



# Department of Pesticide Regulation



Mary-Ann Warmerdam  
Director

## MEMORANDUM

Arnold Schwarzenegger  
Governor

TO: Linda O'Connell  
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**HSM-08010**

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DATE: September 18, 2008

SUBJECT: GUIDANCE FOR THE DEVELOPMENT OF SCOPING DOCUMENTS

Attached is the *Guidance for the Development of Scoping Documents* prepared by Human Health Mitigation Program, as suggested in Department policy (Jones 2004a and 2004b) and in coordination with Human Health Assessment Program, to standardize elements of the Initial Scoping Document and Mitigation Scoping Document.

Attachment



**California Environmental Protection Agency  
DEPARTMENT OF PESTICIDE REGULATION  
Worker Health and Safety Branch, Human Health Mitigation Program**

**HSM-08010**

**GUIDANCE FOR THE DEVELOPMENT OF  
SCOPING DOCUMENTS**

**INTRODUCTION**

In 2004, the Department of Pesticide Regulation (DPR) created the Human Health Mitigation Program (HHMP) within the Worker Health and Safety Branch to separate the process of risk assessment and characterization from the process of mitigation, and to ensure that mitigation strategies adequately address unacceptable human health risks (Jones, 2004a and 2004b). As part of that reorganization, the HHMP was given responsibility for developing documents that lay the groundwork for assessing exposure and the adequacy of existing protective measures listed on pesticide product labels.

To accomplish this objective, the HHMP reviews all labels, pesticide use data, pesticide illness data, and pertinent background information. The HHMP scientist develops an Initial Scoping Document and works with the Human Health Assessment Program (HHAP) to finalize the document. Upon completion of the risk assessment process, if mitigation is deemed necessary, the HHMP goes through a second process, which generates the Mitigation Scoping Document. This document incorporates changes from the time of the initial scoping process.

**INITIAL SCOPING DOCUMENT**

**TITLE PAGE**

Active Ingredient  
Author(s) Name, Classification, Program, Branch, Department  
Date of Document

**TABLE OF CONTENTS**

**I. SUMMARY**

**II. PURPOSE**

**III. REGULATORY HISTORY/STATUS**

- a. Brief description
- b. Applicable regulations (Include URL; insert table below and answer Yes / No)

	Restricted Material	Toxic Air Contaminant	Groundwater Protection List	Proposition 65 List
Yes / No				
Law	FAC Division 7, Chapter 3, Article 1.5, Section 14001	FAC Division 7, Chapter 3, Article 1.5, Section 14021(b)	FAC Division 7, Chapter 2, Article 15, Section 13141	HSC Section 25249.5
Regulation	3 CCR Section 6400	3 CCR Section 6860	3 CCR Section 6800	27 CCR Section 25000 - 27001
FAC: California Food and Agricultural Code HSC: California Health and Safety Code CCR: California Code of Regulations				

- c. California regulatory status
  - Pending issues
  - Contact Registration Specialist
- d. Federal regulatory status
  - U.S. Environmental Protection Agency (U.S. EPA) Reregistration Eligibility Decision (RED) Interim Reregistration Decision (IREDD)
  - U.S. EPA Report of Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)
  - Tolerances (Title 40 Code of Federal Regulations Part 180)
  - Member of chemical group for cumulative risk (common mechanism of toxicity)
  - Studies by registrant(s)

#### **IV. PESTICIDE USE AND SALES**

- a. By year for past 5 years
  - County
  - Crops
  - Pounds active ingredient applied per year
  - Average annual trend for 5 years
  - Percent of total in pesticide use reports (PUR)
  - Regional differences

#### **V. FORMULATIONS**

- a. Copy every active label and permit conditions
- b. Summarize all active labels, Federal Insecticide Fungicide and Rodenticide Act registration types (It is important to review ALL labels)
  - Section 3 labels ([www.epa.gov/opppmsd1/PPISdata](http://www.epa.gov/opppmsd1/PPISdata))
  - Section 18 labels (Emergency exemption, [www.epa.gov/opprd001/section18](http://www.epa.gov/opprd001/section18))
  - Section 24(c) labels (Special Local Needs, SLN, [www.epa.gov/opppmsd1/PPISdata](http://www.epa.gov/opppmsd1/PPISdata))
  - Restricted use pesticide (Title 40 Code of Federal Regulations Part 152.160)
  - California restricted material (Title 3 California Code of Regulations Section 6400)
- c. Prepare tabular summary of formulations
  - Number of products currently registered in California
  - Formulation types and concentrations

#### **VI. LABEL REQUIREMENTS**

- a. Label approved uses (e.g., agricultural, non-agricultural)
- b. Signal words
- c. Personal protective equipment (PPE)
- d. Maximum application rate (e.g., pounds active ingredient/acre)
- e. Maximum number of applications/season, if applicable
- f. Restricted entry interval (REI) - If multiple REIs, use all combinations in exposure scenario
- g. Preharvest interval (PHI) - If multiple PHIs, use all combinations in exposure scenario
- h. Specific restrictions or prohibitions
- i. Other

## **VII. POTENTIAL EXPOSURE SCENARIOS**

- a. Occupational (agricultural, non-agricultural)
- b. Non-occupational
- c. Residential
- d. Bystander

## **VIII. PESTICIDE ILLNESS REPORTS FOR THE LAST 5 YEARS**

- a. Summarize illnesses and evaluate compliance with applicable label requirements
- b. Include illnesses from other states and countries
- c. Review of published literature

## **IX. REFERENCES and APPENDICES**

### **X. DOCUMENT DISPOSITION**

- a. Obtain *HS Memo Number* and prepare cover Memorandum to HHMP Supervisor
- b. Forward the Initial Scoping Document for HS Memo Review, including peer review by HHAP
- c. Make revisions as appropriate and forward the completed Initial Scoping Document to HHAP

## **POLICIES PERTAINING to the SCOPING DOCUMENTS**

Jones, T. 2004a. California Performance Review. Memorandum to Chuck Andrews, Chief, Worker Health and Safety Branch, from Tobi Jones, Assistant Director, Division of Registration and Health Evaluation, dated March 16, 2004. Sacramento, CA: Department of Pesticide Regulation, California Environmental Protection Agency.

Jones, T. 2004b. Reforms in Managing Product Registration and Related Activities. Memorandum to Branch Chiefs, Division of Registration and Health Evaluation from Tobi Jones, Assistant Director, Division of Registration and Health Evaluation, dated June 30, 2004. Sacramento, CA: Department of Pesticide Regulation, California Environmental Protection Agency.

## **MITIGATION SCOPING DOCUMENT**

Once a Risk Characterization Document is complete, the Chief Deputy Director determines the need for mitigation and prepares the Risk Management Directive. Upon receipt of the Risk Management Directive, the HHMP prepares the Mitigation Scoping Document. The HHMP scientist will again review all active labels, pesticide use and sales data, illness data, pertinent State and USEPA documents, and published literature. The Mitigation Scoping Document will incorporate all changes since the time of the initial scoping process.

### **I. ELEMENTS**

- a. Update elements III through VIII of the Initial Scoping Document
- b. In element III add a summary of DPR documents (include the URL links)
  - Initial Scoping, Exposure Assessment, Risk Characterization
- c. In Element VI, if new uses on current labels are identified that were not addressed in the Exposure Assessment Document, coordinate with the HHAP to ensure all exposure scenarios are covered by an exposure value
- d. In Element VIII, if there is a current illness incident, make an onsite visit for the purpose of evaluating additional mitigation measures.

### **II. REFERENCES**

### **III. DOCUMENT DISPOSITION**

- a. Obtain an *HS Memo Number* and prepare cover Memorandum to HHMP Supervisor.
- b. The Mitigation Scoping Document will be peer reviewed by HHAP before it becomes final.