THE CHLOROPICRIN MANUFACTURERS' TASK FORCE
c/o Niklor Chemical Co., Inc., 1667 Purdy Avenue, Mojave, CA 93501
Telephone (661) 824-2494 Fax (661) 824-2904

November 5, 2007

Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: EPA-HQ-OPP-2007-0350

Dear Sirs:

The Chloropicrin Manufacturers' Task Force is pleased to submit the attached comments to EPA on its Phase 5 Revised Risk Assessment for Chloropicrin. The Task Force looks forward to working with EPA through the reregistration process.

Sincerely,

Stephen Wilhelm
Chairman

Enclosure

Comments on
USEPA's Chloropicrin Revised Risk Assessments Phase 5

FRL: 8125-9
EPA-HQ-OPP-2007-0350

Submitted By:

Chloropicrin Manufacturers' Task Force

November 5, 2007

EXECUTIVE SUMMARY

The Chloropicrin Manufacturers' Task Force (CMTF), which represents all U.S technical registrants and some end-use registrants of chloropicrin,[1] appreciates the opportunity to comment on USEPA's Revised Risk Assessment. Chloropicrin has been used for over sixty years for pesticidal purposes with a low number of reported incidents. Chloropicrin is a key component of the methyl bromide alternatives program and is a critical tool for growers for a wide variety of crops including fruits and vegetables, orchards, forest seedlings and tobacco.

CMTF agrees with EPA that transient human eye sensory irritation is the most sensitive endpoint and that protecting against transient eye irritation and would also protect against adverse irritation of the eyes, nose and respiratory tract. CMTF believes that human data can be used for the short and intermediate term exposures calculations as well as for the acute calculations. Moreover, even if animal data are used for these calculations, the current assessment overstates the risk. Appropriate use of the animal data supports uncertainty factors lower than those in the revised risk assessment.

CMTF commends EPA's interest in mitigation measures other than buffer zones to address fumigant emissions. Good Application Practices (GAPs) that reduce emissions are more effective tools than buffer zones in reducing exposures. CMTF encourages EPA to consider factors such as depth of injection, pre-application soil moistures and other GAPs in its analysis of exposure potential. CMTF has provided EPA with a list of specific GAPs for chloropicrin.

Current exposure modeling does not reflect the impact of soil moisture, injection depth, soil type, and other factors. EPA should incorporate these factors into its exposure analysis. CMTF has provided EPA with specific factors regarding pre-application soil moisture based on data from the fields used in the chloropicrin studies. CMTF also has provided information on tools such as CHAIN_2D that EPA could use to better assess the impacts of parameters such as soil type and injection depth. This information can be used in conjunction with the existing air dispersion models to provide more realistic assessments of exposure potentials.

EPA's ecological fate and effects analyses do not accurately reflect the real-world commercial use of chloropicrin, but contain artifacts of generic modeling approaches used to estimate the potential environmental effects of a pesticide. Given the physical chemistry and particular field application methods used for chloropicrin, the CMTF believes these fumigant-specific considerations must be incorporated into the ecological risk assessment to accurately evaluate the fate and behavior of chloropicrin in the environment.

[1] Member companies of the CMTF are Arysta Life Science North America, ASHTA Chemical Company Inc., Niklor Chemical Company, Trinity Manufacturing,, Dow AgroSciences, Chemtura Corporation, and TriCal, Inc.

Finally, in evaluating the risks of chloropicrin use, EPA must also consider the benefits of its use. Numerous growers, researchers, and commodity groups have provided EPA with information on the benefits of chloropicrin and the potential economic loss of severe restrictions on its continued use. CMTF encourages EPA to carefully consider this information.

TABLE OF CONTENTS

Page

TABLES

Page

GRAPHS

Page

APPENDICES

Page

I. INTRODUCTION

The Chloropicrin Manufacturers' Task Force (CMTF) appreciates the opportunity to comment on USEPA's Phase 5 Revised Risk Assessment for chloropicrin. The CMTF represents all U.S. technical registrants of chloropicrin as well as some end-use registrants. Member companies of the Task Force are Arysta Life Science North America, ASHTA Chemical Inc., Niklor Chemical Company, Trinity Manufacturing, Inc., Dow AgroSciences, Inc., Chemtura Corporation, and TriCal, Inc.

CMTF appreciates the complexities of working with soil fumigants and the refinements that EPA has made regarding the Human Risk Assessment to better quantify the potential risk associated with the use of this chemical. CMTF also commends EPA for seeking additional information on Good Application Practices (GAPs). GAPs focus on keeping the fumigant in the soil which provides greater benefits for growers and reduces the potential for exposure to humans and wildlife. CMTF believes that focusing on GAPs will facilitate risk management decisions that are protective of human health and the environment while providing U.S. growers with the necessary tools to remain competitive in the world market.

Chloropicrin is a pre-plant soil fumigant used alone or in combination with other fumigants. It also is used in the remediation of wood poles and railroad timbers. Chloropicrin has been used as a soil fumigant for over sixty years with significant benefits to American agriculture. Crops for which chloropicrin is a key pest management tool include strawberries, potatoes, forest nursery, vine and tree fruit, nuts, peppers, tomatoes and tobacco. Chloropicrin is the backbone of virtually all methyl bromide alternative fumigant programs and is used with other alternative fumigants including 1,3-dichloropropene, metam sodium, iodomethane, and dimethyl disulfide. Researchers throughout the US, as well as international programs, have recognized the importance of chloropicrin in the methyl bromide replacement program. Various factors affect the field volatility of chloropicrin from soils after application including application method, sealing techniques, soil moisture, injection depth and meteorological conditions. Chloropicrin has a long history of use with only a limited number of incidents, most of which can be traced to an accident or application technique that is not considered a good application practice.

CMTF believes EPA is moving in the right direction when it focuses on GAPs as a means of reducing emissions from field applications of chloropicrin. GAPs which focus on keeping the fumigant in the soil offer growers more flexibility and are a better approach than buffer zones for reducing potential exposures. The Agency can use tools such as CHAIN_2D to quantify the emission reductions from GAPs and the resulting exposures potential to both humans and wildlife. EPA should also further refine its Ecological Fate and Risk Assessment to more appropriately reflect the actual use of chloropicrin.

Comments on specific sections of the revised risk assessment are set forth in the following chapters. The CMTF remains committed to working with EPA to provide the information needed for the reregistration of chloropicrin consistent with the mandates of FIFRA.

II. BYSTANDER AND OCCUPATIONAL RISK ASSESSMENT

In assessing bystanders and occupational risks, EPA's risk managers must consider both the hazard of exposure and the likelihood of exposure. Chloropicrin is a sensory irritant and the use of a sensory response in the Agency's assessment of chloropicrin requires different risk management considerations than other toxicological endpoints regarding the severity of the effect and the percent of the population at risk. This section discusses both the hazard assessment and the likelihood of exposures.

A. Hazard Assessment

The Task Force agrees with several key points EPA has stated in its current risk assessment for chloropicrin including:

(1) "Transient human eye sensory irritation is the most sensitive endpoint determined for the sensitive subpopulation used in the human subject study, therefore, protecting against transient eye irritation would also protect against adverse irritation of the eyes, nose, and upper respiratory tract"[2]

(2) "The $BMCL_{10}$ of 73 ppb represents a level (of exposure) at which the most sensitive subpopulation failed to detect eye irritation."[3]

(3) "Acute inhalation exposures to bystanders and workers is the greatest risk concern and that Phase 3 of the human exposure study most closely resembles the acute bystander inhalation scenario (1-8 hours of exposure) for the human health risk assessment."[4]

By recognizing that ocular chemesthesis (sensation or irritation) is the most sensitive endpoint measured for exposure to airborne chloropicrin it follows that local effects (eye and portal-of-entry irritation effects) are a more sensitive response than systemic effects. It also follows that protection against sensory irritation effects of airborne chloropicrin will also protect against non-sensory, direct irritation-mediated respiratory effects of chloropicrin overexposure which could occur subsequent to, but not as a result of sensory irritation. This is true for short-term and intermediate-term exposures as well as acute exposure because the key event in the mode-of-action for chloropicrin inhalation effects is respiratory cell inflammation – an acute portal-of-entry effect.

1. Short-Term And Intermediate-Term Exposure Limits To Chloropicrin Should Be Based On Human Response Data And Not Animal Study Data

All mammalian toxicology studies conducted by the Task Force showed portal-of entry damage in tissue proximal to the administration route. Inhalation studies in rats and mice, acute

[2] Chloropicrin: Revised Human Health Risk Assessment for Phase 5, US EPA April 12, 2007, page 1.

[3] Id. at page 27.

[4] Id. at pp 8, 21.

through two-year dosing, have consistently established respiratory tissue as the target tissue for chloropicrin. Importantly, the rat and mouse inhalation studies have shown that respiratory tissue changes in rodents are seen only at chloropicrin levels that induce portal-of-entry inflammation. In the absence of respiratory tissue inflammation, nasal and lung cytotoxicty has not been reliably observed despite prolonged and high-concentration exposures in multiple studies. The Agency is familiar with the type and degree of chloropicrin respiratory effects demonstrated in mammalian inhalation studies. From these studies the mode-of-action for chloropicrin respiratory tissue damage can be seen as cytotoxicity at the portal-of-entry secondary to inflammation. The key event is cellular inflammation in respiratory cells. This is a measurable effect demonstrated in virtually every inhalation study on chloropicrin. The effect is reliably dose-related across both sex and species and temporal associations among markers for this effect:

Respiratory Cell Inflammation → Cytotoxicity → P-of-E Effect in Target Organ

Empirical support for the mode-of-action is compiled in Tables 1 through 6 below. The subchronic and chronic rodent inhalation NOAEL (100 ppb) suggest that protection against respiratory tissue inflammation protects against respiratory tract damage from chloropicrin, again independently of exposure duration.

Since the UCSD study[5] showed that pulmonary inflammation does not appear to occur in humans even in the presence of sensory irritation, protection against sensory irritation in humans should be protective of respiratory system effects. Accordingly, a reasonable standard for short-term and intermediate-term exposure can be based on prevention of sensory irritation, the most sensitive endpoint of chloropicrin exposure.

A weight-of-evidence approach supports short term and intermediate-term exposure based on sensory irritation.

Tables 1 through 6 present a weight-of-evidence argument for chloropicrin which can be used to establish a reasonable standard for short-term and intermediate-term exposure based on prevention of sensory irritation. A model for this analysis is the World Health Organization International Programme on Chemical Safety (IPCS) Framework for Cancer Risk Assessment. The IPCS Framework has gained acceptance within EPA for cancer risk assessment, especially for establishing the lack of relevance of certain specific animal cancers to human health. That model has been proposed for noncancer endpoints. In March, 2006 an IPCS Meeting convened to consider whether the Framework for Cancer Risk could be applied to other endpoints/modes-of-action (noncancer). A decision on the utilization of the IPCS Framework model for noncancer endpoints is pending.

Tables 1 through 6 list respiratory system effects in animal studies following inhalation exposure to chloropicrin vapor. The effects are presented by anatomical region beginning with the nose and extending to lung alveoli. Pathology data from seven studies are presented for males and females of two species. The studies range from 4-hour acute exposure to lifetime

[5] MRID # 46443801.

inhalation exposures. With the exceptions listed below, the tables show that inhalation of chloropicrin vapor, regardless of the length of time, does not produce target tissue cytotoxicity without inflammation at the same or lower exposure level:

1 90-day study, male rats: the low incidence of pulmonary hemorrhage (control 1/10 vs 2/10 low dose) which may be the direct result of inflammatory vascular changes is seen to be increased at 0.3 ppm (high dose) not statistically significantly increased;

2 90-day study female rats: a statistically-significant incidence of nasal cavity goblet cell hyperplasia in the respiratory epithelium was reported at the low exposure dose (0.3 ppm). Clear inflammatory changes were not reported at this exposure level, but were reported at the next higher exposure level. The study pathologist described the hyperplasia as "a nonspecific sign of irritation" and stated that it "is not considered to be a biologically significant lesion."

It is very likely that the goblet cell hyperplasia seen in these low-dose females resulted from resolution of inflammation of the nasal respiratory epithelium;

3 Nasal cavity hemorrhage was seen across all groups in the 90-day and chronic studies. According to the study pathologist, nasal cavity hemorrhage was "known to be the result of periorbital blood collection technique" performed prior to sacrifice and was not considered treatment related;

4 90-day study female mice. Nasal epithelial hyaline inclusion, a sign of non-specific irritation, was reported for the mid-exposure group. Rhinitis was elevated in this group, also.

5 Yoshida, et al, (1987), who reported finding inflammation only in the nasal mucosa despite using relatively high exposures, found pulmonary bronchial epithelial hypertrophy in male rats exposed to 1.58 ppm in a 90-day study. This finding could be a result of inflammation and is somewhat in contrast to Chun and Kintigh who described rhinitis in male rats exposed to 1.0 ppm for 90 days;

6 In the chronic inhalation study with rats, nasal respiratory hyaline membrane inclusions were reported in the low dose group. The incidence of this finding was elevated in test and the control groups but was not dose-related and considered an incidental finding by the study pathologist. The study pathologist concluded that the only treatment-related effect in male rats was rhinitis (there were no treatment-related respiratory lesions in female rats). According to the study pathology report, "the rhinitis which appeared to be exposure-related, and was present in rats without other contributory lesions, affected only the anterior nasal cavities and was generally minimal or mild. There were no corresponding lesions in the lower respiratory tract or in non-respiratory tract tissue which were attributed to chloropicrin exposure."

These data establish that regardless of the exposure timeframe, acute through chronic, exposures to chloropicrin below the level that causes target organ damage, i.e., respiratory cell inflammation do not lead to respiratory or other portal-of-entry effects and should be considered below the threshold for human effects. The risk of adverse effects as a result of repeated or long-term exposure to chloropicrin exists only at exposure levels that first cause inflammation to respiratory tissue. The USCD study assessed both sensory irritation and respiratory tissue (upper and lower) inflammation. That study showed sensory irritation to be more sensitive than any other as an indicator of chloropicrin effects and defined the exposure level at which both sensory irritation and respiratory inflammation do not occur.

(a) HSRB Did Not Preclude Use of the UCSD for Short Term and Intermediate Exposures

In its consideration of the chloropicrin human subject study, EPA's Human Studies Review Board (HSRB) meeting minutes stated that "the study was well-designed and provided information on acute exposure and interspecies variability."[6] The Final Report for the June 27-30, 2006 meeting concluded that "[t]he chloropicrin acute inhalation, human toxicity study, was scientifically sound for the purpose of estimating a safe level of inhalation exposure to chloropicrin."[7] No stipulation was included for duration of exposure.

There was a comment made during the HSRB meeting regarding the lack of chronic data and EPA noted that no chronic exposures were anticipated even for workers.[8] EPA noted during the meeting that the study was only being used to inform acute threshold limit setting.[9] The final report does not address this issue. The HSRB neither specifically prohibited nor endorsed the UCSD study for short-term and intermediate exposures. However, HSRB's decision and its final report, would not prohibit the use of the human data for short-term and intermediate exposures.

(b) Additional Factors to Consider

Additional factors that should be considered in establishing human sensory irritation as the basis for chloropicrin exposure are:

Lack of Severity of the Endpoint[10]: Sensory irritation of the eye or nose is reversible, transient, and without adverse sequella. It is not progressive or persistent, recovery time is

[6] Minutes of the EPA's Human Studies Review Board Meeting, June 27-30, 2006, p 8.

[7] EPA's Human Studies Review Board Final Report for the June 27-30, 2006, pp. 1, 68.

[8] "Board discussion noted that the lack of chronic data was considered less important because chronic exposure to chloropicrin was not expected. There are custom applicators who start in Florida and move north with the seasons but even they were not expected to be exposed for 180 days per year. Soil fumigants are typically used once a year. The human study is only being used to inform the acute threshold limit setting." Minutes of the EPA's Human Studies Review Board Meeting, June 27-30, 2006, p. 8.

[9] Id. at 6 and 8.

[10] As pointed out on page 27 of the draft Risk Assessment, the severity of symptoms reported by all individuals impacted by the Kern County drift incident (2003) was low.

relatively quick and termination of exposure is usually the only intervention necessary for affected individuals.

Sensitivity of the Endpoint: Chloropicrin-induced human sensory irritation produces symptoms within moments that humans can be aware of and feel ocular symptoms of at concentrations that produced no effects at all in animals following a lifetime of exposure for 6 hours per day.

Immediate Onset of Endpoint Symptom: Sensory irritation is not a subtle, adaptive or imperceptible effect, as are those usually derived from animal studies. The time lag between overexposure and response is measured in minutes.

No Evidence of Fatigue or Potentiation: Repeated exposures (four consecutive days) to concentrations that produced sensory irritation did not show evidence of loss of sensitivity or carryover of symptoms.

Clarity or Lack of Ambiguity in Sensory Irritation Endpoint: Sensory irritation is recognizable even in the extremes of age groups, can be readily identified and is not easily mistaken for general malaise.

Basing short-term and intermediate-term chloropicrin exposure on human response offers the advantage of unmistakably signaling the potential for an overexposure, albeit via transient effect, versus accepting uncertainty in estimating an appropriate margin between animal NOAELs and a human equivalent exposure. This approach eliminates the need for extra but imprecise assurance in estimating effects in respiratory systems known to differ between species. Since HED has stated that its focus "in assessing exposures resulting from chloropicrin applications is acute exposures to bystanders because chloropicrin produces peak off-gassing concentrations in the first 24 or 48 hours after application"[11] and that "acute risks from potential multiple ambient air sources of exposures do not exceed HED's level of concern,"[12] protection against acute respiratory inflammation will protect against respiratory system effects. The weight-of-evidence and proposed mode-of-action for chloropicrin respiratory system effects provide a rationale for this protection. In humans, the protection is afforded by preventing sensory irritation because field experience and clinical testing have established that people are a reliable indicator of their own exposure.

[11] Chloropicrin: Revised Human Health Risk Assessment for Phase 5, US EPA April 12, 2007, page 30.

[12] Chloropicrin: Revised Human Health Risk Assessment for Phase 5, US EPA April 12, 2007, page 10.

Table 1 Chloropicrin Inhalation Studies: Rat And Mouse Respiratory Effects

Acute (4-Hour) Rat Inhalation Study LOAEL = 10.5ppm REFERENCE: Hoffman, 1999					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Male rats: **Nasoturbinate**		Control	10.5 ppm	18.0 ppm	23.5 ppm
Inflammation marker	Nasal lumen inflammatory cells	0/5	5/5	5/5	5/5
Cytotoxicity marker	Nasal mucosa respiratory epithelial erosion/necrosis	0/5	5/5	5/5	3/5
	Nasal mucosa olfactory epithelial degeneration/atrophy	0/5	5/5	4/5	2/5
Male rats: **Larynx**					
Inflammation marker	Larynx lumen inflammatory cells	0/5	0/5	4/5	5/5
Cytotoxicity marker	Mucosa epithelial erosion/necrosis	0/5	0/5	4/5	5/5
Male rats: **Trachea**					
Inflammation marker	Mixed inflammatory cells	1/5	5/5	5/5	3/5
Cytotoxicity marker	Mucosa epithelial erosion/necrosis	0/5	0/5	3/5	2/5
Male rats: **Pulmonary Effects**					
Inflammation marker	Bronchiolar lumen inflammatory cells	0/5	5/5	5/5	5/5
Cytotoxicity marker	Bronchiolar mucosa edema	0/5	5/5	5/5	5/5
	Bronchiolar mucosa necrosis	0/5	5/5	5/5	0/5
	Bronchiolar epithelial erosion	0/5	5/5	5/5	5/5
Female rats: **Nasoturbinate**					
Inflammation marker	Nasal lumen inflammatory cells	0/5	5/5	5/5	5/5
Cytotoxicity marker	Nasal mucosa respiratory epithelial erosion/necrosis	0/5	5/5	5/5	5/5
	Nasal mucosa olfactory epithelial degeneration/atrophy	0/5	5/5	5/5	4/5

Table 1 Continued

Acute (4-Hour) Rat Inhalation Study LOAEL = 10.5ppm REFERENCE: Hoffman, 1999					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Female rats: **Larynx**		Control	10.5 ppm	18.0 ppm	23.5 ppm
Inflammation marker	Larynx lumen inflammatory cells	0/5	0/5	1/5	4/5
Cytotoxicity marker	Mucosa epithelial erosion/necrosis	0/5	0/5	0/5	5/5
Female rats: **Trachea**					
Inflammation marker	Mixed inflammatory cells	3/5	5/5	5/5	5/5
Cytotoxicity marker	Mucosa epithelial erosion/necrosis	0/5	0/5	2/5	2/5
Female rats: **Pulmonary Effects**					
Inflammation marker	Bronchiolar lumen inflammatory cells	0/5	5/5	5/5	5/5
Cytotoxicity marker	Bronchiolar mucosa edema	0/5	5/5	5/5	5/5
	Bronchiolar mucosa necrosis	0/5	5/5	5/5	4/5
	Bronchiolar epithelial erosion	0/5	5/5	5/5	5/5

Hoffman. G.A. (1999). Chloropicrin: An Acute (4-Hour) Inhalation Toxicity Study in the Rat via Whole-Body Exposure, Huntingdon Life Sciences, report 99-5387

Table 2 Chloropicrin Inhalation Studies: Rat And Mouse Respiratory Effects

Subchronic (90-day) Rat Inhalation Study LOAEL = 0.3ppm REFERENCE: Chun and Kintigh, 1993					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Male rats: **Nasal cavity**		Control	0.3 ppm	1.0 ppm	3.0 ppm
Inflammation marker	Rhinitis	2/10	2/10	4/10	10/10**
Cytotoxicity marker	Respiratory epithelial hyperplasia/dysplasia	1/10	0/10	2/10	10/10**
	Goblet cell hyperplasia	7/10	7/10	8/10	9/10
Male rats: **Pulmonary effects**					
Inflammation marker	Bronchitis/ Bronchiolitis	0/10	0/10	0/10	7/10**
	Pneumonitis	2/10	0/10	0/10	5/10
Cytotoxicity marker	Hemorrhage	1/10	2/10	2/10	4/10
	Emphysema	0/10	0/10	0/10	1/10
	Bronchial/Bronchiolar epithelial hyperplasia	0/10	0/10	4/10	9/10**
	Peribronchial/ peribronchiolar muscle hyperplasia	0/10	0/10	3/10	8/10**
	Peribronchial/ peribronchiolar fibrosis	0/10	0/10	2/10	9/10**
Female rats: **Nasal Cavity**					
Inflammation marker	Rhinitis	1/10	1/10	7/10*	8/10**
Cytotoxicity marker	Respiratory epithelial hyperplasia/dysplasia	0/10	0/10	0/10	9/10**
	Goblet cell hyperplasia	0/10	6/10*	7/10**	5/10*
	Squamous metaplasia	0/10	0/10	0/10	1/10
Female rats: **Pulmonary effects**					
Inflammation marker	Bronchitis/ Bronchiolitis	0/10	0/10	0/10	7/10
	Pneumonitis	0/10	0/10	0/10	1/10
Cytotoxicity marker	Hemorrhage	0/10	1/10	0/10	0/10
	Bronchial/Bronchiolar epithelial hyperplasia	0/10	0/10	5/10*	7/10**
	Peribronchial/peribronchiolar muscle hyperplasia	0/10	0/10	6/10*	7/10**
	Peribronchial/peribronchiolar fibrosis	0/10	0/10	0/10	8/10**

Table 2 Continued

Subchronic (90-day) Rat Inhalation Study LOAEL = 0.3ppm REFERENCE: Chun and Kintigh, 1993					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Male mice: **Nasal Cavity**		Control	0.3 ppm	1.0 ppm	3.0 ppm
Inflammation marker	Rhinitis	0/10	1/10	1/10	10/10**
Cytotoxicity marker	Epithelial hyaline inclusions	0/10	0/10	3/10	10/10**
	Hemorrhage	5/10	5/10	10/10*	8/10
	Respiratory epithelial hyperplasia/dysplasia	0/10	0/10	1/10	7/10**
	Mucosal ulceration	0/10	0/10	1/10	7/10**
Male mice; **Pulmonary Effects**		Control	0.3 ppm	1.0 ppm	3.0 ppm
Inflammation marker	Alveolar histiocytosis	2/10	1/10	5/10	9/10**
	Bronchitis/ Bronchiolitis	0/10	0/10	1/10	5/10*
	Pneumonitis	1/10	0/10	0/10	4/10
Cytotoxicity marker	Hemorrhage	0/10	0/10	0/10	1/10
	Bronchial/Bronchiolar epithelial hyperplasia	0/10	0/10	1/10	8/10**
	Peribronchial/peribronchiolar muscle hyperplasia	0/10	0/10	3/10	6/10*
	Peribronchial/peribronchiolar fibrosis	0/10	0/10	1/10	6/10*
Female mice: **Nasal Cavity**					
Inflammation marker	Rhinitis	1/10	0/10	4/10	9/10**
Cytotoxicity marker	Epithelial hyaline inclusions	0/10	2/10	6/10*	10/10**
	Hemorrhage	9/10	10/10	9/10	8/10
	Respiratory epithelial hyperplasia/dysplasia	0/10	0/10	0/10	8/10**
	Mucosal ulceration	0/10	0/10	0/10	2/10

Table 2 Continued

Subchronic (90-day) Rat Inhalation Study LOAEL = 0.3ppm REFERENCE: Chun and Kintigh, 1993					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Female mice; **pulmonary effects**		Control	0.3 ppm	1.0 ppm	3.0 ppm
Inflammation marker	Alveolar histiocytosis	1/10	2/10	8/10**	10/10**
	Bronchitis/ Bronchiolitis	1/10	0/10	2/10	4/10
	Pneumonitis	0/10	0/10	0/10	4/10
Cytotoxicity marker	Hemorrhage	1/10	0/10	1/10	0/10
	Bronchial/Bronchiolar epithelial hyperplasia	0/10	0/10	1/10	8/10**
	Peribronchial/peribronchiolar muscle hyperplasia	0/10	0/10	0/10	9/10**
	Peribronchial/peribronchiolar fibrosis	0/10	0/10	1/10	8/10**

* = $p<0.5$ ** = $p<0.01$

Chun, J. S. and K. Kintigh. (1993) Chloropicrin; Ninety-Day Inhalation Toxicology Study in Rats and Mice. Bushy Run Research Center Laboratory Project 91N0098.

Table 3 Chloropicrin Inhalation Studies: Rat And Mouse Respiratory Effects

Subchronic (90-day) Rat Inhalation Study NOAEL = 0.67ppm REFERENCE: Yoshida, et al. (1987)						
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**				
Male rats: Nasal cavity		Control	0.37 ppm	0.67 ppm	1.58 ppm	2.93 ppm
Inflammation marker	Respiratory mucosal inflammation	0/12	0/12	0/12	2/12	9/12***
Male rats: Larynx						
Cytotoxicity marker	Epithelial thickening	0/12	0/12	0/12	0/12	5/12**
Male rats: Trachea						
Cytotoxicity marker	Epithelial hypertrophy	0/12	0/12	0/12	0/12	10/12***
Male rats: **Pulmonary effects**						
Cytotoxicity marker	Bronchial epithelial hypertrophy	0/12	0/12	0/12	9/12***	12/12***
	Bronchial epithelial degeneration/necrosis	0/12	0/12	0/12	0/12	4/12*
	Bronchial gland epithelial Hypertrophy	0/12	0/12	0/12	0/12	4/12*
	Thickening of bronchial wall	0/12	0/12	0/12	0/12	7/12**
	Bronchiolar hypertrophy	0/12	0/12	0/12	9/12***	9/12***
	Bronchiolar epithelial degeneration/necrosis	0/12	0/12	0/12	0/12	12/12***
	Thickening of bronchiolar wall	0/12	0/12	0/12	0/12	12/12***

*= $p<0.05$ **=$p<0.01$ ***=$p<0.001$

Yoshida, M., et al, (1987). Subchronic Inhalation Toxicity of Chloropicrin Vapor in Rats, J. Pesticide Sci. 12,673-681.

Table 4 Chloropicrin Inhalation Studies: Rat And Mouse Respiratory Effects

Chronic Rat Inhalation Study NOAEL = 0.1ppm REFERENCE: Burleigh-Flayer and Benson, 1995					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Male rats: Nasal cavity		Control	0.1 ppm	0.5 ppm	1.0 ppm
Inflammation marker	Rhinitis	20/50	24/50	21/50	35/50**
Cytotoxicity marker	Epithelial hyaline inclusion	20/50	33/50*	22/50	22/50
	Mucosal hyperplasia/ squamous metaplasia	0/50	0/50	1/50	2/50
	Necrosis/ulceration	0/50	0/50	0/50	2/50
Male rats: **Pulmonary effects**					
Inflammation marker	Bronchitis/ Bronchiolitis	0/50	1/50	2/50	3/50
	Pneumonitis	6/50	2/50	1/50	3/50
Cytotoxicity marker	Bronchial epithelial hyperplasia	0/50	0/50	0/50	1/50
	Bronchioalveolar hyperplasia	2/50	1/50	0/50	2/50
Female rats: **Nasal Cavity**					
Inflammation marker	Rhinitis	18/50	17/50	26/50	23/50
Cytotoxicity marker	Necrosis/ulceration	0/50	0/50	0/50	1/50
Female rats: **Pulmonary effects**					
Inflammation marker	Bronchitis/ Bronchiolitis	2/5	3/50	2/50	0/50
	Pneumonitis	4/50	9/50	5/50	7/50
Cytotoxicity marker	Bronchial epithelial hyperplasia	0/50	1/50	0/50	0/50

*=p,0.05 **=p<0.01

Burleigh-Flayer, H. D. and C. L. Benson, (1995). Chloropicrin: Vapor Inhalation Oncogenicity Study in CD Rats, Bushy Run Research Center Project Number 92N1106.

Table 5 Chloropicrin Inhalation Studies: Rat And Mouse Respiratory Effects

Chronic Mouse Inhalation Study NOAEL = 0.1ppm REFERENCE: Burleigh-Flayer, Kintigh and Benson, 1995					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Male mice: Nasal cavity		Control	0.1 ppm	0.5 ppm	1.0 ppm
Inflammation marker	Rhinitis	6/50	7/50	17/50**	35/50**
	Olfactory epithelial atrophy	5/50	6/50	8/50	40/50**
Cytotoxicity marker	Necrosis/ulceration	0/50	1/50	1/50	0/50
Male mice: Pulmonary effects					
Inflammation marker	Alveolar histocytosis	18/50	17/50	22/50	29/50
	Peribronchial lymphocytic infiltrates	1/50	6/50	10/50	12/50
Cytotoxicity marker	Epithelial hyaline inclusion	3/50	6/50	7/50	16/50**
	Hemorrhage	4/50	4/50	10/50	12/50
	Bronchiectasis	0/50	3/50	28/50	41/50
	Bronchial submucosal fibrosis	0/50	0/50	16/50	19/50
	Bronchioalveolar hyperplasia	2/50	0/50	5/50	2/50
Female mice: Nasal Cavity					
Inflammation marker	Rhinitis	3/50	6/50	18/50**	32/50**
Cytotoxicity marker	hyaline epithelial inclusions	10/50	11/50	24/50**	37/50**
	Olfactory epithelial atrophy	13/50	14/50	39/50**	36/50**
	Necrosis/ulceration	0/50	0/50	1/50	2/50
Female mice: Pulmonary effects					
Inflammation marker	Alveolar histocytosis	14/50	14/50	19/50	35/50**
	Peribronchial lymphocytic infiltrates	5/50	10/50	17/50**	28/50**
Cytotoxicity marker	Hemorrhage	8/50	10/50	8/50	13/50
	Bronchiectasis	0/50	5/50	28/50**	44/50**
	Bronchial submucosal fibrosis	0/50	0/50	13/50**	22/50**
	Bronchioalveolar hyperplasia	0/50	1/50	2/50	6/50*

*=p,0.05 **=p<0.01

Burleigh-Flayer, H. D. Kintigh, W. J. and C. L. Benson, (1995). Chloropicrin: Vapor Inhalation Oncogenicity Study in CD-1 Mice, Bushy Run Research Center Project Number 92N1105.

Table 6 Chloropicrin Inhalation Studies: Rat And Mouse Respiratory Effects

2-Generation Inhalation Reproduction/Fertility Study in Rats SYSTEMIC NOAEL = 1.0 ppm REFERENCE: Schardein, J. L., 1994					
RESPIRATORY SYSTEM EFFECTS		**RESPIRATIORY EFFECT EXPOSURE LEVEL & INCIDENCE**			
Female rats: Pulmonary effects		Control	0.5 ppm	1.0 ppm	1.5 ppm
Inflammation marker	Peribronchiolar eosinophil Infiltration	8/16 50%	10/21 48%	8/24 33%	5/18 28%
	Inflammation	7/16 44%	10/21 48%	12/24 50%	10/18 56%
Cytotoxicity marker	Hemorrhage	5/16 31%	5/21 24%	6/24 25%	6/18 50%
	Necrosis	0/16 0%	0/21 0%	0/24 0%	1/18 5%
	Edema	1/16 6%	1/21 5%	2/24 8%	1/18 5%

Schardein, J. L. (1994). Two-Generation Inhalation Reproduction/Fertility Study in Rats

2. Appropriate Use Of Animal Toxicology Data To Establish Short-Term And Intermediate-Term Levels Of Concern For Inhalation Exposure To Chloropicrin

Alternatively, if EPA were to use animal data for the intermediate and short-term exposures, the uncertainty factors should still be lower than in the revised risk assessment. The Task Force asked Dr. John Ross of Risksiences.net LLC, and formerly of the California Department of Pesticide Regulation, to discuss the use of animal data to establish a short-term and intermediate-term level of concern for chloropicrin. Dr. Ross's analysis begins with a discussion of interspecies uncertainty and how that can be addressed for chloropicrin by pharmacokinetic interspecies uncertainty factors. Dr. Ross also discusses the regulatory precedent for using uncertainty factors less than default factors and uncertainty in permissible exposure levels for working populations. His discussion is provided in the following paragraphs.

(a) Interspecies Uncertainty

Pharmacokinetic interspecies UF has been assigned a value of one by EPA, meaning that there is no difference between species' pharmacokinetics for chloropicrin (EPA, 2006). Given that the effect of concern (irritation or sensation) occurs on the surface of mucous membranes, the use of an UF of one for interspecies uncertainty with regard to pharmacokinetics is reasonable. However, EPA has assigned by default a value of 3 for interspecies uncertainty for pharmacodynamics of chloropicrin. Again, given that the effects in laboratory animals and humans are the same (irritation, histopathology of the lungs and death at high concentration), any uncertainty is not with regard to effect, but rather the dose at which the effect occurs. For example, the effect with the lowest LOEL is sensation subsequently leading to measurable physiologic effects e.g., eyeblink, respiratory rate, lachrimation, etc. at higher concentration. From the standpoint of intoxication, there appears to be no qualitative difference between rodents and humans

based on the lack of histopathology in human eye or nasal cells at 150 ppb, and a rat and mouse NOAEL of 100 ppb for histopathology for 90+ days of exposure.

Because of the highly developed sense of smell and vision in animals compared to man, animals should be more sensitive (have a lower NOEL) to chloropicrin as a sensory irritant. The RD50 method was developed as a very quantitative, reproducible measure of respiratory tract irritation for rodents using head-only exposure and plethysmographic measurements of respiration rate (Kane et al., 1979). However, it does not measure the more sensitive endpoints utilized by Cain (2004). The RD_{50} study in mice with chloropicrin was conducted under GLP (Hoffman, 1999), and is probably the closest quantitative experimental study to the sensory irritation study in humans conducted by Cain (2004). The RD_{50} in mice was 2.3 ppm for the standard duration of the study (30 minutes), and the mice exhibited no evidence of histopathology. This value compares very favorably with the mouse subchronic LOAEL of 1.0 ppm, and indicates that histopathology is seen only at irritating doses and following prolonged exposure. Since all of the mice responded in the RD_{50} study, a better comparison with the human endpoint would be the RD_{10}. This value was estimated using EPA's Benchmark Dose Software (EPA, 2001) assuming a continuous response and using the polynomial model. The RD_{10} value (BMC = 260 ppb; BMCL = 130 ppb) compares favorably with the maximum dose tested in the Cain study (150 ppb) for exposure up to one hour, and indicates that humans are less than 2-fold more sensitive than rodents as EPA assumed with an interspecies pharmacodynamic uncertainty factor of 3. In those situations where there are adequate human data, there is no need to use an interspecies factor, because there is no uncertainty associated with an extrapolation between species, i.e., from laboratory animal to man. Similarly in those situations where the sensitivity of the test species to the agent is the same as that of humans, the interspecies factor is one.

Concordance in the toxicokinetics of the test agent in animals and man argues strongly for an uncertainty factor of less than ten (10). There are several examples of U.S. EPA reducing the toxicokinetics portion of the interspecies uncertainty factor to one. For these chemicals, US EPA concluded that the interspecies uncertainty factor could be reduced from the default value, based upon dosimetric considerations in the extrapolation of animal data to humans.[13] EPA (2006) made this same determination with chloropicrin, i.e., that the interspecies uncertainty factor for toxicokinetics was one (1). With respect to toxicodynamics, following the method of WHO, the interspecies uncertainty for chloropicrin can be assigned a value of 2.5, very similar to the value of 3 assumed by EPA (2006).

[13] *See* US EPA IRIS summaries for the establishment of RfCs for ethyl benzene (www.epa.gov/iris/subst/0051.htm), ethyl chloride (www.epa.gov/iris/subst/0523.htm), 2-ethoxyethanol (www.epa.gov/iris/subst/0513), and acetylnitrile (www.epa.gov/iris/subst/0205.htm). The basis for the reduction by the US EPA of the interspecies uncertainty factors for these chemicals can be found in the document entitled "Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry" (EPA/600/8-90/066F, October 1994).

(b) Regulatory Precedent for Using Overall UFs Less than Default Values

There are precedents for using a regulatory uncertainty factor less than the default. In the case of the irritant soil fumigant MITC, California Environmental Protection Agency's Department of Pesticide Regulation risk management decision was to allow an uncertainty factor of 1 for intraspecies uncertainty based on a NOEL of 220 ppb for increased rate of eye blink in human volunteers (Gosselin, 2002). Factors cited in the decision to regulate on the basis of a unit uncertainty factor included:

1. The endpoint measured (eye irritation) was an effect that was noticeable to the majority of individuals exposed at the LOEL of 800 ppb;

2. The endpoint was a common, reversible effect; and

3. Prevention of irritation precludes development of adverse lung effects.

(c) Uncertainty in the PEL for Working Populations

Chloropicrin produces physiologic responses such as tearing, and stinging or burning of the eyes, nose and throat following short term exposures at sub ppm levels (300 to 370 ppb; ACGIH, 1991). It is these "warning properties" that make chloropicrin a desirable additive to sulfuryl flouride and other fumigant gases that are tasteless, odorless and colorless. Australian, German and United Kingdom regulatory bodies have recognized the critical impact of the duration of chloropicrin exposure and have allowed excursions of 200 to 300 ppb for short (minutes) time periods (ACGIH, 1991). The Permissible Exposure Level (PEL) established by the Occupational Safety and Health Administration (OSHA) is 100 ppb as an eight hour time-weighted-average (TWA) value. The PEL reflects several factors. First, the PEL was based upon human data. There is a long history of human experience with chloropicrin in conjunction with its uses as a manufacturing intermediate worldwide and as a warning agent for fumigations in the U.S. Secondly, the effects observed at the lowest level (tearing, coughing and nasal irritation) are rapidly and completely reversible and these effects are not cumulative. Finally, while the Short Term Exposure Limit (STEL) for chloropicrin was delisted in 1990 (ACGIH, 1991), the standard recommendation for excursion above the TLV is that it should not exceed three times the value for 30 minutes (ACGIH, 1996).

The current NIOSH and OSHA recommendations for occupational exposure to chloropicrin is 0.1 ppm (0.7 mg/m^3) as an 8 hour time-weighted-average (reference NIOSH Pocket Guide to Chemical hazards, Publication 2005-151). The same exposure value is recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) and is derived from human eye irritation observations (0.3-0.37 ppm). According to the ACGIH (1991), a "TLV-TWA of 0.1 ppm is recommended for repeated exposure to chloropicrin to prevent eye irritation and the potential for pulmonary changes." A suggested occupational exposure limit (OEL) for chloropicrin is presented below. This OEL is based on the most relevant and sensitive endpoint to human chloropicrin exposure and, therefore, is the most protective for human health.

To summarize the results of Cain (2004) chloropicrin behaved as a mild sensory irritant and at concentrations up to 150 ppb chloropicrin did not cause lower respiratory inflammation or irritation or changes in pulmonary function. 150 ppb was the highest concentration evaluated for lower respiratory effects and none were found. Animal studies have shown that subchronic and lifetime inhalation exposure to chloropicrin vapor produces respiratory tissue inflammation at 300 ppb but no effects at 100 ppb (Chun and Kintigh, 1993; Burleigh-Flayer, et al., 1995; Burleigh-Flayer and Benson, 1995).

To put this into perspective, humans can be aware of the presence and feel ocular symptoms of chloropicrin vapor within moments at concentrations that produced no observable effects of any kind in animals following 90+ days of exposure for 6 hours per day. The effects in humans, however obvious to the individual experiencing them, are temporary and not serious but will trigger an avoidance response and cause the exposed individual to take steps to reduce or terminate exposure. The chloropicrin concentrations that produces this effect in at least 10% of the population has been calculated. Toxicology Excellence in Risk Assessment (TERA) developed a benchmark concentration (BMC_{10}) for chloropicrin using human ocular irritation as the critical effect. The BMC_{10} is 73ppb and this value represents the lower bound on the response of 10% of the test population. It is considered to adequately represent the sensitive end of the general population. No Uncertainty Factor is necessary for extrapolation of these effects to humans because the data were derived on humans. Moreover, the human subjects studies by Professor Cain were young adults, a population considered to be the most sensitive to sensory irritant effects and odor. Because the critical effect is direct irritation which shows minimal variability, an intraspecies Uncertainty Factor is also unnecessary for occupational exposure. Accordingly, an Occupational Exposure Level of 73 ppb is proposed for chloropicrin.

According to TERA (2005) benchmark concentration (BMC) analysis is superior to the traditional No Observed Adverse Effect Level (NOAEL) or Lowest Observed Adverse Effect level (LOAEL) approach for defining a threshold for effects from a toxicology data set. The US Environmental Protection Agency has advocated the use of BMC for human risk assessment at least since 1995 (EPA, 1995; EPA 2000; EPA 2001) and continues to do so today. Calculation of the BMC involves three steps: fitting a curve to concentration-response data, identifying from that curve the concentration (BMC) corresponding to a specified change in response (the benchmark response, BMC), and determining the lower bound on that concentration at a specified confidence limit (BMCL). The advantages of BMC over the traditional NOAEL/LOAEL approach are that the BMC considers the concentration-response character of all of the study data, study size (and therefore power) is accounted for, and the BMC does not have to be one of the study dose (or concentration) levels meaning that extrapolation slightly below the lowest dose is possible.

The Permissible Exposure Limit (PEL) reflects a combination of both uncertainty factors-intra- and inter-species variability. The judicious use of human experience in setting regulatory exposure limits for workers is best exemplified by the process used by OSHA in adopting PELs recommended by ACGIH (ACGIH, 1991). A key question asked in

periodic re-examination of the previously adopted PELs is whether there is epidemiologic evidence that suggests the PEL is too high, i.e., an effect was observed in workers exposed at or below the PEL. ACGIH, OSHA and NIOSH recommend 0.1 ppm TWA as the TLV, PEL and REL, respectively for chloropicrin. This is the value that an individual worker may be exposed to daily for 8 hours per day for a working lifetime. This PEL has been in place for 30+ years. Thus, there is a very large cohort of exposed workers that have been living with this PEL for an extended period of time. Use as a warning agent requires that both users exposed to concentrate and those accidentally exposed will not be permanently harmed, and chloropicrin has been used safely for over 60 years. A literature search produced no evidence of published epidemiologic studies of chloropicrin handlers who are arguably the cohort with greatest short or intermediate term exposure.

However, the overall interspecies UF derived from comparing either the BMCL from humans vs rodents for an irritant endpoint (150 vs 130 ppb, respectively) or the NOAEL for histopathology in humans vs rodents (150 vs 100 ppb, respectively) suggests that the true UF for interspecies is less than 2.

Thus as Dr. Ross' discussion above shows, EPA's approach to short-term and intermediate exposure using animal data is overly conservative.

3. EPA Has Incorrectly Characterized The 2-Generation Reproductive Toxicity Study On Chloropicrin As Unreliable.

In its revised risk assessment EPA compared results issuing from studies of extremely different design and purpose to support a conclusion that the reproductive toxicity study was unreliable. The studies cited by EPA actually produced consistent results when examined in the context of the study designs. Moreover, in November, 1996 EPA concluded in its Data Evaluation Report (DER) for the Two Generation Reproduction Toxicity Study with Chloropicrin that the study was acceptable.

A proper comparison of design and relevant results for each of the studies mentioned by EPA on page 8 and 9 of the draft PRA is presented in Table 7. From the table it is clear that the range finding reproductive toxicity study was conducted for a shorter time at a higher exposure level (dose) than the definitive reproductive toxicity study. The effects noted by EPA (decreased litter size and decreased uterine implant sites – as well as reduction in parental and pup body weight) occurred only in the highest exposure group, a higher exposure concentration than that used in the definitive study. The presence or absence of portal-of-entry effects, as considered by EPA, were not evaluated in the range finding study, so there are no points for comparison.

As opposed to the reproductive toxicity study, the 90-day subchronic toxicity study was a comprehensive evaluation of the potential for inhalation exposure to chloropicrin vapor to produce local and systemic toxicity (and to assess recovery). The number of exposure days in that study, 65, is less than the number of exposure days the F1 generation of rats experienced in the reproductive toxicity study, 83, but the high-exposure group in the subchronic study was twice the chloropicrin concentration as the high-exposure group in the reproductive toxicity study. The purpose of that study was to evaluate reproductive function and the potential for transgenerational effects in rats exposed to chloropicrin vapor. Although systemic toxicity was

produced in the adults of the reproductive toxicity study, organ weight data was not collected on respiratory organs, i.e., lungs, and the only respiratory tissue examined microscopically was the lungs and only a single lobe was examined. In that study lungs from the low-and mid-dose groups were examined only for female animals or males with gross lung lesions.

In the subchronic study, tissue from all regions of the respiratory tract were examined microscopically, and lung sectioning included two coronal cuts through all lobes (5) and mainstream bronchi. This means that a minimum of 10 sections of lung from each animal in each dose group were examined in the subchronic study, far greater than the number of lung specimens examined in the reproductive toxicity study. This difference in the level of examination notwithstanding, lung discoloration and adhesions were described in mid-and high-dose rats of the reproductive toxicity study and frank lung changes were observed in the high-exposure group (1.5 ppm) and in the mid-dose group (1.0 ppm) just as they were for the 3.0 and 1.0 ppm exposure groups of the subchronic study. EPA is incorrect in stating that inconsistencies exist between pulmonary effects produced in the reproductive and the subchronic toxicity studies of chloropicrin.

Table 7 Inhalation Study Detail Of Chloropicrin Reproductive Toxicity And Subchronic Studies In Rats

Study design/ Observation/ Endpoint	Reprotox Rangefinding Study	Reprotox Definitive Study	90-Day Inhalations Toxicity Study
Daily Exposure	6 hrs/day	6 hrs/day	6 hrs/day
Number of days of Exposure	43 days (high dose)	FO parents 43 days F1 parents 83 days	65 days
Exposure Concentrations	2.0, 1.0, 0.4 ppm	1.5, 1.0. 0.5 ppm	3.0, 1.0, 0.3 ppm
Chamber Analysis	GC/ECD hourly each exposure day	GC/ECD hourly each exposure day	GC/FID twice hourly each exposure day
Chamber Distribution	Evaluation of homogeneity of chloropicrin distribution 95-109% in 4 locations	Evaluation of homogeneity of chloropicrin distribution 93-107% in 4 locations	Evaluation of homogeneity of chloropicrin distribution within 10% in 5 locations
Test material identity & purity	Chloropicrin lot number 920130-1 >99% pure	Chloropicrin lot number 920130-1 >99% pure	Chloropicrin lot numbers 31291-A and 920130-2 99.6% pure
Animal Observations			
Survival	Twice daily	Twice daily	Twice daily
Appearance	Twice daily	Twice daily	Twice daily
Behavior	Twice daily	Twice daily	Twice daily
Body Weight	Males weekly; Females weekly through gestation and pnd 0 and 4	Males weekly; Females weekly through gestation and pnd 0, 7, 14, 21	Weekly
Food Consumption	Weekly	Weekly	Weekly
Study design/ Observation/ Endpoint	Reprotox Rangefinding Study	Reprotox Definitive Study	90-Day Inhalations Toxicity Study

Parturition/ Litter Obsv.	Litter size, weight, survival, behavior, stillbirth, livebirth, gross anomalies	Litter size, survival, stillbirth, livebirth, gross anomalies	Not applicable
Anatomic Pathology – Gross	Males – gross necropsy; Females – gross necropsy and uterine implant sites; Pups – external exam	Males - gross necropsy; Females – gross necropsy and uterine implant sites; Pups – Gross necropsy with attention to repro organs	Hematology, clinical chemistry, urinalysis, gross necropsy
Anatomic Pathology – Microscopic	Not performed as per study protocol	Testis, epididymis, prostate, seminal vesicle, lung, ovary, uterus, vagina, gross lesions	49 tissues plus gross lesions examined microscopically from all high-dose & conrtol animals; Lungs, larynx, nasopharyngeal tissues, trachea and all gross lesions examined microscopically from mid- and low-dose animals.
Organ Weights	Not performed as per study protocol	Testes weight males that did not impregnate	Liver, kidney, brain, adrenals, lungs spleen and testes
Findings	Survival unaffected; No clin signs or necropsy findings; No effect on repro parameters; High-dose group reduction in parental and pup body weight, litter size.	Adult survival, behavior, weight gain and food consumption un affected by treatment. Slightly reduced fertility index.	30% mortality in high-dose males. Decreased body weight gain and food consumption in high-dose male and female rats. Hematology changes in high-dose males. Increases in female and male mid- and high-dose relative lung weight. The only gross lesion was hyperinflation of male and female high-dose lungs.
Respiratory System Examination	Not performed as per study protocol	Lung discoloration/adhesion in high- and mid-dose F0 males & F0 and F1 females none or fewer in control or low dose. Female F0 dose-related subacute and chronic lung inflammation.	High-dose: rhinitis, hyperplasia of respiratory epithelium of nasal cavity, Goblet cell hyperplasia. Bronchitis/bronchiolitis (males only), epithelial hyperplasia and peribronchiolar fibrosis Mid-dose – rhinitis, Goblet cell hyperplasia. Epithelial hyperplasia and peribronchiolar fibrosis – males only. Low-dose - Goblet cell hyperplasia.

B. Exposure Issues

A second key component of the risk assessment process is the evaluation of potential exposure. The output from models in the current risk assessment is not consistent with the real world experience for chloropicrin. EPA has used certain predictive models as tools in its risk assessment process. There are, however, limitation in using these tools that must be recognized and addressed in the overall risk assessment.

1. Current EPA Modeling Does Not Reflect Real World Experience with Chloropicrin

CMTF appreciates the substantial work that EPA has devoted to modeling emissions from soil fumigants. The models that EPA are using, primarily PERFUM, but also FEMS and SOFEA, use air dispersion modeling to generate off-site air concentrations of the fumigant of interest given a discreet flux profile. However, there are inherent limitations to any air dispersion model used to predict the potential for bystander exposure. EPA has acknowledged that factors such as soil type, soil moisture, and farming practices can impact the chloropicrin emissions, thus impacting the output from air dispersion models. The current revised risk assessment does not reflect these factors. For example, the existing data show that soil moisture can have a substantial impact on emissions resulting in some cases in greater than 50% reduction in emissions from shank applications.[14] Other application practices such as soil preparation and depth of injection of the fumigant also can significantly reduce emissions. A risk assessment that looks only at the conditions at a specific field for model inputs would have an incomplete analysis that overlooks key emission factors. EPA should adjust exposure predictions factors to account for the reductions from factors such as soil moisture in its overall risk analysis.

Drs. Jeff Driver, John Ross and Muhilan Pandian have looked at the relationships between the toxicological and chemical properties of chloropicrin and the inherent limitations of the models and have discussed these in a documented which is attached as Appendix A. In making risk management decisions, EPA must recognize the inherent limitations of air dispersion models and adjust the risk analysis to account for those parameters that are not addressed by the current modeling.

2. Use of Near Field Activity Zone with PERFUM

PERFUM can be used to predict a distribution of concentrations within various zones from the edge of the treated field. Drs. Driver, Ross and Pandian considered the impact of these near field activity zones and concluded that these distributions provided a "more plausible range or potential time-weighted air concentrations that might be experience by intermittently mobile receptors." [15] An example of a PERFUM output with the near field activity zone is shown in Appendix A and discussed therein in more detail. Near field activity zone is another tool that EPA can use to develop a risk potential that is more closely tied to the real world experience with the use of chloropicrin.

3. Good Application Practices Are More Effective Than Buffer Zones in Reducing the Risk of Exposure

CMTF appreciates the complexities that EPA faces in developing potential exposure scenarios and characterizing risks from field applications. Chloropicrin air concentrations within and around treated fields, during and following fumigant application, are influenced by a number of factors. These factors include site-specific meteorological conditions, site-specific soil

[14] See discussion in Section II. 3 supra.

[15] See Appendix A page 7.

conditions such as soil type, moisture, organic content, temperature, application methods, soil sealing methods and application rates. Field monitoring studies however, cannot represent the entire range of potential factors that influence fumigant emissions. In this section, the CMTF presents application data, soil conditions and ambient conditions from agricultural fields where chloropicrin emissions have been studied. The CMTF proposes realistic emission data based on practical mitigation measures as presented in the GAPs discussed below. The data presented demonstrate a 50% reduction in emissions for shank applications when these mitigation measures are incorporated into chloropicrin field applications.

(a) Field Emission Data

Agricultural field volatility data was provided to EPA from 8-acre (nominal) fields where chloropicrin emissions were measured and cumulative emission ("mass loss") values were calculated. These fields were located in Phoenix, Arizona; Yakima, Washington; and Bradenton, Florida (HEH160)[16], Salinas, California (PRS02004[17], GH-C 5081)[18] and Douglas, Georgia (GH-C 5081, an unpublished report of Dow AgroSciences)[19]. The four shallow shank (9" -13" deep) application methods (broadcast non-tarped (Plot #1), bedded non-tarped (Plot #2), bedded tarped (Plot #3), and broadcast tarped (Plot #4) were near Phoenix AZ. Two drip irrigation applications were studied near Salinas, CA and one drip irrigation site was studied at Douglas, GA. A supplemental field flux study (TC246)[20] conducted near Salinas, CA, was also considered since it was a comparable shank, broadcast, tarped application of chloropicrin alone, at 350 lb/acre.

Emission data from these study sites can be used to estimate mass loss rates for the standard range of chloropicrin field applications. Cumulative emission mass loss data are typically reported as "percent of applied" to account for different application rates between methods. Field flux rates coupled with applicable regional weather data, appropriate application rates and field sizes are used to model offsite concentrations for bystander risk characterization.

(b) Emissions for Shank Application Methods

Chloropicrin mass loss from the HEH160 shank applications varied from 34% to 69% of applied chloropicrin for the six sites where mass loss values were determined. The shank, bedded, tarped field had emission totals that were 7% higher than the other Phoenix plots which may be related to bed sealing factors such as increased surface area and tarp anchoring limitations. In HEH160, mass loss rates for the four broadcast, tarped application sites ranged from 34% to 63% of applied chloropicrin. This wide variation in mass loss values cannot be

[16] MRID# 441492-01; EPA's Appendix D Field Volatility Description states that soil characteristics was not included in the Study Report. Soil characterization was presented in the Study Report in pages 68 through 77.

[17] MRID# 464202-01

[18] MRID# 449882-01

[19] MRID# 451129-02

[20] H. Lee, K. V. Natta and M. Gillis. 1994. Chloropicrin Worker Exposure, Flux and Offsite Monitoring and Dispersion Modeling for Tarped Broadcast Application-Pilot Study. Unpublished study being submitted to EPA.

explained entirely by regional differences since similar application equipment was used throughout the study. Polyethylene tarping was used for all shank applications. Three drip irrigation applications incorporated plastic tarping.

Differences in meteorological data can have a significant effect on off-site concentrations (e.g. high wind vs. calm conditions). For this reason, appropriate meteorological data representative of each region are used to model emissions for that region. The lower ambient temperatures experienced in Yakima, WA (~7^{o}C) may explain the 10% reduction in emissions over Bradenton, FL (~20^{o}C). However, differences in meteorological conditions do not explain the wide variation in mass loss values from HEH160. For example, average air temperatures at the Phoenix and Bradenton sites were 20^{o} C and 17^{o} C respectively, but mass loss at Bradenton was approximately half of the Phoenix rate.

Shank, deep broadcast applications ($\geq$ 18" deep) are expected to have lower emissions than shallow applications. Gao et. al (2007[21]) reported a 20% mass loss of chloropicrin when applied at a depth of 18" to small field plots in a Telone C35 formulation. A field flux study is planned for spring of 2008 to measure chloropicrin emissions from deep shank applications. Until those data are available, a 20% mass loss is appropriate for deep shank applications, using the Phoenix Site #1 as a surrogate flux profile. Soil moisture should be limited for proper fumigant efficacy (McKenry and Thomason, 1974[22]).

Soil moisture data from HEH160 and TC246 was used to determine the relationship between field emissions and soil moisture. The soil data are summarized in Table 8 and are graphed by study field site in Graph A. Two basic mass loss rates can be derived based on the two soil moisture conditions, "Low Moisture" and "Moist", which are shown in Graph B. The "Low Moisture" bar is an average of the four Phoenix plots; shank broadcast non-tarped, shank bedded non-tarped, shank bedded tarped and shank broadcast tarped. The "Moist Soil" graph is an average of the Yakima, Bradenton, and Salinas shank broadcast tarped sites.

[21] Gao, S., R. Qin, J. McDonald, R. Hanson and T. Trout. 2007. Field Tests on Emissions Reduction Methods from Telone C35 Application. 2007 MBAO Proceedings 42-1.

[22] McKenry, M.V., and I.J. Thomason. 1974. 1,3-Dichloropropene and 1,2-Dibromoethane Compounds; I. Movement and Fate as Affected by Various Conditions in Several Soils. Hilgardia 42(11):383-421.

Table 8 Shank Applications Of Chloropicrin; Soil Conditions And Mass Loss Studies: HEH160, TC246

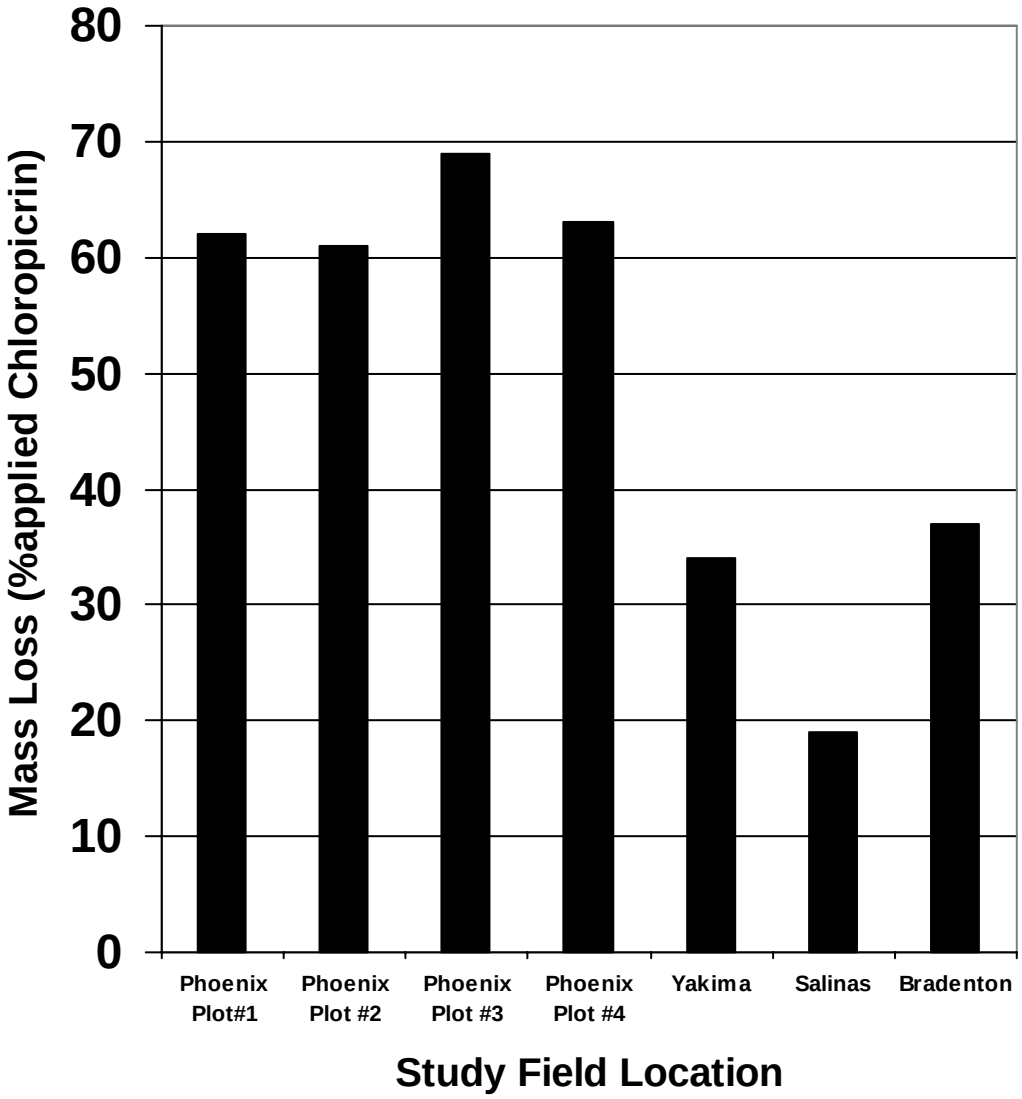
STUDY	FIELD LOCATION	APPLICATION METHOD	SOIL TEXTURE	SOIL BULK DENSITY	SOIL MOISTURE (0-6")			AIR TEMP (deg C)	MASS LOSS CHLOROPICRIN (% OF APPLIED)
					WEIGHT[23] %	VOLUME[24] %	%FIELD CAPY[25]		
HEH 160	Phoenix AZ Plot #1	Shank Broadcast Nontarped	Loam	1.47	10.12	14.88	55	~20	62
	Phoenix AZ Plot #2	Shank Bedded Nontarped	Sandy Loam	1.65	8.11	13.38	64	~20	61
	Phoenix AZ Plot #3	Shank Bedded Tarped	Sandy Loam /Loam	1.47	8.28	12.17	51	~20	69
	Phoenix AZ Plot #4	Shank Broadcast Tarped	Loam	1.43	6.74	9.64	36	~20	63
	Yakima WA	Shank Broadcast Tarped	Loam	1.41	19.17	27.02	>100	~7	34
	Bradenton FL	Shank Broadcast Tarped	Sand	1.42	9.53	13.53	>100	~17	37
TC246	Salinas CA	Shank Broadcast Tarped	Sandy Loam	1.6	9.1	14.6	69	~14	19

[23] All soil moisture values are averages of 2-3 field samples taken at 0"-6" depth, prior to application

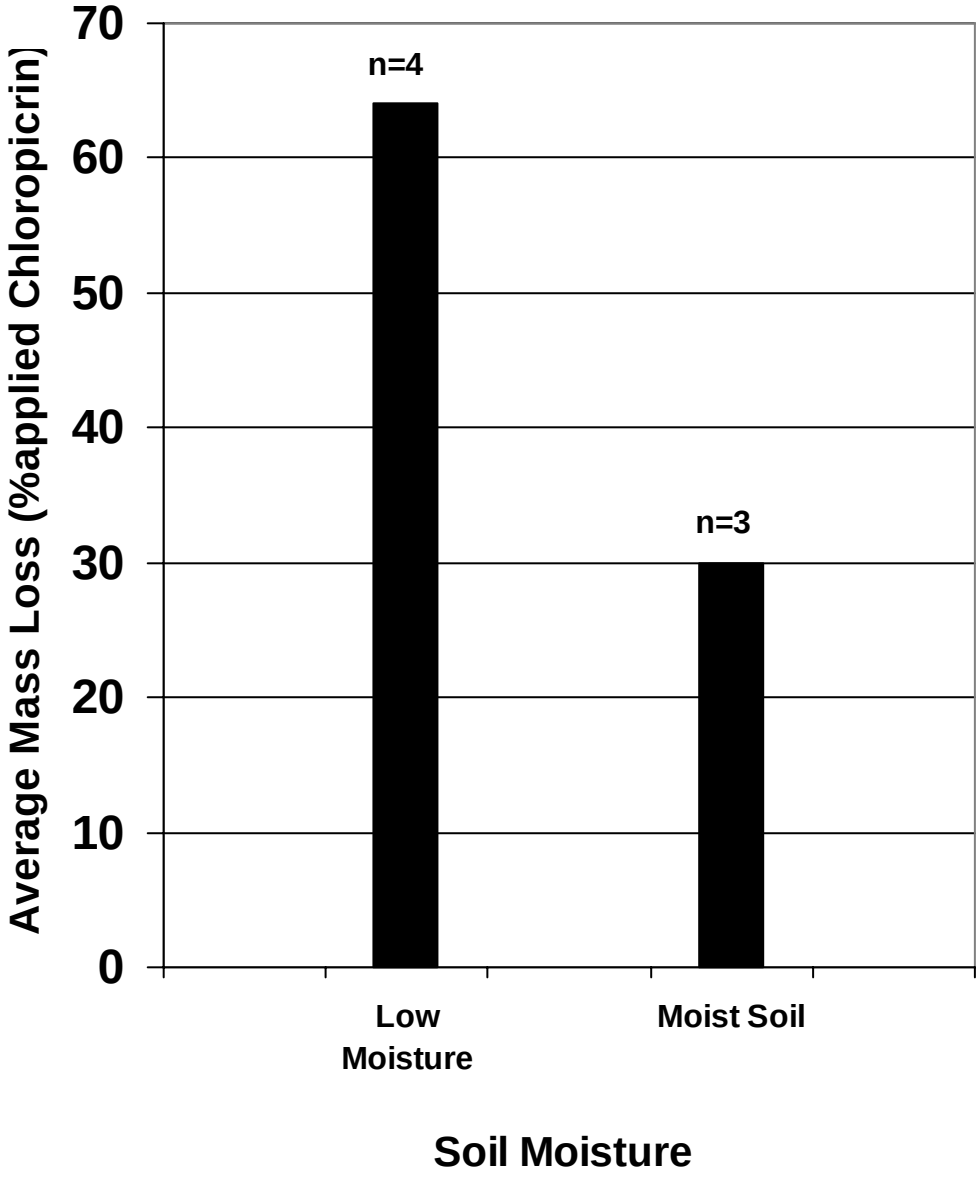
[24] %Volume= (%wt) x (bulk density)

[25] %Field capacity (FC) was derived from the following: For sand texture, 10%vol=100% FC, for Sandy loam, 21%vol=100%FC, for Loam, 27%vol=100%FC, for Sandy loam/Loam, 24%vol=100%FC. (Ratliff, L.F., J.T. Ritchie and D.K Cassel. 1983. "Field-measured limits of soil water availability as related to laboratory-measured properties." *Soil Science Society of America Journal,* Vol. 47:770-775.)

Graph A Mass Loss by Study Field Location (Shank Applications)



Graph B **Chloropicrin Mass Loss by Pre-Application Soil Moisture Condition (Shank Applications)**



(i) Impacts of Pre-Application Soil Moisture On Emissions

Average mass loss was reduced by a factor of 0.48[26] when the shank applications were made to moist soils compared to the sites where soil moisture was low. This factor is applied to all shank application methods that were measured in HEH160 (under low moisture conditions) to estimate moist soil condition mass loss values as shown in Table 9. The study flux profile for modeling should be calculated as follows:

"Low Moisture" soil conditions: For all shank methods use mass loss values and profiles from the appropriate Phoenix AZ Plots #1-4.

"Moist" soil conditions: For shank, broadcast, tarped application, use 30% mass loss (0.48 x Phoenix mass loss profile). For all other shank application methods, multiply the appropriate Phoenix site flux profile by 0.48. In cold weather (<10^{o}C average air temperatures), the Yakima flux profile should be used for the tarped broadcast method. For other shank methods, multiply the appropriate Phoenix site flux profile by 0.43[27] to account for lower emissions due to lower ambient conditions.

The importance of soil moisture in controlling chloropicrin emissions has been confirmed in recent studies conducted by researchers at the USDA-ARS San Joaquin Valley Agricultural Sciences Center, Water Management Research Unit in Parlier, (Gao and Trout, 2007)[28]. Gao, et al, (2007)[29] demonstrated a reduction of greater than 50% in total chloropicrin emissions when pre-application moisture was added. However, for some crops and cultivation systems, adjusting soil moisture is not possible prior to fumigant application, and options must be available for all ranges of soil moisture.

(ii) Proposed Soil Moisture Language

Given the importance of pre-application soil moisture, EPA could require label language such as:

> For shallow shank applications, at the time of application soil must contain at least enough moisture above the depth of application to meet the following test appropriate to the soil texture:

[26] The ratio of the Bradenton shanked broadcast emission rate to the Phoenix shank broadcast emission rate.

[27] The ratio of Yakima shanked broadcast emission rate to the Phoenix shank broadcast emission rate.

[28] Gao S. and T. Trout. 2007. Surface Seals Reduce 1,3-Dichloropropene and Chloropicrin Emissions in Field Tests. J. Environ. Qual. 36:110-119 (2007).

[29] Gao et al. 2007. Field Tests on Emission Reduction Methods from Telone C35 Application. Proceedings of the 2007 Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions. October 29-November 1, 2007 42-1.

For fine texture soils (clay loam, silty clay loam, sandy clay, silty clay, sandy clay loam and clay) at least enough moisture so that the soil is pliable, not crumbly but does not form a ribbon when squeezed between thumb and forefinger."[30]

For coarse soils (sand and loamy sand), there must be enough moisture to allow formation of a weak ball when compressed in the hand. Due to soil texture, this ball is easily broken with little disturbance. In loamy, moderately coarse, or medium textured soils (coarse sandy loam, sandy loam, and fine sandy loam), a soil sample with the proper moisture content can be formed into a ball which holds together with moderate disturbance, but does not stick between the thumb and forefinger.

For fields with more than one soil texture, soil moisture content in the lightest textured (most sandy) areas must comply with this soil moisture requirement. Whenever possible, the field should be divided into areas of similar soil texture and the soil moisture of each area should be adjusted as needed. Coarser textured soils can be fumigated under conditions of higher soil moisture than finer textured soils; however, if the soil moisture is too high, fumigant movement will be retarded and effectiveness of the treatment will be reduced. Previous and/or local experience with the soil to be treated or the crop to be planted can often serve as a guide to conditions that will be acceptable. If you do not know how to determine the soil moisture content of the area to be treated, consult your local extension service or soil conservation service specialist or pest control advisor (ag consultant) for assistance.

(c) Replant Wand Application Method

Mass loss for the replant wand application method is expected to be significantly less than for the shank methods, as injections are made one per tree site and the injection point is compacted following withdrawal of the application wand. A mass loss factor of 20% of applied is a conservative estimate since applications are made at $\geq$ 18" deep. Tree site applications involve small treated areas (10' x 10') of existing orchards. No emission modeling is necessary as the application rate per gross acre is low.

[30] Fine textured soils have limited air space for gaseous diffusion of a fumigant. If the air space contains water to the point of creating a ribbon using the feel method, the soil would be too wet and therefore unacceptable for fumigation.

(d) Drip Irrigation Application Method

The importance of soil moisture in reducing field emissions is illustrated in the mass loss data for drip irrigation methods, where soil moisture is >100% field capacity during and following application. Mass losses for the three drip irrigation application sites were 15% for the Salinas chloropicrin application (PRS02004), 11.9% for the Douglas chloropicrin/1,3-D application (MRID 45112902), and 10.8% for the Salinas chloropicrin/1,3-D application (MRID 44988201). Some variation in drip irrigation flux rates could be expected due to factors such as application time (the PRS02004 application was made in one hour instead of four hours due to an equipment malfunction) and differences in drip irrigation equipment. The average mass loss factor for these three studies is 12% of applied chloropicrin.

For the buried (≥ 5") non-tarped drip irrigation method, field moisture conditions are >100% field capacity. Chloropicrin mass loss is therefore expected to be less than or equal to the surface tarped method. A mass loss factor of 15% of applied chloropicrin is a conservative mass loss value, using the Salinas poly drip flux emission profile.

(e) Greenhouse Drip Irrigation

The only greenhouse application method that is being supported by the Chloropicrin Manufacturers Task Force is the drip, surface, tarped method. This method is the same as the field drip irrigation method, conducted in greenhouses. Since this method is intended for treating soil only, all windows, doors, vents and sides were opened during the study to allow for natural air movement during and following the application. For the greenhouse drip irrigation method, the appropriate "released amount" should be 15% of the applied chloropicrin.

4. Alternative Emission Factors

The CMTF has presented application data, soil conditions and ambient conditions from agricultural fields where chloropicrin emissions have been studied. Using the relationship between pre-application moisture and mass loss, the CMTF has proposed realistic alternative emission factors incorporating this mitigation measure. To determine the emission profiles for fields under moist soil conditions, the CMTF proposes that EPA attenuate the emission profiles from the field studies listed in the "Low Soil Moisture" column to correct for moist pre-application soil conditions. These data demonstrate a 50% reduction in emissions when these mitigation measures are incorporated into chloropicrin field shank applications

The following mass loss factors and flux emission profiles, based on the above studies, should be used for modeling the listed application methods. These mass loss factors apply to all regions of the U.S.

Table 9 Percent Mass Loss for All Chloropicrin Application Methods; Pre-Application Soil Moisture Emission Mitigation Factors For Sand, Sandy Loam and Loam Soils

Application Method	Mass Loss, % of Applied Chloropicrin			
	Low Soil Moisture (Pre-application)	Study Field Flux Profile	Moist Soil (Pre-application)	Study Field Flux Profile
Shank, Broadcast Non-tarped	62%	Phoenix Site #1	30%	0.48 x Phoenix site #1
Shank, Broadcast Tarped	63%	Phoenix Site #4	30%	0.48 x Phoenix site #4
Shank, Bedded Non-tarped	61%	Phoenix Site #2	30%	0.48 x Phoenix site #2
Shank, Bedded Tarped	69%	Phoenix Site #3	33%	0.48 x Phoenix site #3
Shank, Broadcast, Deep Non-tarped*	20%	0.32 x Phoenix site #1	N/A	N/A
Drip Irrigation Surface Tarped	12%	0.80 x Salinas Poly tarp	N/A	N/A
Drip Irrigation Buried Non-tarped	15%	Salinas Poly tarp	N/A	N/A
Replant Wand	20%	N/A	N/A	N/A
Greenhouse Drip Irrigation	15%	Salinas Poly tarp	N/A	N/A

Note: In cold weather (<10^{o}C), use Yakima flux profile for tarped broadcast. For other shank methods, multiply appropriate Phoenix site by 0.43).

Phoenix Site #1 = Shank, Broadcast Non-tarped; Phoenix Site #2 = Shank, Bedded Non-tarped
Phoenix Site #3 = Shank, Bedded Tarped; Phoenix Site #4 = Shank, Broadcast Tarped

*Mass loss value for shank, broadcast, non-tarped under moist soil conditions was used. Shank deep non-tarped applications should be done under dry conditions only.

5. Modeling Using CHAIN_2D Can Provide Useful Information For Risk Managers Regarding Emission Reductions from GAPs

Air dispersion modeling predicts fumigant concentrations surrounding a treated field and provides a snapshot of transient air concentrations based on a unique fumigant flux (emissions) profile. Previously this modeling had been limited to predictions based on flux measurements taken from field volatility studies. The time needed and the costs of the studies have limited the numbers of field volatility studies. CHAIN_2D, a soil diffusion model, allows one to take existing data and bridge it across the diverse conditions faced by agriculture to predict the impact on emissions of various factors such as injection depth, soil type, etc.

The USEPA 2004 Scientific Advisory Panel that reviewed the air dispersion models suggested that a comparison of estimated fluxes with predictions using soils-based transport models (such as CHAIN_2D) would be useful.[31] CHAIN_2D is a comprehensive two-dimensional finite element model based on first principles. The model was developed by soil physicists[32] and over 250 peer-reviewed journal publications or conference proceeding exists for CHAIN_2D and its sister model HYDRUS. A user-friendly interface for use with soil fumigants has been developed[33] and the model with the interface, information on variables and other technical has been provided to USEPA. In addition, the model was the subject of presentation at the recent 2007 Methyl Bromide Alternative Conference.

CHAIN_2D provides a useful tool for EPA to assess the impact of a variety of GAPs that will reduce the emissions, and, therefore, the potential for exposure. Use of this tool will enable EPA to consider a broader range of scenarios. Flexibility for growers is essential. For example, for certain regions and crops tarping and irrigation are routinely used and the emissions profiles should reflect the impacts of increased soil moisture and tarps. For other crops tarps are not feasible. These crops, however, may use applications with deeper injections, which also reduce emissions. It is important to note that the crop and pest pressures impact the depth of injection, and, therefore, it is not possible for some crops, such as strawberries, to use deep applications ($\geq$ 18 inches). To base regulations on the lowest common denominator for each variable would unfairly burden growers, who as discussed in the economic section need this useful tool. CHAIN_2D would allow EPA to consider a variety of application variables.

---

[31] "The Panel suggested comparisons of estimated fluxes with predictions using soils-based transport models (such as CHAIN_2D) that deterministically compute, in a forward fashion, emission fluxes using mainly soils (and dosage) information. These transport models can also be run simultaneously with a parameter generator in a stochastic fashion, thus providing an assessment of uncertainties in the output such as the emission fluxes." Meeting Minutes from FIFRA Scientific Advisory Panel Meeting, August 26-27, 2004. p. 35.

[32] J. Simunek and M. Th. Van Genuchten (1994).

[33] S.A. Cryer, Dow AgroSciences; S.A. Cryer. 2007 "An Alternative Air-Soil Boundary Condition for Predicting VOC Transport from Soil. Journal of Env, Quality (In review).

6. Good Application Practices for Chloropicrin

The following paragraphs provide descriptions of various Good Application Practices (GAPs) for chloropicrin. In most instances growers are already using these GAPs as part of their normal application practices and in many cases the GAPs may be reflected on the label. However, CMTF expects that as part of the RED EPA will require the incorporation of GAPs on the labels.

Shank applications and drip irrigation applications require slightly different GAPs due to the applications and they are discussed below in two separate sections.

(a) GAPs for Shank Applications of Chloropicrin

Fumigant Application Rate: The application rate should be optimized for the given target pest, soil type and conditions, application method, and other site- and application-specific characteristics.

Wind speed: Wind must be sufficient to provide mixing (approximately 2 mph or greater) at the beginning of each application. Applications should not commence if atmospheric inversion conditions are anticipated.

Soil Temperature: The maximum soil temperature at the point of delivery should not exceed 90 degrees F at the beginning of the application. Chloropicrin and other fumigant emissions increase with soil temperature. At lower temperatures, fumigant emissions are comparatively reduced, allowing for greater soil-phase degradation of fumigant and a reduction of emission concentrations and rates.

Soil Preparation: Soil should be properly prepared and free of large clods, as large clods prevent effective soil sealing. The spaces around large clods can act as chimneys, allowing fumigant vapors to escape at a greater rate than if the soil was properly prepared. In many soils, clods are not an issue (sand, sandy loam, etc.). On heavy soils, proper soil preparation is necessary.

Soil Moisture at Depth of Injection: For shank applications of less than 18 inches in depth, the soil must be moist from two inches below the surface to at least 12 inches deep. The amount of moisture needed in this zone will vary according to soil type and shall be determined using standard field testing methods. Surface soil generally dries very rapidly and should not be considered in this determination.

Soil Moisture Adjustment: If there is insufficient moisture at the two to six inch depth, the soil moisture must be adjusted. If irrigation is not available and there is adequate soil moisture below six inches, soil moisture may be brought to the surface by discing or plowing before or during the injection. To conserve existing soil moisture, pretreatment or treatment tillage practices should be done as close to the time of application as possible.

Field Management: Field trash must be properly managed. Residue from the previous crops should be worked into the soil to allow for decomposition prior to fumigation. Trash pulled by the shanks to the ends of the field must be covered (with tarp, soil, or other suitable material, depending on the application method) before making the turn for the next pass.

Prevention of End Row Spillage: Do not apply or drain chloropicrin onto soil surface. For each injection line either have a check valve, located as close as possible to the final injection point, or use a system to purge the line of any remaining fumigant prior to lifting shanks from the ground. Do not lift injection shanks from soil until the shut-off valve has been closed and the fumigant has been cleared and/or purged from the system.

Bed Injection Depth: For preformed beds, the injection point shall be a minimum of 12 inches from the nearest, final soil/air interface. For beds formed at the time of application (listing), the bed forming shall be accomplished in a manner that places the fumigant at least 12 inches from the nearest, final soil/air interface.

Bed Sealing: Preformed beds shall be sealed by disrupting the chisel trace using press sealers, bed shapers, or by re-shaping (relisting, lifting and replacing, etc.) the beds immediately following injection. Beds formed at the time of application shall be sealed by disrupting the chisel trace using press sealers, bed shapers, or other means that will effectively compact the soil. In addition to mechanical sealing, a high barrier tarp may be used for either preformed beds or beds formed at the time of application.

Broadcast (flat fume) Soil Sealing: Broadcast applications should be sealed immediately after injection by tarping or by discing and/or cultipacking the treated areas or a similar method.

Types of Tarps: Depending on the circumstances plastic films (e.g. LDPE, HDPE, etc.) should be used, if and when tarps are needed. Highly retentive films that have been adequately field tested may be used.

Reentry restrictions: Minimum time intervals from application to reentry of a field to perform specific work functions are common mitigation measures for post-application workers in all types of agriculture. For methyl bromide use in California, a minimum of 5 days is required to elapse between application and cutting of tarps prior to their removal. The same time interval typically is applied to chloropicrin applications. This measure minimizes exposure to tarp cutters while also promoting maximum efficacy. Furthermore, a minimum of 24 hours is also required to elapse between tarp cutting and removal of tarps from the field. This measure allows the fumigant to dissipate before tarp removers enter the field, and, thus, minimizes their exposure.

Proximity to Bodies of Water: Shank applications should not be conducted within 10 feet of any body of water, including irrigation ditches.

(b) GAPs for Drip Applications of Chloropicrin

Application Rate: The application rate should be optimized for the given target pest, soil type and conditions, and other site- and application-specific characteristics.

Product and Dosage: Plan the application by calculating the amount of chemical required at the appropriate rate for the crop, acreage and target pest. Chemical must be metered into the water supply line and then passed through a mixing device, such as a centrifugal pump or static mixer, to assure proper agitation.

Proximity to Bodies of Water: Drain or flush lines of the irrigation system used for chemigation should not empty into or within 10 feet of any body of water, including irrigation ditches.

Wind speed: Wind must be sufficient to provide mixing (approximately 2 mph or greater) at the beginning of each application. Applications shall not commence if atmospheric inversion conditions are anticipated. Adequate wind at the start of an application is necessary to reduce worker exposure and offsite methyl bromide concentrations.

Soil Tilth and Preparation: Remedy fields with known plowpans, as they can lead to puddling of fumigant due to improper soil drainage. Depth and degree of tillage should be appropriate to disrupt the plowpan and break apart clods. Soil should be properly prepared and free of large clods, as large clods prevent effective soil sealing. The spaces around large clods can act as chimneys, allowing fumigant vapors to escape at a greater rate than if the soil was properly prepared. In many soils, clods are not an issue (sand, sandy loam, etc.). On heavy soils, proper soil preparation is necessary.

Field Management: Field trash must be properly managed. Residue from the previous crops should be worked into the soil to allow for decomposition prior to fumigation.

Placement of Drip Tape: Tarps must be used when drip lines are less than 5 inches deep. For non-tarped applications, drip lines must be greater than 5 inches deep. Drip tape at the ends of rows must be covered with tarp, soil, or by other means to limit off-gassing from terminal emitters. Likewise, drip tape should also be covered if there are exposed emitters between the water supply line connection and the treated bed.

Plastic Mulch (Tarps): Depending on the circumstances plastic films (e.g. LDPE, HDPE, etc.) should be used, if and when tarps are needed. Highly retentive films that have been adequately field tested may be used. Embossed films should not be used for drip application. Use smooth or non-embossed films and ensure that tarp edges are adequately buried at the furrow and at the ends of rows.

System Controls and Integrity:

- The irrigation system (main lines, headers, drip tape) should be thoroughly checked for leaks before the start of the application. An adequate run-time (at

least 2 hours) and pressure (at or slightly above normal operational pressure) are needed to detect leaks. Look for puddling along major pipes (holes in pipe or leaky joints), at the top and ends of rows (leaky connections, open drip tape), in the furrows and on bed surface (damaged drip tape, malfunctioning emitters).

- Do not use drip tube (drip tape) materials made of aluminum, magnesium, zinc, cadmium, tin and alloys, vinyl, PVC pipe, as under certain conditions some fumigants may be severely corrosive to such materials.
- The system must contain a functional check valve, vacuum-relief valve, and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination and backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check value to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated value located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- An accurate metering of fumigant into the water supply lines is critical. Make sure ppm calculations are based on accurate measurements of the area to be treated, flow volume (gpm), etc. Inaccurate ppm concentrations can lead to off-gassing problems and/or irrigation system damage.
- Use a metering system, such as a positive displacement injection pump (e.g., diaphragm pump, a positive pressure system, or a Venturi system), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Site of Injection and Irrigation System Layout: Site of injection should be as close as possible to the area being treated, such as direct injection of fumigant into the header pipe/manifold or into an above ground delivery pipe attached to the header. The length of the pipe should be limited based on the volume of fumigant that could leak from it during a spill (i.e., larger diameter pipe should be of a shorter length than a narrower diameter pipe). If main line injection is used, make sure irrigation pipe is level as fumigant may pool in low sections of pipe if the flow velocity is low.

System Flush: After application of the chemical, continue to irrigate the area with untreated water to flush the irrigation system. Do not allow chemical to remain in the irrigation system after the application is complete. The total volume of water, including the amount used for flushing the irrigation system, should not exceed 1.5 acre-inches (40,000 gallons) of water per acre. If common lines are used for both the fumigant

application and water seal, these lines should be adequately flushed before starting the water seal and/or normal irrigation practices. When flushing the irrigation system at the completion of the injection of the chemical, all water used for flushing must stay on the target treated area.

Providing a Water Seal: Water seals are not always used or needed. If used, the sprinkler system should be in place before the start of the drip application. Initiation of the water seal should start immediately upon completion of the fumigant injection (most areas) or even during the injection. The water seal(s) should maintain adequate moisture in the top inch of soil.

Reentry restrictions: A minimum of 5 days is required to elapse between application and hole punching of tarps for seeding or transplanting. Furthermore, a minimum of 7 days is also required to elapse between tarp punching and seeding or transplanting.

III. COMMENTS ON EPA'S PROPOSED MITIGATION MEASURES

EPA has asked for comments on various mitigation measures. The following paragraphs respond to EPA's questions.

- **Which fumigant(s), geographic region(s), and crop(s) do your comments address?**

These comments address all geographic regions of the country and all crops for which chloropicrin is used as a soil fumigant.

- **Please estimate the quantitative impacts of requiring buffer zones set at the following distances: 100 feet, 100 to 300 feet, 300 to 500 feet, 500 to 1,000 feet, ¼ to ½ mile, and greater than ½ mile.**

The impacts of buffer zones will vary significantly by region and at the field-scale level as the density and proximity of human occupied structures to fumigated fields are highly variable. However, most areas where fumigants are used have occupied structures nearby. In particular, most farms have a house located on the farm itself. In addition, the coastal areas of California and Florida are prime examples of urban encroachment into previously agricultural areas. These intensive agricultural zones surrounded by urban sprawl are the primary production areas for the nation's fresh fruit and vegetable crops due to their mild climates. These climates, however, are also very attractive for human development.

In high-density urban-agriculture interfaces, the impact of large buffer zones would be severe. Table 10 below estimates the loss of high-productivity farmland (i.e., fumigated acres) based on varying buffer zones distances. The sources of these data are primarily professional fumigant applicators.

Many commodity groups also have submitted information on the impact of buffer zones. While there may be some minor differences in the extent of impacts, the clear consensus of all of the information is that large buffer zones can have a potential disastrous impact on growers.

Table 10 Estimations of Percent Loss to Existing Crop Acreage For Different Buffer Zone Distances

Crop and State *	Percent loss to existing crop acreage for different buffer zone distances (in feet) **						
	100	**200**	**400**	**800**	**1600**	**3000**	**4000**
Strawberry, southern California [1]	3	6	9	25	75	100	100
Pepper, southern California [1]	5	15	50	100	100	100	100
Tomato, southern California [1]	2	4	10	40	100	100	100
Sweet Potato, North Carolina [2]	20	40	95	98	100	100	100
Strawberry, North Carolina [2]	30	60	98	100	100	100	100
Tomato, North Carolina [2]	30	55	95	100	100	100	100
Tobacco, North Carolina [2]	15	30	95	98	100	100	100
Strawberry, central/southern Florida [3]	7	19	37	44	58	99	100
Tomato, central/southern Florida [3]	15	30	70	80	95	95	98
Pepper, central/southern Florida [3]	15	30	70	80	95	95	98
Tomato, Tennessee and Arkansas [4]	5	15	40	80	95	100	100
Tomato, Alabama, Mississippi, and Louisiana [4]	5	20	40	60	80	100	100
Pepper, Alabama, Mississippi, and Louisiana [4]	5	20	40	60	80	100	100
Strawberry, Alabama, Mississippi, and Louisiana [4]	60	70	100	100	100	100	100
Cucurbits, Alabama, Mississippi, and Louisiana [4]	5	20	50	60	80	100	100
Forestry, Alabama, Mississippi, and Louisiana [4]	10	30	50	80	100	100	100
Tobacco, Kentucky [4]	3	10	25	50	80	100	100
Cucurbits, Michigan [4]	5	30	60	80	100	100	100
Potato, Michigan and Wisconsin [4]	10	20	40	60	80	100	100
Strawberry, n. Florida and s. Georgia [4]	60	70	100	100	100	100	100
Tomato, n. Florida and s. Georgia [4]	5	20	50	60	80	100	100
Pepper, n. Florida and s .Georgia [4]	5	20	50	60	80	100	100
Cucurbits, n. Florida and s. Georgia [4]	5	20	50	60	80	100	100
Potato, n. Florida and s. Georgia [4]	10	30	50	70	100	100	100
Forestry, n. Florida and s. Georgia [4]	10	30	50	80	100	100	100
Vegetables, Texas [4]	3	15	30	60	75	100	100
Forestry, Texas [4]	20	40	60	80	100	100	100
Northern Forest Seedling Nurseries [4]	10	30	50	75	100	100	100
Strawberry, central California [5]	13	35	57	72	88	100	100
Cut Flower, central California [5]	90	100	100	100	100	100	100

* Data sources are as follows:
[1] Daryl Ito, Pest Control Advisor and Field supervisor, Trical, Inc., Hollister, CA.
[2] Carroll Mclawhorn, Executive Vice President, Hendrix & Dail, Inc., Greenville, NC.
[3] Roger Hruby, Chief Operating Officer, Hendrix & Dail, Inc., Palmetto, FL. 2007 MBAO proceedings.
[4] Perry Fuller, Regional Manager, Hendrix & Dail, Inc., Tifton, GA.
[5] Doug Buessing, Pest Control Advisor and Field Supervisor, Trical, Inc., Hollister, CA. CSC sponsored data for Salinas, Monterey.

** These are average estimates based on measurement from the treated area to the property line as done for methyl bromide in California. In some instances, a 300-foot buffer zone may eliminate a grower's ability to fumigate.

- **As part of the explanation of these impacts please discuss how the buffer zone distances listed above would change crop production practices (fumigation schedules and size of treated fields, crop yields) and what would be the associated costs?**

Growers operate within narrow activity windows, which are based on crop production cycles, weather forecasts, market opportunities and pressures, disease and pest life cycles, etc. Unreasonably large buffer zones would result in the loss of fumigated acres and the need to reduce the number of treated acres at any given time into smaller application blocks. The costs associated with leaving acres untreated are addressed under Question 3 below. It is important to note that due to buffer zone impacts a grower may have some strips of land that are technically available for fumigation, but the size and configuration of the strips will mean that the land cannot be feasibly fumigated.

Growers in California have adopted the approach of breaking larger fields into small application blocks to deal with large methyl bromide buffer zone distances, but not without additional costs. Most chloropicrin fumigations in California are performed by custom applicators, so breaking a 30-acre field, for example, into three 10-acre fields will triple travel expenses and labor costs which will increase the costs to growers significantly. For grower-applicators, there will be similar increased costs. Breaking larger fields into smaller application blocks will have additional risks as well. There will be additional equipment moving and handling time and therefore more opportunities for accidents.

Furthermore, for some bedded applications, it is not possible to divide a larger application block into smaller fields as drip tape, fertilizer, fumigant and tarp may be applied simultaneously with bed listing. Starting and stopping can be done only at the end of the row, which may be several hundred feet long. For broadcast applications, splitting a larger application block into smaller blocks may be possible; but it could result in excess costs and, in some cases irregular fields that cannot be economically treated.

The effect of buffer zones on yield losses could be severe. The economic impact assessments performed by the Biological and Economic Analysis Division (BEAD) clearly demonstrate that fumigants have a high economic benefit to agricultural production. To calculate potential yield losses, one simply has to take the total number of acres of each crop currently being fumigated, factor in the projected loss of acres listed in Table 10, and then multiply these values by the crop-specific value-added economic return of fumigated acres in the BEAD analysis. Collectively, hundreds of millions, if not billions, of dollars in agricultural revenue would be lost via unreasonably large buffer zones.

- **What are the costs of leaving areas untreated as a result of the buffer zones (e.g., fields near homes)?**

The costs of leaving areas untreated as a result of the buffer zones will vary by crop, region, the existing and potential soil pest complexes, and other factors. In all cases,

non-fumigated fields will harbor soil pests and will be significantly less productive. Depending on the pests involved (e.g., bacteria, fungi, nematodes, weeds), the loss of crop productivity can be severe with crop losses up to 100% for susceptible crops. Experience in California strawberry production has demonstrated yield differentials of 20% between fumigated and non-fumigated crops Some growers operate within a very narrow profit margin, where even a 5% yield loss can mean a net loss for the year. For other crops, such as commercial nursery plants affected by quarantine restrictions, the cost of leaving acres untreated equates to a 100% loss of yield, as these growers cannot sell plants grown on soils that cannot be certified as disease-free. Only fumigation allows these soils to be reliably certified as disease-free.

Addition risks are associated with leaving acres untreated. Growers will be forced to increase their use of post-plant pesticides, fertilizers, and irrigation to counteract the loss of plant vigor and increased root damage on the non-fumigated acres. These additional pest control measures increase the total cost to the grower, yet provide only a limited benefit in comparison to the yields that would have been obtained if the ground were fumigated. The additional input of post-plant pesticides and increased use of fertilizers also may have negative impacts on the surrounding environment; impacts that would not be realized if the ground was fumigated in the first place. Soil pests also can be readily dispersed via soil, water, and post-fumigation farm machinery movement. Therefore, treated ground that is adjacent to untreated ground has a high potential to become re-infested with pests shortly after fumigation. Re-infestation of treated ground with pests will negatively impact crop yields, thereby also forcing the grower to utilize additional post-plant pesticide, fertilizer, and irrigation inputs to counteract yield loss from pests that would have otherwise been managed by fumigation.

- **What are the costs of subdividing application blocks to achieve workable buffers?**

These costs are discussed above. Subdividing will only work if the agronomic and economic issues can be resolved. Subdividing an application so that there are 10 applications over a 20-day period to treat all of the ground may look feasible on paper, but the additional costs, planting window limitations, as well as the potential for inconsistent results due to the extended treatment time, make this type of system impractical.

- **To the extent possible, describe what buffer zone distance is not feasible and why.**

The answer to this question is highly dependent on the region in which the crop is being grown. Growers in California's urban interface areas have learned to maintain buffer zones for methyl bromide between 60 and 200 feet by adjusting the application rate, reducing the application block size, changing application methods and utilizing fumigants with smaller buffer zones. Growers have indicated that, in most cases any buffer zone greater than 100 feet poses significant economic hardships for their operations.

- **Please discuss what you would do if new EPA restrictions made it impractical to continue using chloropicrin. Please identify the next best alternative(s) to your current practice and what costs would be associated with shifting to alternatives?**

If the buffer zones for chloropicrin effectively prohibit its use, growers will attempt to switch to another fumigant. If all suitable fumigants have equally large buffer zones, then the only choice for the grower will be to leave ground untreated (as discussed above). Non-chemical methods are largely ineffective and pose a serious risk to the livelihood of growers. In many cases, banks require soil fumigation as a requirement for annual loans to growers to increase the likelihood of profitable yields and ensure prompt and complete repayment. Non-chemical methods are not effective or consistent enough for banks to risk large loans to growers. For example, solarization has potential only in areas that receive adequate solar radiation, leaving growers in areas with long periods of cloud cover unable to use this option. Moreover, researchers have demonstrated that solarization can actually increase the pest problem, as the heat treatments kill off beneficial and competitive soil microbes, leaving only (and possibly even selecting for) thermophilic pathogens (e.g., see Reveni et al. 1983, Phytopathology 73: 1223-1226). Steam treatments are significantly more expensive than fumigants, making this option also impractical. The effective treatment zone for steam is the upper six inches of the soil profile, making steam treatments useless for any crop that is susceptible to pathogens that reside greater than 6 inches deep. The primary usefulness of steam would be for shallow-dispersed weeds, but few, if any, crops have shallow weeds as their sole pest pressure. Additionally, the amount of fuel (e.g., diesel) needed to generate steam make this option very costly. Worldwide, non-chemical methods have been studied intensively for over a decade as potential alternatives to methyl bromide fumigation and yet the principal alternatives for most cropping systems are still fumigant based systems.

- **Growers in California and Wisconsin are asked to comment on the transition process from having no buffers to having buffers. Also, please provide comments related to cost and feasibility of situations where bystanders voluntarily moved while buffer zones were in effect to comply with buffer zone requirements.**

In California, three major problems arose during the transition process from no buffer zones to buffer zones. These problems related to defining occupied structures, determining the distances from the treated field, and an increase in the number of applications due to measures taken to reduce buffer zones.

Regarding the cost and feasibility of relocating bystanders to circumvent buffer zones, this is not a practical solution in almost all cases. Residents do not normally want to move out of their homes for any amount of time. In terms of cost, relocating a single household may be affordable for some growers; however, if multiple residences are involved, the economic cost would make this impractical.

- **How could you modify practices to get a smaller buffer? Growers in California, please comment on modifications that you have made to achieve smaller buffer zones.**

Occupied structures determine whether or not a buffer zone exists. Moving residents out to classify the structure as non-occupied is not feasible because residents are usually not willing to move out and costs are often prohibitive. Application rate reductions to decrease buffer zones in California have created scenarios where the rates are below what is necessary to achieve adequate efficacy. Allowing occupancy for portions of a day for certain structures helps in certain situations, mainly with on-farm structures. The simple presence of a structure does not necessarily result in a buffer zone, as the structure may not be continuously occupied.

Other methods of mitigating large buffer zones in California include switching to different application methods, switching to different formulations, and switching to non-methyl bromide fumigants that have smaller or no buffer zone regulations in place. In California, methyl bromide/chloropicrin use is already streamlined for existing buffer zones while maintaining an adequate level of product efficacy. Any additional buffer zone restrictions over and above the current methyl bromide distances will a cause severe economic impact.

- **Growers and/or other stakeholders, please comment on the proximity (e.g., in meters or feet) of residential or other occupied areas that are located near fields that are treated with soil fumigants. Please comment on the density of these areas within the proximity of application blocks (i.e., 1 or 2 homes or subdivisions of multiple houses).**

Proximity will vary by region and crop. Most farms have at least one house located on-farm. In areas such as southern California, housing developments may border the treated field. In areas such as northern California, where urban pressure is not as severe, several houses may be located on different sides of a treated field.

- **Specify whether fumigated sites are owned or leased by growers.**

This depends on the crop and region. Undoubtedly, many growers across the US operate on lands they own. However, in some areas, such as coastal California, the leasing of land by growers from landowners is very common, and it is typically on a year-to-year basis. In some cases, growers do not know which fields they will be using until late in the year, making their fumigation window very narrow. In these cases, which are not uncommon, forcing growers to subdivide larger fields into smaller application blocks presents difficulties in time management. Crops often have optimum planting dates, and any deviation from these dates will result loss of acreage and reduced yields.

- **EPA proposes setting a buffer zone for fumigants based on the worst case scenario (fixed buffer zones). Applicators should comment on the cost and inefficiency of this "one size fits all" approach.**

Unless the fixed buffer zone is manageable, it can present a serious burden to growers. In addition, the use of GAPs should be incorporated as a means to reduce buffer zone distances. There are many, site specific factors that impact emissions and movement of fumigants. Placement of the fumigant, soil type and moisture content, sealing techniques, covering mulches and, potentially, chemical scavengers, may all affect concentrations of fumigants around the application site. Buffer zones are a relatively crude mitigation tool. If worst-case buffers are imposed, significant production acreage will be lost and significant costs will be incurred, without any corresponding health or environmental benefit. Buffer zones do not reduce emissions and large, fixed buffer zones do not encourage good agricultural practices that can have many ancillary benefits. Scenario-based buffer zones are strongly preferred over a large fixed buffer zone.

- **If scenario-based buffer zones were required by the Agency, please provide increments of application rates and field sizes that should be reflected in buffer zones look-up tables.**

If scenario-based buffer zones were required by the Agency, the CMTF supports application rate increments of 25 pounds at 5-acre increments in the look-up buffer zone tables. However, as noted above there are many factors that impact emissions other than application rates and field size. Imposing buffer zones solely on these two variables will result in unnecessary burdens on growers and will do nothing to encourage good agricultural practices. A system that recognizes the impacts of GAPs would provide greater benefits by reducing emissions and placing less of a burden on growers.

- **EPA proposes allowing site-specific buffer zone distances to be based on the results of modeling performed by applicators, registrants, growers, or other persons using site- or regional-specific conditions (e.g., using local weather data).**

Determination of site-specific buffer zones would allow for a more refined buffer zone for growers, however it would not be as effective as GAPs. However, to the extent EPA uses buffer zones it should adopt a policy that allows for monitoring data and models to cover geographic regions or other areas of similar climate patterns. Regional or sub-regional studies to represent distinct areas would ensure that the most applicable meteorological conditions are used. Models have been developed that facilitate assigning a range of values to various site specific parameters, such as soil depth, soil moisture, the effect of mulches, etc. GAPs that involve manipulating these parameters to reduce emissions could lead to more tailored and smaller buffer zones for each application.

- **Minimum Buffer Zones. Comments should address whether EPA should impose a minimum buffer zone for all fumigant uses to address potential variability in emissions rate over a field and other factors not accounted for by its computer model.**

Minimum buffer zones are unnecessary. The computer models already integrate worst-case scenarios such that emissions variability is accounted for and addressed. In some areas, depending on the application rate and method, no buffer zone may be needed, so a required minimum buffer zone would be a burden in these instances. In most cases, there is already a minimum buffer zone of 10-30 feet or more, as there is typically an access road around the field to accommodate the movement of farm machinery.

- **Occupied Structures. EPA proposes allowing buffer zones to contain structures (e.g., homes or other buildings) that are normally occupied if certain conditions are met.**

Allowing some structures to be intermittently occupied within a buffer zone should be allowed, as in many cases it may be impossible for all types of buildings to be unoccupied for long periods of time. These structures could be sporadically occupied and not pose a significant risk. These include sheds, barns, workshops, garages, storage buildings or carports. Intermittent access to homes should also be allowed during daytime hours.

- **Are there any additional exemptions that the Agency should consider?**

Exemptions should be considered for tree-site applications, raised-tarpaulin nursery fumigations of one acre or less, potting soil, greenhouses and similar structures. The amount of chloropicrin used in these situations is small, and, thus, the risk of potential exposure is very low.

- **Will having both inner and outer buffer zones be practical and feasible?**

Requiring inner and outer buffer zone system would result in an overly complicated system. It will not be practical or enforceable in states other than California. Due to the excellent warning properties of chloropicrin, having an inner and outer buffer zone is not necessary.

- **The Agency believes that it may be prudent to require additional protective measures for schools, child/adult day car facilities, hospitals, nursing homes, prisons, and other sensitive sites.**

The revised risk assessment already includes safety factors that take into account the most sensitive individuals in a population, so there is no rationale for the Agency's suggestion that it may be prudent to require additional protection for some types of sites.

Current labels and work practices already require that the site and immediate surrounding area be cleared of people (except the fumigation crew) when the fumigation is in progress.

- **Are there other additional data or citations for data and information related to emission reduction or pest control not listed in the risk assessments or Appendix B?**

The citation list appears to be current. However, there are many publications each year that describe new or novel emissions reduction technologies. For example, the Methyl Bromide Alternatives Outreach (MBAO) Conference at the end of October 2007 had many presentations on new emissions reduction techniques, and the CMTF looks forward to discussing some of these with the Agency. The effect of any new mitigation measure on fumigant efficacy should also be carefully examined before the measure is included on labels.

- **For growers that are currently using one or more of these tarps, how did the use of these tarps affect rates or efficacy? Please specify the fumigant you applied and whether you used LDPE, HDPE, high barrier films, or metalized tarps.**

Tarps are frequently used for shallow applications of chloropicrin. In California, tarps that are required for shallow applications of methyl bromide are typically used for chloropicrin. Only HDPE (high-density polyethylene) tarps that have a distinct permeability range are currently allowed. Please refer to California Department of Pesticide Regulation (CDPR) website for permeability requirements of tarps used for methyl bromide.

Most states have no regulations in place on the type of tarps that can or should be used. In these states, growers have started testing other film types, such as multi-layer LDPE, VIF, and metallic films. To the best of CMTF's knowledge, these other films are only in the experimental phase and are not poised for wide-spread adoption. Many of these experimental films have logistical issues that need to be resolved. For example, metalized films currently are only available in bed-sized rolls, and so are unavailable to applicators or growers who utilize the broadcast (i.e., flat-fume) application method. Tarp disposal and recycling may be difficult for some of these high retention films.

Not all shallow applications of chloropicrin require tarps. For example, growers using lower rates of chloropicrin on crops where the profit margin does not allow the extra expense of tarps should not be required to use tarps, as long as other application criteria are met. *See* the Good Application Practices and Field Emissions discussions in Section II.

Also deep applications (18 inches or greater) of chloropicrin should not require the use of tarps, as the depth of injection itself is a mitigation measure. Deep injections have lower emissions profiles for all fumigants. However, many crops cannot be deep

fumigated, as the specific pathogens or pests may reside near the soil surface. In these cases, only shallow applications of chloropicrin or other fumigants are effective in controlling near-surface pests.

- **Growers that are not using these tarps and researchers, please provide comments on the feasibility of using tarps or upgrading to tarps that have increased emission control. Also include information on effect of tarps on rates and efficacy.**

Tarps can be helpful in reducing peak emissions such that the air concentrations of the fumigant are attenuated during and after application. However, there are a number of field practices that also reduce emissions and that do not require tarps. Injecting the fumigant deeper into the soil serves the same purpose as tarps in that peak and total emissions are reduced. Deep-rooted crops, such as orchards, vineyards, and some nurseries, require deep injection to ensure pest control in the soil profile where the roots will eventually grow. Tarps should not be required for deep applications, as they are unnecessary and presents a serious economic burden to growers of deep-rooted crops. Additional rate and efficacy studies are needed to study the new highly retentive tarps recently introduced.

- **Please comment on potential problems with disposing of used tarps, including cost and availability of tarps. Are there any fees/costs associated with disposal in your area? Are there any recycling programs for tarp materials?**

Much of the HDPE tarps used in California are collected and shipped to China for recycling. It is not cost effective to recycle tarps in the U.S., due to the extra processing steps required to remove the dirt, seam glue, and other field artifacts. In California, some local waste management agencies, with the encouragement of the California Integrated Waste Management Board, have increased fees for disposal of tarps and other agricultural plastic. This trend is expected to continue, involving more and more local agencies. VIF and metalized tarps are currently not recyclable, due to the mixed composition (polymer layers for VIF and coatings for metalized) of these tarps.

- **EPA understands that historically there have been problems with gluing VIF sections together. Have newer generation VIF tarps, metalized tarps, and glues addressed this problem?**

VIFs still have gluing issues. Some companies have been able to glue VIF using custom formulations with reduced solvent content, but these glues are very difficult to work with and can create other problems. For example, if the glue spray is interrupted, the nozzles become clogged, forcing the applicator to stop mid-application to take corrective measures in the field, which could result in a potential worker exposure hazard since the fumigation is still in progress. VIFs have other problems as well. The best VIFs tend to have a nylon or similar middle layer sandwiched between layers of HDPE. It is this middle layer that provides the greatest emissions barrier. However, these middle

layers are typically not capable of handing the mechanical stress associated with laying a tarp in the field. HDPE tarps stretch, which accommodates the mechanical stress during tarp installment. VIFs do not stretch well, which disrupts the integrity of the crucial middle layer, or they simply sheer (split) outright from mechanical stress. If the middle layer is distorted, broken, or otherwise impaired, or if the VIF splits outright, then the gas-retention benefits of VIF are nullified. Unless VIFs can be made that can be glued, laid properly, and can be recycled, it would be better to continue using HDPE tarps where tarps are a useful emissions reduction tool. It is also important to note that while a tarp may be qualified as a "VIF" during a laboratory permeability test, this tarp have behave entirely different in the field due to temperature fluctuations, mechanical stress, and other effects.

Metalized tarps are currently only available in bed-width sizes. The consistency of metalized films at reducing emissions is also in question, as there currently are not enough studies yet done under varying field conditions to confirm that metalized films perform consistently with different soil types, temperatures, and fumigants.

Regardless of the technical specifications of highly retentive tarps, it is important to realize that the use of these tarps may present a worker exposure hazard since there tends to be a build-up of fumigant under the tarp that can be released over a short period of time during the tarp cutting phase of tarp removal or hole punching activities on pre-formed beds. Requiring that tarps stay on for a longer duration (e.g., 10-14 days instead of 5-7 days) may not be a practical solution, as the glue seams on even standard HDPE tarps end to degrade within 5-7 days.

- **For what types of application methods would water applications effectively reduce off-site emissions?**

The use of water seals to reduce field emissions has not been shown to be effective unless multiple additions of water are applied. Increasing pre-application moisture is much more effective than post-application water seals. In general, water seals would only be an option where: (1) the irrigation equipment (sprinklers) can be deployed before the fumigant application, as in the case of some bedded applications and (2) there is an ample water supply. However, in many areas, such as the San Joaquin Valley of California, the water supply is limited and water costs are very high. For broadcast applications, the use of post-application overhead-applied water seals is impossible since one cannot install sprinkler systems over broadcast tarped fields;

- **Can water applications be effectively used to reduce emission from other fumigants besides the MITC-generating fumigants?**

Preliminary research by the USDA-ARS suggests that water seals have limited efficacy in reducing emissions. Adjusting pre-application moisture is much more effective in reducing emissions.

- **For which fumigants can compaction sealing effectively be used to reduce emissions? To the extent possible, please cite supporting data and/or references.**

Compaction sealing is common for all non-tarped broadcast chloropicrin applications. However, compaction cannot be done during tarped broadcast applications due to spatial limitations on tractors fitted for simultaneous tarping. For bed applications, bed listers and shapers provide adequate surface compaction.

- **When compaction is used, please provide a detailed description of the process (e.g., rollers or other devices); amounts of pressure needed; limitations based on soil type; moisture content; and injector type/depth.**

Ring rollers and cultipackers are implements pulled by the tractor that immediately erase the chisel trace near the soil surface, as they crush remnant clods, remove air pockets, and press down small stones and other surface artifacts from the shank injection process. The sheer weight of these metal implements is sufficient to accomplish the compaction. Light soils are easily compacted, whereas heavy soils need to be adequately prepared before application to assist the compaction implements. Moisture effects on compaction vary by soil type, but in general, moist soils aid broadcast compaction by reducing pore spaces and act as a binding element for sandy soils during bed injection and formation.

- **EPA proposes to limit applications to daylight hours when atmospheric conditions favor better dispersion.**

All field applications of chloropicrin are currently conducted during daylight hours.

- **How could fumigators, fumigant distributors, and/or growers ensure that nearby growers are not fumigating within the same time frames?**

Providing prior notification to occupants of adjoining properties within a buffer zone will be sufficient to ensure that no concurrent applications occur.

- **Size of Application Blocks. Please describe scenarios that require application blocks of greater than 40 acres. For these scenarios, would it be feasible subdivide the application blocks into smaller areas, to be treated on different days?**

In California, shank broadcast applications are limited to a 40-acre per day application block limit for methyl bromide/chloropicrin mixtures. In other states, there may be no regulations on maximum application block size, but there are simple logistical limitations as to how many acres can be fumigated per day. If the application requires tarps, then 40 acres is a typical maximum treated area due to the time involved in laying

tarps. If the fumigant is applied deep (18 inches or greater), 40 acres per day may be sufficient. For some crops, especially those that receive low application rates and utilize shallow, non-tarped application methods, over 40 acres per day may be possible. Some applications to bedded crops can also be greater than 40-acre per day, however, the treated area (percent of treated ground per acre) is typically 65% of the total area. The Agency should refer to specific comments supplied by commodity groups and growers.

- **Please estimate the quantitative impacts of limiting application blocks to the following sizes: 40 acres, 40 to 60 acres, 60 to 80 acres, and greater than 80 acres.**

For methyl bromide/chloropicrin use in California, 40 acres per day is the current limit. For other states and other fumigants this restriction may not be practical. If GAPs are utilized, the need for application block limitations may be eliminated. The Agency should refer to specific comments supplied by commodity groups and growers.

- **To what extent are workers who are currently required to wear respirators fit-tested, medically qualified, and trained? Please specify if fit testing is qualitative or quantitative.**

In California, respiratory protection is required any time a worker handles or applies methyl bromide/chloropicrin mixtures or 1,3-D/chloropicrin mixtures. Applicators must be medically qualified, fit-tested and trained.

- **What procedures, if any, should the EPA require to ensure that workers who are required to wear respirators are fit-tested, medically qualified, and trained (e.g., require on all labels, recordkeeping, etc.)?**

Adequate enforcement already exists for label-required PPE, which includes respirator restrictions.

- **Fumigators or growers, please describe what air monitoring is currently performed during and after each fumigation application. Please also include measurement method(s) as well as LOQ.**

For chloropicrin use in California, no monitoring is required during application. Chloropicrin worker exposure studies indicate that the warning properties of chloropicrin provide adequate protection of workers during normal application practices. Air monitoring is only required when reentry of a treated field occurs before the re-entry interval has elapsed, such as when a tarp needs repairing. Detector tubes, such as Matheson-Kitagawa tubes which change color at a specific air concentration, are used for post-application air monitoring and field re-entry activities when necessary.

- **Agency is considering: a minimum time between application and tarp cutting (e.g., 7-10 days); use of respiratory protection; or the use of mechanical devices (e.g., all-terrain vehicles with cutting implements attached). In addition, if the tarp is to be removed within 14 days of application, the Agency is considering that tarps be cut (but not removed) at least 24 hours prior to tarp removal.**

The chloropicrin air monitoring studies conducted by the CMTF included a 5-day tarping period. This is sufficient for chloropicrin applications utilizing the current tarps approved for methyl bromide/chloropicrin mixtures. Simply extending the tarping duration by several days is not an easy solution to the potential for exposure spikes to tarp cutter when high-barrier films are used. In windy areas, even HDPE tarps can be lifted at the glue seam due to environmental deterioration. In these areas, keeping the tarp down for more than five days can be problematic. Tarp glue technology needs to be developed to address the effects of environmental stress on the binding properties of glues used under field conditions. Respirators should only be required if the Agency's level of concern will be exceeded during the tarp cutting and removal process. All-terrain vehicles are commonly used by professional tarp removal services in California, and a 24-hour waiting period is required between tarp cutting and removal for methyl bromide/chloropicrin applications in California.

- **What post-application activities are performed within the 7 to 10 day period following fumigant applications?**

Post-application activities for chloropicrin are restricted to tarp cutting and removal, or in the case of a tarp being damaged, tarp repair measures. However, additional tasks may be performed and are crop specific, such as field cultivation or bed listing.

- **What impact, if any would result from extending the current entry-restricted period?**

Specific impacts on extending the re-entry period are crop-specific and the Agency should rely on commodity group/grower comments.

- **The Agency is considering prohibiting application methods and/or practices that have been shown to have high emission potential or that can lead to risks that exceed the Agency's level of concern.**

Eliminating or restricting application methods should only be a last resort. For all application methods of chloropicrin, appropriate GAPs have been supplied.

Site-specific fumigation management plans are a potentially valuable risk reduction option. Such plans generally require the fumigator to engage in good planning to ensure safe and effective fumigation with adherence to GAPs and adequate buffer zones, should they be necessary. Although formal written plans are not currently imposed as a requirement on chloropicrin product labeling, fumigators already use

planning and monitoring to mitigate risk. The CMTF generally supports the development of FMPs for chloropicrin. The list of sample elements provided in the options document goes well beyond what should be necessary to ensure a good planning process. The agency should simplify the FMPs and limit the elements to those that are practical and necessary.

- **Besides California where worksite plans are required to obtain a permit, to what extent are fumigators currently using FMPs?**

Although FMPs could be a workable risk mitigation options, the "Worksite Plan" approach in use for methyl bromide applications in California is a very burdensome system. Most, if not all, other states may not have the regulatory infrastructure to accommodate that type of system. As such, the California system should not be adopted nationally, as it represents considerable a financial and personnel burden to state and local agencies. If the concept of an FMP is adopted, it must be implemented as a self-certifying measure. Moreover, the CMTF encourages the Agency to streamline an FMP template to instruct fumigators on the elements that should be included in such plans.

- **Should the fumigator/applicator be the responsible party for all aspects of the fumigant application process in regard to label requirements including tarp cutting and removal?**

The applicator cannot shoulder the responsibility for all aspects of the fumigation process, as in many cases there is an existing division of duties among different parties. Therefore, there must be a division of responsibility among the parties involved. The grower should be responsible for ensuring that the proper soil and field preparation management practices are completed, as well as any neighbor notification measures (if adopted) and completion of any required FMP. The applicator should be responsible for ensuring that the field preparation practices are completed and appropriate, that the product labels and directions for use are followed, and that GAPs are employed and customized for the particular field conditions and fumigant to be used. The grower should assume responsibility of post-application activities, such as ensuring the tarps (if used) remain intact and enforcement of the re-entry period. The grower and applicator should coordinate in the case of a tarp problem, such as a tarp seam lifting or otherwise needing repair. Tarp cutting and removal can be done by the grower, the applicator, or even a third-party. In California, there are companies that specialize in agricultural tarp removal as their sole business service. In other states, growers typically remove their own tarps. If used, the tarp removal service acts independently of either the grower or the applicator, and assumes the responsibility of ensuring that all tarp removal requirements are fulfilled. This includes the physical splitting of the tarps, waiting for the aeration interval to pass, and the final physical removal and disposal of the traps from the field. Because tarp removal businesses are separate entities from the custom applicators, there must be a division of responsibility. Commercial applicators cannot be responsible for a service that another company is hired to do as an independent contractor.

- **What are the pros and cons of allowing the responsible party duties to be shared among different parties (e.g., fumigator, growers, and other parties)?**

The advantage of allowing the responsibilities to be shared among different parties is that each party's responsibility will be clearly understood. The CMTF is not aware of any situations where the division of responsibilities has created a problem.

- **The Agency is considering requiring that the person supervising the fumigation, or the responsible party, certify in writing that he/she has reviewed the FMP and that it addresses all elements required by product labels, and that all decisions on the fumigation process, buffer zones, and PPE are appropriate and protective.**

As the Agency points out, most States do not have an infrastructure like California's with county agricultural commissioners. Therefore, if any certification of FMPs is adopted by the Agency, the CMTF strongly supports self-certification, as this is the only feasible approach for nationwide uniformity.

- **The Agency solicits comments on whether to require reporting and tracking of fumigant applications as part of a site-specific FMP.**

Most fumigators already keep detailed records of their operations as required under USDA regulations for certified applicators. However, a uniform program, developed in cooperation with fumigators, could be implemented to ensure compliance and proper use of chloropicrin. It is likely that all growers who fumigate their field(s) already do some form of tracking already, as it is a crop production (business) expense for accounting purposes. Mandatory reporting of all pesticide applications is obligatory in California. However, it is doubtful that the USEPA or individual states have the infrastructure to receive, review, store, and track the thousands of fumigant use reports that would arise from such a reporting requirement each year. Nationwide fumigant reporting and tracking may not be enforceable without a county system such as California has. It is not clear how these reports would benefit growers or the agencies involved.

Warning signs are already required when sites are fumigated. Applicators are required to make certain all non-authorized personnel have vacated the site.

- **What information not listed above should be provided to potential bystanders? Include rationale for providing information.**

The information listed above is adequate notification.

- **Who should be notified prior to applications?**

Owners of adjacent properties should be notified only if the buffer zone extends onto their properties. If the buffer zone does not extend onto the adjacent property, then

no notification should be necessary, as the buffer zone will provide an adequate notification distance. On-site notification should be limited to posting signs around the treated fields. No legal access to site-specific FMPs should be allowed for non-government third-parties including the general public or other commercial applicators, as FMPs will contain confidential business information.

- **Where and when should notification be given?**

Written notification to adjacent property owners within 7 days of the application is adequate. If the buffer zone does not extend onto the adjacent property, the re-entry posting of the field perimeter should be only the notification required.

- **How often should notification be given?**

Once per year prior to application.

- **What is the best way to provide this information?**

Written notification to adjacent property owners within 7 days of the application could be performed if the buffer zone extends on the adjacent property. If the buffer zone does not extend onto the adjacent property, the re-entry posting of the field perimeter should be only the notification required to warn against premature reentry.

- **EPA proposes that applicators of chloropicrin and other restricted-use fumigants be required to take specific training on the safe handling of soil fumigants. The Agency suggests the training program could be developed either by registrants or state agencies based on programs already being used by such agencies and industry.**

The need for specialized training only applies to applicators who conduct these activities infrequently. Custom applicators that specialize in soil fumigations would not benefit from such training exercises, as in-house training is already conducted that is more specialized than a general training seminar conducted by a state or local agency. For non-specialized applicators, a Soil Fumigation Manual would serve as a more efficient and effective tool for educating these applicators.

- **The Agency requests specific examples of a) GAP risk reduction strategies for chloropicrin, (b) information where the employment of GAPs would have prevented incidents, as well as (c) ways to make sure GAPs are followed.**

CMTF has provided a description of GAPs for chloropicrin in Section II above. Information regarding how GAPs might have prevented an incident is discussed in Section V below. Finally, the most effective way to have the GAPs followed is to include them on the label. Where there are GAP options, a fumigation manual may be helpful for those applicators or growers who do not specialize in fumigant applications.

- **Should GAPs apply to all, or only some, of the fumigants?**

GAPs should apply to all fumigants, as the proper implementation of GAPs would serve to reduce or even eliminate the need for buffer zones for many fumigant applications. GAPs serve a dual purpose in that their objective is to increase the time in which fumigants stay in the soil. As such, GAPs simultaneously reduce emissions and increase product efficacy, as a longer soil residency time equates to greater control of target pests.

Although GAPs should apply to all fumigants, not all of them are appropriate across the different fumigants or even for the same fumigant applied by different methods and for different crops. Each fumigant has its own physiochemical properties and while there is some cross-over in application methods for some fumigants (methyl bromide, chloropicrin, and 1.3-dichloropropene), other fumigants (metam sodium, dazomet) have considerably different application methods.

Many of the recommended GAPs are either already on product labels or followed by applicators as a matter of efficacy and product stewardship. The inclusion of additional fumigant-specific GAPs onto product labels is an achievable and simple way to their ensure adoption. As a whole, GAPs should be mandatory, but the implementation of specific GAP options must remain flexible so that applicators can customize the application to the particular needs of the crop to be grown.

- **What changes, if any, would result if GAPs were required?**

Most of the GAPs that are listed are commonly used by applicators and growers. A smaller buffer zone or elimination of the need for a buffer zone would be a powerful incentive for the adoption of GAPs. GAPs would not only reduce the buffer zone distance or need, but many of the measures would also increase the relative efficacy of the fumigant being used. For example, proper soil preparation decreases the off-gassing potential of a fumigant while increasing the fumigant's dispersion and distribution in the soil profile.

- **Should GAPs be advisory or mandatory?**

Relevant and appropriate GAPs should be mandatory, as the proper implementation of GAPs would serve to reduce or even eliminate the need for buffer zones. However, EPA must understand that in some cases the relevant GAPs vary by region, crop and pest.

- **EPA is considering developing a manual to provide guidance to fumigators, growers, and other stakeholders on how to conduct soil fumigations that are in compliance with EPA labels. The manual could potentially include guidance on how to determine buffer zones with site-specific modeling and monitoring data.**

A Soil Fumigation Manual would be useful for those individual growers who perform their own fumigant applications, particularly if these events are only annually or otherwise sporadic. For custom applicators that specialize in fumigation, a Manual would be of less value. If a Soil Fumigation Manual will be developed, EPA would benefit greatly from discussions, feedback, and review of the Manual by custom applicators that perform these tasks on a daily basis, as well as federal and university researchers. When completing a FMP, the grower (or applicator) could state that the Soil Fumigation Manual had been reviewed prior to the application.

- **EPA is considering requiring fumigant registrants to conduct a stewardship program or together with the other fumigant registrants.**

The CMTF believes that a Soil Fumigation Manual will be much more effective than a stewardship program. The cost and personnel commitment to sponsor stewardship meetings would be a significant burden for most registrants, and the need to travel to these meetings would be equally costly for the growers. The objectives EPA states as possible inclusions of a stewardship program are more readily achieved via the Soil Fumigation Manual approach. Educational/training materials can be included in the Manual in both English and Spanish (or any other language as needed), that are designed to educate workers regarding work practices that can reduce exposure to fumigants, including:

- Good agricultural practices (GAPs) that reduce emissions and minimize bystander exposure;
- The recognition of symptoms associated with fumigant exposures; and
- How to seek medical attention in the event workers experience such symptoms.

IV. ECOLOGICAL FATE AND EFFECTS

EFED has used assumptions for its modeling that are not consistent with real world application parameters for chloropicrin. Moreover the models have various limitations which EFED consider as "uncertainties." The combination of incorrect assumptions and uncertainties have resulted in an overly conservative risk assessment.

A. Estimates Are Overly Conservative

Adequate conservatism is already accomplished via the Level of Concern (LOC) index. For example, for aquatic species exposure, the Endangered Species LOC is 0.05. This equates to a safety margin of 20X above the model-predicted peak Estimated Environmental Concentration (EEC). Given the numerous assumptions and limitations of the model, the safety margin quickly rises to 100X or more, since all or most of what EFED considers "uncertainties" overestimate the EECs.

The limitations of the models EPA currently relies on and the Agency's inaccurate estimates of off-site environmental concentrations of chloropicrin, could result in the significant loss of farm acreage to be treated with chloropicrin for successful control of injurious plant diseases and pest organisms. Just as buffer zones should not be the first measure to address human exposures, ecological set-backs are not the best approach for addressing ecological issues. The cost to growers of lost production acres through erroneous set-back distances could be enormous. CMTF seeks to work with EFED to accurately assess the environmental fate of chloropicrin when applied under real-world use practices and the impacts of such applications.

Therefore, in addition to our previous Phase III comments on the Ecological Risk Assessment for the Reregistration of Chloropicrin, CMTF offers the Agency specific comments to the responses made by EFED on our Phase III comments.

B. Species Comments

1. Terrestrial Exposure and Modeling

(a) Acute Terrestrial Exposure

EFED Comment: The CMTF's calculated RQ was based on monitoring data at 60 feet away from the edge of the field. Reported RQ in the chloropicrin chapter was based on the estimated air concentration at the edge of the field. If RQs are calculated based on ISCTS3 estimated air concentration values at 25 meters from the edge of the field (Table 5), they will be comparable with CMTF's RQs, and below the acute risk LOC for endangered species. However, EFED is concerned with ground-level residues at the edge of fields.

CMTF Response: EFED is incorrect in saying that the CMTF-calculated RQs were based on monitoring data taken at 60 feet from the edge of the treated field. The CMTF calculated RQs were based on monitoring data taken from the **center-of-field** flux masts, not at 60 feet away from the edge of the field and, as such, these data represent worst-case scenarios of wildlife exposure where the animal enters directly onto the treated field. The seven graphs previously submitted by CMTF demonstrate that the concentrations of chloropicrin at 15, 33, and 55 cm heights **on the field** are well below the concentration at which the RQ would exceed any LOC, even under the most conducive conditions for off-gassing (high ambient temperatures, low soil moisture, non-tarped plots in Phoenix; MRID# 441492-01).

EFED appears to have relied on the HED Human Health Risk Assessment of this study (MRID# 441492-01), where off-site data (60-180 feet from the field edge) were used for indirect back-calculation to determine flux rates and model off-site concentrations of chloropicrin. It is important that EFED review the actual study volumes because (1) EFED and HED may not necessarily use the same datasets from any given study, as is the case here; and (2) while it may not have affected the results of their modeling, HED committed numerous errors in its unit conversions from ug/m^3 to ppm (all conversions in all tables on pages 106-167 of the Agency's *Chloropicrin: Revised Human Health Risk Assessment for Phase 5* are off by a 45-fold factor).

Data from MRID# 441492-01 and PRS02004 indicate that the highest on-field air concentrations were 1.470 ppm at the 15-cm height, 0.988 ppm at the 33-cm height, and 0.565 ppm at the 55-cm height. These on-field concentrations are likely upper bound representatives of the concentrations that could be expected at the field edge due to aerial diffusion and dispersion of emissions. When the highest air concentration measured (1.470 ppm) is used along with an LC50 value of 17 ppm (as used by EFED), an RQ of 0.0865 (1.470/17) is derived, which is below the acute risk LOCs for endangered species (0.1), acute restricted use (0.2), and acute risk (0.5). Again, we point out that these LOCs are for oral exposures, as EFED has no LOCs for inhalation exposure.

The use of actual air monitoring data from seven different studies with seven different application methods and/or locations (MRID# 441492-01 and PRS02004) indicate that chloropicrin air concentrations do not exceed the wild mammal LOCs. While these seven studies may not be representative of all end-use sites, the studies conducted in Phoenix should be considered as worst-case, real-life (non-modeled) scenarios.

EFED Comment: The revised risk assessment used both deterministic and ambient monitoring data to estimate exposures to terrestrial organisms that the edge of treated fields. The deterministic approach is based on Registrant's field monitoring data and the use of the EPA's ISCST3 model. Since defining the ISCST3 method, EFED is working with Heath Effects Division (HED) and is considering using additional modeling (e.g., PERFUM model) that allows for the incorporation of actual meteorological data for future assessment.

CMTF Response: CMTF previously commented that while HED considers the ISCST3 model unsuitable as the sole approach to modeling chloropicrin air concentrations for human bystander exposure assessments, since ISCST3 does not incorporate realistic meteorological effects, EFED relied solely on ISCST3 in the Environmental Risk Assessment for Chloropicrin. CMTF continues to encourage EFED to pursue and implement a refined modeling approach which allows for a realistic assessment. If a refined modeling simulation was used, it is likely that the estimated highest concentration of chloropicrin would be a value such that the RQ would not exceed any LOC. In the revised (Phase IV) *Ecological Risk Assessment for Chloropicrin*, the Agency did not use a refined modeling approach to provide a refined risk assessment for wildlife exposure to chloropicrin. However, the Agency did use a refined modeling approach for quantifying chloropicrin air concentration exposure risk to the California Red-Legged Frog (Khan and Felkel 2007). In the *Risks of Chloropicrin Use to Federally Listed Threatened California Red Legged Frog (Rana aurora draytonii)* (Khan and Felkel 2007), the

Agency used the PERFUM model to incorporate more realistic meteorological effects on chloropicrin air concentrations, which is in contrast to the Agency's reliance on the ISCST3 model the Phase IV Ecological Risk Assessment for Chloropicrin. The Agency's results and conclusions from using the PERFUM model support CMTF's position, which is that a refined modeling approach demonstrates that there is no risk to mammalian wildlife even at 0-5 meter radius from the field edge when the CMTF-supported maximum application rates are used in the model (350 lbs/A for tarped applications and 175 lbs/A for non-tarped applications). The Agency should use the same refined modeling approach (PERFUM or equivalent) it used for the Red-Legged Frog risk assessment for the *Ecological Risk Assessment for the Reregistration of Chloropicrin*.

EFED Comment: The CMTF clearly admits that chloropicrin would be highly irritating to wildlife. Nesting birds could experience substantial disruption. Adults fleeing their nests could leave nestlings exposed to heat, cold, and predators, as well as to the toxic effects of chloropicrin.

CMTF Response: Effects of chemicals on wildlife when applied to an agricultural field usually diminish with distance, and chloropicrin is no exception. Thus, it is necessary to examine the likely effects of chloropicrin under realistic application scenarios. As cited above from MRID#441492-01, the maximum chloropicrin air concentrations on the field or at the field edge are likely to be below 1.5 ppm at the ground-level height (15 cm), and even less than this at higher heights (33 cm, 55 cm, and so on; decreasing as height increases). Birds generally have no opportunity to build nesting sites at the edge of treated fields during active farming practices. The field preparation measures, such as soil tilling, performed prior to fumigant application would have already disturbed these animals and discouraged close-by activity, including nesting. Nesting sites could be located some distance away from the field, but emitted chloropicrin vapors would disperse, dilute, and degrade rapidly, as measured in the offsite monitoring data from this same study. The CMTF maintains that chloropicrin field use as a soil fumigant poses no risk to avian species.

(b) Chronic Terrestrial Exposure

EPA Comment: The potential for repeat and/or continuous exposure of wildlife may be similar to that identified by HED for humans. The exposure may not be negligible for wildlife.

CMTF Response: HED concluded that chronic exposure to chloropicrin by human bystanders is unlikely. The same conclusion should be reached by EFED, based on the available data. EFED already acknowledges that the comparison of the previously cited maximum ambient air residues (0.000014 mg/L) to the 0.003 mg/L NOAEL (rabbit inhalation developmental toxicity) implied that ambient air residues are likely to be well below developmental effects levels for mammalian species. EFED should adopt the same conclusion for chronic avian exposure. Ambient chloropicrin air concentrations are sufficiently low to be protective of chronic risk to all wildlife species. For example, in order to exceed the chronic risk LOC of 1, the NOAEL for an avian species would have to be equal to or less than the EEC which, based on CARB monitoring data would be a

maximum air residue of 0.000014 mg/L. It is unreasonable for EFED to assume that the NOAEL for any avian species could be equal to or less than 0.000014 mg/L. Even if avian species were 100 times more sensitive than mammals (e.g., a NOAEL of 0.00003 mg/L), the RQ (0.000014/0.00003 = 0.467) would still be well below the LOC of 1.

As cited in our previous comments, ambient air concentrations of chloropicrin have been measured over extended periods of time in high-use areas during the active fumigation season, and the results indicate that chloropicrin concentrations from multiple, simultaneous and/or sequential applications even in a relatively small area are well below any level of concern for chronic risks to wildlife due to the rapid environmental breakdown of chloropicrin. As EFED noted in its Risk Assessment, the California Air Board (2004) demonstrated that 8-week average concentrations of chloropicrin ranged from 406 ng/m3 (60 pptv) to 2270 ng/m3 (340 pptv) in rural residential areas of Santa Cruz and Monterey Counties, which are two of the most heavily fumigated areas in the country and so represent high-use scenarios. During the eight-week monitoring period (September 8 to November 8, 2001), there were 659 soil applications totaling 1,049,710.3 pounds of chloropicrin applied to approximately 8,164.5 acres (CAL-EPA online Pesticide Use Report database). These counties represent high-density chloropicrin usage, and even then the ambient air monitoring results demonstrated low chloropicrin air concentrations and, therefore, low sort-term and chronic exposure risk to wildlife. CMTF also notes that the highest 8-week average (0.00034 ppm) is far below the conservative human-protective values used by HED for Short- and Intermediate Term Inhalation Exposure (HEC = 0.008 ppm) and Long-Term Inhalation Exposure (HEC = 0.004 ppm) for Non-Occupational (bystander) risk. For these reasons, it is not reasonable to conclude that there would be significant effects on terrestrial wildlife under application practices now routinely performed for chloropicrin.

2. Aquatic Exposure

EFED Comment: Once EFED receives and reviews these toxicity data for the aquatic organisms, EFD will consider refining the aquatic exposure and risk assessment.

CMTF Response: The EPA has assigned the following MRID numbers for the three aquatic studies as follows: MRID#47102101 (Acute toxicity to *Daphnia magna*); MRID#47102102 (Acute toxicity to fish; Rainbow Trout); and MRID# 47102103 (Acute toxicity to Bluegill Sunfish).

EFED Comment: EFED's methods for estimated surface water concentrations use standard modeling procedures and input parameter guidance that have been subject to rigorous internal and external quality assurance review.

CMTF Response: These reviews largely, and possibly exclusively, may have consisted of generic assessments to develop a broad tool, such as PRZM/EXAMS. However, the reviews, standard modeling procedures and input parameter guidance likely did not address the need for additional model refinements required for a valid assessment of soil fumigants, which are used and applied in manners very different from most other

pesticides and have physiochemical properties unlike most other pesticides for which PRZM/EXAMS may be more useful (e.g., foliar-applied insecticides).

The *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency: Endangered and Threatened Species Effects Determinations* (2004) document clearly states that, "…*that the ecological risk assessment process within OPP may, on a case-by-case basis, incorporate additional methodologies, models, and lines of evidence that are technically appropriate for risk management objectives*."

CMTF encourages EFED to look at additional models now available, such as CHAIN_2D, for a more refined assessment of wildlife exposure risks. EFED has acknowledged that the PRZM/EXAMS models likely overestimate the Estimated Environmental Concentrations (EECs) for chloropicrin, yet no estimate has been given of the magnitude of this overestimation. Also, this overestimation appears not to have been taken into account in the models by correcting, amending, or adjusting either the model input parameters or the context in which EECs are interpreted. To simply note these errors, address them as ambiguous "uncertainties," and take no further action to correct these obvious errors does not provide an accurate assessment of the risk or lack thereof. The overestimations are the result of numerous and compounding factors, including basic model limitations, erroneous scenario assumptions, and departures from the reality of the physical world, resulting in predicted EECs that should not be considered valid or useful for risk management decisions. The five main sources of modeling error are discussed below.

Chemical Volatilization and Temperature Effects: This uncertainty overestimates the EECs. EFED acknowledges that the PRZM/EXAMS model likely overestimates the Estimated Environmental Concentrations (EECs) for chloropicrin due to its inherent limited capabilities in capturing the partitions of volatile chemicals, such as chloropicrin, in air, water and sediment. Simply stating that the model has these limitations does not address the error, nor is it a valid approach to simply chalk this error up to an ambiguous, undefined "uncertainty" that requires no further evaluation. A more appropriate approach is to account for these limitations by adjusting, to the degree possible, the model input parameters, operative features, or other means of correction. Additionally, it appears that a constant soil temperature of 25^{O}C was modeled, which likely underestimates actual soil temperature in many areas. This is an important parameter for EFED to reconsider, since available research demonstrates that in-soil degradation of chloropicrin is greatly enhanced by increasing temperatures. Gan et al. (2000) observed that at a soil temperature of 50^{O}C, the degradation rate of chloropicrin was 8, 11, and 7 times greater than at 20^{O}C for three different soils. At 40^{O}C or greater, the soil half-life of chloropicrin ranged from 0.05 to 0.7 days (1.2 to 16.8 hours). Soil temperatures also would be significantly higher during tarped applications than non-tarped applications, leading to a significant increase in soil metabolism. EFED should model the effect of higher soil temperatures on soil degradation rates and predicted EECs.

Tarping Effects: This uncertainty also overestimates the EECs. The effects of rain events on treated fields, tarped and non-tarped, are not well established by EFED and are not appropriately accommodated in PRZM/EXAMS modeling. The unknown effect of tarping was acknowledged by EFED, but it does not appear to have been appropriately accounted for in the models. In our meeting with EPA on March 8, 2007, EFED indicated it accounted for tarp effects. However, Waterborne Environmental (Ritter 2007) found no evidence in the model inputs that any adjustments were made to account for the effect that tarps would have on the amount and rate of chloropicrin incorporation into rain water and subsequent field runoff. EFED's position on this issue seemed to be that chloropicrin would still volatilize through the tarps and be captured by rainfall, apparently at 100% capturing efficiency. In other words, EFED appears to have assumed a 100% efficient and instantaneous wet redeposition of chloropicrin vapors through the tarp. If this is an accurate interpretation of EFED's comments during the meeting, there appears to have been no actual mathematical accounting in the agency's calculations to date for the actual effects of tarps. This step should be taken.

In contradiction to EFED's apparent instantaneous redeposition argument, EFED stated elsewhere in the Risk Assessment that (1) the high vapor pressure of chloropicrin results in limited partitioning into water; (2) that rapid volatilization of chloropicrin from water is expected; (3) that if tarping is used to minimize the volatilization, then the loading of chloropicrin through runoff will be limited until the tarp is sliced or removed from the field; and (4) that exposure from redeposition of volatized chloropicrin via precipitation in terrestrial environments is expected to be negligible. These and other statements contradict the assumption of 100% rain capturing efficiency and instantaneous wet re-deposition.

The Agency's approach to handling the effect of tarps on chloropicrin field runoff is not accurate. Researchers have demonstrated that overhead sprinkler-applied water seals, which are similar to rain events, effectively inhibit chloropicrin volatilization (see research presentations by Dr. Ajwa and Dr. Gao at the California Department of Pesticide Regulation's Voc Research Symposium: http://www.cdpr.ca.gov/docs/emon/vocs/vocproj/voc_symposium.htm).
Chloropicrin is also hydrophobic and, as such, a 100% capturing efficiency by rainfall is highly unlikely to occur. EFED's modeling approach is even more hamstrung by the fact that that chloropicrin emissions do not leave the soil all at once, but over several days or more. In addition, chloropicrin is known to partition reversibly from soil, water, and air. Therefore, even if chloropicrin vapors were captured by rainfall, some of the chloropicrin would partition out of the runoff water and back into the air before the runoff entered the water body. Neither EFED nor the PRZM/EXAMS models account for volatilization of chloropicrin from the runoff water. In fact, in the Drinking Water assessment for chloropicrin by the Agency (Reaves et al. 2007), EPA concluded that "*rapid volatilization of chloropicrin from surface water is expected to be an important route of dissipation*", and that "*based on environmental fate data, modeling estimates, and monitoring data, the Agency does not expect the pesticidal uses of chloropicrin to adversely impact ground water or surface water*". This contradicts the conclusions reached by EFED for aquatic species exposure.

Waterborne Environmental (Ritter 2007) used a different, more accurate approach to account for the effects of tarps. In these model simulations, rainfall was turned off until the tarp was removed. In this way, Ritter's modeled tarp effect better reflects reality in that the tarp, being in place during and for 5 or more days after the fumigation application, effectively prevents soil erosion (the rain and soil are not in direct contact, and the tarp confines the soil preventing its erosion and sediment transport) and acts to retard volatilization (such that rapid soil degradation processes can take place). As mentioned above, soil temperatures under tarps are significantly greater than non-tarped fields, resulting in enhanced soil degradation. Therefore, tarps not only prevent direct rain contact with treated soil, eliminating the erosion and sediment movement effects, but also result in considerably less chloropicrin being available for aquatic transport once the tarps are removed. For broadcast applications of chloropicrin, the tarps are in place for 5-7 days. For bedded applications, the tarps are in place during the entire cropping cycle of the crop. For example, on bedded strawberries, the tarp stays on the field from fumigant application through the final harvest several months later.

Chemical Application Method (CAM=8): This uncertainty also overestimates the EECs. PRZM/EXAMS do not appear to be suited for modeling water transport of soil-incorporated fumigants. For example, none of the CAM inputs are representative of how chloropicrin is applied to the field. The CAM input that is the most similar to actual field applications is CAM=8, where the pesticide is injected at 25 cm (10 inches deep) and is assumed to have uniform distribution in the upper 25 cm of soil. However, it is unclear if the CAM=8 input is capable of accounting for the downward diffusion of chloropicrin in soil, which is a very real effect. If the PRZM/EXAMS model assumes that the entire volume of applied chloropicrin is distributed only in the upper 25 cm of soil, then this is clearly inaccurate and it would result in exaggerated EECs. Chloropicrin undergoes some downward diffusion. In fact, soil injection at 25 cm ensures pest control down to a depth of 40+ cm in most soils and soil conditions. Therefore, the CAM=8 assumption should be adjusted to reflect that only about 50% of the applied chloropicrin would be uniformly distributed in the upper 25 cm of soil and available for transport.

Distance from Field to Water Body: This is a fourth uncertainty that overestimates the EECs. The model assumes that there is no distance between the treated field and the water body receiving the runoff. This assumption is not in line with reality since there would need to be at least 10 feet of space between the field and pond, such as an access road that allows for the maneuvering of tractors and other farm machinery. EFED should attempt to account for a distance effect, with and without vegetative groundcover, between the treated field and water body to generate a more realistic and accurate risk assessment.

Inflow, Dilution, and Outflow: This uncertainty also overestimates the EECs. PRZM/EXAMS assume that the runoff water does not add to the total volume of water in the pond, i.e., EFED is unable to account for the dilution effect from the inflow of runoff water. Given that the Pond is a relatively small body of water (1 hectare x 2 m deep), the inflow of runoff that would accompany the pesticide would dilute the EECs by some factor. For example, if it took as little as one acre-inch of rain to induce a runoff event,

then the added water to the pond system would be over 670,000 gallons of water or about a 12% increase in total volume. In reality, one acre-inch of water is unlikely to produce runoff from any field, as this is a typical irrigation rate for growers, and no runoff is experienced. One acre-inch of water would have to fall in a very short period of time to induce runoff, in which case, there would be very little opportunity for chloropicrin to partition into the runoff water and the EECs would be negligible. If it took two acre-inches of water to induce runoff, then the pond would increase by 25% in total volume. EFED should be able to account for inflow water volume and the dilution effect it would have on EECs since this would provide for a more accurate risk assessment. The models also assume that, regardless of the inflow volume, at no time does the pond experience outflow of water.

By ignoring the effect these errors have on the modeling results, EFED has overestimated the risks.

EFED Comment: In the CMTF meeting with EPA on March 8, 2007, EFED noted that the CMTF- and Waterborne-revised aquatic model inputs did not contain all of the needed environmental fate values.

CMTF Response: Revised calculations for selected environmental fate values are presented below. The environmental fate values EFED used in its preliminary freshwater aquatic risk modeling were deficient. Specifically, CMTF questions EFED's derivation and selection of the Aerobic Soil Metabolism half-life value and the calculated Aerobic Aquatic Metabolism half-life values. EFED used an aerobic soil metabolism half-life value of 15.71 days, using data cited from two submitted documents: (1) MRID# 43613901, with a calculated half-life of 10 days; and (2) Wilhelm et al. (1996). The Agency's selection of the aerobic soil metabolism and aerobic aquatic metabolism values and their use in modeling erroneously overestimates the environmental persistence of chloropicrin and its subsequent, "predicted" ability to be mobilized into surface water. A soil half-life value of 15.71 days is inconsistent with actual field experience, as this length of time is longer than the plant-back interval on most product labels for fumigants containing chloropicrin. If EFED's estimate for soil metabolism was accurate, then growers would experience crop phytotoxicity on a regular basis. In reality, growers do not observe phytotoxic effects on the planted crops, including transplanted crops which are particularly sensitive during field establishment. Therefore, EFED's estimated aerobic soil half-life is inaccurate and should be adjusted to better reflect reality.

The principle cause of this exaggerated soil metabolism value (15.71 days) is likely the use of the 10-day half-life value from MRID#43613901. As EFED noted in its evaluation, this aerobic soil study was conducted without supplying the system with continuous flow to remove volatile materials. EFED also commented that this type of system does not closely mimic field conditions where volatilized materials are relatively free to escape. Essentially, in the study system, an unknown amount of volatized chloropicrin partitioned back into the soil phase, thereby resulting in a half-life value (in days) that is longer than would be expected under actual field conditions. Therefore, the 10-day half-life value from this study should be considered upper bound. Recalculating

the half-life value, by accounting for mass loss via volatilization and system removal, would result in a more accurate half-life value.

Other studies support an aerobic soil half-life value that is considerably less than the 15.71 days EFED calculated or the 10 days as calculated in MRID#43613901. For example, Gan et al. (2000) determined the half-life values of chloropicrin at 20^{O}C to be 1.5, 4.3, and 0.2 days in a sandy loam, loamy sand, and silt loam, respectively. At 40^{O}C or above, chloropicrin became extremely liable and half-live values were less than 0.4, 0.7, and 0.05 days for the same three soils. These values are in general agreement with Wilhelm et al. (1997) who reported a half-life of 4.5 days in a sandy loam and 1.3 hours in an anaerobic soil. Gan et al. (2000) also determined the half-lives of chloropicrin in sterilized samples of these same soils that ranged from 2.7 to 13.9 days. However, since chloropicrin does not sterilize soils and because microbial degradation of chloropicrin is an important route of degradation (Wilhelm et al. 1997), these values were not used in calculating a refined aerobic soil half-life value.

The half-life values from Gan et al. (2000) and Wilhelm et al. (1997) are also supported by the half-life values determined in the Terrestrial Field Dissipation study (MRD#43085101), where chloropicrin dissipated with half-lives of 11.6, 16.4, and 33.4 hours from the soil air at the 3-, 6-, and 12-inch depths, respectively, following treatment with 665 lbs a.i./A chloropicrin to a tarped clay loam; and half-lives of 18.0, 20.3, and 28.7 hours from the soil at 3-, 6-, and 12-inch depths, respectively, following treatment with 792 lbs a.i./A to a tarped sand soil in California. Because chloropicrin partitions reversibly between air and soil compartments, a measurement of the vapor phase would reflect what is in the soil phase. The decline in the vapor phase represents a decline in the soil phase. The Terrestrial Field Dissipation Study, therefore, represents the cumulative effect of off-gassing and degradation of chloropicrin during actual field fumigation practices. However, because EFED does not appear to use Field Dissipation data in these calculations, these half-life values were not used to calculate a revised aerobic soil half-life value. This information is presented to support the fact that EFED's original aerobic soil half-life value is incorrect and that other data (Gan et al., 2000) should be included in the evaluation.

For the aerobic aquatic metabolism half-life value, EFED doubled its estimated aerobic soil metabolism half-life value of 15.71 days to derive the aerobic aquatic metabolism half-life value of 31.42 days, according to EPA policy to account for this specific data gap. Because EFED's estimated aerobic soil half-life of 15.71 days is clearly incorrect, EFED's estimated aerobic aquatic half-life value is also incorrect.

Waterborne Environmental, Inc. (Ritter 2007) calculated a more realistic aerobic soil metabolism half-life value of 6.68 days using the student t-test per USEPA guidelines (USEPA 2002), using the following values: 10 days (MRID#43613901); 4.5 days (Wilhelm et al., 1997); and 1.5, 4.3, and 0.2 days (Gan et al. 2000). This estimated half-life value is also an overestimate due to the use of the 10-day value from MRID#43613901, as discussed above. Ritter (2007) then doubled the aerobic soil metabolism half-life value of 6.68 days to derive an aerobic aquatic metabolism half-life

value of 13.36 days per USEPA guidelines. Again this aerobic aquatic half-life value is an overestimate due to the use of the 10-day value from MRID#43613901, as discussed above. A comparison of EPA's original environmental fate values and those that more accurately reflect the actual environmental fate of chloropicrin are presented in Table 11.

Table 11 Comparison of Environmental Fate Values used in the PRZM/EXAMS Freshwater Risk Models

Parameter	Original value used by EPA	Waterborne value
Molecular weight	164.39 g/mole	164.39 g/mole
Vapor pressure 25°C	23.8 mm Hg	23.8 mm Hg
Water solubility @ pH 7.0 and 25°C	1621 mg/L	1621 mg/L
DAIR	4858.6 cm^2/day	4858.6 cm^2/day
ENPY	9.39 kcal/mole	9.39 kcal/mole
Henry's Law Constant @ 25°C	2.05 x 10^{-3} atm M^3/mole	2.05 x 10^{-3} atm M^3/mole
Hydrolysis Half-Life (pH 7)	Stable	Stable
Aerobic Soil Metabolism $t_{1/2}$	15.71 days	6.68 days
Aerobic Aquatic Metabolism	31.42 days	13.36 days
Anaerobic Aquatic Metabolism	0.05 days	0.05 days
Aqueous Photolysis	1.3 day	1.3 day
Soil Water Partition Coefficient	36.05 L Kg^{-1}	36.05 L Kg^{-1}
Pesticide is Wetted-In	No	Sometimes

Model Limitations: As discussed above, there are at least five major error-introducing limitations in EFED's current approach to modeling aquatic transport of chloropicrin from treated fields. These are: (1) limited ability to adequately characterize a volatile chemical and the effects of temperature on volatilization and degradation rates; (2) limited ability to adequately characterize the effects of tarping; (3) limited suitability of the Chemical Application Method (CAM=8) to adequately characterize fumigant soil distribution; (4) the assumption that the treated field directly abuts the water body; and (5) the assumption that the runoff water does not add to the water body volume nor does it dilute the chemical concentration in the water body.

There are at least three approaches for addressing and correcting the shortcomings of PRZM/EXAMS. One approach would be to use a different model, such as CHAIN_2D, that may be more suitable for estimating the environmental fate of chloropicrin, since PRZM/EXAMS is clearly limited in its capabilities. Another approach would be for EPA to have a policy for adjusting the Level of Concern (LOC) values for the various categories of exposure risk when the current models are known to be grossly inaccurate. For example, instead of LOC values of 0.5, 0.1, and 0.05 for acute risk, acute restricted use, and acute endangered species, respectively; revised LOC values could be increased to 0.55, 0.15, and 0.1 for acute risk, acute restricted use, and acute endangered species, respectively. This translates into a conservative adjustment of 0.01 for each of the models' main problems. Given the number of modeling problems and their cumulative degrees of added uncertainty, a proposed revision of the LOC values is

warranted and necessary to provide a more realistic evaluation of aquatic exposure risks from chloropicrin field applications.

The third approach would be to assign an EEC correction factor to the modeled outputs that corrects for obvious overestimations. For example, if each of the five main sources of error were assigned a highly conservative EEC correction factor of 0.02 ppb, then collectively, each modeled EEC would be reduced by 0.1 ppb. Given the number of modeling problems and their cumulative degrees of added uncertainty, a proposed correction of modeled EEC values is warranted and necessary to provide a more realistic evaluation of aquatic exposure risks from chloropicrin field applications.

(a) Crop Scenario Input Parameters

The crop scenarios EFED used in its preliminary and revised freshwater aquatic risk modeling were deficient, including the use of the maximum application rate for all scenarios, an injection depth of 10 inches applied to all scenarios, and the lack of tarps for all scenarios. Recent data from an ad-hoc applicator survey were used to produce a revised crop scenario table with more accurate crop-specific data, such as accounting for different application methods (broadcast and bedded shank injection, and drip application), accurate depth of injection values and duration of the tarping period, and an adjusted application rate which incorporates the CMTF-supported maximum rates (as noted by EPA in the risk assessment, but not used in the models), as well as an adjustment to the actual application rate if the field was drip or bed fumigated, since approximately 65% of an acre would be treated via drip or bed injection versus the whole-acre rate as would occur during broadcast applications. In addition, more crops were added to the aquatic risk assessment such that all primary uses of chloropicrin were represented and evaluated. The revised crop scenarios and their respective scenario-specific model inputs values are given in Table 12. In addition to the new crop scenarios, two of the model simulations were run with and without irrigation to determine its effects on EECs. This is in contrast to the Agency's approach, which employed irrigation effects for all scenarios where the fumigant application coincided with the growing season.

Table 12 Revised Crop Scenarios With Actual Commercial Application Practices

EPA Crop	Surrogate For	Application Method (CAM=8)	Application Date	Injection Depth (inches)	Tarping (days)	Modeled Irrigation	Application Rate (lbs. a.i./A)		
							Maximum	Typical	Modeled
CA Onion	CA Onion	Broadcast	1-Sep	14	0	Over canopy	175	80-175	175
CA Onion	CA Onion	Broadcast	1-Sep	14	0	None	175	80-175	175
CA Onion	AZ Melon	Drip	15-Apr	10	0	None	300	80-300	300
CA Onion	CA Vegetables	Bedded	15-Apr	12	0	None	350	80-230	350
CA Tomato	CA Strawberry	Broadcast	15-Aug	12	5	Furrow	350	150-230	350
CA Tomato	CA Strawberry	Broadcast	15-Aug	12	5	None	350	150-230	350
CA Tomato	CA Strawberry	Drip	1-Sep	1	90+	None	300	80-195	300
CA Tomato	CA Vegetables	Bedded	1-Sep	11	90+	None	350	80-228	350
FL Tomato	FL Tomato	Bedded	15-Jul	11	90+	None	350	80-228	350
FL Cucurbits	FL Vegetables	Drip	1-Jun	1	90+	None	300	80-195	300
FL Strawberry	FL Strawberry	Bedded	15-Aug	12	90+	None	350	80-228	350
NC Sweet Potato	NC Sweet Potato	Broadcast	15-Apr	12	0	None	175	80-175	175
NC Tobacco	NC Tobacco	Broadcast	15-Apr	12	0	None	175	80-175	175
ID Potato	ID Potato	Broadcast	15-Oct	18	0	None	175	50-130	175

(b) Estimated Environmental Concentrations (EECs), Aquatic Risk

Based on the refined environmental fate values and crop scenario-specific inputs, revised EEC values were generated for each of the 12 crop scenarios (6 original EPA scenarios, plus 6 surrogate crop scenarios, where two of which considered irrigation effects). These upper 10^{th} percentile EECs of chloropicrin are presented in Table 13 (reproduced from Ritter 2007). These EECs more accurately represent the estimated concentrations of chloropicrin in water bodies, at least in comparison to EPA's original modeling outputs. However because of the limited capabilities of PRZM/EXAMS to handle volatile chemicals and its other modes of adding uncertainty (addressed above, and in Ritter 2007), EPA should consider these refined EECs as overestimates and as representing upper-bound values for the theoretical loading of chloropicrin from field runoff into bodies of water.

Table 13 Upper 10th Percentile Estimated Environmental Concentrations (EECs) of Chloropicrin with Revise Crop Scenarios and Actual Commercial Application Practices

EPA Crop (Surrogate For)	Application Method	Irrigation	Upper 10th Percentile EEC (ppb)					
			Peak	96-hr	21-day	60-day	90-day	Annual
CA Onion (CA Onion)	Broadcast	Over Canopy	1.254 E-01	8.982 E-02	3.016 E-02	1.076 E-02	7.174 E-03	1.769 E-03
CA Onion (CA Onion)	Broadcast	None	2.872 E-01	1.906 E-01	6.180 E-02	2.251 E-02	1.501 E-02	3.691 E-03
CA Onion (AZ Melon)	Drip	None	1.779 E-02	1.318 E-02	4.737 E-03	1.690 E-03	1.127 E-03	2.772 E-04
CA Onion (CA Vegetables)	Bedded	None	1.038 E-02	7.498 E-03	3.31 E-03	1.142 E-03	7.617 E-04	1.878 E-04
CA Tomato (CA Strawberry)	Broadcast	Furrow	7.345 E-02	5.089 E-02	1.838 E-02	8.391 E-03	5.652 E-03	1.394 E-03
CA Tomato (CA Strawberry)	Broadcast	None	9.861 E-02	6.834 E-02	2.467 E-02	1.099 E-02	7.395 E-03	1.825 E-03
CA Tomato (CA Strawberry)	Drip	None	2.942 E-05	2.455 E-05	1.328 E-05	5.144 E-06	3.429 E-06	8.517 E-07
CA Tomato (CA Vegetables)	Bedded	None	2.447 E-04	1.997 E-04	1.066 E-04	4.126 E-05	2.750 E-05	6.973 E-06
FL Tomato (FL Tomato)	Bedded	None	1.038 E-04	6.607 E-05	2.691 E-05	9.988 E-06	6.657 E-06	1.641 E-06
FL Cucumber (FL Vegetables)	Drip	None	1.066 E-05	7.439 E-06	2.620 E-06	9.586 E-07	6.392 E-07	1.576 E-07
FL Strawberry (FL Strawberry)	Bedded	None	8.801 E-05	6.108 E-05	2.355 E-05	1.389 E-05	9.260 E-06	2.292 E-06
NC Sweet Potato (NC Sweet Potato)	Broadcast	None	2.971 E-02	2.159 E-02	8.999 E-03	3.291 E-03	2.208 E-03	5.448 E-04
NC Tobacco (NC Tobacco)	Broadcast	None	1.874 E-01	1.329 E-01	4.802 E-02	1.737 E-02	1.159 E-02	2.858 E-03
ID Potato (ID Potato)	Broadcast	None	3.175 E-01	2.470 E-01	1.078 E-01	4.535 E-02	3.072 E-02	7.646 E-03

(c) Acute Risk Quotients for Freshwater Fish and Freshwater Invertebrates

Based on the refined EEC values, revised Risk Quotient (RQs) values were generated for each of the 12 crop scenarios for (1) freshwater fish, where the Toxicity Reference Value (TRV) is 16.98 ppb (FTLR 425/McCann/1971); (2) freshwater fish, where the TRV is 4.8 ppb (Flatman, 2004a), (3) freshwater aquatic invertebrates, where the TRV is 71 ppb (130704/Cody and Shema/1983), and (4) freshwater aquatic invertebrates, where the TRV is 150 ppb (Flatman, 2004c) (Table 14).

Table 14 Acute Risk Quotients (RQs) for Freshwater Fish and Invertebrates Based on Revised Crop Scenarios and Environmental Fate Parameters

EPA Crop (Surrogate For)	Application Method	Irrigation	Peak EEC (ppb)	RQs for Freshwater Fish		RQs for Freshwater Invertebrates	
				Where TRV = 16.98 ppb [1]	Where TRV = 4.8 ppb [2]	Where TRV = 71 ppb [3]	Where TRV = 150 ppb [4]
CA Onion (CA Onion)	Broadcast	Over Canopy	1.254 E-01	0.007385	0.026125	0.001766	0.000836
CA Onion (CA Onion)	Broadcast	None	2.872 E-01	0.016914	0.059833	0.004045	0.001915
CA Onion (AZ Melon)	Drip	None	1.779 E-02	0.001048	0.003706	0.000251	0.000119
CA Onion (CA Vegetables)	Bedded	None	1.038 E-02	0.000611	0.002163	0.000146	6.92E-05
CA Tomato (CA Strawberry)	Broadcast	Furrow	7.345 E-02	0.004326	0.015302	0.001035	0.00049
CA Tomato (CA Strawberry)	Broadcast	None	9.861 E-02	0.005807	0.020544	0.001389	0.000657
CA Tomato (CA Strawberry)	Drip	None	2.942 E-05	0.00000173	0.00000613	0.000000141	0.000000196
CA Tomato (CA Vegetables)	Bedded	None	2.447 E-04	0.0000144	0.000051	0.00000345	0.00000163
FL Tomato (FL Tomato)	Bedded	None	1.038 E-04	0.00000611	0.0000216	0.00000146	0.000000692
FL Cucumber (FL Vegetables)	Drip	None	1.066 E-05	0.000000628	0.00000222	0.00000015	0.0000000711
FL Strawberry (FL Strawberry)	Bedded	None	8.801 E-05	0.00000518	0.0000183	0.00000124	0.000000587
NC Sweet Potato (NC Sweet Potato)	Broadcast	None	2.971 E-02	0.00175	0.00619	0.000418	0.000198
NC Tobacco (NC Tobacco)	Broadcast	None	1.874 E-01	0.011037	0.039042	0.002639	0.001249
ID Potato (ID Potato)	Broadcast	None	3.175 E-01	0.018698	0.066146	0.004472	0.002117

[1] MRID/Accession (ACC) No./Author/Year: FTLR 425/McCann/1971

[2] Flatman, D. 2004. Chloropicrin Acute Toxicity to Fish (Rainbow Trout). Huntington Life Sciences Ltd. GLP, unpublished.

[3] MRID/Accession (ACC) No./Author/Year: 130704/Cody and Shema/1983

[4] Flatman, D. 2004. Chloropicrin Acute Toxicity to *Daphnia magna*. Huntington Life Sciences Ltd. GLP, unpublished.

(d) Conclusions for Acute Risk to Freshwater Fish and Invertebrates

Based on the refined Estimated Environmental Concentrations, none of the crop scenarios exceed the default Levels of Concern for Acute Risk (0.50), Acute Restricted Use (0.1), or Acute Endangered Species (0.05), regardless of which TRV is used for freshwater fish (16.98 v. 4.8 ppb) or freshwater invertebrates (71 v. 150 ppb); except for two of the simulations which exceed the default Acute Endangered Species LOC of 0.05 using the most sensitive TRV of 4.8 ppb for freshwater fish. These are (a) the CA Onion (CA Onion), broadcast, no tarp, no irrigation simulation (RQ = 0.059833) and (b) the Idaho Potato simulation (RQ = 0.066146). However, these two simulations which exceed the Acute Endangered Species LOC of 0.05 are very close to this threshold, and if the uncertainties and errors associated with the PRZM/EXAMS were to be accounted for, then none of the crop simulations would exceed any LOC, regardless of which TRV was used in the analysis. For example, if the LOC values were adjusted to reflect the

cumulative sources of modeling error, then analysis using a revised Acute Endangered Species LOC of 0.1 would indicate that no crop simulation RQs exceed any LOC. Alternatively, if the EECs were adjusted to reflect the cumulative sources of error with an EEC correction factor of 0.02 ppb for each of the five main sources of error, than the highest EEC would be 0.2175 ppb, which results in an RQ (0.0453) that is sufficiently below the default Acute Endangered Species LOC of 0.05.

In summary, only two of the modeled crop simulations exceed the most sensitive LOC using the most conservative Toxicity Reference Value, and even then, the RQ are very close to the default LOC. If EFED were to address and account for the numerous sources of error in the models, then no RQ would exceed any LOC, and the conclusion would be that sub-soil application of chloropicrin does not pose a risk to aquatic organisms.

(e) Chronic Risk to Freshwater Aquatic Animals

In order to equal or exceed the chronic risk Level of Concern (LOC = 1) for freshwater animal species, the chronic Toxicity Reference Value would have to equal or exceed the 21-day EEC for invertebrates and the 60-day EEC for fish. Based on the revised crop scenarios and EECs, the CMTF believes that a waiver should be granted for chronic toxicity studies for freshwater animal species, as the predicted EECs are very low. The highest 21-day EEC (freshwater invertebrate chronic risk) is approximately 108 parts per trillion (0.1078 ppb) and the highest 60-day EEC (freshwater fish chronic risk) is 45 parts per trillion (0.04535 ppb). Given the limitations of PRZM/EXAMS, even these low EECs should be considered worst-case scenarios and represent upper-bound estimates. CMTF also believes that chronic toxicity studies should only be required where there is an actual risk for chronic or repeated exposure. Chloropicrin is applied under the soil surface to fields once per growing season. While it is true that several fields in a given area may be treated sequentially with chloropicrin in any given year, the rapid degradation of chloropicrin in the environment indicates that chronic risk to freshwater animals is highly unlikely, nor is there any historical evidence to suggest a chronic risk to any aquatic species. CMTF repeats its request for a waiver for chronic toxicity studies with freshwater animal species.

(f) Marine/Estuarine Exposure

EPA expressed concern regarding marine/estuarine species exposure risk to chloropicrin and indicated that marine/estuarine toxicity studies would be needed to evaluate the risk of chloropicrin exposure to organisms (fish, mollusk, shrimp) in these environments. However, EPA appears to have misunderstood the potential for marine/estuarine exposure to chloropicrin.

EPA correctly acknowledges that dry or wet redeposition of emitted chloropicrin vapor is negligible and so the risk to marine/estuarine environments via this exposure route is also negligible. However, EPA incorrectly assumes that field runoff of chloropicrin after sub-soil application could be such that the concentration of chloropicrin could be high enough to pose a risk to marine and/or estuarine organisms.

Foremost, as with the freshwater exposure modeling, PRZM/EXAMS has serious limitations for handling a compound like chloropicrin, nor do these models appear to account for any distance between the treated field edge and water body receiving field runoff via a rain event. Treated fields never directly abut an ocean or estuarine water body. There would be at least 10 feet (e.g., an access road) between the field and water body in order for the maneuvering of field equipment. This 10-foot distance represents a theoretical minimum distance. An ad-hoc survey of fumigant applicators contacted via telephone in Fall 2006 indicated that the actual minimum distance between a treated field and any non-agricultural water body, marine/estuarine or freshwater, is typically 25 feet or more in the Pacific Northwest (Washington and Oregon); 30 feet or more in California; and 20 feet or more in Florida. EPA should account for the effect of distances between a treated field and any water body, as there will always be some minimum distance between these two entities. Assuming that a treated field directly abuts an ocean, estuary, lake, pond, creek, river, etc., is an erroneous assumption that does not reflect real-world agricultural practices.

Estuarine environments have continual sharing of marine and fresh waters (tidal ebb and flow) and also continual or near continual tributary input from the surrounding terrestrial watersheds. Estuary and marine environments also have much greater volumes of water than the Pond scenario, and as such, any concentration effects of chloropicrin in a marine or estuarine environment would be negated almost instantaneously via dilution within the voluminous and usually turbulent marine or brackish water bodies.

Aside from the one incident report documenting aquatic organism mortality from chloropicrin and/or 1,3-dichloropropene (EFED, Chloropicrin Ecological Risk Assessment, page 44), there are no other reports that suggest that the use of chloropicrin as a soil fumigant poses a risk to aquatic environments. This one incident was attributed to an accident, a broken value or value mistakenly left open, and as such, it does not reflect an event that would occur under normal use practices for chloropicrin.

(g) Aquatic Plant Exposure

In order to equal or exceed the levels of concern for aquatic plant acute risk (LOC = 1) or the aquatic plant acute endangered species risk (LOC = 1), the Toxicity Reference Value would have to equal or exceed the peak EEC. Based on the revised crop scenarios and EECs, the CMTF believes that a waiver should be granted for aquatic plant studies, as the predicted peak EECs are very low. The highest peak EEC is approximately 0.3175 ppb. This concentration is well below any likely acute toxicity value for an aquatic plant species. Given that EPA has previously acknowledged the limitations of PRZM/EXAMS for handling chloropicrin, in addition to its other shortcomings, even these low EECs should be considered worst-case scenarios and represent upper-bound estimates. Based on these issues, a waiver for any and all aquatic plant toxicity studies is requested.

V. INCIDENT DATA

Chloropicrin has a long history of use as a soil fumigant with relatively few incidents reported. CMTF has given EPA specific information in its previous comments

regarding such incidents including comparing the number of applications to the number of incidents. In many cases incidents could have been avoided through the use of Good Application Practices such as those discussed in Section II B above.

For example, one of the incidents listed in EPA's Phase 5 revised risk assessment involved a drip irrigation application that resulted in chloropicrin being present in the irrigation system following application. The GAPs in Section II have specific instructions regarding system controls and integrity that would have prevented this. Similarly, GAPs regarding proper soil preparation, pre-application soil moisture, depth of injection and sealing techniques would all reduce emissions. CMTF is committed to working with EPA and the agricultural community to make sure that all applications are consistent with GAPs and further reduce the potential for exposure.

VI. DISCUSSION OF ECONOMIC IMPACTS

Numerous commodity groups, academic researchers, individual growers and applicators have submitted information to EPA regarding the impact of the buffer zones and other restrictions on the use of chloropicrin. These comments make clear that chloropicrin is an essential tool for a variety of crops including strawberries, potatoes, forest nursery, vine and tree fruit, nuts, peppers, tomatoes and tobacco. Researchers throughout the US, as well as international programs, have recognized the importance of chloropicrin in the methyl bromide replacement program. Chloropicrin is the backbone of virtually all methyl bromide alternative fumigant programs and is used with other alternative fumigants including 1,3-dichloropropene, metam sodium, iodomethane, and dimethyl disulfide.

CMTF also notes that EPA's current analysis does not appear to take into account the comments of several researchers regarding the importance of chloropicrin as a methyl bromide alternative. For example, experiments conducted by USDA-ARS and University of California researchers have indicated that chloropicrin, as the sole active ingredient, is one of the most promising methyl bromide alternatives for controlling orchard replant disorder.[34] Similarly, other researchers have commented on its importance to other crops. EPA should include consideration of these promising methyl bromide alternative uses as well historical uses in its benefits analysis.

VII. CONCLUSION

The CMTF appreciates the opportunity to provide comments on EPA's revised risk assessment. CMTF encourages EPA to continue to incorporate good application practices into its risk assessment analyses. Incorporation of more real-world criteria into modeling, including environmental fate and effect modeling, will result in a regulatory decision that protects human health and the environment and allows growers to retain the use of a critical pest management tool. CMTF looks forward to working with EPA on mitigation measures to incorporate practices that reduce emissions.

[34] Browne, G., et al. Integrated Pre-Plant Alternatives to Methyl Bromide for Almonds and Other Stone Fruits. Methyl Bromide Conference. 2007.

VIII. REFERENCES

ACGIH (American Conference of Governmental Industrial Hygienists) (1991). Documentation of the Threshold Limit Values and Biological Exposure Indices, Sixth Ed., Cincinnati, OH.

ACGIH, American Conference of Governmental Industrial Hygienists (1996). Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, Cincinnati, OH.

Burleigh-Flayer, H. D., W. J. Kintigh and C. L. Benson (1995). Chloropicrin: vapor inhalation oncogenicity study in CD-1 mice. Bushy Run Research Center, BRRC Union Carbide Chemicals and Plastics Company, Export, PA. , Laboratory Project 92N1105

Burleigh-Flayer, H. D., and C. L. Benson (1995). Chloropicrin: vapor inhalation oncogenicity study in CD rats. Bushy Run Research Center, BRRC Union Carbide Chemicals and Plastics Company, Export, PA. , Laboratory Project 92N1106

Cain, W. (2004). Human Sensory Irritation Testing for Chloropicrin. Chemosensory Perception Laboratory, La Jolla. Study # PIC-1, unpublished. U.S. EPA MRID # 46443801.

Cain, W.S., Jalowayski, A.A., R. Schmidt, J. Jeon, T. C. Bruff and J. H. Butala. (2006). Human chemosensory and physiological responses of chloropicrin vapor. The Toxicologist, Supplement to Toxicological Sciences, 90:1, p478.

Chun, J.S. and W. J. Kintigh (1993). Chloropicrin: ninety-day inhalation study in rats and mice. Bushy Run Research Center, BRRC Union Carbide Chemicals and Plastics Company, Export, PA., Laboratory Project 91N0098.
EPA (U.S. Environmental Protection Agency). (2006). Chloropicrin: Revised HED Human Health Risk Assessment for Phase 3; DP Barcode: D314380, PC Code: 081501. October 4, 2006. Office of Pesticide Programs, U.S. EPA, Washington, D.C.

EPA (US Environmental Protection Agency) (1995). The Use Of Benchmark Dose Approach In Health Risk Assessment. Risk Assessment Forum, Office of Research and Development, Washington, DC EPA/630/R-94/007.

EPA (US Environmental Protection Agency) (2000). Benchmark Dose Technical Guidance Document. National Center for Environmental Assessment. Washington, DC.

EPA (US Environmental Protection Agency) (2001). Benchmark Dose Software Version 1.3.2. National Center for Environmental Assessment. Washington, DC.

Gosselin, P.H. (2002). Letter to interested parties regarding risk management directive for MITC-generating pesticides. California Environmental Protection Agency, Department of Pesticide Regulation, December 2.

Hoffman, G.A. (1999). Unpublished Study. “Chloropicrin: a sensory irritation study in the mouse via head-only exposure” Laboratory Project 99-5388, Huntingdon Life Sciences, East Millstone, N.J., October , 1999.

Kane, L. E., Barrow, C.S. and Alarie, Y. (1979). A short-term test to predict acceptable levels of exposure to airborne sensory irritants. Am. Ind. Hyg. Asso. J. 40: 207-229.

TERA, Toxicological Excellence for Risk Assessment (2005). Use of benchmark concentration modeling and categorical regression to evaluate the effects of acute exposure to chloropicrin vapor Part I. Technical Report.

Appendix A EPA Phase 5 Chloropicrin Draft Risk Assessment: Comments Regarding Risk Mitigation Options to Address Potential Inhalation Exposures Associated with Soil Fumigant Applications (Driver/Ross Paper)

CHLOROPICRIN:

EPA Phase 5 Chloropicrin Draft Risk Assessment: Comments Regarding Risk Mitigation Options To Address Potential Inhalation Exposures Associated with Soil Fumigant Applications

Jeffrey H. Driver, Dr.P.H., D.A.B.T., M.T., C.L.S.
Muhilan Pandian, Ph.D., M.B.A.
John H. Ross, Ph.D., D.A.B.T.

infoscientific.com, Inc.
Henderson, NV Manassas, VA Sacramento, CA

November 2, 2007

INTRODUCTION

Soil fumigation provides a number of important benefits to both consumers and growers, including:

- Consumer access to more fresh fruits and vegetables throughout the year;
- Grower ability to control a wide range of economically important soil-borne pests, so crop yields can be maintained at economically sustainable levels and market quality is satisfactory;
- Reduction of labor costs, due to the increased efficiency of harvesting weed-free crops;
- Shorter time intervals between crop production, avoiding the need to rotate crops or let fields lie fallow for several years to reduce levels of nematodes or pathogens; and
- The role of soil fumigation in quarantines and pre-shipment treatments, such as the production of certified pest-free plant propagation materials.

Given the demonstrable benefits of fumigants, risk management requires careful regulatory consideration, the research and development of effective exposure reduction technologies and agricultural practices, and iterative refinements to quantitative, probabilistic exposure assessment and risk analysis. The U.S. Environmental Protection Agency (EPA; http://www.epa.gov/oppsrrd1/reregistration/soil_fumigants/index.htm), California Department of Pesticide Regulation (CA DPR; see http://www.cdpr.ca.gov/docs/emon/methbrom/mb_main.htm), and the regulated industry continue to commit significant resources in this regard.

In the case of chloropicrin, the key "toxicological endpoint" underlying quantitative risk analyses is human sensory response prior to clinically significant irritation[35]. While this provides a highly sensitive benchmark[36] it also represents an air concentration that would not be detected by some exposed individuals, and is not expected to represent a level at which irritation would be experienced by persons in field situations. Further, irritation (e.g., to the eyes), should it be experienced, represents a transient, reversible effect, upon reduction or cessation of the exposure. The use of a sensory response (and irritation) for regulatory risk management invokes different considerations, compared to other toxicological endpoints (e.g., neurotoxicity, developmental toxicity) regarding severity of effect, percent of the population at risk, and related risk mitigation strategies. EPA has required a smaller uncertainty factor for reversible irritation effects than for effects that may be permanent.

[35] Chloropicrin is a sensory irritant in which the trigeminal nerve mediates sensations in the nose, eyes, throat, and upper respiratory tract.

[36] A Benchmark Concentration (BMC) analysis has been conducted (TERA 2005) that utilizes irritation data from "Phase 3" of the human study (Cain 2004). The lower bound estimate or $BMCL_{10}$ (73 ppb) is based on irritation severity scores of the maximum response period (30 – 55 mins) of phase 3. This benchmark (73 ppb) represents a level at which respiratory histopathologic changes and irritation (eyes, nose) would not be expected to occur.

Risk mitigation options require careful consideration of the exposure assessment component of the risk assessment process. In the case of fumigants, incidence data, field exposure monitoring and predictive exposure modeling provide alternatives for assessment, and for comparison/evaluation opportunities. Each of these approaches has strengths and limitations as discussed by EPA (2007).

The remainder of these comments elaborates on both toxicological and exposure-assessment related considerations in the case of chloropicrin risk mitigation and management as a soil fumigant. These two areas of consideration, in the context of chloropicrin risk mitigation, clearly indicate that a conditional registration program should be devised that allows for the development and demonstration of exposure reduction technologies and agricultural practices, which are then incorporated into refined, probabilistic exposure/risk modeling. This should include the incorporation of more realistic first principal-based parameters (and distributions thereof, e.g., flux rates) in modeling methods, providing more realistic representations of receptor population dynamics (e.g., receptor location-time-duration), and exposure reduction "credits" associated with demonstrable exposure reduction methods (e.g., soil conditions, tarp methods).

ACUTE TOXICOLOGICAL ENDPOINT IN THE CONTEXT OF RISK ASSESSMENT AND MANAGEMENT

As acknowledged by EPA (EPA 2007), the human eye irritation study that serves as the basis of the benchmark concentration (BMCL = 73 ppb) involved young adult subjects (average 23 years) that are considered to be the most sensitive subpopulation for sensory irritation (e.g., can detect chloropicrin at lower concentrations). Further, transient eye irritation is the most sensitive endpoint determined for the sensitive subpopulation used in the human study. Therefore, the human study suggests that protecting for transient eye irritation would also protect against clinically apparent irritation of the eyes, nose, and the respiratory tract. Thus, the endpoint of sensory-related eye irritation is a No-Observed-Effect-Level (NOEL) and not a traditional toxicity benchmark (i.e., a No-Observed-Adverse-Effect-Level). Moreover, risk management based on this NOEL endpoint invokes different considerations with respect to risk assessment and risk mitigation decision-making. In fact, the sensory endpoint effectively serves as an early warning system (for chloropicrin and other co-formulated active ingredients), and with rapid response and exposure mitigation, reduces the likelihood of any actual adverse effects. The endpoint essentially provides a practical, observable, easily documented surveillance opportunity.

It is also noteworthy that the highly sensitive nature of the sensory benchmark concentration may explain, in part, why the relative low incidence of irritation-related events is not consistent with current predictive modeling results which estimate chloropicrin air levels greater than the BMCL for various application rate, field size, and buffer zone/receptor location scenarios (EPA 2007). Other explanatory factors with respect to the actual incidence data include accidents, misapplications, or mismanagement by first responders. In fact, field incidents are likely associated with

chloropicrin air levels that are much higher than the BMCL value (73 ppb). The BMCL is not associated with clinically significant effects or histopathology. Further, no clinical or histopathologic effects were observed at chloropicrin air concentrations up to the highest concentration tested, i.e., 150 ppb. Thus, the NOAEL is significantly higher than 150 ppm, albeit with a steep dose-response for reversible irritation. The BMCL effectively represents a benchmark that includes an additional safety factor (2x or greater) relative to the NOAEL for reversible irritation. Therefore, taking the above into consideration indicates chloropicrin risk mitigation option evaluation should include consideration of the uncertainty distribution (conservative bias) in the toxicological benchmark value.

LIMITATIONS AND UNCERTAINTIES ASSOCIATED WITH FUMIGANT EXPOSURE MODELING AND KEY CONSIDERATIONS FOR REFINEMENT

Chloropicrin air concentrations within and around treated fields, during and following fumigant application, are influenced by a number of variable and time-dependent factors which can be represented in a probabilistic modeling construct. These factors include site-specific meteorological conditions, site-specific soil conditions (moisture, organic content, temperature), the application method and rate, techniques to control emissions (e.g., tarps, water seals, scavengers), and receptor (potentially exposed individuals) time/location and activity patterns.

Varying weather conditions as a function of time, for example, can significantly change the air concentrations at specific sites around a treated area. There is a large range of potential weather conditions which can exist at a given field location where a fumigant such as chloropicrin is used. Field monitoring studies cannot represent the entire range of potential air concentrations and exposure opportunities which may result. Field air concentration monitoring is also somewhat limited by the use of fixed samplers positioned at various distances and directions around the treated area, both downwind and upwind, as well as at points in between. Air concentrations downwind will be relatively high since the fumigant plume will be pushed by the wind in that direction, while concentrations upwind will be low or close to zero since the plume is pushed by the wind in the opposite direction. Predictive models provide a means for extrapolation and prediction beyond the limits of observed field measurements.

EPA utilized the PERFUM (Probabilistic Exposure and Risk Model for Fumigants) model “to develop an understanding of the distribution of potential bystander exposures and thus, more fully characterize the range of risks resulting to bystanders around treated fields”. Variability in wind speed and direction are captured by using meteorological data for five years. Flux rate is not addressed stochastically for a given site or across sites and meteorological conditions. Additionally, receptor time-location-duration and associated conditional probabilities (likelihood of being at a specific location in a buffer zone) is not addressed. PERFUM has be modified to summarize output data as a “receptor cloud” (time-weighted average air concentrations where receptors might be located) within a spatially defined near field zone. This modification provides a more

realistic representation of the fumigant air concentrations that could be experienced by an intermittently mobile hypothetical receptor population.

Modeling improvements to better inform risk mitigation considerations, in conjunction with the development and use of field measurements, should include:

- Representation of a more realistic chloropicrin flux rate by evaluating a greater variety of site-specific conditions (e.g., soil moisture, organic loading, soil amendments such as chloropicrin "scavengers," wind rows; the Arizona site use in EPA's risk assessment (EPA 2007) does not represent variability expected across more diverse site locations and associated soil and meteorological conditions);
- Incorporation of conditional probabilities associated with receptor time/location-duration arrays;
- Consideration of indoor versus outdoor concentrations during and post-application;
- Explicit definition of and incorporation of exposure reduction "credit" parameters for reducing buffer zones (e.g., soil moisture, injection depth, organic content, tarping methods, injection depth);
- Critical evaluation of existing data regarding technology and efficacy;
- Site-specific considerations (soil moisture, organic content, meteorological conditions, spatial location of bystander sites) that could inform appropriate site-specific measures for exposure evaluation and mitigation where necessary;
- Consideration of the full range of air concentration percentiles as a function of different times during and post application;
- Address chloropicrin application frequency in context of the population at risk and the likelihood of exposure;
- Additional predictive model validation via field measurements (temporal, spatial);
- Evaluation of factors that influence flux variability; and
- Investigation of dispersion modeling limitations (building effects, meandering, etc.).

As acknowledged by EPA (EPA 2007) most of the data used for their analysis have been generated in Arizona and California. However, chloropicrin is used in many regions of the country. EPA indicates (EPA 2007) that the results based on Arizona and California data and agricultural practices were used to represent the rest of the country due to a lack of adequate information for any other region. While we agree that the preponderance of data for chloropicrin emissions has been generated in California, there are some additional data available to EPA from other states besides California that have not cited or used. Interestingly, the majority of the currently available data make very clear the conservative nature of EPA's assessment despite their statement that "It is unclear what potential impacts this extrapolation might have on the risk assessment". However, EPA goes on to say "Factors such as soil type, soil moisture, solar radiation levels, or farming practices themselves may impact the overall amounts of chloropicrin emitted and the rate at which it is emitted over time, thus buffer outputs predicted using PERFUM could be impacted". EPA further caveats their modeling of buffer zones by acknowledging

"PERFUM is not a first-principles model" (i.e., it cannot predict results for incremental changes in soil conditions parameters such as soil temperature or percent moisture). Instead, PERFUM is an empirical model that is calibrated to specific emission profiles that then serve as the basis for predicted results. As we point out in some detail later in this discussion, there is a "first principles" model generated by the USDA (http://www.ars.usda.gov/Services/docs.htm?docid=8914) that can take many of these important factors into account.

EPA goes on to further indicate the foibles of the buffer zone predictions they have made: "The premise of the PERFUM-predicted buffer zones assumes that an exposed individual must be in proximity to a chloropicrin application event for a sufficient duration for the effect to occur" - there are 2 key factors to consider for this element including:

1) that the types of applications considered in this assessment are either seasonal or infrequent which limits the number of possible adverse exposure events, and
2) time-activity data indicate that many parts of the population move from site to site on a daily basis (e.g., to go to work and back) and spend most of their time indoors[37] which limits the overall number of possible adverse exposures events (Michael et al. 2006; Kwan and Lee 2003; EPA 1997).

The PERFUM analyses completed in EPA's assessment (EPA 2007) were based on the assumption that an application has an equal probability of occurring each day out of the 5 years of weather data. This method does not take into account the seasonal use patterns of fumigants in different regions of the country. EPA has indicated (EPA 2007) that monthly distributional results were produced in each PERFUM output file but that detail was not extracted for this assessment."

As noted above, PERFUM has been recently modified to also produce distributions of concentrations at various receptor ring distances from the edge of a treated field. This capability was added near the completion timeframe of EPA's assessment. We agree with EPA that this capability should be utilized in the development of risk management decisions. The distributions of concentrations across a range of distances from the treated field edge provides a more plausible range of potential time-weighted air concentrations that might be experienced by intermittently mobile receptors, i.e., individuals who may move within (and out of) a near field zone. It is also noteworthy that individuals may also spend a significant amount of time indoors versus outdoors within a near field zone. Indoor air concentrations relative to outdoor levels would be expected to depend on the time post-application and building ventilation configuration (Woodrow and Krieger, 2006).

An illustration of the modified capability of PERFUM is provided below based on chloropicrin emission profiles from Bradenton, Fl study (MRID 441492-01). The PERFUM modeling results are based on the conditions of this study (shank injection

[37]Persons who are 12 yrs and older spend approximately 21 hrs/day indoors, 1.5 hrs/day outdoors, and 1.5 hrs/day in a vehicle (EPA 1997; Chapter 15, Section 15.4.1).

application - broadcast/tarped; 346 lbs AI per treated acre, scaled to 350 lbs AI per treated acre) emission profiles and 5 years of daily meteorological data for Ventura, CA (1995 to 1999). The results represent the predicted distributions (75th to 99.9th percentile values provided) of daily 4-hour time weighted average chloropicrin air concentrations (µg/m^3) within a "near field activity zone" representing 100 feet to 1,320 ft (¼ mile) from defined application areas (1, 5, 10, 20 and 40 acres). The graph below (Figure 1) presents the predicted chloropicrin air concentrations at various percentiles that were estimated within the defined spatial "near field" areas for each application area (1, 5, 10, 20 and 40 acres, tarped). The results show that air concentrations (distributions of maximum 4 hr time-weighted average values across 5 years of daily meteorological data) in the near field area or zone never exceed the level of concern (490 µg/m^3). This is in contrast to the PERFUM results for a 10 acre site based on the Arizona study site results (see Figure 2; MRID # 441492-01; un-tarped; 171 lbs AI per treated acre; Ventura, CA meteorological data set).

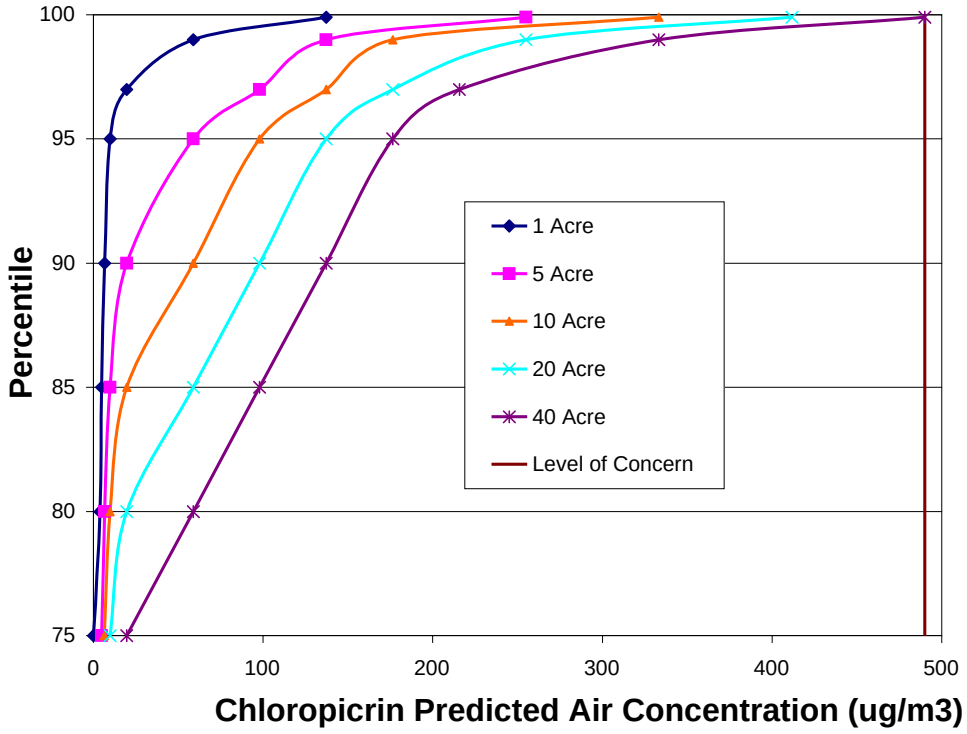


FIGURE 1. Predicted Chloropicrin Air Concentrations Within Near Field Zones Based on Bradenton, FL Study Results.

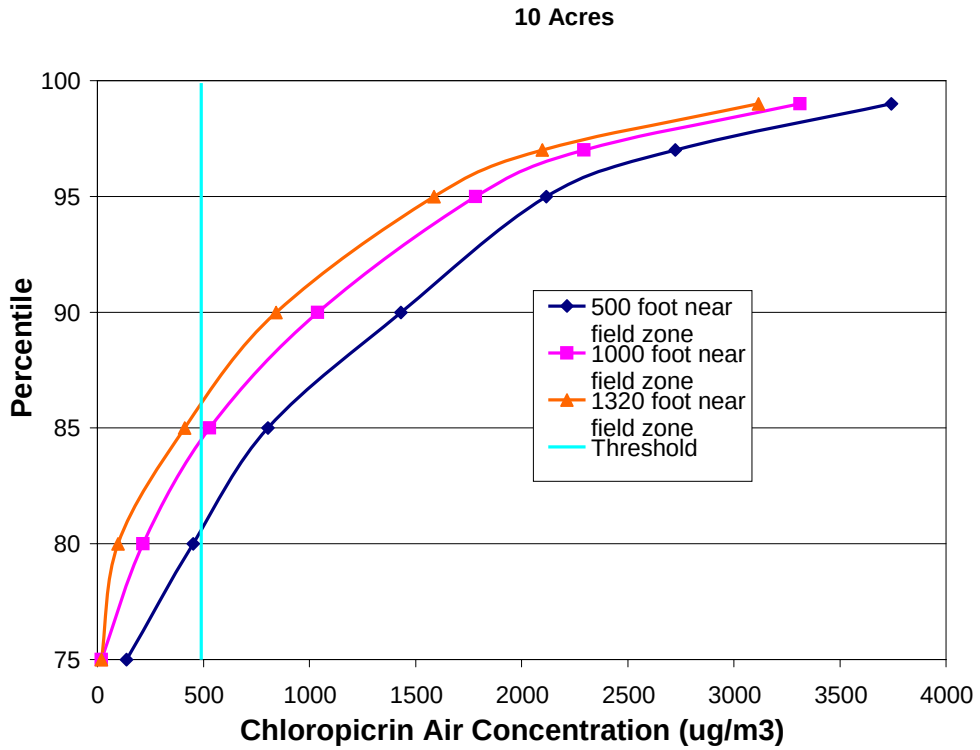


FIGURE 2. Predicted Chloropicrin Air Concentrations Within Near Field Zones Based on Phoenix, AZ Study Results.

Based on our analysis of the data, the Arizona site is not a typical site; rather a worst-case scenario, given the soil moisture, organic content, and other factors present at that site. Emission reduction measures, and associated "buffer zone credits," at a site such as that represented in Arizona, would be a meaningful case study. However, using the Arizona site's emission profile for simulating air concentrations at other geographic locations is not appropriate. Shown for comparison in Table 1 are the air emission studies considered by EPA in the chloropicrin RED (EPA 2007). If one compares soil moisture and resulting emissions from the three locations with tarped broadcast applications (Bradenton, Phoenix and Yakima), the differences are striking. The disparity of the Phoenix data with any other emission data (including studies that EPA did not review in EPA 2007) is a significant concern.

Table 1: Comparison of emission rates from various studies

Application Scenario	Study Effective Broadcast Rate (lbs ai/total acre)	Soil Moisture as % Field Capacity	% of Total Applied Re-emitted
Phoenix Bedded/Tarped	189	51	69
Phoenix Bedded/Untarped	86	64	61
Bradenton Broadcast/Tarped	346	>100	37
Phoenix Broadcast/Tarped	332	36	63
Yakima Broadcast/Tarped	343	>100	34
Phoenix Broadcast/Untarped	171	55	62

To better inform the range of inter-site variability and investigate the magnitude of emission reduction due to procedures such as tarping, a more complete investigation of existing monitoring data is needed. EPA's evaluation (EPA 2007) has not included all of the available chloropicrin-specific studies. For example, Ajwa et al. (2007) have produced an excellent study on the influence of tarping on emissions of chloropicrin from treated soil. Dow Agrosciences has also produced data for chloropicrin emissions when used with Telone (http://www.epa.gov/oppsrrd1/reregistration/REDs/0328red.pdf).

There may also be other data that EPA is aware of that are pertinent. Chloropicrin is used in conjunction with many fumigants (metam sodium, dimethyl sulfide, methyl iodide, Telone and methyl bromide) to functionally reduce the amount of a second fumigant used or strictly for its warning properties. As a result, it is in the interest of most soil fumigant users to have a buffer zone for chloropicrin that would not exceed its use without it.

Perhaps more importantly, the data available to EPA has not been analyzed to better characterize the flux rate by using a first principles model such as CHAIN-2D (http://www.ars.usda.gov/Services/docs.htm?docid=8914). This model and the application of data that EPA used in the RED for chloropicrin have been presented to EPA recently (October, 2007); the presentation clearly demonstrated that both peak levels and total emissions can be accurately predicted. The additional data that is available for chloropicrin emission characteristics, cited above, could be input into this model to further refine it. However, the model already can be used to demonstrate those parameters that most affect the emission rate of chloropicrin from soil. The sensitivity analysis demonstrates that the data EPA used to model all non-drip buffer zones is not only unrepresentative of typical application practice, but also is some of the most extreme emission data available for chloropicrin. A case in point is that the emissions rates from several Arizona sites were very high (60-70%). Additionally, the soil moisture was well-below holding capacity, soil temperature was higher than many use situations, and chisel traces may not have been well-sealed. While the Arizona data may be usable in conjunction with chloropicrin emission data generated at other sites to characterize the effect of a full range of variables, it should not be considered in isolation as the basis for setting buffer zones.

Soil moisture has been shown to be a key determinant of off gassing using CHAIN-2D. Moist soils aid broadcast compaction by reducing pore spaces and act as a binding element for sandy soils during bed injection and formation. More soil water means more solvent capacity for keeping chloropicrin in the liquid phase (Gao and Trout, 2007). Injection depth is another very significant deterrent to emission of chloropicrin. Increasing injection depth by 10% can reduce off gassing proportionately. Models such as SOFEA include application depth in modeling loss from the soil (Cryer, 2005). Organic matter and organic reactants reduce off gassing of chloropicrin significantly (Zheng et al., 2003; Thomas et al., 2004).

Additional CHAIN-2D model runs, beyond those presented to EPA, should be done to properly characterize the chloropicrin temporal flux rate after soil injection. Databases that house soil characteristics on a national scale (e.g., USDA's Soil Survey Geographic (SSURGO) Database, USDA's General Soil Map (STATSGO), and USGS's National Geochemical Survey Database) can be tapped to determine soil-specific input parameters for regional model runs of CHAIN-2D. Since program code for CHAIN-2D is available as a downloadable FORTRAN file, modifications can be made to the program to generate temporal flux rates that can be fed into PERFUM.

Clearly EPA recognizes that some factors are more critical than others in determining buffer zones. EPA's document summarizing iodomethane buffer zones specifically indicates that factors such as tarp thickness, specific injection technology and soil moisture all can be used to quantitatively reduce buffer zone distance. It is important that chloropicrin users understand that factors can be modified to allow flexibility in how the fumigant is used. The data for chloropicrin emissions has been generated by numerous government and industry groups, but it can be used collectively to refine buffer zones so that they are both rational and protective.

In evaluating the buffer zone for chloropicrin, it is very important to understand that this material has been used in agriculture for six decades. Since the 1980s, California has required buffer zones for its use with other fumigants near populated areas. The low rate of incidents with the current buffer zones suggests that increases in buffer zones should be considered with great care, i.e., there is not a great deal of room for improvement. With this in mind, regulators should be cognizant that with any chemical the potential for accidental release is a possibility. No buffer zone will prevent some of the types of accident that have occurred in the past. Moreover, even with more intense use regulation future incidents will occur.

Because of the timing of most chloropicrin use, there are particular factors not previously considered for this fumigant that should be. For example, inversions and meteorologic sequelae such as fog can be reasonably well predicted 24 to 48 hours in advance of occurrence. Since this interval corresponds to the peak emission time from treated soil, restricting use prior to these conditions is not unreasonable. One factor that has not been adequately quantified in any model is the rate of air intrusion into a structure. Although ambient air levels of fumigant several hundred yards from an application may be in equilibrium with air in a house (Woodrow and Krieger, 2006), air levels inside a home

with closed doors and windows much closer to an application have not been thoroughly studied. No monitoring has been done at distances beyond approximately 50 meters to validate the model output for outdoor air concentration.

Indoor and outdoor air concentrations of contaminants can be different (Sheldon et al., 1992). Human habitations tend to be controlled environments, and the level of air contaminants inside a home compared to outside is not an exception. In response to noxious air contaminants, homes can be closed and residents can rely on air recycling and purifying devices (Hoppe and Martinac, 1998). Studies relating the differences between outdoor and indoor concentrations of air contaminants require considerations of factors such as whether the source is solely outdoors (Sundell, and Zuber, 1996: Jo and Oh, 2001), the reactivity of the air contaminants (Gold et al., 1996; Jakobi and Fabian, 1997), and the chemical and physical properties of the contaminants (Kinney et al., 2002).

In some cases there can be a substantial difference between indoor and outdoor air concentrations. For example, in 1990, the California DPR monitored the indoor and outdoor air concentrations of malathion (Segawa et al., 1991). That study indicated that in more than 30 homes the indoor air concentrations of malathion averaged only of 25% of the measured outdoor concentrations in the same areas. It is plausible that typical chloropicrin post-application indoor air concentrations (inside of structures located in near field zones) would be lower relative to transient concentrations that are associated with an outdoor-only source, i.e., soil fumigation; this would particularly be expected for peak, short-term (e.g., 4 hr) time-weighted average levels, which are of greatest interest in the case of chloropicrin.

REFERENCES

Ajwa, H.A., D. Sullivan, M. Holdsworth, S. Gao, R. Segawa, P. Wofford, S. Shem-Tov, W. Ha, R. Qin, D. Shatley. 2007. Reduced Fumigant Emissions Using Impermeable Film and Water Seal In Strawberry Raised Beds. University of California, Davis. Salinas, CA 93905.

Cain, W. (2004) Human Sensory Irritation Testing for Chloropicrin. Chemosensory Perception Laboratory, La Jolla. Study # PIC-1, unpublished. U.S. EPA MRID # 46443801.

Cryer 2005. Predicting Soil Fumigant Air Concentrations under Regional and Diverse Agronomic Conditions. J Environ Qual 34:2197-2207.

EPA (U.S. Environmental Protection Agency). 1997. Exposure Factors Handbook (http://www.epa.gov/ncea/efh/).

EPA (U.S. Environmental Protection Agency). 2007. Chloropicrin: Revised HED Human Health Risk Assessment for Phase 5. DP Barcode: D305336. FROM: Elissa Reaves and Charles Smith, TO: Nathan Mottl. Office of Pesticide Programs, U.S. EPA., Washington, D.C.

Gao S, Trout TJ. 2007. Surface seals reduce 1,3-dichloropropene and chloropicrin emissions in field tests. J Environ Qual. 36:110-119.

Gold, D.R., G. Allen, A. Damokosh, P. Serrano, C. Hayes, and M. Castillejos. 1996. Comparison of outdoor and classroom ozone exposures for school children in Mexico City. J. Air Waste Manag. Assoc. 6:593.

Hoppe, P. and I. Martinac. 1998. Indoor climate and air quality. Review of current and future toxics in the field of ISB Study Group 10. In. J. Biometerolo. 42:1-7.

Jakobi, G. and P. Fabian. 1997. Indoor/outdoor concentrations of ozone and peroxyacetyl nitrate (PAN). Int. J. Biometerol. 40:162-165.

Jo, W.K. and J.W. Oh. 2001. Exposure to methyl tertiary butyl ether and benzene in close proximity to service stations. J. Air Waste Manag. Assoc. 51:1122-1128.

Kinney, PlL., S.N. Chillrud, S. Ramstrom, J. Ross, and J.D. Spengler. 2002. Exposures to multiple air toxics in New York City. Environ. Health Perspect. 110 Suppl. 4:539-546.

Kwan, Mei-Po and Jiyeong Lee. 2003. Geovisualization of Human Activity Patterns Using 3D GIS: A Time-Geographic Approach. In: Michael F. Goodchild and Donald G. Janelle. Eds. 2003. *Spatially Integrated Social Science: Examples in Best Practice*, Chapter 3. Oxford: Oxford University Press.

Michael, K., A. McNamee, M.G. Michael, and H. Tootell. 2006. Location-Based Intelligence – Modeling Behavior in Humans using GPS. In Proceedings of the International Symposium on Technology and Society, New York: 8-11.

Segawa, R.T., J.A. Sitts, J.H. White, S.J. Marade, and S.J. Powell. 1991. Environmental monitoring of malathion aerial applications used to eradicate Mediterranean fruit flies in Southern California. 1990. Calif. Dept. Food & Agriculture, Environmental Hazards Assessment Program, Sacramento, CA.

Sheldon, L., A. Clayton, B. Jones, J. Keever, R. Perritt, D. Smith, D. Whitaker, and R. Whitmore. 1992. Indoor pollutant concentrations and exposures. Final report contract no. A833-156 prepared for California Air Resources Board. Research Triangle Institute, Research Triangle Park, NC.

Sundell, J. and A. Zuber. 1996. Ozone and other photochemical oxidants in ambient and indoor air- properties, sources and concentrations. Scand. J. Work Environ. Health. 22 Suppl. 3:5-14.f.

TERA, Toxicological Excellence for Risk Assessment (2005). Use of benchmark concentration modeling and categorical regression to evaluate the effects of acute exposure to chloropicrin vapor Part I. Technical Report.

Thomas JE, Ou LT, Allen LH Jr, McCormack LA, Vu JC, Dickson DW. Persistence, distribution, and emission of Telone C35 injected into a Florida sandy soil as affected by moisture, organic matter, and plastic film cover. J Environ Sci Health B. 2004 39:505-516.

Woodrow, JE, and Krieger, RI 2006. Assessing exposure to agricultural fumigants in outdoor and indoor air environments. In: Assessing Exposures and Reducing Risks to People from the Use of Pesticides. ACS Symposium Series 951, RI Krieger, N Ragsdale, and JN Seiber, eds., Oxford University Press.

Zheng W, Papiernik SK, Guo M, Yates SR. Competitive degradation between the fumigants chloropicrin and 1,3-dichloropropene in unamended and amended soils. J Environ Qual. 2003 32:1735-1742