

FINAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION
Title 3. California Code of Regulations
Adopt Sections 6450.1, 6450.2, and 6450.3, and Amend Sections 6000, 6450, and 6784
Pertaining to Methyl Bromide Field Fumigations

UPDATE OF THE INITIAL STATEMENT OF REASONS

The originally proposed regulatory action was noticed in the *California Regulatory Notice Register* on September 26, 2003. As requested, the Department of Pesticide Regulation (DPR) extended the public comment period for an additional 30 days and issued a notice of extension of public comment period.

During the public comment period, DPR received comments on the originally proposed text from over 873 individuals via mail, e-mail, fax machine, and the three public hearings. These comments have been numbered and categorized according to the issues addressed by each commentor, and added to the rulemaking file. The comments are discussed under the heading "SUMMARY AND RESPONSE TO COMMENTS RECEIVED" and the subheading "Comments Received During the Public Comment Period" of this Final Statement of Reasons (FSR). During the review of these comments, DPR determined that a number of the suggested changes should be included in a modified text. A list of these changes and the reasons for them are found below under the heading "CHANGES TO THE TEXT OF PROPOSED REGULATIONS."

DPR mailed four documents--a "Notice of Modifications to Text of Proposed Changes in the Regulations Pertaining to Methyl Bromide Field Fumigations," a revised "Methyl Bromide Field Soil Fumigation Buffer Zone Determination, Est. 2/04," the document incorporated by reference, a "Notice of Addition of Documents to Rulemaking File," and a "Modified Text of Proposed Regulations"--to every commentor and public hearing attendees who provided a legible return address. Copies were also e-mailed to those individuals who had commented via e-mail. These documents are also posted on DPR's Internet Home Page <<http://www.cdpr.ca.gov>>.

DPR received comment letters addressing the modified text during the first 15-day public comment period. These comments are discussed under the subheading "Comments Received During the First 15-Day Public Comment Period" in this FSR.

In response to comments received, DPR prepared a "Notice of Second Modifications to Text of Proposed Changes in the Regulations Pertaining to Methyl Bromide Field Fumigations" and a new "Modified Text of Proposed Regulations." These changes are found below under the heading "CHANGES TO THE TEXT OF PROPOSED REGULATIONS." DPR mailed the notice and modified text to everyone who had previously commented on the proposed regulations. DPR received 11 comment letters during the 15-day public comment period. These comments are discussed under the subheading "Comments Received During the Second 15-Day Public Comment Period" in this FSR.

DPR is not attempting to adopt comprehensive prescriptive regulations covering every possible methyl bromide use situation in all 58 California counties. To try to do so would be unworkable as well as overly prescriptive and not scientifically supported. What may be appropriate for a field fumigation in rural Shasta County, for example, would most likely not be suitable for a coastal community in Ventura County. DPR's intent is to adopt minimum regulatory standards which county agricultural commissioners (CACs) can and should supplement with permit stipulations addressing local conditions. Pursuant to Food and Agricultural Code (FAC) Division 6, Chapter 2, section 11501.5, DPR and the CACs have joint responsibility for enforcing California's pesticide laws and regulations. Pursuant to FAC Division 7, Chapter 3, section 14006.5, no person can use a restricted material without a permit issued by a CAC. DPR must allow CACs to retain the responsibility to issue restricted materials permits covering the use of methyl bromide.

CHANGES TO THE TEXT OF PROPOSED REGULATIONS

DPR made numerous sufficiently related changes to the text since it was originally proposed. Many of these changes were in response to comments received during both the 45-day comment period and the two subsequent 15-day comment periods. DPR also made other minor changes for grammatical and "plain English" reasons. The changes and some of the reasons behind them are listed below. DPR also listed these changes in the "Notice of Modifications to Text of Proposed Changes in the Regulations Pertaining to Methyl Bromide Field Fumigations" and the "Notice of Second Modifications to Text of Proposed Changes in the Regulations Pertaining to Methyl Bromide Field Fumigations" that were sent to commentors.

First Modified Text

- In section 6450, the phrase "supervising the fumigation operation" was added to clarify that this is considered a fumigation-handling activity.
- In subsection 6450(a), reference to subsection 6784(b)(6) was changed to section 6784(b)(2)(C).
- DPR revised subsection 6450(d) to allow an application block to exceed 40 acres only if approved by the Director. With additional restrictions, the Director has determined that an application block over 40 acres could be allowed while continuing to protect the public and agricultural employees from possible acute methyl bromide exposure. The Director would provide the CAC with additional requirements to assist him/her in conditioning the restricted materials permit.
- Subsection 6450(e) specifies permeability factors for tarpaulins used in fumigations. DPR revised this subsection to allow an exception to these requirements for experimental research purposes covered under a valid research authorization issued pursuant to section 6260.
- DPR modified the notification requirements. Section 6450.1(b)(1) was revised to add the requirement that when written notification is given, it shall be in both English and Spanish. DPR believes it is a reasonable requirement without being overly burdensome to property operators.

The section also allows the commissioner to require other means of communication to allow for communication in other languages. The overall intent of this section is to ensure that notification is provided to people in a language they can understand. Also, section 6450.2(g) was modified to require notification to be given to employees on adjoining agricultural properties be in manner that the person can understand. This is consistent with other employee notification requirements.

- In subsection 6450.2(a), the document *Methyl Bromide Field Fumigation Buffer Zone Determination, Est. 6/03*, which has been incorporated by reference, was revised. DPR revised the buffer zone requirements (emission ratios in Table 1) for tarp/deep/broadcast fumigations specified in *Methyl Bromide Field Fumigation Buffer Zone Determination, Est. 2/04*. The revision is based on new monitoring data submitted to DPR. This document was incorporated by reference since it would be cumbersome and impractical to publish it in Title 3, California Code of Regulations (3CCR).
- DPR revised the minimum inner buffer zone in subsections 6540.2(a) and 6540.2(e)(1) to 30 feet for limited acreages and use rates. The modeling procedures that established the buffer zone tables indicated at small acreage and use rates that no buffer zone was needed. DPR established a uniform minimum buffer zone of 50 feet. The buffer zone table continues to maintain the minimum buffer zone of 50 feet but extrapolated back to 30 feet in some limited instances. DPR has determined that this reduction from 50 feet to 30 feet will continue to provide adequate protection from possible acute methyl bromide exposure hazards to the public and agricultural employees.
- Subsections 6450.2(e)(3)(B) and (i) have been revised primarily for clarity.
- Supervising the fumigation operation was clarified as a fumigation-handling activity in section 6450; and therefore, DPR revised work-hour tables one and two in section 6784(b)(3) to include work hours for "supervising." Additionally, subsection 6784(b)(3)(B) was revised to clarify that the employee's total workdays restriction applies when performing fumigation-handling activities.
- Subsections 6784(b)(4) and (5), which pertain to tarpaulin cutting, removal, and repair, were revised primarily for clarity and consistency.
- Originally proposed subsection 6784(b)(6) was revised and placed into new subsection 6784(b)(2)(C). The change removed the sentence, "Any requirements for respiratory protection on the product label shall not be superseded by this regulation." This requirement is already stated in 3CCR section 6700.

Second Modified Text

- Section 6450(h) was revised to require DPR to ensure that ambient air concentrations of methyl bromide do not exceed an average daily nonoccupational exposure of nine parts per billion in a calendar month. This replaces the proposed limit of 270,000 pounds of methyl bromide used in any township in any calendar month. The lack of completed peer review mandated Health and Safety Code section 57004 on the methodology that derived the 270,000 pounds per month in any township equating to nine parts per billion precludes establishing the limit in regulation at this time. DPR received a significant number of comments questioning the methodology. In order to ensure that adequate subchronic restrictions are implemented, DPR is establishing a performance-based standard instead of a prescriptive standard, while still continuing to protect the public from any possible subchronic methyl bromide exposure. Placing the peer-reviewed health standard in regulation will allow DPR to address many concerns raised during the comment period, including the ability to meet the target value by other means such as larger buffer zones or by limiting the amount of methyl bromide in geographic areas smaller than townships. Under this change, DPR intends to limit methyl bromide to 270,000 pounds in a township per calendar month through permit guidance as well as other mitigation options such as increasing buffer zones.
- Section 6450.2(a) has been revised to remove the CAC's requirement to consult with the Director prior to approving any deviation resulting in buffer zone sizes or durations less than specified in the Methyl Bromide Field Fumigation Buffer Zone Determination, Est. 2/04.

The provision was deemed unnecessary, potentially confusing, and redundant to existing policies regarding interaction between the CACs and DPR. CACs shall rely on the information provided in the Methyl Bromide Field Fumigation Buffer Zone Determination, Est. 2/04, to determine the appropriate buffer zone size and other protective measures. Under the existing permit system, the CACs must craft methyl bromide permits based on their evaluation of the actual use conditions that exist at the specific fumigation site. CACs are responsible for knowing local conditions and utilizing such knowledge in making these evaluations. CACs shall approve buffer zone sizes and durations based upon local conditions. This is in accordance with FAC Division 2, Chapter 2, section 2281, which states, "Except as otherwise specifically provided, in all cases where provisions of this code place joint responsibility for the enforcement of laws and regulations on the director and the commissioner, the commissioner shall be responsible for local administration of the enforcement program. The director shall be responsible for overall statewide enforcement and shall issue instructions and make recommendations to the CAC" DPR will continue to provide oversight of the county programs.

- Subsection 6450.2(f)(4) was revised primarily for clarity.

Nonsubstantial Changes Contained in the Final Text of Regulations

In the final text of regulations, DPR has reinstated the letter "(h)" in section 6450. This letter was inadvertently deleted in the second 15-day modified text

This change does not alter the requirements, rights, responsibilities, conditions, or prescriptions contained in the originally proposed text or the two subsequent modified texts.

PUBLIC HEARINGS

DPR scheduled and held three public hearings to receive oral comments on the proposed regulations. The hearings were held in Sacramento, Ventura, and Salinas. Transcripts of the hearings and the hearing attendance registers are contained in the rulemaking file.

MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DPR has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts requiring reimbursement by the State pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of Section 6 of Article XIII B of the California Constitution. DPR has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED

Comments Received During the 45-Day Public Comment Period

DPR received over 873 comments during the 45-day public comment period; 808 of the written comments were form letters addressing the same issues. DPR assembled these 808 form letters unnumbered in binders 3 and 4. All the other written letters (or packets of documents) received with an identifying number (1 through 65). People testifying at the three public hearings have been assigned numbers T1 through T17. All of the letters of comment are assembled in binders 3, 4, and 5, and contained in the rulemaking file. Commentors addressed many of the same issues. DPR has prepared a matrix (Attachment A) that lists, categorizes, and summarizes the issues raised and includes a corresponding comment number (and assigned commentor number) for each comment. The matrix also contains DPR's responses to each of the comments. Also, DPR received a number of comments pertaining specifically to scientific issues regarding toxicology studies and reference concentrations which formed the basis for the proposed regulation for possible acute and subchronic exposure. These comments and responses are found in Attachment B.

Comments Received During the First 15-Day Comment Period

During the first 15-day period provided for comment on both the modified text and the documents added to the rulemaking file, DPR received 33 comment letters pertaining to both the modified text and some of the documents. These 33 letters have each been marked with a number--1A through 33A--and are assembled in binder 5 contained in the rulemaking file. DPR has prepared a matrix (Attachment C) that lists each comment along with the assigned comment numbers and commentor numbers. The matrix also contains DPR's responses to each of the comments.

Comments Received During the Second 15-Day Comment Period

During the second 15-day period provided for comment on the modified text to the rulemaking file, DPR received 11 comment letters. These 11 letters have each been marked with a number--1B through 11B--and are assembled in binder 5 contained in the rulemaking file. DPR has prepared a matrix (Attachment D) that lists each comment along with the assigned comment numbers and commentor numbers. The matrix also contains DPR's responses to each of the comments.

ALTERNATIVES DETERMINATION

In the Initial Statement of Reasons, DPR stated that it "has not identified any satisfactory alternatives to the proposed regulatory action that would lessen any adverse impacts, including any impacts on small businesses, and invites the submission of suggested alternatives."

Comments received suggested amended language for the proposed regulations that would lessen the adverse impact on small businesses yet still fully protect worker and public health. DPR has considered this language an alternative pursuant to California Government Code, Administrative Procedures Act (APA), sections 11345(a)(12) and 11346.9(a)(5). DPR has considered these alternatives and incorporated some of the suggested text into the modified text of regulation.

CONSULTATION WITH THE OTHER AGENCIES

DPR has consulted with the California Department of Food and Agriculture during the development of the text of proposed regulations as specified in FAC section 11454, and the February 6, 1992, Memorandum of Agreement which was developed as provided in section 11454.2.

As required by FAC sections 12980 and 12981, DPR has consulted with the Office of Environmental Health Hazard Assessment (OEHHA) during the development of the text of proposed regulations, and OEHHA played a part in the development of the regulations as well as provided health-based recommendations. There remained divergent opinions on the interpretation of the toxicology data, strength of the evidence needed to establish a no-observed-effect level, interpretation of the National Research Council and external scientist reviews, the weight of the evidence, and the adequacy of reference concentration to address potential increased sensitivity of infants and children from exposure to methyl bromide. During the interagency consultation with OEHHA, OEHHA recommended an acute target air concentration level of 90 ppb calculated from a

1-hour reference exposure level of 1 part per million (ppm), while DPR calculated a target air concentration of 210 parts per billion (ppb). Subsequently, OEHHA (memorandum of November 10, 2003) recommended the use of both OEHHA reference exposure level of 1 ppm and DPR's 210 ppb reference concentration, depending on the exposure scenarios. For subchronic exposure, OEHHA recommended the 1 and 2 ppb levels (for children and adults, respectively). DPR's subchronic reference concentration levels are 9 ppb and 16 ppb.

Comments submitted did not provide any additional scientific data or information to require revisions to DPR's current acute or subchronic reference concentration levels used to develop these regulations. These concentrations were derived after a comprehensive evaluation of the data using the weight of evidence approach, and thorough considerations of all external review comments to select the most appropriate no-observed-effect levels to address the potential toxicity from acute and subchronic exposures to methyl bromide.

DPR also consulted with the Department of Industrial Relations and University of California.

In order to meet additional consultation requirements under law, DPR consulted with other representatives from different agencies to discuss the regulatory target value and control measures for methyl bromide. These agencies included Air Resources Board, County Air Pollution Control Districts, the California Agricultural Commissioners and Sealers Association, and Department of Health Services.

DPR also notified these agencies concerning the modified text of proposed regulations and took into consideration their comments received.

Copies of correspondence with these agencies are contained in the rulemaking file.

ALTERNATIVES DETERMINATION

The Director has determined that no alternative considered by DPR would be more effective in carrying out the purpose for which this regulation is proposed, or would be as effective and less burdensome to affected private persons or businesses than the proposed regulatory change.

POSTING REQUIREMENT

Title 3 CCR, section 6110, states in part that, "The public report shall be posted on the official bulletin boards of the Department, and of each commissioner's office, and in each District office of the DPR [Division of Pest Management, Environmental Protection and Worker Safety] for 45 days." DPR has posted its Initial Statement of Reasons and Public Report on its official bulletin board, which consists of the Department's Internet Home Page <<http://www.cdpr.ca.gov>>. In addition, copies were provided to the offices listed above for posting.

Attachments