requirements, including buffer zones and Fumigant Management Plans (FMPs)

USEPA FIFRA Pesticide Regulation: Buffer Zones for Methyl Bromide

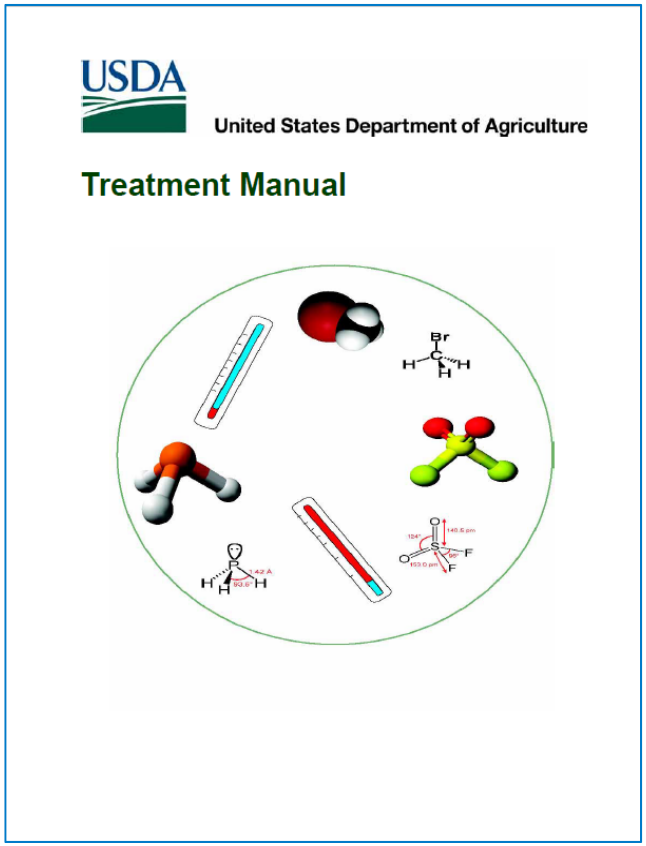
- Air emission modeling and risk assessment (RA)
  - RA established safe buffer zones for both workers and bystanders
- Customized model: Probabilistic Exposure and Risk Model for Fumigants (PERFUM)
- Buffer zone lookup tables based on six site-specific fumigation factors
  - Hundreds of tables for thousands of operating scenarios
  - ~ 700 pages
- Separate buffer zones for the treatment phase and aeration phase
- https://www.epa.gov/pesticide-registration/mbcommoditybuffer

USEPA FIFRA Pesticide Regulation: Facility-Specific Fumigant Management Plans (FMPs)

- FMPs are customized for each facility and treatment
- Require details on at least 22 topics; see detailed comments submitted by Ecolab Inc.
- Fumigation workers and supervisors must sign that they have reviewed the FMP
- FMPs are in addition to the state's recordkeeping requirements for pesticide applications

USDA APHIS Plant Protection & Quarantine (PPQ) Programs

- Establishes program for quarantine and pre-shipment (QPS) fumigations to control import/export of invasive species
- PPQ Treatment Manual, over 900 pages of fumigation guidance and requirements, including detailed protocols and treatment schedules for specific commodities
- https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf

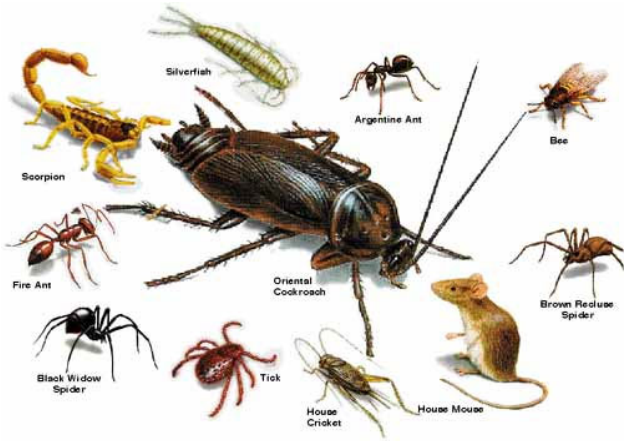


USDA APHIS PPQ Treatment Manual

- Addresses, step-by-step, every aspect and practice of fumigation:
  - Requirement that the site be approved by APHIS
  - Labor requirements
  - Equipment standards
  - Logistical requirements for an effective outcome
  - Fumigant application and aeration protocols
  - Contingencies (weather changes, emergencies)
  - Requirements for releasing the site and allowing the public to enter
- See detailed comments submitted by Ecolab Inc.

NC DA&CS, Structural Pest Control and Pesticide Division

- Pesticide licensing and certification requirements
- Required by the NC Pesticide Law of 1971
- Applicable to firms and individuals – e.g., Pesticide Business Licenses, Registered Technicians, and Certified Applicators



- Requirements include mandatory training, examinations, and continuing education requirements to maintain certifications

Acute & Chronic: Toxicity Standard

- Reference Concentration (RfC)
  - "the RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily inhalation exposure of the human population (***including sensitive subgroups***) that is likely to be without an appreciable risk of deleterious effects ***during a lifetime." (emphasis added)***
- EPA IRIS Lifetime RfC for Methyl Bromide
  - 5×10^{-3} mg/m^3
  - 5 µg/m^3
  - 0.00129 ppm
  - 1.29 ppb
- https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0015_summary.pdf

Acute & Chronic: Federal Agency Definitions

- US EPA, IRIS
  - Acute Toxicity: Any poisonous effect produced within a short period of time following an exposure, usually ***24 to 96 hours***.
  - Acute Exposure: Exposure by the oral, dermal, or inhalation route for ***24 hours or less.***
- ATSDR*
  - Acute Exposure: Exposure to a chemical for a duration of ***14 days or less***, as specified in the Toxicological Profiles.

Agency for Toxic Substances and Disease Registry (ATSDR)

- US EPA, IRIS
  - Chronic Effect – An effect that occurs as a result of ***repeated or longer term*** (chronic) exposures.
  - Chronic Exposure – Repeated exposure by the oral, dermal, or inhalation route for ***more than approximately 10% of the life span*** in humans (more than approximately 90 days to 2 years in typically used laboratory animal species).
- ATSDR*
  - Chronic Exposure: Exposure to a chemical for ***365 days or more***, as specified in the Toxicological Profiles.

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Acute & Chronic: State Agency Risk-Based Methyl Bromide Values

- Long-term/chronic (e.g., ***annual***) concentration:
  - 5 µg/m^3 (= 0.00129 ppm = 1.29 ppb); same as IRIS RfC
- Short-term/acute concentration:
  - 3,900 µg/ m^3 (= 1 ppm), based on an averaging time of ***one hour to 24 hours***
- e.g., California and New Jersey

AAL Compliance Challenges

- Real-time monitoring equipment commonly employed by the methyl bromide fumigation industry includes:
  - Photo-ionization detectors
  - Infra-red detectors
  - Thermal conductivity detectors

- None can reliably detect down to 5 µg/m^3 (= 0.0013 ppm = 1.3 ppb); MB detection limits are an order or magnitude and more higher
- Non-specific, thus subject to false positives
- Background interferences at low concentrations

Thank You, Questions?