

Fumigant RED Documents

RED Process Timeline Risk Assessment



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Pesticide Review Council

September 30, 2008

RED Process

- **Comprehensive EPA review of older pesticides (registered before Nov. 1984; 15 year cycle)**
- **Ensure that they meet current scientific and regulatory standards**
- **Considers latest available data on**
 - **Environmental fate**
 - **Toxicology- Human and ecological**
 - **Incident data- Human and ecological**
 - **Benefits**
- **Results in development of mitigation measures to address unacceptable risks**

RED Process

- **Open process**
- **Agency solicits stakeholder input (registrants, growers, farmworker associations, environmental groups, the public, etc.)**
- **Agency considers this input in the final decision to**
 - **Reregister the pesticide**
 - **Reregister with mitigation/conditions- i.e., label changes or prohibitions of use**
 - **Cancel registration of pesticide**

Fumigant RED

- **Considering fumigants as a group**
 - **Methyl bromide**
 - **Chloropicrin**
 - **Metam Sodium/Metam Potassium**
 - **Dazomet**
 - **1,3-dichloropropene- RED completed in 1998**
 - **Iodomethane to be re-evaluated this year**
- **Ensure consistency in the evaluation and management of all soil fumigants**

Timeline for Fumigants

- **July 2008 - Federal Register Notice opens 60-day comment period**
- **Comment period extended by 45 days**
- **October 30, 2008 - Comment period closes**
- **Late 2008 to Early 2009 - EPA considers comments, develops responses**
- **Early 2009 - EPA issues RED amendments if needed and issues product specific and generic data call-ins (DCIs)**

Timeline for Fumigants

- **2009 - Registrants begin implementing training and community outreach and education programs**
- **Late 2009 - Product data and revised labels submitted to EPA**
- **Early 2010 - EPA reviews, approves new soil fumigant labels**
- **2010 - New labels begin appearing in the field**
- **2013 - EPA begins reevaluation of soil fumigants under the Registration Review program**

Risk Assessment

- **Endpoints of toxicity (Points of Departure) are the same as the previous RED documents**
- **Eye irritation- chloropicrin, metam, dazomet**
- **Neurological- methyl bromide**
- **Uncertainty factor for chloropicrin reduced from 30 to 1**
 - **Human exposure study**
 - **Most sensitive age group tested (~23 years)**
 - **Level of Concern is a MOE of 1 (0.073 ppm)**
 - **0.15 ppm was the lowest dose causing mild irritation without progression to severe**

Questions?

Fumigant RED Documents

OVERVIEW: USEPA RED REQUIREMENTS



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Key Components

- Buffer zones
- Posting requirements
- Agricultural worker protections
- Applicator and handler training programs
- Good agricultural practices
- Application method, practice, and rate restrictions
- Restricted use pesticide classification
- Site-specific fumigant management plans
- Emergency preparedness and response requirements
- Notice to state and tribal lead agencies
- Community outreach and education programs

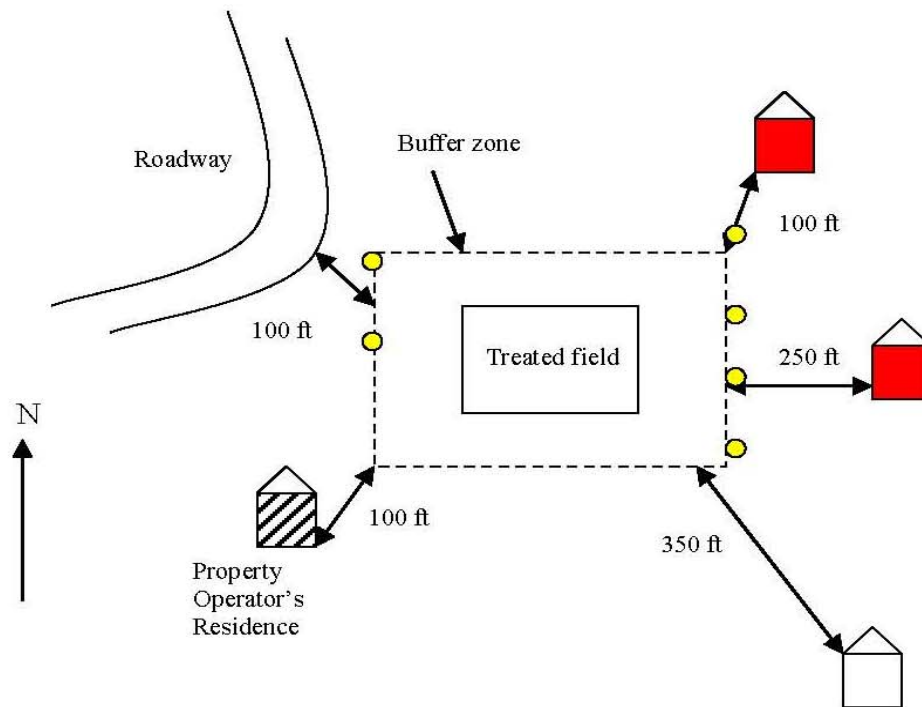
Buffer Zones

- **Reduce bystander risks from acute inhalation exposure**
- **Buffer zone size determined by**
 - application rate;
 - field size;
 - application equipment and methods;
 - emission-control measures (e.g., tarps).
 - Proximity to schools, hospitals, nursing homes, etc
- Calculate with look-up tables on label
- BZ credits (e.g. high barrier tarps, org. soils)

Posting Requirements

- **Inform bystanders of buffer zone**
- **Post at usual points of entry and likely routes of approach to the buffer, unless:**
 - physical barrier prevents access to the buffer, or
 - all of the area within 300' of the buffer is under the control of the owner/operator.

Posting Requirements



Red Houses = Structure within 300 feet of the buffer zone edge. Yellow dots = posted signs

- The structures in **red** are (1) within 300 feet of the edge of the buffer zone, and (2) there is no physical barrier between the two structures and the buffer zone, and (3) the land operator does not control these structures.
- Although the **property operator's building** (striped building) is within 100 feet of the edge of the buffer zone, since it is controlled by the property operator, **no posting** of the buffer zone is necessary here.
- There is a **road** within 100 feet of the edge of the buffer zone. Since there is a possibility of people from the road entering the buffer zone area, the buffer zone needs to be posted in the northwest corner.

Agricultural Worker Protections

- “Handlers”
 - operate fumigation equipment
 - assisting in fumigant application
 - monitor fumigant air concentrations
 - manipulate tarps
- Respiratory protection – new labels require monitoring to inform handlers if respirators needed, etc.
- Tarp perforation/removal schedules
- Reentry intervals for workers (e.g. 5 days post application)

Applicator and Handler Training (Dual Training)

- State certification required
- Registrants:
 - develop and implement training programs for applicators
 - distribute training materials for handlers
 - include worker education components

Good Agricultural Practices

- Some former recommendations have become requirements
- Examples:
 - proper soil preparation
 - optimal soil moisture and temperature
 - appropriate use of sealing techniques
 - equipment calibration
 - weather criteria (inversion avoidance)

Agricultural Methods, Practices, Rate Restrictions

– Examples:

- untarped applications for some fumigants will be prohibited
- maximum application rates lowered

Restricted Use Pesticide Status

- All soil fumigants to become RUPs
- Metam sodium/potassium and dazomet are currently general use products

Site-Specific Fumigation Management Plans (FMP)

- Written FMP prepared prior to application
- Multi-element plan designed to avoid accidents, document compliance
- Post fumigation summary report required
- Retain records at least 2 years

Emergency Preparedness and Response

- Assumes incidents will occur due to accidents, errors, weather changes
- Early detection and response to reduce risks
- Community outreach by registrants for first responders
- Site specific response/management activities by applicators

Emergency Preparedness and Response

- Site specific response/management activities by applicators:
 - Monitor buffer zone perimeter during BZ period if neighbors within 300' of BZ
 - If unacceptable levels detected, implement FMP emergency response plan
 - As alternative to monitoring, provide emergency response info to neighbors prior to application

Notice to State and Tribal Lead Agencies

- Applicators must notify state and tribal lead agencies prior to application

Fumigant RED Documents

USEPA RED REQUIREMENTS

FDACS General Comments



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General Comments

- Soil fumigant REDs pose stringent and sweeping mitigation measures which run counter to experiences in Florida, where reported incidents are rare.
- FDACS specific comments focus on regulatory policies and issues.
- EPA should carefully consider industry comments on reasonability of risk assumptions, economic impacts of proposed mitigation, and suggestions for refining mitigation to allow for continued, prudent use of fumigants.

General Comments

- Mitigation measures will impose significant burdens on our state pesticide regulatory program at the same time programs are facing significant budget cuts. Complex new requirements will require additional staff and staff training and will cause increased complaints and violation rates.
- Registrant product stewardship roles should be expanded beyond training to include compliance assistance, incident follow up, product access control and regular communication with state lead agency.
- EPA will need to continue to work closely with all stakeholders to assure that practical, effective requirements are developed.

General Comments

- Provide flexible milestones for implementation. Allow adequate time to make informed implementation decisions.
- Allow state lead agency opportunity to review labels before they are finalized by USEPA

EPA Fumigant Risk Mitigation Measures: Key FDACS Issues (DRAFT)

General

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Toxicity Risk Assessment

- A. Endpoints of toxicity (Points of Departure) are the same as the previous RED documents
 - Eye irritation- chloropicrin, metam sodium, dazomet
 - Neurological- methyl bromide
- B. Uncertainty factor/MOE for chloropicrin reduced from 30 to 1
 - Human exposure study
 - Most sensitive age group tested (~23 years)
 - Level of Concern is a Margin of Exposure of 1 (0.073 ppm)
 - 0.15 ppm was the lowest dose causing mild irritation without progression to severe

Buffer Zones

- A. **Buffer zones extending onto roads or public areas**
 - Roads/public areas usually operated by local governments; owner/operator will most likely not have authority to post the area or prohibit entry
 - Unreasonable to hold owner/operators liable for assuring restrictions of persons from public areas

- Therefore, buffer zones extending onto public areas or roads should be prohibited
- B. EPA requires generic, rather than site-specific approach for buffer zones –**
- Site-specific approach preferred- Agency and stakeholders should prioritize field studies needed to develop refined, site-specific risk mitigation measures.
 - Studies to support additional buffer zone reduction credits are encouraged.
 - Registrants should take primary responsibility for conducting field studies.
- C. Buffer zones extending onto residential and agricultural areas not under the control of the owner/operator**
- The owner/operator should keep records of neighbors' signed consent allowing buffer zones to extend onto their properties and agreeing to vacate the area during the buffer zone period.
 - Prohibitions on overlapping buffer zones are impractical and may be unnecessary

Fumigant Monitoring Requirements

A. In field and at buffer perimeter

- Why is monitoring necessary? Accidents, leaks, or spills? Inconsistent with outcome of risk assessment and typical risk assessment procedure
- Little mention of equipment calibration, maintenance, quality assurance, and data recording and documentation.
- Are real-time devices available and reliable for all fumigants?
- Can devices simultaneously measure two or more fumigants (Pic/MeBr) without analytical interference resulting in false positive or false negative results?
- Encourage registrants to conduct generic tests to determine situations in which application according to label may result in unacceptable emissions, rather than requiring on-site routine monitoring by applicators

B. In-field: Devices must monitor handler breathing zones every two hours.

- Little guidance on how the monitoring is to be conducted.
- What is adequate frequency and spatial monitoring scheme?
- If multiple applicator crews in a field, monitor workers at all rigs?
- Sensory irritation could prompt respirator requirements.
- Will workers come forward if experiencing mild irritation?
- Significant use of resources

C. Edge of buffer

- Monitoring requirement "between the buffer zone and the residences or other occupied areas" assumes that the buffer zones will not be adequately protective
- Off-site incidents in Florida have proven rare, even without a buffer zone.
- Limited guidance: Down-wind? Single point of monitoring OK?
- Response information for neighbors can substitute for monitoring
- Response information may provoke neighbor concerns and complaints
- The method of provision of information is unspecified. State lead agencies will be forced to judge compliance without adequate criteria.

D. Monitoring inside residences: If homeowner authorization is granted to include a residential structure within a buffer zone, homeowners not allowed in until 2 samples (1 hour apart) are acceptable.

- Impractical and resource intensive.
- Consider informing returning residents of early signs and symptoms of exposure after monitoring outdoors?

Posting Requirements

A. Posting not required when owner/operator controls area within 300 feet of periphery of the buffer zone

- If edge of buffer zone not clearly marked, workers may enter the area unaware that it is part of the buffer zone.

Respiratory Protection

A. Structural pest control use of chloropicrin as a warning agent requires respirator fit test and annual medical evaluation- Inconsistent: no similar requirements for use of sulfuryl fluoride (the primary fumigant).

B. Structural pest control use of chloropicrin prohibits routine use of SCBA- fumigators are required to use SCBA with the primary fumigant and should have the equipment on site when performing the work.

Tarp Removal

A. Groundwater protection label statement refers to “soils with shallow ground water.” The term is unenforceable.

B. RED stipulates for all fumigants, no cutting may occur before 5 days post-treatment. Experience with iodomethane and VIF suggested 5 days may not be sufficient.

Applicator and Handling Training Programs - Stewardship

A. Need for Federal Certification and Training – The federal certification program and worker safety regulations are unlikely to include a soil fumigation category soon. Training by registrants needed.

- Fumigant label requirements are very complex; adequate training prior to use is essential.
- Registrant’s stewardship should include product-specific training and certification for applicators (reviewed by EPA and interested states).
- EPA should encourage uniformity among registrants of the same active ingredients for core training requirements, allowing for product-specific variations where necessary.

B. Expand stewardship requirements for registrants to include on the ground program support in cooperation with applicators and regulators.

Good Agricultural Practices

A. GAPs traditionally are recommendations rather than requirements; if the practices in this section are intended to be requirements, the name of the section should be changed.

- B. Registrants should assist applicators in understanding how to forecast inversions

Restricted Use Pesticide Classification -FDACS concurs that all soil fumigants should be RUPs

Site Specific Fumigant Management Plans

- A. Appears that individual FMPs will be required for each portion of a field that is fumigated. Can an overall FMP be created for a site, with block-specific information added as appropriate?
- B. A checklist of all information to be included in an FMP should be created.

Notice to SLAs and Tribes

Notification of the state lead agency prior to application is required

- Many soil fumigations are performed in Florida each year, requiring a significant use of resources for processing and handling such notices and associated public records requests.
- Any notice of an application that FDACS receives would be considered a public record and would have to be provided to any party requesting this information under Florida's Public Record Law.
- Alternatively, require that applicators provide notification to registrant or third party, for file maintenance and provision to FDACS upon request.

Community Outreach and Education Programs on Bystander Risk

- A. **Registrants ensure that emergency responders are trained and informed to effectively identify and respond to fumigant exposure incidents.**
- Registrants should coordinate outreach efforts to avoid overlaps and promote uniformity.
- B. **Registrants required to provide information on risk, exposure recognition, etc. in high use areas**
- Great care is needed in planning outreach programs.
 - Focus registrant outreach efforts on emergency responders and related professionals.
 - For the general public, consider generic EPA outreach programs, crafted in collaboration with states and other stakeholders

