Soil Fumigants Preliminary Risk Assessments

Office of Pesticide Programs
Technical Briefing
July 13, 2005

Soil Fumigants Preliminary Risk Assessments Introduction

Debra Edwards, Director Special Review & Reregistration Division Technical Briefing July 13, 2005



- Present novel aspects of the assessments
- Facilitate understanding of the assessments
- Enable stakeholders to provide constructive comments to the docket during the 60-day comment period
- Open the public part of our process



Technical Briefing Docket

- EPA has established a docket for the technical briefing
- All materials and presentations will be placed in the docket
- www.epa.gov/edocket
- Docket ID # OPP-2005-0168



- 4 of the 6 Soil Fumigants:
 - Metam sodium/potassium
 - #OPP-2005-0125
 - Methyl bromide
 - #OPP-2005-0123
 - Dazomet
 - #OPP-2005-0128
 - 1,3-Dichloropropene (1,3-D, telone)
 - #OPP-2005-0124
- Later:
 - Chloropicrin
 - lodomethane



Scope

- Human health risk assessment
- Focus on acute bystander and worker exposure
- Will not cover
 - Ecological risk
 - Other human exposure scenarios, e.g.,
 - Longer-term exposures
 - Commodity and structural fumigation
 - Dietary



- Bystander assessment is different from typical non-occupational assessments
- Provide stakeholders an opportunity to ask clarifying questions
- Get stakeholders involved



Today's Focus

- Soil fumigation use and usage
- Risk assessment methods
 - Inhalation
 - Bystander exposure
 - Workers
- Data

Why Assess the Fumigants as a Group?

- Address risks of concern while maintaining key agricultural benefits
- Ensure a level playing field by using similar risk assessment methods and data inputs, to the extent possible
- Make informed risk management decisions, i.e., decisions that take into account likely real-world outcomes
- Methyl bromide phase out, alternatives assessments



6-Phase Public Participation

http://www.epa.gov/oppsrrd1/public.htm

- 1. Error correction comments
- 2. Correct any errors
- 3. Public comment on risk assessment
- 4. Revise risk assessments; develop benefits analysis and risk management options
- 5. Second public comment period
- 6. Issue regulatory decision



Schedule

- Each chemical is somewhat different with regard to process and schedule
- Handout describes the unique aspects of each



Overview of Today's Agenda

- Use and Usage
- Human Health Assessment
 - Hazard
 - Break
 - Exposure
 - Monitoring
 - Modeling



Agenda

- Questions
- Lunch
- Bystander risk characterization
- Questions
- Worker exposure assessment approach
- Questions
- Refining the risk assessments



Agenda

- Break
- Framework for risk management
- Coordination with States and stakeholders
- Timing and how to get involved
- Questions



Expected Outcomes

- Enhance understanding of Methods
- Generate stakeholder interest
- Prompt comments during Phase 3
- Open public dialogue



Briefing Team

- Jonathan Becker, BEAD
- Al Jennings, USDA
- Sherrie Kinard, HED



Briefing Team

- Elizabeth Mendez, HED
- Jeff Dawson, HED
- Bill Smith, HED
- John Leahy, SRRD

Use and Usage of Soil Fumigants

Jonathan Becker Biological and Economic Analysis Division Office of Pesticide Programs July 13, 2005



- Methyl Bromide
 - Brom-O-Gas, Terr-O-Gas, Tri-con
- Chloropicrin
 - Chloro-O-Pic
- 1,3-Dichloropropene
 - InLine, Telone II, Telone, Telone C-17
- Metam Sodium
 - Metam CLR, Vapam, Busan, Nemasol, Sectagon 42, Sistan
- Metam Potassium
 - K-Pam HL, Metam KLR, Raisan K-50, Sectagon K-54
- Dazomet
 - Basamid, Dacron



- Control a wide range of economically important soil-borne pests
- Increased yields
- Reduced labor costs
- Reduced crop rotation time
- Required for some quarantine and preshipments treatments



 Crops using more than 5 million pounds of soil fumigants

| Crop | Pounds of All Soil Fumigants Used Annually (millions) | |
|------------|---|--|
| Potato | 42.0 | |
| Tomato | 19.6 | |
| Tobacco | 12.0 | |
| Carrot | 10.6 | |
| Strawberry | 9.6 | |
| Pepper | 5.3 | |



Pests Controlled By Soil Fumigants

| | Major Types of Pests Controlled | | | | |
|---|---------------------------------|--------------------|-------|--|--|
| Fumigant | Nematodes | Plant Pathogens | Weeds | | |
| Methyl Bromide | • | • | • | | |
| Chloropicrin | | • | | | |
| 1,3-Dichloropropene | • | | | | |
| MITC Generators (Dazomet, Metam sodium, & Metam potassium) | • | • | • | | |
| lodomethane (pending) | • | • | | | |



Soil Fumigant Formulations

- Formulations
 - Granular
 - Liquid (pressurized)
- Often applied as mixtures
 - Provides better control of multiple soilborne pests
 - Chloropicrin used as a chemical warning agent and as a fumigant
 - Most common mixtures (total pounds) are
 - methyl bromide + chloropicrin
 - 1,3-dichloropropene + chloropicrin



| Fumigant | Broadcast | Hot Gas | Shallow Soil Injection | Deep Soil Injection | Chemigation |
|-------------------------|-----------|---------|------------------------------|---------------------------|-------------|
| Methyl Bromide | | • | • | • | |
| Chloropicrin | | | • | • | • |
| 1,3- Dichloropropene | | | • | • | • |
| Dazomet | • | | | | |
| Metam sodium / | | | | | |
| Metam potassium | | | • | • | • |



- Field Treatments
 - Broadacre and strip treatments
 - Flat fume and bed fume



- Soil Compaction (Untarped)
- Deep Injection
- Tarps
 - LDPE, HDPE
 - High Barrier Films
 - Metalized HDPE
- Water Seals
 - Only for the MITC Generators
 - Can be Standard or Intermittent



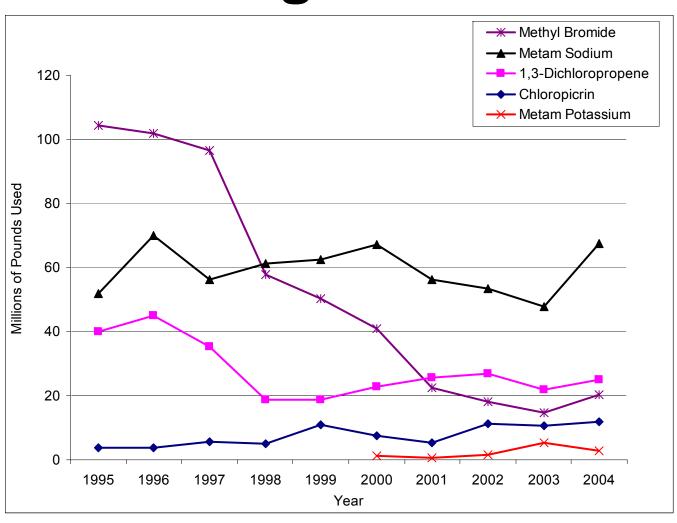








General Trends in Soil Fumigant Use





Alternatives

- Chemical Alternatives
 - May be alternative for each other
 - May be possible to use a fungicide, nematicide and herbicide combination
- Non-chemical alternatives
 - Usually limited to niche application
 - Examples
 - Fallow or crop rotation
 - Resistant cultivars
 - Solarization
- Methyl Bromide Alternatives Outreach
 - www.mbao.org



Methyl Bromide

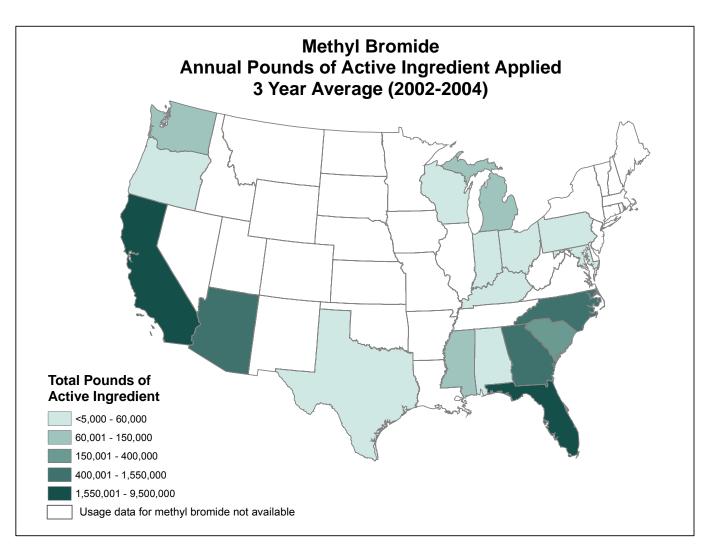
- About 37 million pounds used annually
- Major Use Sites (PCT)
 - Strawberry, Eggplant, Tomato, Pepper
- Major Use Sites (Total Pounds)
 - Tomato, Strawberry, Pepper, Almond, Watermelon
- Non-Soil Uses
 - Commodities
 - Structures and Food Processing Facilities



- Methyl bromide use in the United States phased out as of 1 January 2005, except for exempted uses.
- Continued use is allowed for
 - Quarantine and preshipment, and
 - Critical and emergency uses
- Critical uses are those that
 - (i) The specific use is critical because the lack of availability of methyl bromide for that use would result in a significant market disruption;
 - (ii) There are no technically and economically feasible alternatives available to the user that are acceptable from the standpoint of environment and health and are suitable to the crops and circumstances of the nomination
- Many growers and food processors have transitioned to other fumigants, crops or different production practices



Geographical Usage of Methyl Bromide



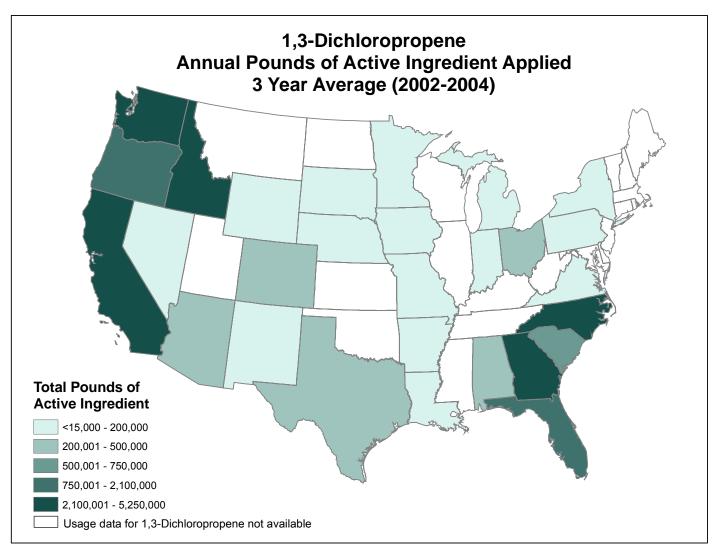


1,3-Dichloropropene

- About 29 million pounds used annually
- Major Use Sites (PCT)
 - Brussels Sprouts, Sweet Potato, Cucumber, Carrot, Tomato
- Major Use Sites (Total Pounds)
 - Potato, Tobacco, Carrot, Peanut, Cotton



Geographical Usage of 1,3-Dichloropropene

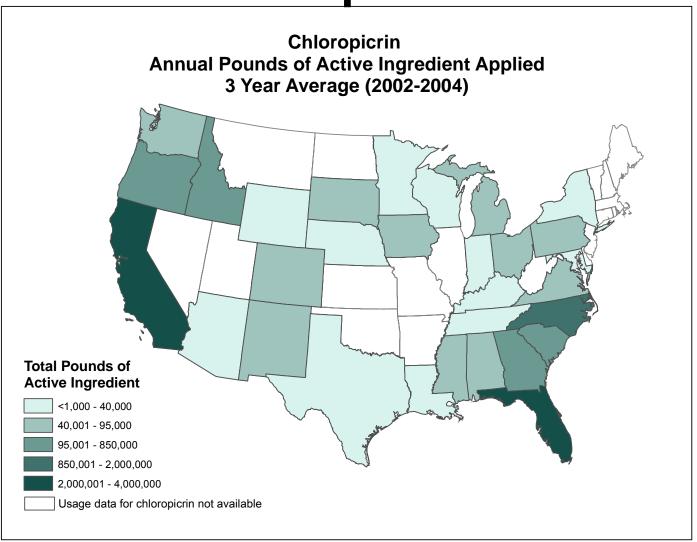




- About 10 million pounds used annually
- Used as a chemical warning agent, in fumigant mixtures, and as a stand alone fumigant
- Major Use Sites (PCT)
 - Strawberry, Tobacco, Tomato, Pepper
- Major Use Sites (Total Pounds)
 - Tobacco, Strawberry, Tomato



Geographical Usage of Chloropicrin





Dazomet

- Major Use Sites
 - Ornamentals, Turf, Nonbearing fruit trees
- Relatively small amounts used compared to other soil fumigants
 - Smaller number of use sites
 - Small acreages
- Pending Registration
 - Strawberry

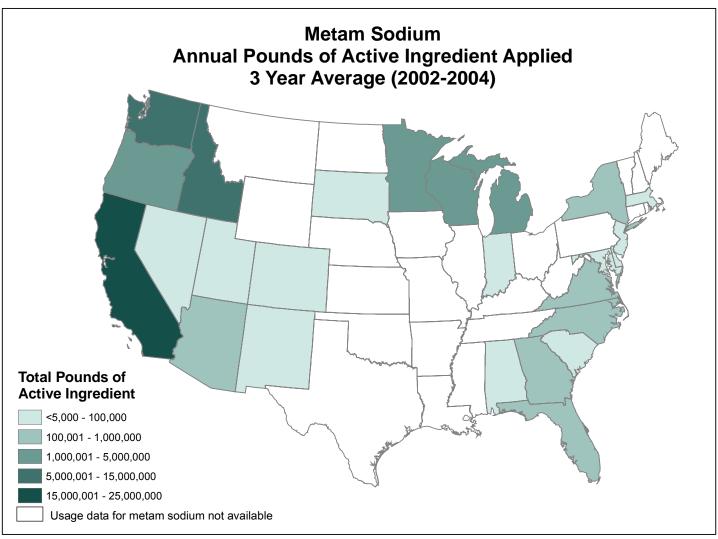


Metam Sodium

- About 56 million pounds used annually
- Major Use Sites (PCT)
 - Carrots, Brussels Sprouts, Potato, Tomato, Celery
- Major Use Sites (Total Pounds)
 - Potato, Carrot, Tomato, Onion, Peanut



Geographical Usage of Metam Sodium



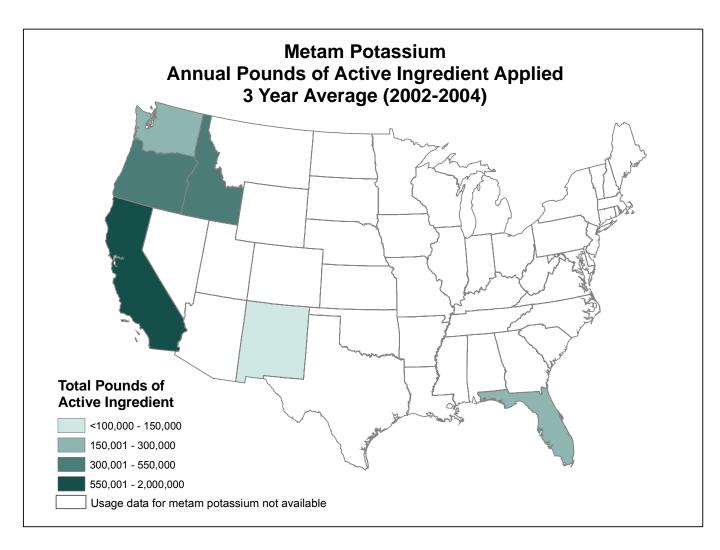


Metam Potassium

- About 3 million pounds used annually
- Major Use Sites
 - Lettuce, Potato, Watermelon, Tomato, Onion



Geographical Usage of Metam Potassium





USDA-EPA Collaboration

Al Jennings Office of Pest Management Policy United States Department of Agriculture





Identify EPA's Information Needs

- Exposure Assessments
- Benefit (Economic) Assessments
- Risk Reduction Options and Strategies



Outreach to Ag Producers

- Crop Production practices
- Fumigant Use
- Economics





Crop Production Practices

- Enterprise Acreage
- Rotations
- Limitations on Fumigant Use
 - physical, biological, regulatory
- Alternatives and options





Fumigant Use

- Largest area of Information Needs
 - Who
 - What
 - When
 - Where
 - Why
 - How





Economics

- Yield and Quality Impacts
- Market Strategies
- Pest Management Costs
 - Material
 - Labor
 - Management





Better Data Better Regulatory Decision



Soil Fumigants Human Health Risk Assessment

Health Effects Division Technical Briefing July 13, 2005

Soil Fumigants Human Health Risk Assessment Introduction & Overview

Sherrie Kinard Health Effects Division Technical Briefing July 13, 2005



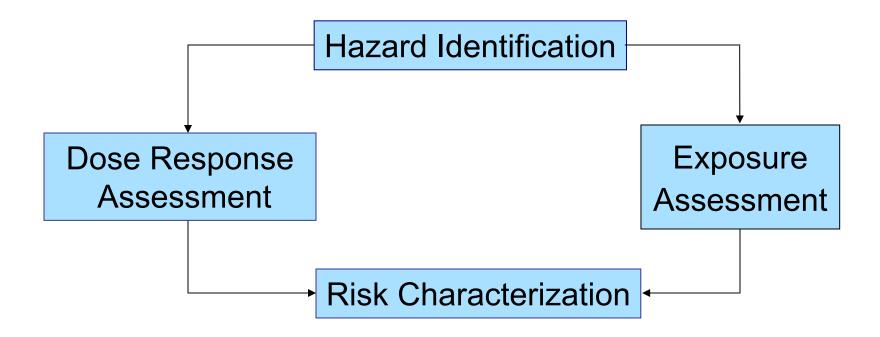
Human Health Assessment

- Introduction & Overview
- Hazard Assessment
- Residential Exposure
- Occupational Exposure
- Potential Refinements



- Hazard Assessment
 - Elizabeth Mendez, Ph.D
- Residential Exposure
 - Jeff Dawson
- Occupational Exposure
 - Bill Smith
- Potential Refinements
 - Jeff Dawson

Human Health Assessment: Introduction and Overview



Today's presentations will focus on acute inhalation risks which appear to present most concern

Human Health Assessment: Introduction & Overview - Hazard

- Fumigants have both local and systemic effects
 - Most sensitive type of effect varies by chemical and exposure duration
- Databases are not equal some are robust, others limited
 - Increased uncertainty with limited data
- Endpoints for quantifying hazard used best data and methodology
 - Human Equivalent Concentrations (HECs)
 - Human Concentrations (HCs)



Human Health Assessment: Introduction & Overview - Incidents

- Documented incidents
- Typically, incidents resulting from soil fumigation are not severe
- Incidents are generally consistent with risk assessments

Human Health Assessment: Introduction & Overview - Exposure

- Exposure to workers in fields, bystanders near fields, bystanders far from fields
 - Focus on one-day exposure to bystanders near fields:
 - Most concern
- Exposure estimates:
 - Field measurements:
 - Limited utility
 - ISCST3:
 - High end estimates
 - Distributional Models:
 - Best estimates of range of potential exposures

Human Health Assessment: Introduction & Overview – Exposure

Three distributional models:

- PERFUM: Used for current assessments; gives the most resolution around peak emissions
- FEMS and SOFEA: Also very good models that provide information on the broader distribution of potential regional exposures (FEMS), and longer duration exposures (SOFEA)

EPA will consider submissions using all 3 models, and incorporate results as appropriate into risk characterization

Human Health Assessment:

Introduction & Overview – Risk Assessment

- Characterize <u>range</u> of potential bystander risks at different distances from a treated area
- Risks to bystanders farther away from treated fields from ambient air
- Risks to applicators and field workers
- Dietary and drinking water risks for fumigants with food or water residues

Human Health Assessment:

Introduction & Overview – Risk Assessment

- Highly refined hazard and dose-response, and exposure assessments
- Use of HECs that provides a significantly refined hazard and dose-response assessment
- Use of distributional assessments and incident reports allow full characterization of risks to all populations exposed

Soil Fumigants Human Health Risk Assessment Hazard Assessment

Elizabeth Mendez
Health Effects Division
Technical Briefing
July 13, 2005



Human Health Assessment

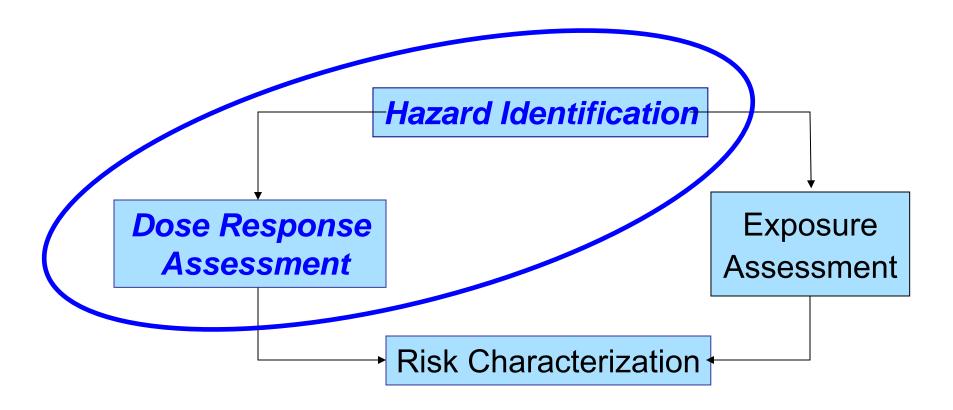
- Introduction & overview
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Goals:

- Define if a chemical is toxic and what it does
- Estimate how much it takes to cause the effect
- Estimate how much time one needs to be exposed to cause the effect
- Define what factors should be used to establish a level of concern

Human Health Assessment: Hazard Assessment*



*Fundamental element of risk assessment process which is described in the "Red Book" From the National Research Council's *Risk Assessment in the Federal Government: Managing the Process,* 1983. http://books.nap.edu/books/030904894X/html/1.html



Human Health Assessment: Hazard Assessment

Overview:

- Soil Fumigants: Background
- RfC Methodology
- Chemical-specific Acute Bystander Risk Assessments
 - Endpoints, HECs, HCs, and uncertainty factors
- Summary



Human Health Assessment: Hazard Assessment

- Traditionally identifies
 - Toxic effects, and
 - NOAELs/LOAELs
- For inhalation exposures, identifies
 - Toxic effects, and
 - Human Equivalent Concentration (HECs) or,
 - Human Concentrations



Background For Soil Fumigants:

- Methyl bromide, dazomet and metam sodium/potassium (MITC generators), and 1,3-D
- Different acute inhalation toxicity profiles
 - Including a range of systemic effects and irritation
- Focus: Inhalation primary route of exposure



Soil Fumigant Scenarios:

- Different durations of exposure are possible: acute through chronic
 - Focus on acute bystander hazard highest concern
- Different exposure routes possible (oral, dermal, and/or inhalation depending on chemical)
 - Focus on inhalation highest concern

Human Health Assessment: Hazard Assessment

Hazard Assessment Methodology:

- US EPA's RfC methodology used to derive human equivalent concentration (HEC) from animal studies (MeBr and telone)
 - HEC: human concentration of exposure extrapolated from animals used to estimate risks
- HC: Human concentration value used to estimate risks directly from human toxicity study – derivation of HEC from animal study using RfC methodology not required (dazomet and metam sodium)



Reference Concentration (RfC) Methodology Background:

- RfC Methodology
 - Methodology to estimate values for noncancer toxicity of inhaled chemicals
 - Developed by EPA's ORD National Center for Environmental Assessment (NCEA)
 - Reviewed by a Science Advisory Board
 - Background documentation publicly available at:
 - http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm? deid=71993

Human Health Assessment: Hazard Assessment

RfC Methodology:

- Includes dosimetric adjustment to account for the species-specific relationships of exposure concentrations to deposited/delivered doses
- Uses known physiological differences between animals and humans (e.g. anatomical differences, air flow)
 - Allows reduction of interspecies UF from 10X to 3X
- Influenced by physicochemical characteristics of the inhaled compound



RfC Methodology:

- Influenced by type of toxicity observed
 - Portal of entry vs. systemic effects
- Takes into account the pharmacokinetic differences between animals and humans
- Incorporates mechanistic determinants of disposition
 - Can be applied to less than lifetime inhalation exposures

Human Health Assessment: Hazard Assessment

RfC Inhalation Risk Equation:

GASES

HECNOAEL = NOAELADJ* RGDR

$$NOAEL_{ADJ} = NOAEL_{Study} * \frac{D (hrs) \text{ animal exposure}}{D (hrs) \text{ human exposure}} * \frac{W(days) \text{ animal exposure}}{W (days) \text{ human exposure}}$$

 $RGDR_r$ = factor used to relate dose in lab animal species to that of humans for region (r) of interest for the toxic effect



RGDR_r: Basic Concepts

- Portal of Entry Effects (i.e., respiratory tract)
 - RGDR_r based on ventilation rate and surface area of respiratory tract affected

$$RGDR = \frac{MV_{animal}/SA_{animal}}{MV_{human}/SA_{human}}$$

Where:

MV = minute volume SA = surface area of the region affected

- Influenced by:
 - Region of respiratory tract affected
 - Species, strain, sex, and age of test animal



RGDRr: Basic Concepts

- Systemic effects
 - RGDR = animal/human ratio of blood:gas partition coefficient.
 - Default value of 1 used when the blood:gas partition coefficient is unknown
 - Blood:gas partition coefficient is usually greater in animals than in humans [Gargas et al. (1989), Toxicol. Appl. Pharmacol. 99(2):344-353]
 - Default value of 1 is used to ensure that we have not underestimate the animal to human blood:gas partition coefficient ratio

Human Health Assessment: Hazard Assessment

Acute Bystander Risk Assessment Approach:

- Calculate HECs using all studies appropriate for the acute exposure assessment, choose the lowest HEC value to estimate risks
- If human toxicity data are available, choose HC to estimate risk if it is the lowest concentration that does not cause the toxic effects of the chemical

Chemical-Specific Acute Bystander Risk Assessment

Methyl Bromide (MeBr) Acute Toxicity Profile

- Robust database via the inhalation route
 - Developmental Neurotoxicity Study is expected to be submitted to the Agency by mid-September
- Critical study for acute risk assessment:
 Developmental Toxicity Study in Rabbit
 - Endpoint: neurotoxicity in does and developmental effects (missing gall bladder, fused sternebrae)
 - HEC_{NOAEL} = 10 ppm; HEC_{LOAEL} = 20 ppm

MeBr: Acute Endpoints for Bystander Risk Assessment

- Endpoint:
 - Neurotoxicity and developmental effects (fused sternebrae, missing gall bladder)
- HEC_{NOAEL} = 10 ppm
- UF = 300
 - 3X interspecies UF,
 - 10X intraspecies UF,
 - 10X database UF (DNT required)
- HEC/UF = 0.03 ppm

MITC Acute Toxicity Profile

- Majority of studies via oral route
- Limited database via the inhalation route
 - Two subchronic studies in rodents available
 - One of the studies is unacceptable
- Critical study for acute risk assessment:
 Human Eye Irritation Study
 - Human Study RfC methodology not needed
 - Endpoint: eye irritation and subjective responses
 - $HC_{NOAEL}^* = 0.22 \text{ ppm } HC_{LOAEL} = 0.8 \text{ ppm}$

HC_{NOAEL}*: Human concentration at the NOAEL

Relevance of Eye Irritation for MITC Bystander Risk Assessment

- Incidence data provides support for eye irritation
 - Eye irritation is often expressed in conjunction with other effects
 - e.g. chest pains, respiratory distress, nausea, breathing rate, etc.
- Animal database does not provide adequate characterization for the range of possible toxic effects
- RfC Guidance lists eye irritation as an adverse effect



- Endpoint:
 - Eye Irritation and subjective responses
- $HC_{NOAFI} = 0.22 \text{ ppm}$
- UF = 10
 - 10X intraspecies UF
- HC/UF = 0.022 ppm

MITC Human Toxicity Studies: Ethical Issues

- Two studies evaluating toxic effects in human subjects
 - Odor Threshold Study
 - Eye Irritation Study
- Both subjected to ethics review in accordance with the "Summary Framework for Ethical Assessment Using Seven Criteria of Emanuel et al." developed by the EPA Science Policy Committee's Human Studies Work Group



- A number of deficiencies identified in the odor threshold study relative to standard ethical procedures
- Eye Irritation study appears to be in compliance with standard ethical procedures
 - Effect used for risk assessment purposes



- Robust database via the inhalation route
- Critical study for acute risk assessment: Acute Inhalation Study
 - Endpoint:
 - Decreased body weight and clinical signs
 - $HEC_{NOAEL} = 75.7 \text{ ppm}$
 - $HEC_{I,OAFI} = 97.2 \text{ ppm}$

1,3-D: Acute Endpoints for Bystander Risk Assessment

- Endpoint:
 - Decreased body weight
 - Acute Inhalation Study
- HEC_{NOAEL} = 75.7 ppm
- UF = 30
 - 3X interspecies UF
 - 10X intraspecies UF
- HEC/UF = 2.5 ppm

Human Health Assessment: Hazard Assessment

Summary:

- The soil fumigants produce a range of toxic effects, both local and systemic
- The toxicity databases for these chemicals are not equal – some have robust data sets, others have more limited data sets
- RfC Methodology (HECs) or human toxicity data (HCs) used for hazard assessment, rather than using animal NOAELs directly
 - Allows more accurate quantification of hazard and reduction of interspecies uncertainty factor (UF)
- Overall, hazard component of these risk assessments is highly refined

Soil Fumigants Human Health Risk Assessment Residential Exposure

Jeff Dawson
Health Effects Division
Technical Briefing
July 13, 2005



Human Health Assessment

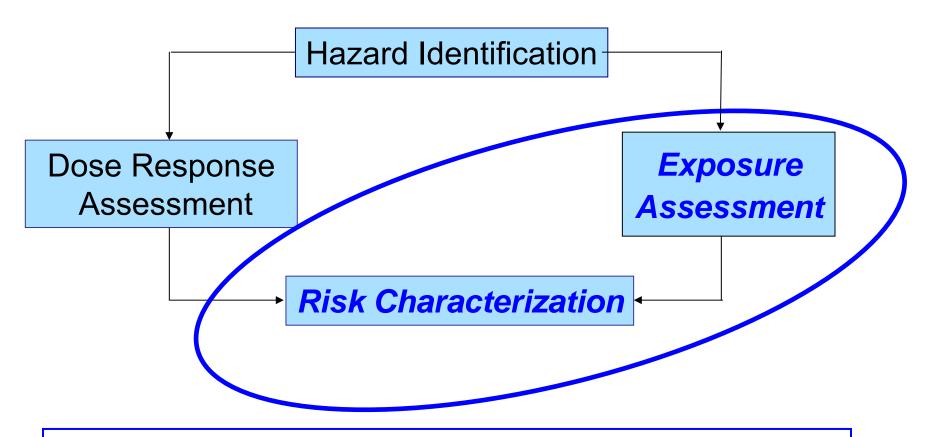
- Introduction & overview
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Goals:

- Define how much, how often, and the source of exposure for the general population
- Estimate risks, which are a product of toxicity and exposure
- Describe how realistic and reliable results are by "telling their story"
- Characterize a broad range of estimated risks (e.g., percentiles on a distribution)

Human Health Assessment: Hazard Assessment*



*Fundamental element of risk assessment process which is described in the "Red Book" From the National Research Council's *Risk Assessment in the Federal Government: Managing the Process*, 1983. http://books.nap.edu/books/030904894X/html/1.html



 $MOE = HEC \text{ or } HC \div Exposure$

MOE = Margin of Exposure is a ratio of the dose at which a toxic effect occurs relative to exposure, calculated for different routes and durations

[Note: Target MOE (or our level of concern) defined by factors that account for the use of animal tests to extrapolate to humans, how humans differ amongst themselves, and possible sensitivities of groups such as children (e.g., 300 for MeBr acute exposures)]

<u>HEC or HC</u> = value that describes the potential toxicity of a chemical (e.g., MeBr acute residential HEC = 10 ppm)

Exposure = represents the amount of a chemical inhaled or otherwise ingested



Considerations about the term "Exposure":

- Results for an individual if they were at a specific location for the entire duration of exposure
- Results do not represent a population
- When distributional results are considered, they can be described by:
 - "Risks are not a concern for a person X % of the time they spend at a specific location"

Human Health Assessment: Residential Exposure*







Residential (Bystanders)



Water*

*Note: Dietary and water apply only to MeBr, they are introduced here for convenience and are typically not referred to as a residential exposure







- MeBr is only one with food tolerances which result from post-harvest uses
- Acute and chronic MeBr food risks not of concern
 - Exposures are 4 to 22% of target level (aPAD) for acute dietary
 - Exposures are 1 to 9% of target level (cPAD) for chronic dietary
- For MeBr, estimated drinking water levels do not exceed levels of concern

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Human Health Assessment: Residential Exposure



2 Types of Residential Exposure:

- 1) "Bystander" from a known source
- 2) "Ambient" from regional use

Human Health Assessment: Residential Bystander Exposure



Wind direction

Wind blows emissions from

a treated field to a receptor of concern (e.g., house or school)



Occurs from known sources, single applications used in assessment

Human Health Assessment: Residential Bystander Tiered Approach

Increased Predictive Capabilities

PERFUM Air Model

EPA's ISCST3 Air Model

Field Volatility Monitoring Studies







Vacuum Cylinder



Colorimetric Tubes



Personal Sampler

Basic Sampling Methods Used

| Chemical | No. Studies | States Where Conducted |
|----------|-------------|------------------------|
| MeBr | 50 | CA |
| 1,3-D | 20 | CA, FL, WI, TX, GA |
| Metam | 11 | CA, FL, WA |
| Dazomet | 1 | CA |

| Chemical | Values Used | |
|----------|---------------------------------|--|
| MeBr | Max 24 hr TWAs | |
| 1,3-D | Max 24 hr TWAs | |
| | (Max 7 Day TWAs For Short-term) | |
| Metam | Max 4-6 hr TWAs | |
| Dazomet | Max 4 hr TWAs | |

TWA = Time-Weighted Average

430' 0.072 & ND ppm

430' - ND & ND ppm

288' 0.13 0.21 ppm

30' - 0.52 & 0.029 ppm

430' 0.042 ND ppm

30' 0.24 & 0.005 ppm

MeBr Field 8 Results

19A; tarped raised bed in CA 200 lb/A; 98/2 MeBr/Pic

12 hr samples; LOD 0.005 ppm

<u>5'</u> 0.65 1.0 ppm 405' 0.46 & 0.69 ppm

30' - 0.39 & 0.23 ppm

430' 0.072 & 0.74 ppm

430' - 0.028 & 0.65 ppm

408' 0.089 & 0.017 ppm

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Summary of MeBr

Field Results

26 - 34 ft: max TWA = 1.4 ppm

35 - 79 ft: max TWA = 0.59 ppm

80 - 115 ft: max TWA = 0.47 ppm

>115 ft: max TWA = 1.5 ppm



Residential Bystander Tier 1 – Field Studies

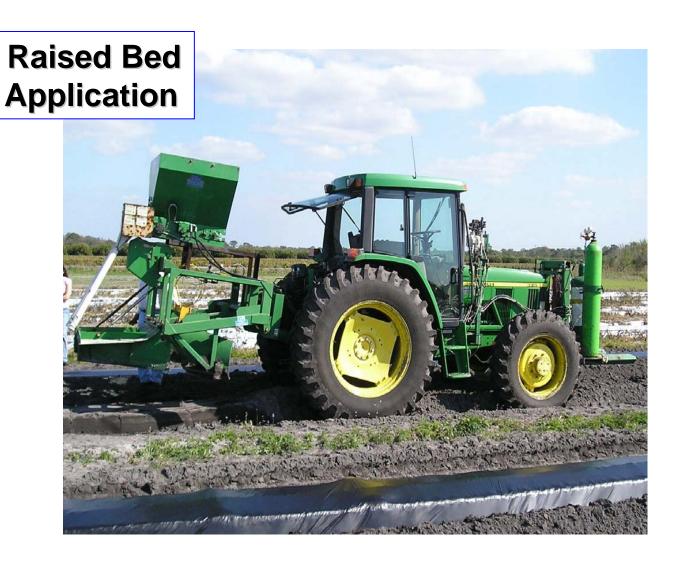
- Studies are generally categorized based on various application & control technologies including:
 - Application methods: shank injection in flat fields or raised beds, granulars, via irrigation, hot gas
 - Control technologies: depth of injection, shape and orientation of shank, use of tarp materials, water sealing methods, time of day of application



Raised Bed Application

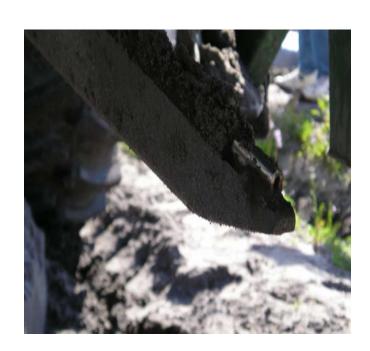












Shanks used for subsoil injection



Flat Fume Application





Human Health Assessment: Residential Bystander Tier 1 – Field Studies



Human Health Assessment: Residential Bystander Tier 1 – Field Studies

<u>Issues to be considered include:</u>

- Analytical issues such as breakthrough and sampler calibration
- Application and control methods
- Application rate and formulation
- Timing relative to season of use
- In general, studies are of acceptable quality for consideration in the risk assessment process



Monitoring data are considered Tier 1 because:

- Limited to weather conditions which occurred on particular study days
- Results represent specific topography and other factors (e.g., soil type and temperature) which can impact emissions and transport
- Fixed sampler locations

Human Health Assessment: Residential Bystander Tier 1 – Field Studies

In Summary:

- In general, monitoring data indicates a risk concern under some circumstances for the soil fumigants considered except 1,3-D
- Monitoring data utility for estimation of risks are limited, but these data are critical for use as the basis for modeling as will be described for Tiers 2 and 3

Human Health Assessment: Residential Bystander Tiered Approach

Increased Predictive Capabilities

PERFUM Air Model

EPA's ISCST3 Air Model

Field Volatility Monitoring Studies

Human Health Assessment: Residential Bystander Tier 2 – ISCST3 Model

Premise: Why go beyond monitoring data?

"Due to limitations in spatial and temporal coverage of air quality measurements, monitoring data are not normally sufficient as the sole basis for demonstrating the adequacy of emission limits ...Air quality measurements can be used in a complimentary manner to dispersion models, with due regard to the strengths and weaknesses of both techniques." (40CFR51/AppW)

Residential Bystander Tier 2 – ISCST3 Model

Our goal for using air models in this assessment:

 To use a broad range of inputs to evaluate the potential risks to bystanders associated with soil fumigants across many situations



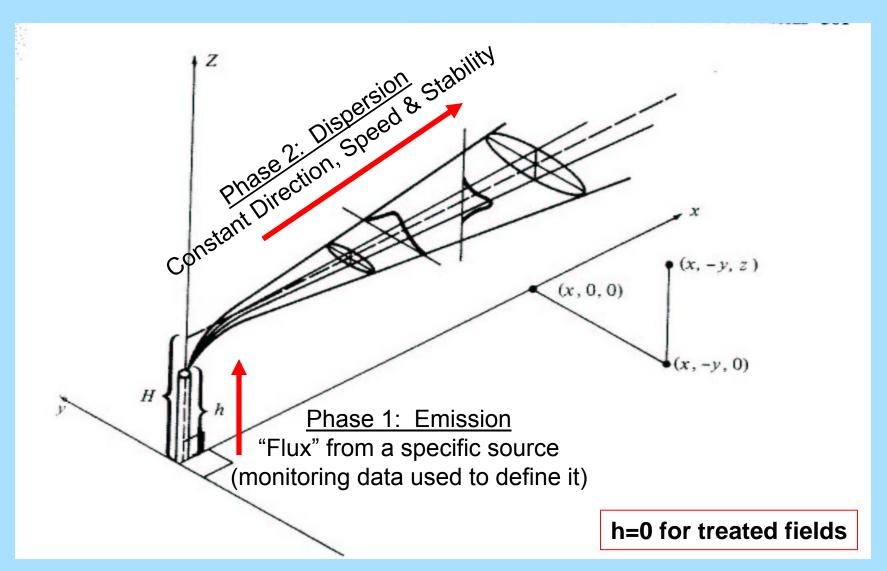
- ISCST3 = Industrial Source Complex Short-Term Model (V3)
- ISCST3 is an Agency recommended air modeling tool for regulatory purposes, it is available at:
 - (http://www.epa.gov/scram001/tt22.htm#isc)
- ISCST3 has undergone extensive review, see 40CFR51 App. W for details:
 - (http://www.epa.gov/scram001/guidance/guide/app w 03.pdf)

Residential Bystander Tier 2 – ISCST3 Model

How ISCST3 Works:

- Phase 1 Emissions: Specific flux values are defined using monitoring data. The range of flux values considered is limited to the available monitoring data.
- Phase 2 Dispersion: Airborne residues are transported via a Gaussian plume approach downwind. A Gaussian distribution of residues occurs in both the horizontal and vertical planes (i.e., near field to 1000s of meters downwind).

Human Health Assessment: Residential Bystander Tier 2 - ISCST3 Model



Residential Bystander Tier 2 – ISCST3 Model

ISCST3 allows for:

- Varying combinations of flux and weather conditions to be considered if appropriate data are available*
- Consideration of distances from treated fields other than sampler locations from field studies

*Note: Even though ISCST3 allows for additional flexibility, it is not a "1st principles" model so it cannot be used to establish how, for example, a change in soil temperature or type may impact results



Residential Bystander Tier 2 - ISCST3 Model

How we used ISCST3:

- Step 1: "Calibration" Used with field study data to define flux (µg/m²/sec) in most cases
- Step 2: Risk Assessment Use flux values from Step 1 to calculate downwind air concentrations under differing conditions for risk calculations

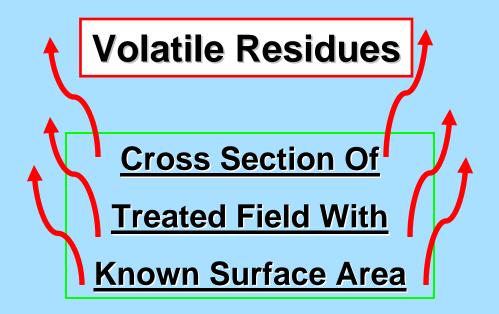
Residential Bystander Tier 2 – ISCST3 Model

The Inputs For The ISCST3 Analyses Included:

- Flux Rates
 - Application Methods
 - Emission Control Technologies
- Weather Conditions
 - Windspeed
 - Direction is held constant over analysis
 - Stability
 - A measure of turbulence
- Field Sizes
- Application Rates

Human Health Assessment: Residential Bystander Tier 2 – Field Studies

Emissions Are Described As Flux Values (µg/m²/sec)



Emissions measured by samplers in the field over a known time, area treated is also known so flux can be calculated

Human Health Assessment: Residential Bystander Tier 2 – ISCST3 Model

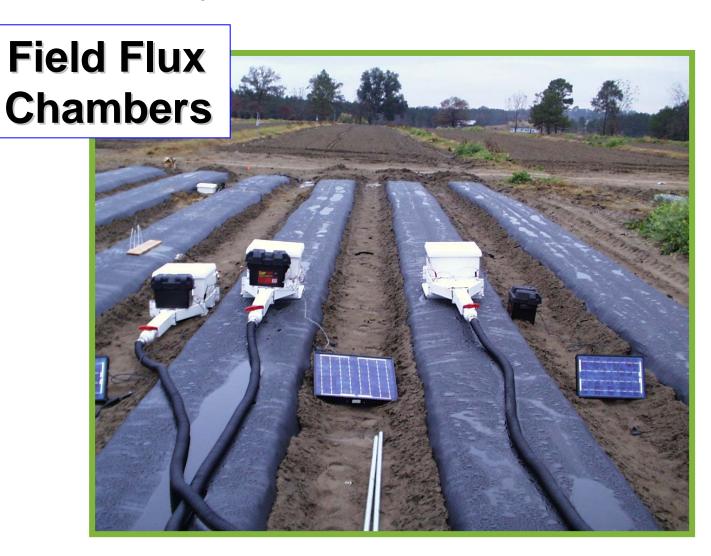
Flux (µg/m²/sec) Calculated Using 1 of 3 Methods:

- 1. Chamber: direct measurement of flux using a small housing from the treated surface
- 2. Aerodynamic Flux: samplers are placed on a mast at different heights in a treated area and results are analyzed using a published methodology (e.g., Majewski et al).
- 3. Indirect Back-Calculation: measured concentrations and measured weather data from monitoring studies are input into ISCST3 and it is used to solve for flux

(http://www.cdpr.ca.gov/docs/empm/pubs/ehapreps/eh9903.pdf)

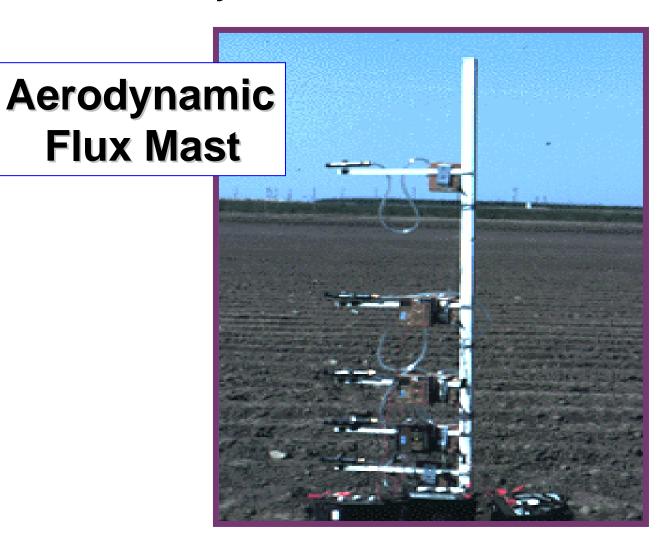


Residential Bystander Tier 2 – ISCST3 Model





Residential Bystander Tier 2 – ISCST3 Model



Human Health Assessment: Residential Bystander Tier 2 – ISCST3 Model

| Chemical | No. Flux Values | Parameters | | |
|----------|--------------------|--|--|--|
| MeBr | 5 | Shank Injection or Hot Gas; Tarped or Untarped; Flat Fume or Bed; 2 Depths | | |
| 1,3-D | 10 | Shank Injection or Drip Irrigation; Tarped or Soil Seals; Flat Fume or Bed; 2 Depths | | |
| Metam | 9 | Sprinkler or Drip Irrigation, Shank Injection Tarped or Water Seals; Flat Fume or Bed | | |
| Dazomet | 2 | Danuba Drop Spreader Either on Surface or Soil Incorporated | | |



Residential Bystander Tier 2 – ISCST3 Model

3 Key Weather Factors Resulting In 10 Input Combinations Were Considered:

- Wind Direction: held constant in a single direction downwind
- Windspeed: varied from 1 meter/second to 4.5 meters/second (i.e., 10 mph)
- Stability (a measure of turbulence): from relatively calm atmosphere "E" or "D" to a relatively turbulent "B" atmosphere
 - See section 4.3 at: http://www.epa.gov/scram001/userg/relat/pcramtd.pdf

Residential Bystander Tier 2 – ISCST3 Model

5 Different Field Sizes Were Considered:

- Square Fields
- 1, 5, 10, 20 & 40 Acres

Human Health Assessment: Residential Bystander Tier 2 – ISCST3 Model

| Chemical | Maximum Application Rate (lb ai/A) | | |
|----------|------------------------------------|--|--|
| MeBr | 430 | | |
| | Field crops – 202 | | |
| 1,3-D | Vegetables – 295 | | |
| | Fruit/Nuts - 365 | | |
| Metam | 320 | | |
| Dazomet | Surface – 265 | | |
| Dazoniet | Incorporated - 530 | | |

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Human Health Assessment: Residential Bystander Tier 2 – ISCST3 Model

| Summary Of ISCST3 Analyses | | | | | | | |
|----------------------------|--------------------|------------------------------|--------------------|--------------------|-------|--|--|
| Chemical | No. Flux Values | No. Weather Conditions | No. Appl. Rates | No. Field Sizes | Total | | |
| MeBr | 5 | 10 | 1 | 5 | 250 | | |
| 1,3-D | 10 | 10 | 1 | 5 | 500 | | |
| Metam | 9 | 10 | 1 | 5 | 450 | | |
| Dazomet | 2 | 10 | 1 | 5 | 100 | | |

Residential Bystander Tier 2 – ISCST3 Model

What We Get From ISCST3:

- Each analysis provides air concentrations for locations downwind of a treated field which can be used to estimate risks
- Locations range from near a field to 1000s of meters downwind

Human Health Assessment: Residential Bystander Tier 2 – ISCST3 Model

Example ISCST3 Outputs – Methyl Bromide (Flat fume/deep shank/tarp)

| Distance (Meters) | MeBr Concentrations For Varying Weather Conditions (ug/m3) | | | | | |
|----------------------|--|--------------|--------------|--------------|--------------|--|
| | 1 m/s D | 1.4 m/s C | 1.8 m/s C | 2.2 m/s C | 2.7 m/s C | |
| 25 | 4411 | 2035 | 1583 | 1295 | 1055 | |
| 50 | 3042 | 1369 | 1065 | 871 | 710 | |
| 100 | 1949 | 823 | 640 | 524 | 427 | |
| 200 | 1099 | 390 | 303 | 248 | 202 | |



Residential Bystander Tier 2 – ISCST3 Model

ISCST3 is considered Tier 2 because:

- Weather conditions, including wind direction, the same over entire period (as it was used in this case)
- Single flux estimate used over entire period (flux is known to change significantly over time)

Residential Bystander Tier 2 – ISCST3 Model

In Summary:

- In general, ISCST3 results indicate a risk concern of some manner for the soil fumigants considered except 1,3-D at distances downwind from treated fields that are currently considered reasonable under common agricultural practice
- The utility of ISCST3 is limited based on above, but the data and analyses used are critical for modeling included in Tier 3

Human Health Assessment: Residential Bystander Tiered Approach

Increased Predictive Capabilities

PERFUM Air Model

EPA's ISCST3 Air Model

Field Volatility Monitoring Studies

3 Different Modeling Approaches Were Considered Including:

PERFUM:

Probabilistic Exposure and Risk model for FUMigants

•FEMS:

•Fumigant Exposure Modeling System

•SOFEA:

•SOil Fumigant Exposure Assessment System



The FIFRA Science Advisory Panel (SAP) Evaluated Each System In 2004:

- **PERFUM:** August 24/25
- **FEMS**: August 26/27
- **SOFEA:** September 9/10
- SAP reports for each meeting and all background materials are available at:

(http://www.epa.gov/scipoly/sap/2004/index.htm)

The Key SAP Comments Included:

- Suggested Refinements:
 - Additional flux monitoring and weather data and analysis techniques could further refine risk estimates
 - Better approaches for expressing uncertainty and variability should be considered
 - Regional use of meteorological data was described
- All models were deemed to be useful for risk assessment purposes

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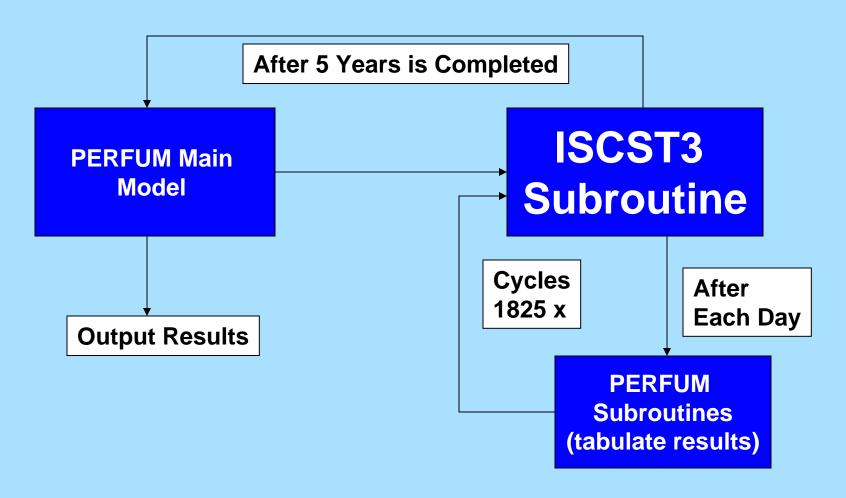


Outputs Differ For Each Model

- PERFUM: outputs based on acute durations
- FEMS: outputs based on 4 day to annualized durations
- SOFEA: outputs based on acute to annualized durations

3 Models Are Available, Why Has PERFUM Been Used?

- Submissions using any of the 3 systems would be considered in the Agency's process
 - Note: A metam sodium assessment using FEMS has been submitted and is available in the docket (http://www.epa.gov/pesticides/docket/)
- All 3 models are capable of being used but PERFUM was used in the current assessments because it provides the most resolution for the acute duration of exposure which is the key concern for soil fumigants

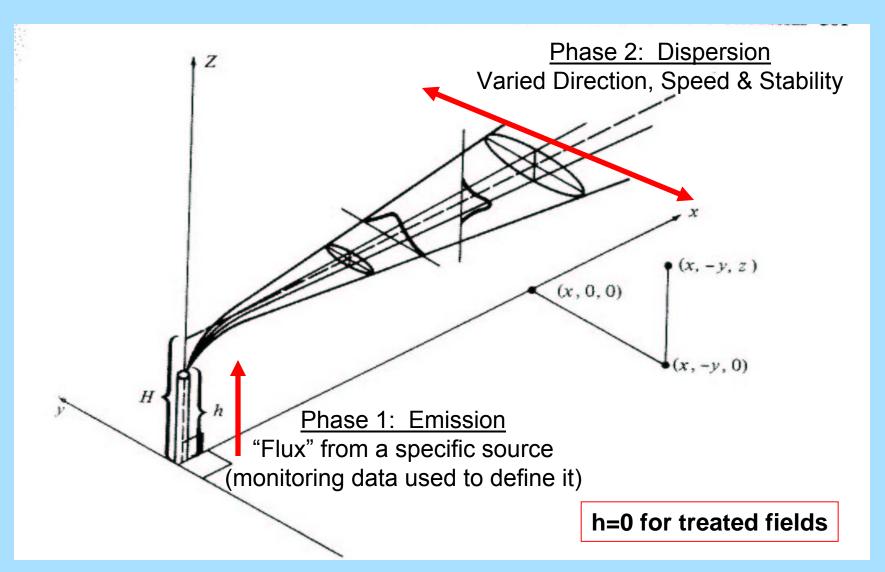


(http://www.epa.gov/opphed01/models/fumigant/

How PERFUM Works*:

- Phase 1 Emissions: Similar to ISCST3 except that distributions of flux and their associated variability can be used (varies based on data)
- Phase 2 Dispersion: Similar to ISCST3
 except outputs based on 5 years of actual
 weather data that allows for changes in wind
 direction, windspeed, and atmospheric
 stability (i.e., turbulence) are used

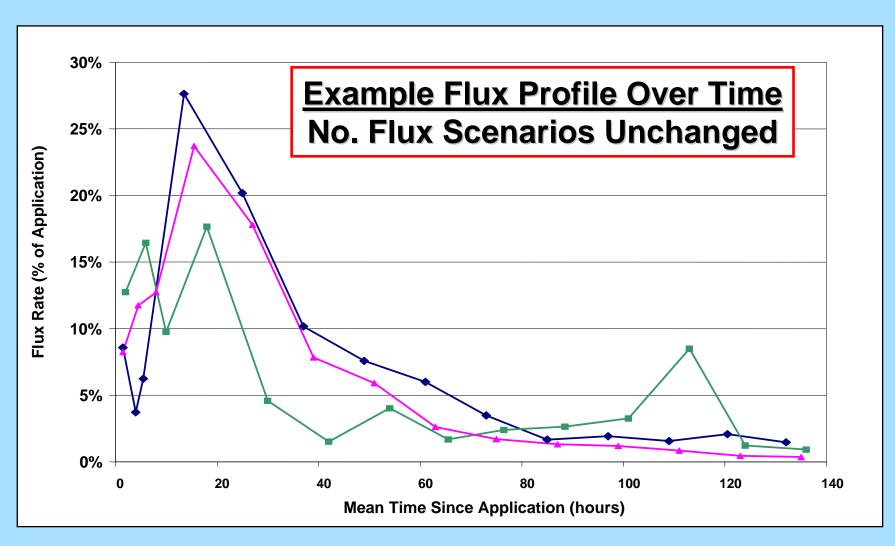
*Note: ISCST3 provides concentrations at varied distances. PERFUM, however, solves for distance needed to achieve a target air concentration at a percentile.



The PERFUM Analyses Are Based On:

- Flux Profiles*
 - Application Methods
 - Emission Control Technologies
- Weather Conditions*
- Field Sizes* & Shapes*
- Application Rates*
- "Maximum" & "Whole Field" Statistical Outputs

*Denotes inputs that are similar to ISCST3 but either formatted differently or with enhanced information

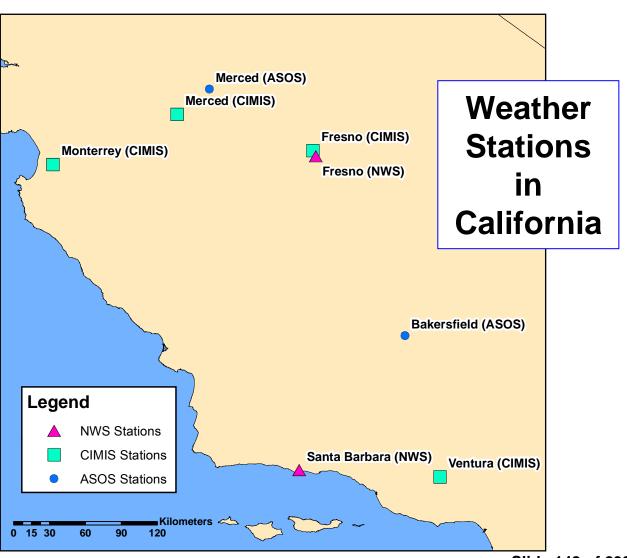


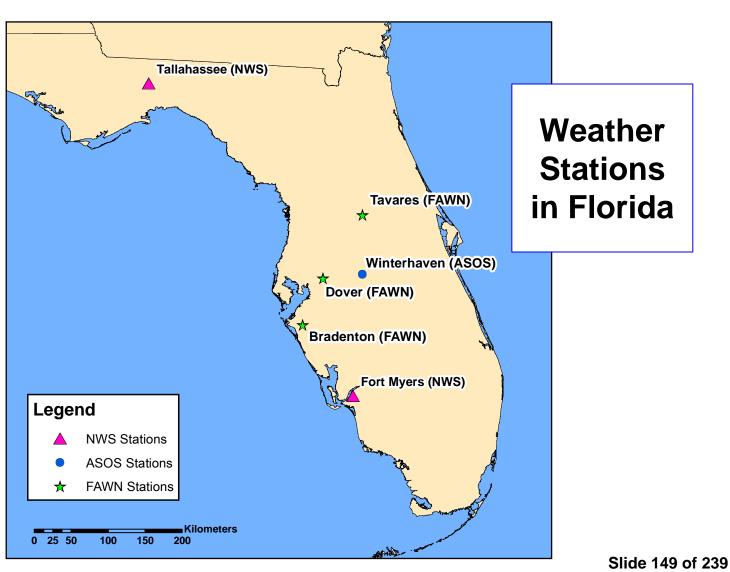
Sources of Weather Data Included*:

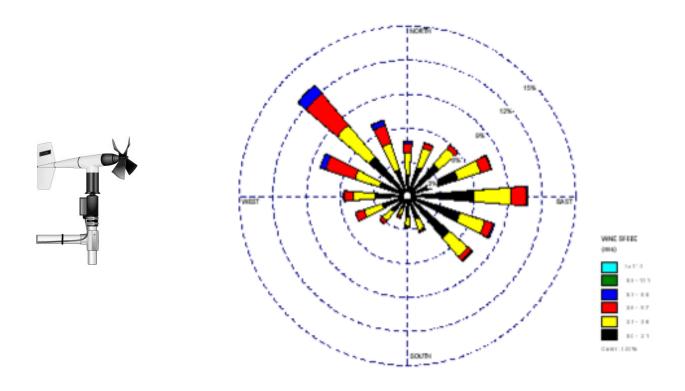
- National Weather Service (NWS)
- FAA's Automated Surface Observing System (ASOS)
- California Irrigation Management Information System (CIMIS)
- Florida Automated Weather Network (FAWN)

*Data from 6 stations used for this analysis including Ventura & Bakersfield CA; Bradenton & Tallahassee FL; Flint MI; Yakima WA

| Weather Data Source | Advantages | Disadvantages |
|-------------------------|---|---|
| NWS | Widely used High quality control | Few stations, not in growing regions |
| ASOS | Large number of stations in growing areas | Only automated quality control Some issues with cloud |
| CIMIS | Large number of stations in growing areas of California | Cover Only automated quality control Collected at 2 m |
| Stations in key growing | | Very little quality control |





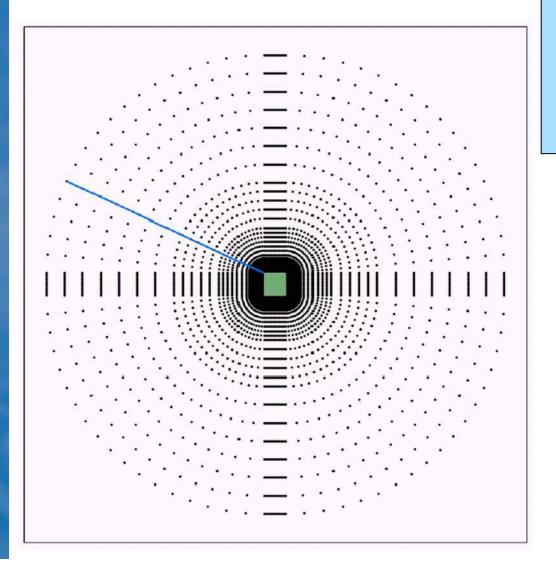


5 Years of weather data (windspeed & direction) from Bakersfield CA

<u>Different Field Sizes & Shapes Were Considered:</u>

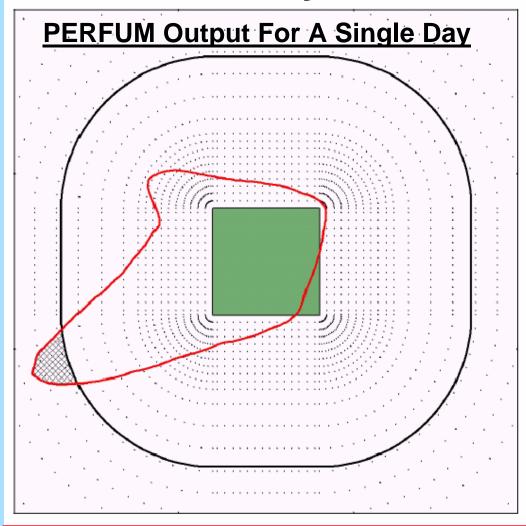
- Square Fields 1, 5, 10, 20 & 40 Acres
- Rectangular Fields 1 & 5 Acres

| Receptor Points for Various Field Sizes In PERFUM | | | |
|---|-------------|-------------|--|
| Field Size ∄ | Number of ¶ | Number of ∃ | |
| (acres) | Spokes | Receptors | |
| 1 | 96 | 2,688 | |
| 5 | 132 | 3,696 | |
| 10 | 152 | 4,256 | |
| 20 | 188 | 5,264 | |
| 40 | 232 | 6,496 | |



PERFUM
5 A Square
Field
Fine Receptor
Grid

| Chemical | Maximum Application Rate (lb ai/A) | Application Rates Considered (% of max) |
|--|---|---|
| MeBr | 430 | 25, 50, 75, 100 |
| 1,3-D | Field crops – 202 Vegetables – 295 Fruit/Nuts - 365 | 25, 50, 75, 100 |
| Metam | 320 | 25, 50, 75, 100 |
| Surface – 265 Dazomet Incorporated - 530 | | 25, 50, 75, 100 |



Red Line = Distance Where Target Conc. Is Met

Statistical Outputs

Generated Daily For 5 Years (1825 Days)

"Maximum"

Farthest Point On Red Line

"Whole Field"

All Points On Red Line For Each Receptor "Spoke"

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| | Summary Of PERFUM Analyses With HEC And Total UF | | | | | |
|----------|--|------------------------------|--------------------|--------------------------------|-------------------|-------|
| Chemical | No. Flux Values | No. Weather Conditions | No. Appl. Rates | No. Field Sizes & Shapes | No. Stat. Outputs | Total |
| MeBr | 5 | 5 | 3 | 9 | 2 | 1350 |
| 1,3-D | 10 | 5 | 3 | 9 | 2 | 2700 |
| Metam | 9 | 6 | 3 | 9 | 2 | 2916 |
| Dazomet | 2 | 6 | 3 | 9 | 2 | 648 |

Note: Additional analyses were completed in order to evaluate the sensitivity of the results to changes in the uncertainty factor for risk characterization purposes.

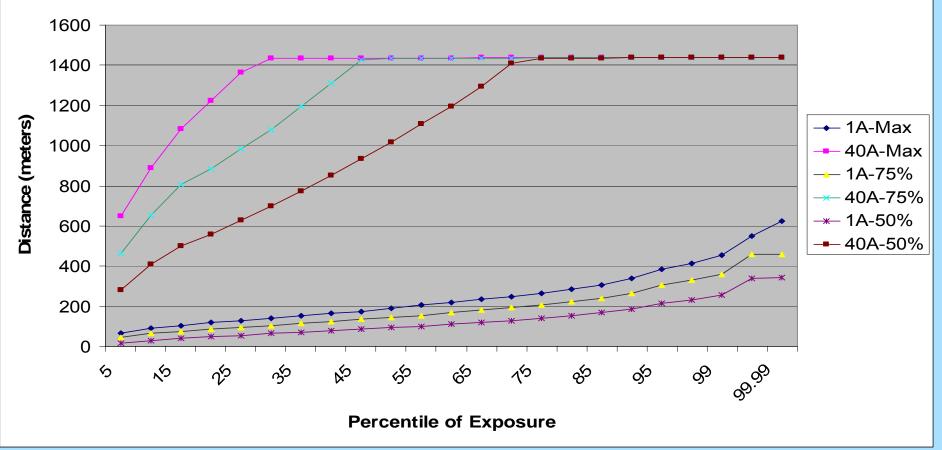
What We Get From PERFUM:

 Each analysis provides the distance from a treated field at which a target air concentration is achieved

[Target] = HEC or HC/UF

 Maximum distance considered is 1440 M





Human Health Assessment: Residential Bystander Tiered Approach

Increased Predictive Capabilities Risk

PERFUM Air Mode

EPA's ISCST3 Air Model

Field Volatility Monitoring Studies

Human Health Assessment: Bystander Risks

- Goals:
 - •Illustrate the approaches used to summarize the bystander risk estimates
 - Provide summary of the results
 - e.g., percentiles on distribution
 - "Tell the story" about the results
 - •i.e., risk characterization

MeBr results used to illustrate basic approach

Human Health Assessment: Bystander Risk - Approach

- Analyze Risk Results Based On Different Parameters In Order To Evaluate Trends
 - Flux Changes
 - Weather Changes
 - Application Rate Changes
 - Field Size & Shape
 - Statistical Outputs
- Illustrate how risk estimates change across distributions

Human Health Assessment: Bystander Risk - Approach

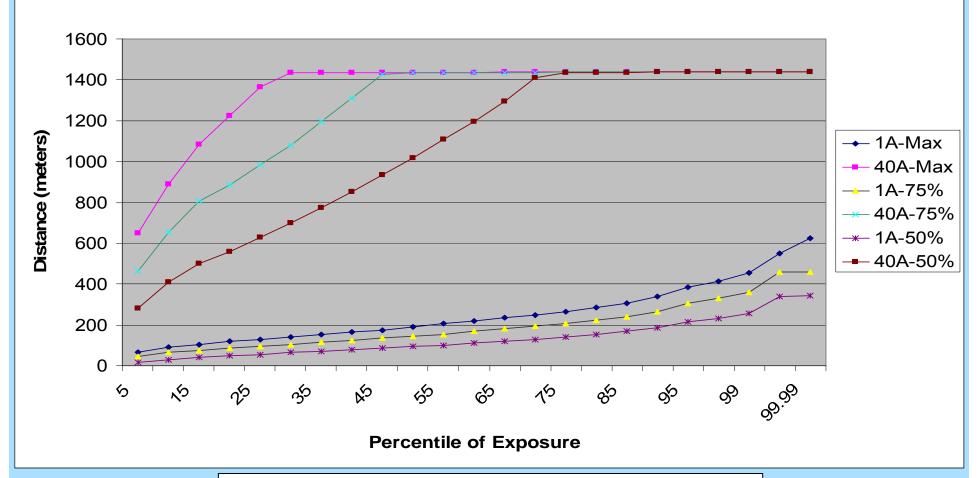
Considerations about the term "Exposure":

- Results for an individual if they were at a specific location for the entire duration of exposure
- Results do not represent a population
- When distributional results are considered, they can be described by:

"Risks are not a concern for a person X % of the time they spend at a specific location"

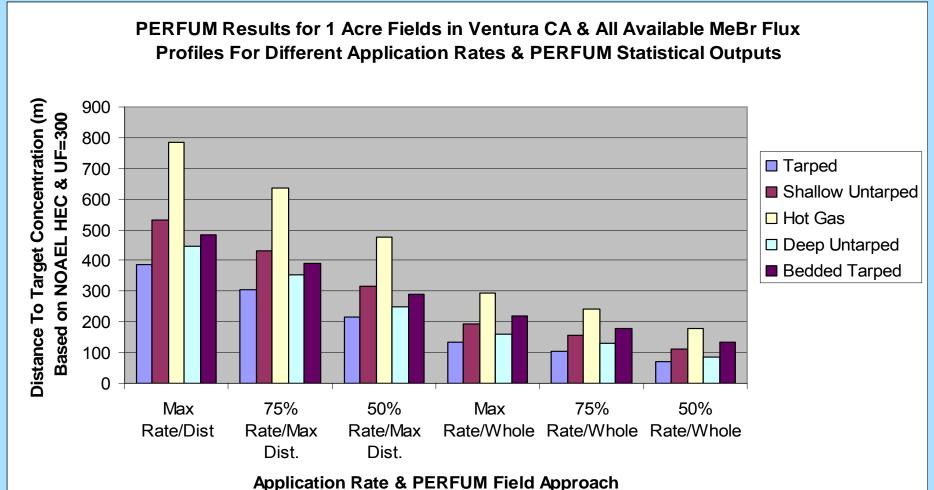
Human Health Assessment: Bystander Risk - Results

MeBr Example Of Maximum Distance Results Ventura California CIMIS & Tarped Flux Profile [Based on 10 ppm HEC & UF = 300]



Basic PERFUM Outputs For A Single Analysis

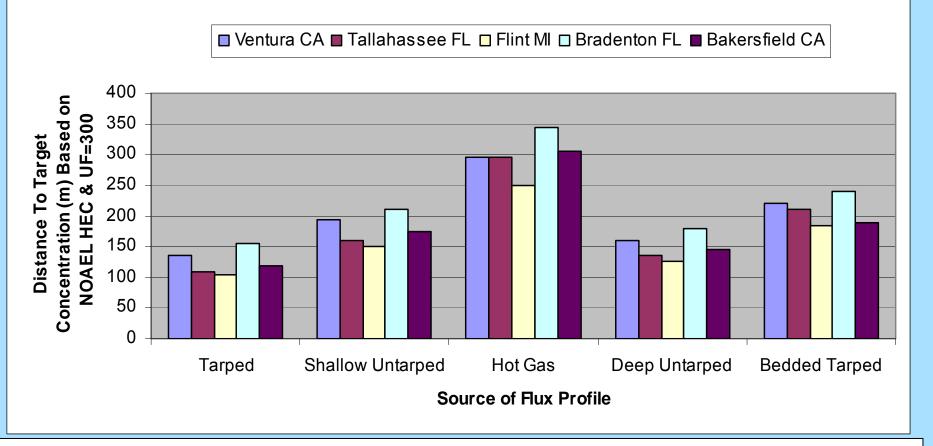
Human Health Assessment: Bystander Risk - Results



Graph Illustrates How Changes In Rate; Statistical Approach; & Flux Impact Results

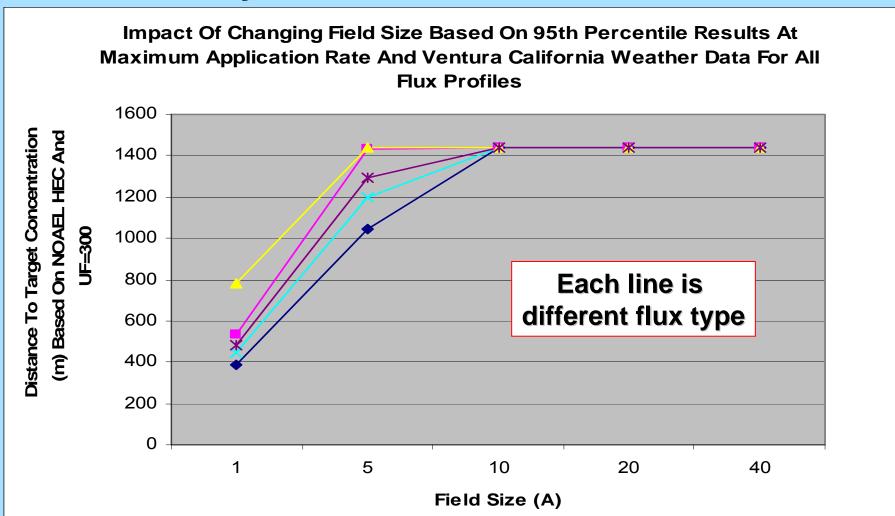
Human Health Assessment: Bystander Risk – Results

PERFUM Whole Field Results For 1 Acre Fields
Based On All Available Meteorological And Flux Data At The Maximum
Application Rate



Graph Illustrates How Changes In Weather Impacts Results For All Flux Values

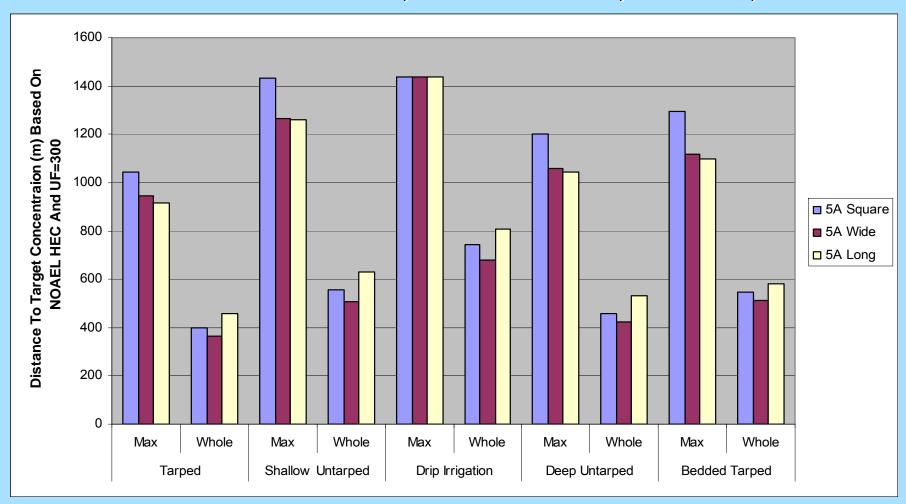
Human Health Assessment: Bystander Risk - Results



Graph Illustrates How Changes In Field Size Impacts Results For All Flux Values

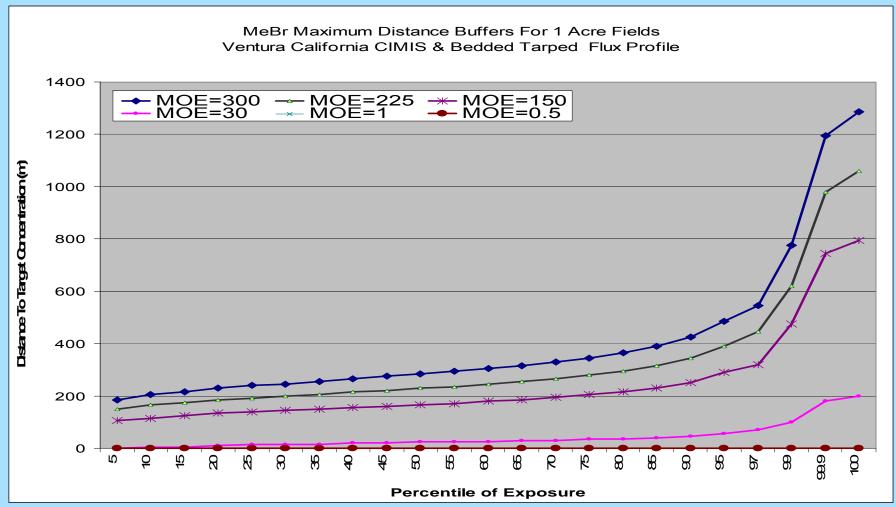
Human Health Assessment: Bystander Risk – Results

MeBr Results For Ventura CA, All Flux Profiles, Max Rate, 5A Fields



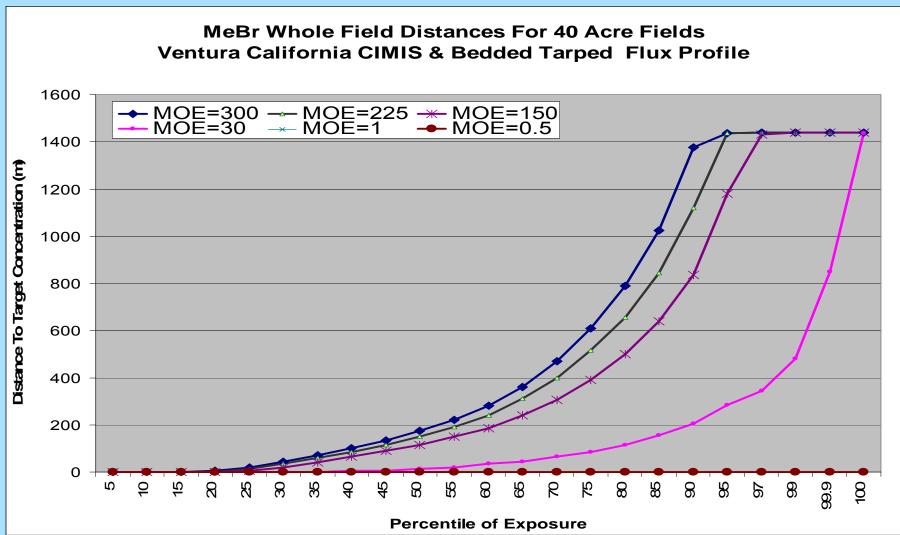
Graph Illustrates How Changes In Field Shape Impacts Results For All Flux Values

Human Health Assessment: Bystander Risk Results



MeBr Risks For A 1Acre Field At Differing Percentiles of Exposure & MOEs

Human Health Assessment: Bystander Risk Results



MeBr Risks For A 40Acre Field At Differing Percentiles of Exposure & MOEs

Human Health Assessment: Bystander Risk Results

| | MeBr Acute MOEs Calculated With Various Methods (Tarped Flat Fume) | | | |
|-----------------|--|------------------------------------|---|--|
| Distance (M) | Field Studies (max values used) | ISCST3 (Stable to turbulent) | Whole Field PERFUM A MOE (%tile) | Max. Dist. PERFUM A MOE (%tile) |
| 0 | 7 (N=206) | 4 to 37 | 1 (up to and including 99.9 th %tile) | 1 (up to and including 99.9 th %tile) |
| 100 | 7 to 21 (N = 197) | 6 to 62 | 30 (~92 nd %tile) | 30 (~50 th %tile) |
| 500 | No data | 13 to 189 | 30 (99.9 th %tile), 150 (~90 th %tile), 300 (~75 th %tile) | 30 (99 th %tile), 150 (15 th %tile), 225 (5 th %tile) |
| 1000 | No data | 20 to 440 | 150 (~96 th %tile), 225 (~92 nd %tile), 300 (90 th %tile) | 150 (50 th %tile), 225 (30 th %tile), 300 (15 th %tile) |

^A The (%tile) is the percentile of exposure where the selected MOE is met at each distance. Total UF = 300

Human Health Assessment: Bystander Risk - Characterization

Relationship between different tiers:

- Models use flux from field studies
- ISCST3 validation studies
- PERFUM is based on ISCST3
- 3 exposure methods provide consistent results



Sensitivities That Were Evaluated Include:

Flux: Approximately 5x

Weather: Approximately 4 to 5x

 Application Rate & Field Size: Approximately 1:1 relationship between predicted distances and changes in either rate or field size

Human Health Assessment: Bystander Risk – Characterization

Overall Uncertainties Include:

- Estimation of flux rates
- Source for meteorology in growing regions
- Indoor versus outdoor exposure
- Time activity assumptions
- Potential for exposure from multiple fields
- Variation of exposure and application likelihood by season
- ISCST3 Calms Processing

Human Health Assessment: Bystander Risk – Characterization

Sources of Incident Data:

- Poison Control Center data (mainly non-occupational, lacks information on circumstances) 1993-2003
- California Poisoning Surveillance (mainly occupational, documented circumstances, 1982-2003)
- 6a2 reports, NIOSH Surveillance, National Pesticide Information Center, Scientific Literature

Human Health Assessment: Bystander Risk – Characterization

Summary of Incident Data:

- Bystander incident rates generally low from soil fumigation uses
- Incidents typically result in mild symptoms
- Reports are consistent with risk assessments based on the nature of effects



In Summary:

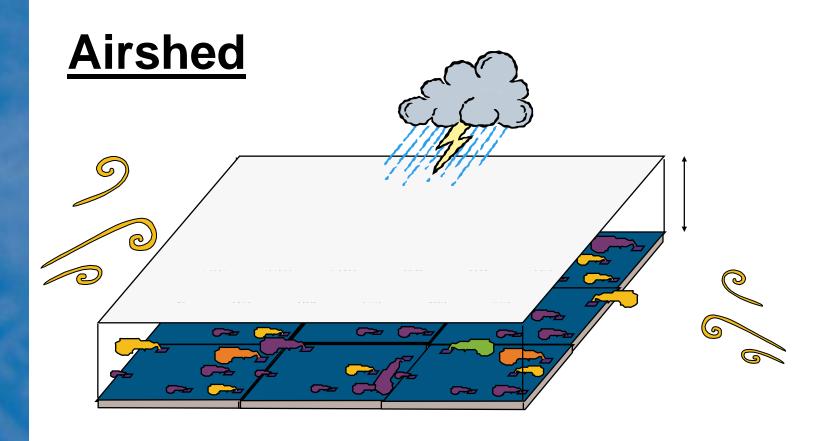
- Bystander risks are generally not of concern for 1,3-D
- Bystander risks of concern have been predicted for the other chemicals when HECs or HCs and total UFs are considered (MeBr, Metam & Dazomet) in proximity to treated fields for many situations
- Analysis based on NOAEL or LOAEL HECs indicate MOEs ≥1 at field edge

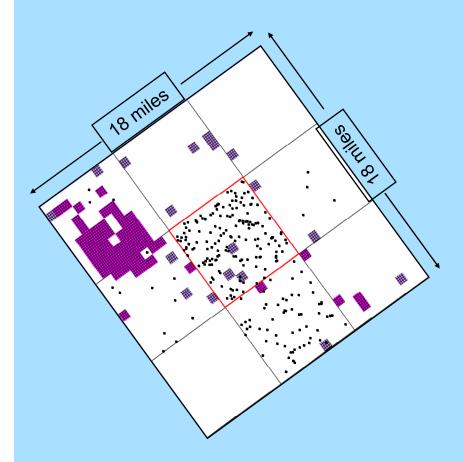




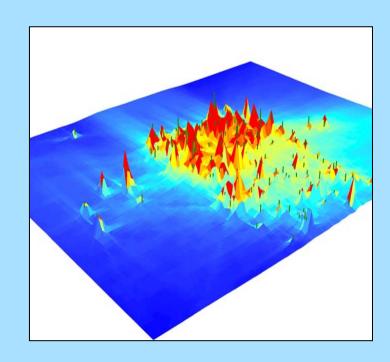
2 Types of Residential Exposure:

- 1) "Bystander" from a known source
- 2) "Ambient" from regional use





Population Density & Applications In A Region



Air Concentration Profile In A Region

All ambient monitoring data are from California

- Data are of 2 types:
 - 1. "CARB Data" Which provide air concentrations in high use areas during the season of use
 - 2. "TAC Data" Which provide air concentrations in urban settings to capture background levels
- Most data available at:
 - http://www.cdpr.ca.gov/docs/empm/pubs

| Summary of "CARB" Monitoring Data | | |
|--|---|--|
| Chemical Dates and Locations of Studies (all CA) | | |
| 1,3-D | Kern (2000, 2001); Monterey/Santa Cruz (2000 & 2001) | |
| MITC* | Bakersfield/Kern (1997 & 1998); Lompoc (1998 & 2000); Kern (2001); Monterey/Santa Cruz (2001) | |
| MeBr | Kern (2000 & 2001); Ventura (2001 & 2002); Santa Barbara (2001); Monterey (2000, 2001 & 2002); Santa Cruz (2000, 2001 & 2002) | |

^{*} Both metam and dazomet emit MITC.

Human Health Assessment: Residential Ambient Exposure

| Summary of "TAC" Monitoring Data | | | |
|----------------------------------|--|--|--|
| Chemicals | 1,3-D & MeBr | | |
| CA Locations | Statewide; Azusa; Burbank; Calexico; Chula Vista; El Cajon; Los Angeles; Long Beach; Riverside; Simi Valley; Bakersfield; Chico; Fremont; Fresno; Roseville; San Francisco; San Jose; Stockton | | |
| Mexico Locations | Mexicali; Rosarito | | |



Human Health Assessment: Residential Ambient Exposure

Summary:

 In general, risks from ambient exposures are not of concern

Soil Fumigants Human Health Risk Assessment Occupational Exposure

Bill Smith Health Effects Division Technical Briefing July 13, 2005



Human Health Assessment

- Introduction & overview
- Hazard Assessment
- Residential Exposure
- Occupational Exposure
- Potential Refinements

Overview:

- General fumigant worker exposure issues
- Worker exposure fumigant sampling methodologies
- Worker exposure fumigant studies
- Worker exposure fumigant tasks
- Results
- Risk Characterization



General Issues:

- Inhalation is the focus
 - Inhalation exposure to MeBr; 1,3-D; and MITC
- Two types of exposure data
 - Handler
 - Postapplication

Sampling Methodologies:

- Personal breathing zone monitors
 - Attached to participants collars
- In-cab monitors
 - Attached to interior of closed cab tractors near the operators breathing zone
- Cab exterior monitors
 - Attached to exterior of closed cab tractors at approximate height of the operators breathing zone





Personal Sampler



Sorbent Tubes

Summary of Worker Studies

| Chemical | No. of Studies | States Where Conducted |
|----------|-------------------|------------------------|
| MeBr | 16 | CA |
| 1,3-D | 4 | AZ, NC, WA |
| Metam | 4 | CA |
| Dazomet | 0 | None |



Worker Exposure Tasks-MeBr:

- Pre-plant Soil Fumigation Tasks
 - First tractor driver (shank injection)
 - Co-pilot
 - Tarp Applicator
 - Shovelman
 - Irrigation worker
 - Tarp cutter
 - Tarp remover

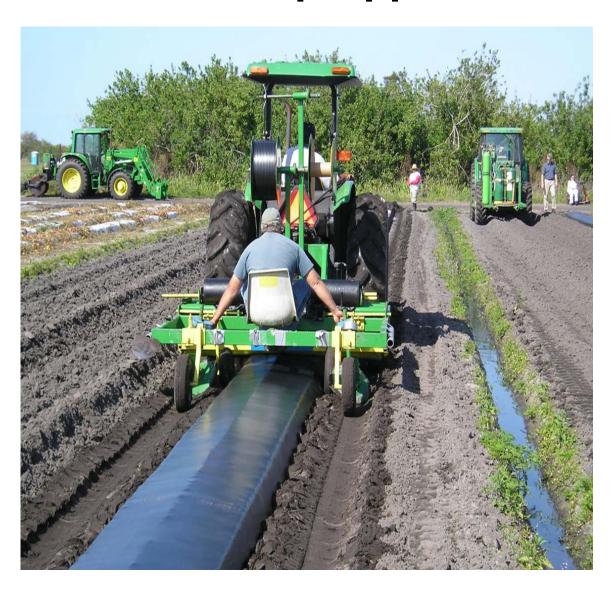


Shank Injection Rig





Raised Bed Tarp Application Rig





Flat Field Tarp Application Rig





Worker Exposure Tasks-1,3-D:

- Pre-plant Soil Fumigation Tasks
 - Bulk loading
 - Mini-bulk loading
 - Yetter rig operator/driver
 - Yetter rig shovelman
 - Irrigation worker
 - Bed shaper



Yetter Rig





Worker Exposure Tasks-Metam:

- Pre-plant Soil Fumigation Tasks
 - Loading for drip and sprinkler irrigation
 - Loading for shank injection
 - Tractor driver (shank injection)
 - Chemigation monitor
 - Water sealer

Worker Exposure Tasks-Dazomet:

- Pre-plant Soil Fumigation Tasks
 - EPA currently has no exposure data to assess worker MITC exposures during or following dazomet applications
 - Based on available worker MITC exposure data (from metam worker studies), EPA has concerns about occupational handlers and postapplication workers during and following dazomet applications.
 - Dazomet itself is not volatile so it is not an inhalation concern



Risk Durations Calculated:

- MeBr and metam
 - Acute and short/intermediate term risks
- 1,3-D
 - Acute, short term, intermediate term, and cancer risks

Noncancer Risks Calculated:

- Acute Risks (MOEs)
 - Calculated by comparing the maximum air concentration level at an individual sample point to the HEC or HC selected for acute exposures
- Short/Intermediate Risks (MOEs)
 - Calculated by comparing the mean air concentration level (for all sampling points for a particular task) to the HEC or HC selected for short and intermediate term exposures

Cancer Risks Calculated (only 1,3-D):

- Calculated by multiplying the Lifetime Average Daily Exposure by the median air concentration value by the Q1*
- Cancer risk assessment assumes 20 days of exposure per year for 20 years per lifetime (from BEAD)

Results for Occupational Assessment:

- Generally, noncancer risks exceed HED's level of concern if no respiratory protection is considered
- Noncancer risks are generally not of concern if an air purifying respirator (PF 10) is used with the exception of some application tasks for MeBr
- Cancer risks are generally not of concern if an air purifying respirator (PF 10) is used with 1,3-D



Risk Characterization:

- Use of engineering controls in the worker exposure studies
- PR 93-7 Requirements
- Incident Data
 - Low numbers of incidents (skin irritation)
 - Most worker incidents from accidents or misuse
 - Incident data generally consistent with assessments

Soil Fumigants Human Health Risk Assessment Potential Refinements

Jeff Dawson Health Effects Division Technical Briefing July 13, 2005



Human Health Assessment

- Introduction & overview
- Hazard Assessment
- Residential Exposure
- Occupational Exposure
- Potential Refinements



For the human health assessment, possibilities include:

- Data
- Modeling
- Statistical Methods

Field Monitoring Data:

- Use flux information for other regions, soil types, application methods, etc.
- Use meteorological data from other regions and locations within regions (e.g., CA & FL)
- More quantitatively evaluate the efficacy of state-of-the-art emission control technologies such as VIF and metalized films
- Better characterize use rates, seasons of use and use locations in order to have assessments more closely reflect actual use conditions

Worker Monitoring Data:

- Develop better understanding of current worker tasks and activities
- Better characterize use rates, seasons of use and use locations in order to have assessments more closely reflect actual use conditions
- Identify and evaluate current state-of-theart engineering control and personal protective equipment technologies intended to reduce worker exposure

Modeling:

- Evaluate uncertainties associated with model use such as "calms" processing and mixing height issues
- Consider multi-field and contiguous field scenarios
- Consider risk assessment submissions using models such as FEMS for metam
- Future consideration of other models such as AERMOD (which is the next generation ISCST3) and CALPUFF which tracks released plumes in a more refined manner



Statistical Methods:

- Better characterize issues related to the use of the origin in linear regressions used for flux determinations
- Comparatively consider the attributes of the various flux determination methods
- Better characterize the uncertainty and variability associated with flux data
 - e.g., such as used in PERFUM

Information Needs

Jonathan Becker Biological and Economic Analysis Division Office of Pesticide Programs July 13, 2005



Information Needs

- To refine risk assessments and to develop benefit assessments
 - Crop Production Practices
 - Fumigant Use
 - Economics



- Average acres of each crop grown per enterprise
- Typical crops following the fumigated crop
- Restrictions on this fumigant or an alternative fumigant
 - Regulatory, soil characteristics, etc
- Best available alternative
 - Another fumigant or strategy such as fallow, etc.
- Could the use of fumigants be alternated
 - e.g., metam sodium followed by 1,3-D
 - Specify how



- For each crop and fumigant:
 - Maximum acres fumigated per day
 - Percent of the acres grown that are fumigated
 - Typical application rate (lb Al/Acre)
 - Minimum effective application rate (lb Al/Acre)
 - Maximum application rate used (lb Al/Acre)
 - For high pest pressure situations
 - Time of year that soil is fumigated
 - Fumigation cycle
 - Every crop cycle, 1 time/year, 1 time/2 years
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- For each crop and fumigant:
 - Target pests
 - By category or specific pests
 - Method of application
 - e.g., chemigation, soil injection, etc.
 - Methods or actions taken to reduce emissions
 - Polyethylene tarps or soil cap
 - Could HDPE or high barrier tarps be used on this crop?
 - Time between treatment and next production activity
 - e.g., time until planting



EconomicsInformation Needs

- Yield or quality impacts that are likely to result from moving to next best available alternative
 - i.e., change in commodity price or grade
- How would moving to the next best alternative impact key market windows?
- Cost per acre of active ingredient
- Cost per acre of other fumigation inputs
 - e.g., tarps and equipment
- Is there a crop budget available for this area and crop?

Soil Fumigants Risk Management Framework

John Leahy Special Review & Reregistration Division Technical Briefing July 13, 2005



Risk Management Goals:

Address risks of concern while maintaining key use benefits

- Soil fumigants are very important to agriculture. . .
- And pose potentially safety concerns
- → Ensure safety and minimize impact on agriculture



Risk Management Framework

Approach:

- Consider risks and benefits at same time, using similar tools, and in light of each other
- Get stakeholder input
- Translate risks and benefits into practical, effective decisions



Risk Management Framework

Need to understand potential consequences of each risk management option:

- How would risks change?
- What would be the impact on benefits?
- How would States be affected?



Risk Characterization

- Hazard
- Exposure
 - Monitoring
 - Modeling



Populations to protect:

- Workers
 - Handlers, postapplication
- Residential bystanders
 - Homes, schools, offices, etc.



Type and severity of effects:

- Systemic
- Local
- Irritation
- Reversibility
- Dose response



Incident data:

- Circumstances
 - Site conditions (e.g., weather, terrain)
 - Proximity to treated area
 - Adherence to labeling and other restrictions
 - Application methods, area treated
 - Accidents



Existing Controls:

- Workers
 - PPE, engineering or administrative controls
 - Entry restrictions
- Bystanders
 - Limiting proximity to sensitive areas (buffers)
 - Techniques to control emissions (sealing)
 - Monitoring (weather, emissions)
 - Area treated limits



Benefits:

- Economic consequences of changes
 - Cost of production
 - Yield or quality
 - Revenue (e.g., market timing)
- Alternative pest control methods
- Specific cropping practices, by region



- Premature to consider specific measures at this point in process
- Focus on circumstances leading to exposure
- Look to State examples for approaches to reducing exposure



- Techniques or technologies to reduce emissions
- Rate, area treated limitations
- Monitoring
 - Conditions that could lead to off-site movement
 - Actual off-site movement
- Designate buffers to sensitive sites
- Restricting use
- Notification to residents/neighbors
- Stewardship programs



- Labeling
- Performance standards
 - Guidance on compliance
 - Monitoring
- Stewardship programs
 - Training
 - Technical assistance
 - → Resource issues



Keys to success:

- Coordination and communication
 - State partners
 - Stakeholders
 - Public interest, private citizens
 - Grower and commodity groups
 - Registrants
 - Regulators
 - → Good input and feedback = Good Decisions

Soil Fumigants State and Stakeholder Coordination

John Leahy Special Review & Reregistration Division Technical Briefing July 13, 2005



Purpose

- Keep States and their stakeholders informed
- Tap expertise of States' scientists and regulators
 - Build on risk assessments done outside EPA
 - Learn from experiences in developing and implementing State/local requirements
- Gain state-specific knowledge of use practices
- Ensure EPA's regulatory proposals build-on and do not undercut State programs
- Encourage participation in EPA's process



- Met w/California, Wisconsin, and Florida scientists/regulators
- AAPCO, March 2005
- SFIREG POM Committee, April 2005
- SFIREG WQ/PD Committee, May, 2005
- Full SFIREG, June 2005
- Input from several States so far on their local requirements and restrictions



- Permits for applications
- Special training and/or certification for applicators
- Guidance to users
- Restricting use
- Extending drift rules to off-site movement of fumigants
- Buffers to sensitive sites
- Notification to nearby residents, schools, etc.
- Application equipment requirements



- Fumigant-focused crop tours
 - California
 - Florida
 - Michigan
 - Northwest States
- Fumigant-focused meetings with various stakeholders
- Collaboration with USDA
- Technical Briefing
- Comment periods
- Stakeholder meetings
- Web page: www.epa.gov/pesticides

Soil Fumigants How to Get Involved

John Leahy Special Review & Reregistration Division Technical Briefing July 13, 2005



How to Get Involved

During Phase 3:

- Provide formal comments
 - E-docket: www.epa.gov/edocket
- Watch EPA's website for information and updates
 - http://www.epa.gov/pesticides/reregistration/
- Call with questions
 - Key contacts listed on last slide



How to Get Involved

During Phase 5:

- Attend stakeholder meetings
 - California
 - Florida
- Provide formal comments to E-docket
- Watch EPA's website for information and updates
 - http://www.epa.gov/pesticides/reregistration/
- Call with questions



How to Get Involved

Submit comments (E-Dockets) regarding . . .

- Risk assessments
- Use and usage information
- Information can be found at
 - http://docket.epa.gov/edkpub/index.jsp



Key Contacts

- General Information—
 - John Leahy, (703) 305-6703
- Methyl bromide
 - Susan Bartow, (703) 603-0065
- Metam sodium
 - Mark Seaton, (703) 306-0469
- Dazomet
 - Mark Seaton, (703) 308-0128
- 1,3-D
 - Diane Sherman, (703) 308-0128

E-mail: lastname.firstname@epa.gov