Notice of Final Decisions to Register Pesticide Products Containing Methyl Iodide and Written Evaluation

Volume 2010-50
December 1, 2010

Department of Pesticide Regulation
Pesticide Registration Branch

POST THROUGH: December 31, 2010

NOTICE OF FINAL DECISIONS TO REGISTER PESTICIDE PRODUCTS CONTAINING METHYL IODIDE AND WRITTEN EVALUATION

Pursuant to Title 3, California Code of Regulations (3 CCR) section (§) 6255, the Department of Pesticide Regulation (DPR) Director files this Notice concerning pesticide products containing methyl iodide with the Secretary of the Resources Agency. Pursuant to 3 CCR § 6254, this Notice includes the attached supplement to the Public Report consisting of a written evaluation of significant environmental points raised in comments submitted pursuant to 3 CCR § 6253.

The Director has reached a final decision to register pesticide products containing methyl iodide to be effective December 20, 2010, the date by which the proposed emergency regulation designating these products as restricted materials pursuant to Food and Agricultural Code § 14004.5 will be approved by the Office of Administrative Law and filed with the Secretary of State.

Tracking Number - EPA Registration Number
Applicant / Brand Name

ID 192894 - (66330-44)
ARYSTA LIFESCIENCE NORTH AMERICA, LLC
IODOMETHANE TECHNICAL
USE: FUMIGANT - FOR FORMULATION AND REPACKAGING INTO END-USE PRODUCTS INTENDED FOR TERRESTRIAL NON-FOOD USES TO CONTROL SOIL-BORNE PESTS SUCH AS NEMATODES, WEED AND GRASS SEEDS AND DISEASES
TYPE: SECTION 3 REGISTRATION
ACTIVE INGREDIENT(S): IODOMETHANE
CAS NUMBER(S): 74-88-4

ID 192893 - (66330-43)
ARYSTA LIFESCIENCE NORTH AMERICA, LLC
MIDAS 98:2
USE: FUMIGANT - FOR USE ON STRAWBERRIES, TOMATOES, PEPPERS AND ORNAMENTAL FLOWERS, PLANTS AND BUSHES TO CONTROL NEMATODES, WEED AND GRASS SEEDS AND DISEASES
TYPE: SECTION 3 REGISTRATION
ACTIVE INGREDIENT(S):
IODOMETHANE
CHLOROPICRIN
CAS NUMBER(S): 74-88-4, 76-06-2

ID 209995 - (66330-57)
ARYSTA LIFESCIENCE NORTH AMERICA, LLC
MIDAS 50:50
USE: FUMIGANT - FOR THE CONTROL OF SOIL-BORNE PESTS SUCH AS WEED SEEDS, NEMATODES AND DISEASES ON VARIOUS CROPS SUCH AS STRAWBERRIES, PEPPERS, TOMATOES, AND TREES AND VINES
TYPE: SECTION 3 REGISTRATION
ACTIVE INGREDIENT(S):
IODOMETHANE
CHLOROPICRIN
CAS NUMBER(S): 74-88-4, 76-06-2

ID 211201 - (66330-59)
ARYSTA LIFESCIENCE NORTH AMERICA, LLC
MIDAS 33:67
USE: FUMIGANT - FOR PRE-PLANT FUMIGATIONS OF FIELDS INTENDED FOR COMMERCIAL PRODUCTION OF CROPS SUCH AS STRAWBERRIES, TOMATOES, PEPPERS, FIELD-GROWN ORNAMENTALS AND CONTROL OF SOIL-BORNE PESTS INCLUDING WEED SEEDS, NEMATODES AND DISEASES
TYPE: SECTION 3 REGISTRATION
ACTIVE INGREDIENT(S):
IODOMETHANE
CHLOROPICRIN
CAS NUMBER(S): 74-88-4, 76-06-2

ID 211199 - (66330-60)
ARYSTA LIFESCIENCE NORTH AMERICA, LLC
MIDAS EC Gold
USE: FUMIGANT - FOR PRE-PLANT FUMIGATIONS OF FIELDS INTENDED FOR COMMERCIAL PRODUCTION OF CROPS SUCH AS STRAWBERRIES, TOMATOES, PEPPERS, FIELD-GROWN ORNAMENTALS AND CONTROL OF SOIL-BORNE PESTS INCLUDING WEED SEEDS, NEMATODES AND DISEASES
TYPE: SECTION 3 REGISTRATION
ACTIVE INGREDIENT(S):
IODOMETHANE
CHLOROPICRIN
CAS NUMBER(S): 74-88-4, 76-06-2

Written Evaluation: Response to Comments Raising Significant Environmental Points

As noted in the Public Report issued with the Proposed Decisions to Register Products Containing Methyl Iodide, the potential for an adverse impact to public health from the use of these products results from the risk of inhalation exposure by workers or bystanders. The risk of dermal exposure is determined to be negligible and dietary exposure is not expected. Also noted in the Public Report was the potential for ground water contamination in susceptible soils by the iodide metabolite that could impact drinking water. The Public

Report set forth the regulatory target levels to limit exposure, and outlined how those levels were determined. The Report described the proposed mitigation measures that would keep inhalation exposure under those levels in order to eliminate any direct or indirect significant adverse impact to human health or to ground water from the use of these products.

Over 50,000 comments were received on the Proposed Decisions. The significant environmental points raised in these comments focused on the two issues also addressed in the Public Report: the risk of exposure to workers and bystanders. Specifically, the comments questioned the adequacy of the regulatory target levels and the validity of the mitigation measures set forth in the Public Report. Some comments also expressed concerns over ground water contamination, a potential also noted in the Public Report. In addition, some comments were received questioning the potential for dietary exposure, an issue not considered significant as discussed in the Public Report. Questions were also raised about the compliance of the registration process with the requirements of the California Environmental Quality Act (CEQA). An evaluation and response to these points raised in the comments follows. With the exception of the potential for dietary exposure, the most comprehensive, specific, and detailed comments dealing with the points noted above were those submitted by a group of environmental organizations under the letterhead of the Pesticide Action Network (PAN). For that reason, in most instances, those comments are quoted or paraphrased and used as the guide in the attached written evaluation.

1 December 2010
Dated

Mary-Ann Warmerdam
Director

Written Evaluation: Responses to Comments Raising Significant Environmental Points

1. **COMMENT: Risks of fetal death from inhalation exposure are high and unmitigated.**

The fetal death endpoint is the observable effect that occurs at the lowest dose. In DPR's finalized risk assessment, a benchmark dose analysis was conducted to estimate a dose that would result in lowered risk of fetal death. DPR scientists selected a level of 1% fetal death, as the acceptable point of departure. Remarkably, DPR management used an even less protective endpoint for fetal death that would result in a 4% fetal death rate being considered acceptable. The current proposed mitigations are thus based on a 4% fetal death rate. In combination with methyl iodide's uncontrollable release into the environment that makes exposure inevitable, DPR is essentially guaranteeing that some fraction of pregnant women living or working near a methyl iodide application will suffer a miscarriage or have a developmentally disabled child as a result of the exposure.

RESPONSE: DPR scientists' selection of 1 percent benchmark dose response (the statistical analysis test where the assumption of risk for fetal resorption is 1 percent for animals tested at that dose) was based upon the recommendation of the Scientific Review Committee (SRC) after an extensive discussion at the Sept. 24, 2009 hearing in Sacramento. However, on page 164 of DPR's risk characterization document (RCD) dated February 2010 <http://www.cdpr.ca.gov/docs/risk/methyliodide.htm>, DPR's scientists discussed the wide data variability at the 1 percent dose response, that is, the fact that it is difficult to ascertain with certainty that the effect was caused by that dose, and that this level could be well within the normal values for fetal resorption. The 4 percent benchmark dose response coincides with the 2 parts per million (ppm) no observable effects level (NOEL) selected by DPR based upon a study evaluated for this risk assessment and consistent with the conclusion reached by the study's author (Nemec). The U. S. Environmental Protection Agency (U.S. EPA) standard benchmark dose response for reproductive and developmental studies is at 5 percent. Additionally, this NOEL selection was also consistent with DPR scientists' original selection in the August 2009 RCD.

The proposed decision to register methyl iodide for use in California was based on all data available for the risk managers to review. These included U.S. EPA's risk assessment, the registrant's comments, the SRC's comments, and published literature. The review of all scientific data available to the risk managers resulted in selecting the 2 ppm NOEL as point of departure (POD) for calculating the regulatory level to which mitigation is keyed to protect against the adverse health effects including risk of fetal loss.

2. **COMMENT: Cancer risks from inhalation exposure are unacceptable at the regulatory target levels.**

The animal test data indicate that methyl iodide causes thyroid tumors, brain tumors (astrocytomas), lung tumors, and urinary and cervical tumors. The proposed regulatory target levels of 96 ppb and 32 ppb for workers and bystanders, respectively result in significantly increased cancer risks for those exposed, 24–56 times higher for workers and 32–800 times higher for bystanders.

RESPONSE: After evaluating the animal studies, DPR scientists agree that methyl iodide can cause thyroid, brain, lung, urinary, and cervical tumors. The animal studies submitted and evaluated by DPR demonstrate two plausible modes of action for the occurrence of animal tumors. As evidenced in DPR's August 2009 RCD, a human equivalent concentration was calculated based on a NOEL of 20 ppm in rats which resulted in a reference concentration of 542 parts per billion (ppb) for workers and 129 ppb for the general population. Based on those, the current regulatory target levels of 96 ppb for workers and 32 ppb for the general population is still protective for both populations.

Although the final RCD reflected different reference concentration levels (RfC's) for plausible modes of action for tumors in rats, those numbers were also based on a benchmark dose response of 1percent using the benchmark dose analysis. As explained earlier in this document, that dose selection also reflects a wide variability on levels well within the normal values for benchmark dose responses for the carcinogenesis endpoint. Additionally, the U.S. EPA standard benchmark dose response for cancer bioassays is at 10 percent. After considering all those variables, including U.S. EPA's conclusion that methyl iodide is not likely to cause cancer in humans, DPR risk managers selected the RfCs presented in the August 2009 RCD for cancer risk endpoint to determine the development of the regulatory target levels.

3. **COMMENT: Tests to address the risk of neurotoxicity submitted by Arysta are inadequate.**

Professor Theodore Slotkin, member of the SRC noted in the June 17, 2010 Senate hearing on methyl iodide that the neurotoxicity tests conducted by Arysta would not have been able to determine that lead (Pb)—a known developmental neurotoxicant—is a neurotoxicant. The SRC report notes:

"The SRC remains concerned about calculations based on supposed measures of "neurotoxicity" when there were in fact, no robust studies of neurotoxicity actually conducted. The studies labeled as "neurotoxicity" were nothing of the sort, but rather acute general toxicity observations that including manifestations such as motor activity. Thus the extrapolations of neurotoxicity as an endpoint are based on studies that did not assess neurotoxicity appropriately in a broadly acceptable scientific sense. Of note, the contract laboratory conducting key studies in this area was demonstrably incapable of detecting neurotoxicity from positive control test compounds. Based on numerous case studies and laboratory findings, there is a strong expectation that methyl iodide is

neurotoxic. The case studies were particularly insightful and demonstrated long term neurotoxic effects of methyl iodide. The mechanism for this is unclear, and therefore uncertainty factors will need to be applied in considering this endpoint."

This analysis indicates poor study quality that does not meet the criteria specified by the California Food and Agricultural Code § 13126.

RESPONSE: The comment made by Dr. Theodore Slotkin at the June 17, 2010 Senate hearing on methyl iodide was raised by the Scientific Review Committee during their review of DPR's risk assessment document. DPR scientists evaluated all the mandatory health effects studies required and submitted following the guidelines set by U.S. EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (Title 40 Code of Federal Regulations [40 C.F.R.] § 158.5800). For acute neurotoxicity studies, U. S. EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS) provides guideline NO. 870.62. The purpose of the submitted study is to screen for neurotoxic effects and not to perform an in-depth research project. Also, the protocol and procedures of the study as written in the report fulfilled the guidelines specified in the Good Laboratory Practice standards in 40 C.F.R. § 160. Consequently, DPR scientists selected neurotoxicity as one of the endpoints based on the submitted studies and identified a NOEL and reference concentration explicitly stated in the risk assessment document. These studies satisfied the requirements for mandatory health effects studies as defined by Food and Agricultural Code § 13123 that are required to be submitted to DPR before the registration of any new active ingredient under Food and Agricultural Code §13126.

4. COMMENT: DPR must require a developmental neurotoxicity study for methyl iodide.

DPR should have required a developmental neurotoxicity study ("DNT") to be carried out for methyl iodide before it made a decision about registration. Under the California Birth Defects Prevention Act of 1984, the purpose of which is to prevent pesticide induced abortions, birth defects, and infertility, "[t]o the extent feasible, health effects studies shall be conducted in accordance with standards and protocols established pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 135 et seq.)." (Food & Agr. Code § 13123.5.)

Regulations promulgated pursuant to FIFRA provide that a developmental neurotoxicity study is required if characteristics of the chemical meet the criteria below. Methyl iodide meets all of these criteria:

(i) The pesticide causes treatment-related neurological effects in adult animal studies (i.e., clinical signs of neurotoxicity, neuropathology, functional or behavioral effects).

(ii) The pesticide causes treatment-related neurological effects in developing animals, following pre- and postnatal exposure (i.e. nervous system malformations or neuropathy, brain weight changes in offspring, functional or behavioral changes in the offspring).

(iii) The pesticide elicits a causative association between exposures and adverse neurological effects in human epidemiological studies.

(iv) The pesticide evokes a mechanism that is associated with adverse effects on the development of the nervous system (e.g., SAR relationship to known neurotoxicants, altered neuroreceptor or neurotransmitter responses).

40 CFR 158.500(e)(28).

RESPONSE: The FIFRA guidelines outlined in 40 C.F.R. § 158.500 regarding conducting a developmental neurotoxicity study (DNT) are "conditionally required" if the stated criteria are met. DPR risk managers reviewed all the information available to them and concluded, consistent with U.S. EPA's evaluation, that a DNT study would not be required for several reasons. First, the only DNT study protocols available and specified in 40 C.F.R. § 158.500 are designed to be performed on rats, not rabbits. The acute toxicity endpoints chosen by DPR and U.S. EPA scientists identified the rabbit as the most sensitive species for the fetal toxicity endpoint. Therefore, performing a DNT study on a less sensitive species is not appropriate. Second, the initial and critical effect that leads to adverse effects on the developing nervous system is an alteration of the thyroid hormone homeostasis. This biochemical alteration of thyroid hormone homeostasis cannot be detected by the less sensitive behavioral and physical measures used in a DNT study. Further, an additional uncertainty factor of 10X (lowering the acceptable level by dividing by10 to account for the absence of a DNT study) is not required because the POD obtained from a DNT study is not expected to be lower than the 2 ppm selected as the NOEL. This premise is based on the fact that the lowest dose that caused maternal effects in the rat inhalation study was 20 ppm which is 10 times higher than the 2 ppm POD selected for the more sensitive species chosen for this endpoint. If a DNT surrogate study is done using the rat, because protocols for the study are only available for rats, the POD is not expected to be lower than 2 ppm.

Pesticides are regulated based on the most sensitive toxicologic endpoints. Considering all the data available, a DNT study conducted in the less responsive rats would not provide a more sensitive endpoint for regulation.

5. COMMENT: Reductions in emissions from virtually impermeable film (VIF) tarps are overestimated.

One of DPR's primary proposed mitigations to reduce methyl iodide emissions from soil fumigations is the use of Virtually Impermeable Film (VIF) tarpaulins. The reduction in emissions credited to the VIF tarps was based on data from three air monitoring studies reviewed by DPR staff, as well as a summary document on the VIF studies and incorporation of the results into mitigation measures.

DPR staff reviewing these monitoring studies marked all of them as "Data/Information Do Not Support Registration." In the reviews, several major problems with the sampling and analysis methodology used in these studies were noted that systematically biased the air monitoring results to lower concentrations than actual concentrations, including: 1) Incomplete capture of methyl iodide by sample tubes, as indicated by breakthough into the

rear sample bed; 2) Incorrect preparation of spike samples and application of recovery adjustments; and 3) Highly variable, but frequently low storage stability. We reproduce the DPR staff assessment of the issues with the VIF studies verbatim below:

DPR scientists concluded that these VIF studies were too flawed to use. Using a lower emission factor than Arysta proposed does not legitimize these studies or correct their flaws.

RESPONSE: This comment just restates DPR's review of the VIF studies and does not provide any new comments or issues to consider. Despite the problems with the studies, it is possible to use them to estimate the maximum possible flux for VIF applications (Barry and Segawa, 2010, <http://www.cdpr.ca.gov/docs/registration/mei_pdfs/mitigation_options_4-29-10.pdf>). A worst-case 24-hour flux can be estimated by assuming that the total flux is 100 percent of the amount applied. For example, if the application rate is 100 lbs/acre, the total flux is 100 lbs/acre over the entire 6-day study period. This is 3.57x higher than the 28 lbs/acre total flux estimated by Arysta as the average for the three VIF flux studies. Applying the same 3.57x adjustment factor increases the average 24-hour peak flux value from 11.0 ug/m^2-day (8.5 lbs/acre or 8.5 percent of the amount applied) to 38.9 ug/m^2-day (30 lbs/ac-day or 30 percent of the amount applied). DPR estimates that the worst-case 24-hour peak flux for methyl iodide applied with the bed-shank method using a Symmetry rig and VIF is 30 percent of the amount applied. This conservative estimate is used as the basis for the mitigation measures required under the proposed registration (Barry, 2010, <http://www.cdpr.ca.gov/docs.registration.mei_pdfs.mei_tarp_duration_4-29-10.pdf>).

6. COMMENT: Use of VIF tarps has never been allowed in California for soil fumigation.

It is not legitimate for DPR to claim that VIF film tarps will significantly reduce bystander and applicator exposure because data in DPR's possession do not support this conclusion. In fact, field tests a decade ago found no reduction in methyl bromide concentrations in air near fields after applications covered with VIF tarps and higher emissions during tarp-cutting. These data led DPR to prohibit use of VIF tarps in California. In addition to being of poor quality (as noted above), the three methyl iodide application monitoring studies using VIF tarps did not include any air monitoring conducted during tarp cutting and removal, nor did they include worker exposure assessment.

In 1998, DPR conducted methyl bromide application monitoring studies using VIF tarps and found no difference in surrounding air concentrations for use of VIF tarps compared to standard high barrier tarps, significant off-gassing during and after tarp cutting and a large range in permeability of VIF tarp samples, indicating quality control problems. As a result of the lack of reliability and efficacy shown in these studies, VIF tarps were never approved for use during methyl bromide soil fumigation. In a presentation at the DPR Pesticide VOC Symposium on May 22, 2007, researcher Hussein Ajwa stated that while he had found significant emission reductions in test plots with VIF tarps, he had concerns about permeability being increased by tarps stretching, that there were no compatible glues available for joining sections or patching and that tarps can and will blow off of fields.

Earlier in the 1990s, when permit conditions for methyl bromide field fumigation were first instituted, DPR assigned a much lower emission factor to very high barrier (VHB) tarpaulins than standard high barrier tarps without conducting any field testing. Subsequently, in 1997 air levels over three times DPR's target exposure limit were measured at the buffer zone of a VHB tarpaulin application and the low emission factor was rescinded.

The potential for leaching of MeI or iodide to groundwater may be higher with VIF tarps. If DPR believes that VIF tarps will reduce MeI flux (as they are counting on in the exposure assessment), then more methyl iodide or its breakdown products methanol and iodide ion will be present in the soil, with higher potential for leaching to groundwater. DPR environmental monitoring staff acknowledge this possibility:

RESPONSE: The initial statement in this comment is factually incorrect. DPR prohibits VIF tarps only for methyl bromide. DPR has always allowed VIF tarps for other fumigants, including chloropicrin and 1,3-dichloropropene. The objection to the use of VIF here relying on some methyl bromide monitoring data, makes the assumption that the flux of methyl iodide is the same as methyl bromide or greater, without supporting data. The comment also assumes that all VIF tarps are ineffective and result in the same flux as standard tarps, based on a single methyl bromide study. As discussed above, field data for methyl iodide demonstrate lower methyl iodide flux with the VIF tarp tested, in comparison to standard tarps. Additionally, more recent laboratory and field studies show that flux varies with different VIF tarps, and that different fumigants have different flux. VIF tarps have improved since the 1990s, and field studies have been conducted with the improved tarps for several fumigants, including 1,3-dichloropropene, chloropicrin, methyl bromide, and methyl iodide. These studies measured emission reductions due to VIF tarps of 19 to 88 percent in comparison to standard tarps (Barry and Segawa, 2010 <http://www.cdpr.ca.gov/docs/registration/mei_pdfs/mitigation_options_4-29-10.pdf>). Laboratory tests have measured the permeability of VIF tarps, before and after field fumigations to determine the effect of stretching and other field activities. While the tarp permeability after fumigation was lower than before fumigation, VIF tarps had much lower permeability than standard tarps (Yates, 2009). Fumigation companies have developed new gluing techniques to ensure that VIF tarps remain intact. Concerns about the leaching of MeI to ground water are addressed in response to Comment 17 below.

7. **COMMENT: Buffer zones will not keep methyl iodide concentrations below DPR's proposed regulatory target levels.**

The proposed buffer zones for use of methyl iodide are based on modeled exposures calculated using the PERFUM model with a 95th percentile maximum direction buffer zones, mean flux profiles and 5 years of Ventura weather data. There are several assumptions contained in this approach that are invalid and inappropriately result in lower modeled concentrations compared to actual concentrations.

Tarp failures: DPR assumes that no tarp failures occur during fumigations. This is not accurate. The precise percentage of fumigations that suffer some sort of tarp failure is unknown, but likely to be high. DPR staff even note that during the Arysta study of VIF tarps,

a deer walked across the tarp and punctured it. During a fumigation in Sisquoc, CA, high winds blew a tarp off of a field being fumigated with methyl bromide. Because of the high winds, the tarp could not be repaired for many hours (see below for more detail on the Sisquoc incident).

Human error: DPR's mitigation measures for methyl iodide rely on eliminating human error. This is not possible. Humans will make mistakes, equipment will fail, applicators will not follow the rules, and they will push the limits of what is legal in the interest of saving time and/or money. The Pesticide Illness Surveillance Program data support this conclusion and call into question DPR's assumption of perfect compliance.

Inadequate enforcement: In these times of reduced funding for state and county agencies, County Agricultural Commissioner offices are having to cut staff. Yet DPR's mitigation measures for methyl iodide—a complex set of requirements that would be difficult to implement—rely on intensive enforcement to be effective.

Inappropriate weather data: Ventura weather data are used in the modeled exposure assessment; yet methyl iodide will be used in a variety of locales in which inversion conditions may prevail more frequently than in Ventura. In the Central Valley, fumigation season generally coincides with the winter Tule fog and inversion layers that can last for days. Exposures under inversion conditions would be substantially higher than modeled exposures. All of these factors indicate that methyl iodide exposures for bystanders will be higher than those modeled under some set of circumstances that is not all that uncommon. Mitigation measures that assume perfect compliance and no equipment failures misrepresent the real-world complexities associated with soil fumigations.

RESPONSE: Animals walking across tarps, or other minor damage to tarps would usually have a minimal effect on the flux over the entire field or air concentrations, and can be repaired. Complete tarp failure is an issue DPR considered prior to its proposed decision. Complete tarp failure occurs due to high winds. High winds serve to dilute the air concentrations, so methyl iodide exposure would remain acceptable. According to the Industrial Source Complex-Short Term computer model used to calculate buffer zones, air concentrations are inversely proportional to wind speed, all other factors being equal. For example, if wind speeds of 4 miles per hour result in an air concentration of 20 ppb at a certain location, the air concentration is 10 ppb with wind speeds of 8 miles per hour at the same location. DPR established buffer zones based on wind speeds of approximately 3 miles per hour. Tarps do not normally fail unless wind speeds exceed 10 miles per hour. As discussed in the response to Comment 5 above, the maximum methyl iodide flux with VIF is approximately 30 percent of the amount applied during the peak 24-hour period. Thus, even if the flux increased to 100 percent of the amount applied during a tarp failure, air concentrations outside the buffer zone would be comparable or less than the regulatory target concentration due to dilution by high winds. The increased wind speed would offset the increased flux due to loss of the tarp.

DPR used Ventura weather data because it resulted in the longest buffer zones. DPR conducted computer modeling using weather data from Ventura and Bakersfield. Buffer

zones using Bakersfield weather data were consistently shorter than Ventura. Moreover, coastal areas represented by Ventura will likely have higher use of methyl iodide than inland areas represented by Bakersfield.

See also response to Comment 8 below that addresses compliance and enforcement.

8. COMMENT: Enforcement of fumigant mitigations is inadequate.

We have recently encountered two examples clearly demonstrating that mitigations that are dependent on local enforcement are doomed to failure, at the expense of the health of the communities and farm workers.

Sisquoc: *In 2007, a catastrophic tarp failure in the Sisquoc community near Santa Barbara released 20 acres worth of methyl bromide and chloropicrin into the air, making children in the community ill. The failure was a result of poor judgment of the applicator, conducting a fumigant application on a day when very high winds (>30 mph) were predicted. When the fumigation went wrong, none of the emergency procedures required by the Santa Barbara County Agricultural Commissioner (CAC) were followed.*

Moss Landing: *Moss Landing Heights (MLH) is a small rural community with approximately 300 residents just north of Monterey on the coast. A local grower decided to fumigate the field adjacent to the community for the first time, as he was transitioning that field from lettuce and artichokes to strawberries. The community was concerned and attempted to work with the Monterey County CAC to request that he decline to permit the application because of its close proximity to homes. The CAC refused, initially even allowing the grower to utilize the front yards of the MLH residents as part of the required 60-foot buffer zone. The final buffer zone border was taken back to the edge of the Potrero Road passing through the community. Potrero Road is the only access to the homes on Potrero Road, to Salinas State Beach, and to the Salinas State Wildlife Sanctuary. Use of Potrero Road necessarily requires residents of Potrero Road to be well within the limited buffer zone. The final permit conditions approved by the CAC included a requirement that "The weather conditions proceeding, during, and following the soil fumigations must be consistent to ensure an* ***on shore*** *wind flow." The applicator did not comply with these permit conditions, and applications were made under wind conditions that transported the fumigant directly from the field into the community. During at least one of these applications, the CAC himself was present, verifying that the fumigation could proceed, even though inversion conditions prevailed at the time of the application, transporting high levels of fumigants into the community. Air monitoring conducted by Pesticide Research Institute during one of these time periods showed levels of chloropicrin in the air exceeding DPR's regulatory target levels for chloropicrin.*

RESPONSE: DPR does not agree with many of the statements describing and characterizing the specific events above nor that they prove that enforcement is inadequate (for example, the Moss Landing application was challenged before it occurred and was allowed to proceed after a hearing, with the court later ruling that there was no evidence that the permit was violated nor that any illness occurred). What is true is that pesticide use

enforcement by the county agricultural commissioners (CACs) and by DPR is rigorous and compliance rates with mitigation measures are high. California has the most extensive pesticide regulatory system in the nation that effectively uses the mechanism of local enforcement of the pesticide use laws by the CACs and locally issued site- and time-specific restricted material permits. The restricted material permit system to which this fumigant will be subject is not found in any other state currently allowing its use. Fumigants are a major focus of DPR and CAC risk reduction efforts, and CACs direct significant enforcement resources toward regulating these pesticides.

In California's 58 counties, local enforcement of pesticide use is carried out by the CACs and their approximately 250 biologists/inspectors. DPR staff provides the CACs with training, coordination, and technical support; helps set statewide guidelines; analyzes compliance trends; and assists with misuse and priority investigations. In 2007-2008, the CAC biologists devoted nearly 675,000 hours to pesticide enforcement.

The CACs collectively conduct about 20,000 pesticide inspections annually. They also issue about 39,000 restricted materials permits with conditions for protective measures that must take into account local conditions, and conduct about 11,000 site inspections before restricted pesticides can be applied. From 2007 to 2009, CAC biologists conducted over 2,000 inspections of field fumigations. In each of these inspections, biologists look for up to 36 different items for compliance, for a total of over 61,000 elements checked. They found an overall compliance rate of more that 99 percent.

Total compliance with any law is rarely possible, but that is always the goal of any enforcement program. DPR helps the CACs plan and carry out their local enforcement programs. Staff in DPR's three regional offices help CACs develop workplans to focus county resources where compliance is lowest and risk is greatest. The workplans are posted on DPR's Web site and detail each county's priorities in improving enforcement, compliance, and permitting. DPR regional staff also evaluate CAC performance and work with counties on areas needing improvement. We use performance measures which examine how well counties are targeting problems and patterns of continuing violations.

The CACs fully investigate each misapplication or misuse by gathering evidence to determine if laws or regulations were violated, and take enforcement action to penalize the violator. State and county staff charged with the enforcement of the pesticide laws are committed to protect the public and the high level of compliance is evidence of their success.

9. COMMENT: A 24-hour average target concentration is not protective.

DPR proposes a bystander level of concern of 32 ppb for a 24-hour average. In addition to the allowable concentration being much higher than that proposed as marginally acceptable by DPR's own scientists and the SRC, a 24-hour average does not adequately reflect the more immediate toxicity caused by methyl iodide and the fact that concentration spikes lasting from a few hours to nearly a day are typical for fumigant applications. These short-term concentration spikes are relevant, since glutathione depletion and increase in serum iodide levels are both relatively rapid responses to methyl iodide exposure: "At 25 ppm MeI,

maximal GSH depletion (40 to 50% of control) was measured in the nasal epithelium, and about 30% in the other tissues, 3 to 6 hours after initiation of exposure" (Volume 1 of DPR's Final Methyl Iodide RCD, p. 34). Serum iodide levels increased from 17 ppm in the control group to 5,070 ppm after one hour of exposure to 25 ppm of MeI and to 25,600 ppm after 6 hours of exposure (Volume 1, Table 8, p. 36). These data indicate that changes in iodide and GSH levels occur very rapidly, and a 24-hour averaging period misrepresents the potential for harm caused by methyl iodide by averaging out the concentration spike.

RESPONSE: DPR is aware that fumigant use may result in concentration spikes especially during the first day of application. DPR also agrees that the data indicates that serum iodide and glutathione (GSH) level changes can occur within the first 24 hours as cited. However, this comment contends that the proposed bystander regulatory target level of 32 ppb is not protective against serum iodide concentration spikes. According to Table 8, page 36 in DPR's RCD, the range of the control average serum iodide levels for the first 24 hours was 17 to 39 ppm (17,000 to 39,000 ppb). As stated in the comment, after exposure to 25 ppm, the serum iodide level was 5,070 ± 721 ppm and 25,600 ± 1,940 ppm after 6 hours. If uncertainty factors (1000) are applied to these levels that take into consideration intraspecies and interspecies differences between humans and animals, the control average serum iodide levels will be between 17– 39 ppb. Therefore, DPR's proposed level falls within the normal range of control for iodide levels and are protective for bystander exposures.

GSH level changes when evaluated tend to be more subjective and open to scientific interpretation. U.S. EPA considers a 50 percent reduction of GSH levels as a concern while DPR uses a more conservative 25 percent reduction in GSH levels as a concern. These levels were chosen with the intent of being health protective, with the assumption that a decrease in GSH levels may result in an adverse health impact. However, there are insufficient scientific analyses and data to support either levels of concern at this point. Since DPR uses more a conservative level of concern for GSH levels, it is more health protective.

10. COMMENT: Exposure assumptions are invalid.

It is not valid or adequately protective to assume a resting respiration rate for workers for children, Dr. Kathryn Hammond and other members of the SRC have stressed repeatedly that the respiration rate used by DPR of 0.8 m^3/hr in exposure calculations is inappropriately low for applicators and field workers because it is the 24 hour average respiration rate which includes time spent sleeping. Agricultural workers can be expected to have elevated respiration rates because work is conducted at a fast pace due to production incentives such as piece-rate, quotas and machine pacing. Elevated respiration rates are also expected during heavy manual labor such as shoveling soil and lifting boxes, even when production incentives are not used.

As recommended by Dr. Hammond, for worker exposure assessment DPR should be using at minimum the respiration rate of 1.2 m^3/hr used by OSHA and recommended by NIOSH for light work . . . DPR is also substantially underestimating the breathing rate for children. ARB breathing rate studies appropriately utilize breathing rates for children walking and running which are two and four times higher than the breathing rate DPR has assumed.

RESPONSE: The comment correctly notes that DPR uses the same respiratory rate for adult bystanders and workers, and that DPR's default respiratory rate represents a 24-hour average value (0.0117 m^3/kg-day). The DPR default breathing rate has been used as a policy when data to indicate actual breathing rates are not available (Andrews and Patterson, 2000, <http://www.cdpr.ca.gov/docs/whs/memo/hsm00010.pdf>). The rates are based on the inhalation rates (m^3/day) and body weights determined by Layton (Layton, 1993). These rates were estimated from the food-energy intakes of hundreds of individuals sampled in the 1977-1978 National Food Consumption Survey data. At the time of establishing the default, DPR considered this data to be the best available. Until additional data is shown to provide a basis for these estimates, DPR will continue to base its regulatory decisions on these breathing rates.

11. COMMENT: Use of a 90 percent respiratory protection factor overestimates protection.

DPR assumes the default 90% or 10-fold protection factor for half-mask respirators required for methyl iodide fumigations. This protection factor is not supportable because even if a respirator is fit-tested, the level of protection will change during the day and from one day to the next.

Respirators are uncomfortable and require constant maintenance. It is difficult to ensure compliance with fit-testing, cartridge-changing, and full-time use of respirators during an 8–10 hour day.

It is also impossible to drink water, blow one's nose or talk intelligibly while wearing a respirator. SRC member Professor Hammond noted in her testimony in the Senate hearing on June 17, 2010, that a worker who removes the respirator for a total of 53 minutes during an 8-hour workday (this would be about 5-6 minutes per hour) doubles their exposure. This increased exposure has not been accounted for by DPR in exposure estimates.

RESPONSE: Specific sections of 3 CCR were designed to ensure the safety of individuals engaged in activities that put them into contact with pesticides. These regulations specify procedures that applicators must follow to ensure that the respirators will fit properly [3 CCR § 6739(e) - fit testing]. The service life of the air-purifying cartridge, when not specified on the label is limited by regulation to a maximum of one shift [3 CCR § 6739(o) - end of service life]. Applicators must be licensed, and therefore know of and how to comply with label requirements and regulations regarding respiratory protection.

The legal use of pesticides is the basis for DPR's risk assessment process. Assuming illegal use would make the process of establishing regulations regarding use to mitigate any adverse effect moot. DPR addresses the issues of regulatory compliance through its Enforcement Branch and the CACs. Applicator noncompliance with label requirements and/or California regulations can result in fines, loss of license, and court action.

12. COMMENT: There has been no efficacy testing of the required respirator.

The DPR Risk Characterization concludes that the fact that a specific type of respirator cartridge is approved for methyl iodide should increase worker protection, it fails to add that no federal or state agency has independently reviewed the efficacy of the TEDA impregnated activated charcoal respirator cartridges which are required specifically on methyl iodide and methyl bromide labels. The 3M Technical Bulletin for these cartridges, which are referenced in the Risk Characterization as supporting a greater protection factor, does not include a detailed description of the efficacy testing.

RESPONSE: The statement that there has been no efficacy testing is incorrect. The National Institute of Occupational Safety and Health and DPR were supplied with the methodology and the methyl iodide raw-data test results for evaluation. DPR's evaluation of the data indicated the 10-fold safety factor was appropriate.

13. COMMENT: A more realistic estimate of fumigant applicator exposure to use as a basis for mitigation is five months.

Many soil fumigations are conducted by commercial application companies which transport both specialized equipment and trained applicators up and down the California coast. The fumigation season in Ventura County extends from June through August and in counties to the north, the fumigation season lasts from August to October. Five months of fumigation work is therefore a more realistic exposure estimate than the three months assumed by DPR's response to comments, in which they noted that in theory it is possible that applicators could travel county to county doing applications and some harvest workers do migrate—but that DPR doesn't believe in using upper bound estimates for seasonal or lifetime exposures. This approach shows a complete disregard for protection of applicators from excessive exposure.

RESPONSE: DPR assumed that the use-pattern of methyl iodide would be similar to that of methyl bromide, the pre-plant field fumigant methyl iodide is designed to replace. The 5-year use pattern of methyl bromide data indicated a three month season in any given county, and that fields in that county are likely to be fumigated only once per year. Seasonal exposure estimates for methyl bromide were based on treatment of average size fields and average application rates in Monterey County (which had the greatest amount of methyl bromide used in pre-plant field fumigations over a 5-year period). The duration of a use-season only affects annual and lifetime exposure estimates, as seasonal exposures are not amortized. Use seasons in different counties may or may not overlap, and it is theoretically possible that methyl iodide handlers could travel from one county to the next doing applications. While it is theoretically possible for handlers to treat the maximum amount of acreage at the maximum application rate of methyl iodide in a high use county, and then move on and continue the process in successive counties, DPR does not believe that these assumptions are realistic, or lend themselves to a credible scientific estimate of potential long-term exposures.

14. COMMENT: The eight-hour day is not a real-world assumption in agriculture.

A 10 or 12 hour work exposure period should be assumed for fumigant applicators and farmworker bystanders because a majority of agricultural work in California is seasonal, and these workers are eager to work as many hours as offered to make up for lean times of the year. Agricultural Wage Order 14 decrees that agricultural workers, including pesticide applicators, are only entitled to the overtime pay rate after 10 hours of work in a day, and irrigation workers are completely exempted from overtime pay rate requirements.

RESPONSE: Based on communication with growers and industry task forces, DPR assumes that 8-hours is a health-protective estimate when defining a single workday. DPR also believes that under specific conditions and situations, single day durations for worker activities can and do exceed 8 hours. Based on communication with growers and farm groups, we know that most crop-related activities require less than a full day of continuous activity, and several types of activities will be performed in a single day. Particularly in days of longer duration, there will be personal and lunch breaks that will interrupt the activity. We do not have adequate data to serve as a scientifically accurate basis for an estimate of how many hours per day would be spent in what activity. However, for acute exposure concerns in connection with tasks involving methyl iodide, the conservative assumption of 8 hours of exposure at the highest exposure level for any task provides a health protective estimate for defining a workday.

15. COMMENT: DPR has ignored significant dermal exposure potential during drip application.

As described in the DPR Risk Characterization, routine duties during methyl iodide drip application would include repair of drip lines and of tears in the tarps. We feel that this work would involve significant dermal exposure because Midas label directions prohibit wearing of gloves in order to keep vapors from being trapped next to the skin.

RESPONSE: It is correct that DPR did not specifically address dermal exposures to methyl iodide as a result of routine duties during drip irrigation procedures. The label requirements adequately protect against such exposure. Drip lines are required to be tested prior to use. If a problem does occur, the new U.S. EPA-approved labels for methyl iodide formulations specifically state:

"When performing tasks with liquid contact potential, all handlers (including applicators) must wear:

- Loose fitting or well ventilated long-sleeved shirt and long pants,
- Chemical-resistant gloves,
- Chemical-resistant apron,
- Chemical-resistant footwear and socks,
- Full face shield or safety glasses with brow, temple and side protection. DO NOT wear goggles, and

- A half face air-purifying respirator with a 3M Brand No. 60928 cartridge filter, or equivalent (NIOSH approval number prefix TC-23C).

In addition, if sensory irritation (tearing, burning, of the eyes or nose) is experienced while wearing a half-face air-purifying respirator, handlers must wear at a minimum a full-face air-purifying respirator with a 3M Brand No. 60928 cartridge filter, or equivalent (NOISH approval number prefix TC-23C). See Directions for Use, Protection for Handlers, Respiratory Protection and Stop Work Triggers, number 1: Handlers Wearing Half-Face Air-Purifying Respirators, for when a full-face respirator is required."

The label further states: "...chemical-resistant to this product are barrier laminate or viton ≥ 14 mils. For more options, follow the instructions for category H on the chemical-resistance category selection chart." Barrier laminate and Viton has been tested against methyl iodide and is effective in blocking the passage of methyl iodide for exposures lasting more than 8 hours. The wearing of chemical resistant gloves, apron, and footwear during spills is assumed to reduce dermal exposures to negligible levels during those activities.

16. COMMENTS: Auger probe or tree hole fumigation allowed under this registration has a history of applicator illnesses.

DPR proposes to allow methyl iodide deep auger probe or "tree hole" fumigations even though the Risk Characterization acknowledges that the Department has no methyl iodide-specific data for auger probe application exposures. The Risk Characterization does not even mention the ongoing problem of methyl bromide auger probe application poisonings. In 1997, the DPR Worker Safety Unit sent a memo to County Agricultural Commissioners expressing concern about the disproportionate number of injuries associated with methyl bromide tree hole fumigations including painful burns to the hands and feet. A query of the DPR Pesticide Illness database found 12 reported illnesses among tree-hole fumigators between 1997 and 2007, many involving burns to the feet. Use of rubber boots is prohibited on the Midas labels because of risk of more serious burns if methyl iodide and chloropicrin are trapped near the skin. This exposure path is especially troubling for methyl iodide in light of the published case report in which a man whose job involved loading methyl iodide tanks onto a truck noticed a breach in soles of his protective suit at the end of the day and subsequently developed a rash and burns on other parts of his body, as well as persistent memory, concentration and task performance problems.

RESPONSE: As noted above, the labels have changed to require the wearing of chemical resistant personal protective equipment when performing tasks with liquid contact potential. The wearing of chemical resistant gloves, apron, and footwear during spills is assumed to reduce dermal exposures to negligible levels during those activities.

17. COMMENT: MeI use may contribute to drinking water contamination (Central Coast Regional Water Board).

The surface waters of the Central Coast region are already highly impaired by registered materials applied as pesticides on agricultural fields. The use of methyl iodide might

contribute to drinking water exposure of iodide, a metabolite of methyl iodide. The proposed mitigation measures to prevent the leaching of iodide into ground water are insufficient because the soil residence time of methyl iodide is expected to be about five times greater than methyl bromide. Computerized models used by investigators at the U.S. Salinity Laboratory, University of California in Riverside, have predicted that methyl iodide will move deeper into soils than methyl bromide when using high barrier plastic, which will enhance downward movement. Furthermore, methyl iodide leaches even several days after fumigation and aeration. Investigators at UC Riverside [laboratory studies: Gan et al. (1996); Yates (1996); Guo et al. (2004)] have observed significant amounts of methyl iodide leaching residuals from the soil columns under the shank-injection and drip-application irrigation methods.

RESPONSE: Iodide is a breakdown product of methyl iodide so the amount present in soil is dependent upon the mass of methyl iodide that does not volatilize from the soil. Iodide is chemically classified as a halide anion. Halide anions are considered stable, which is the source of concern for potential movement to ground water. An important aspect of iodide's fate in soil is that, although it is thought of as a stable halide anion, investigations into soil reactions indicate its highly reactive nature with soil. For example, an important study by Bowman (1984) compared the use of chemicals as surrogates for tracking the movement of water through the soil in laboratory and field experiments. In the laboratory study, Bowman concluded there was no difference between bromide and iodide movement in water in sandy loam soil. The results were different in a follow-up field study conducted in an experimental plot that was subjected to flood irrigation. Bowman concluded from this field study that iodide is rapidly lost under aerobic field conditions, meaning that iodide was reactive with soil under field but not laboratory conditions. Other studies have proposed soil interactions that could provide explanations for these results (Sheppard and Thibaul, 1992; Fuge and Johnson, 1986; Santschi and Schwehr, 2004.). For more detail, see memorandum to Central Coast Regional Water Quality Control Board at <http://www.cdpr.ca.gov/ docs/registration/mei_pdfs/ccrwqcb_memo.pdf>

The Bowman study illustrated that observations made in experiments conducted indoors must be confirmed with studies conducted in the field. The concerns expressed about the potential for methyl iodide or iodide to move and contaminate ground water are based on studies that have been conducted under simulated laboratory conditions. Although they provide initial insight on potential soil movement and interaction, they do not represent the full data set used to determine the environmental fate of MeI upon which the Department based its registration decision. For example, U.S. EPA required the registrant to conduct terrestrial field dissipation studies (TFD) for measuring the environmental fate of methyl iodide and iodide under actual field applications. Targeted rates of application were high at 250 lbs MeI/acre. Although tarps were used, the exact nature of the tarp was not specified. The tarps were removed after 5 days. More importantly, irrigation applications commenced 14 days after application. In the study conducted in California, irrigation water applications followed U.S. EPA guidelines where the amount was applied at 110 percent of the 10-year monthly average of evapotranspiration (evaporation from the soil and vegetation or ETo). These treatments limited downward movement in the soil and were not believed by DPR scientists to reflect realistic water treatment that would occur in actual practice. Realistic

irrigation practices would likely result in much more percolating water, and, therefore, these studies likely underestimate downward movement from actual applications. However, through a combination of field sampling and subsequent modeling, DPR has determined that limiting irrigation water application to 133 percent ETo at each irrigation is an appropriate mitigation measure that both minimizes the rate of water percolation and enhances the rate of degradation of pesticides residues in the upper layers of soil. Troiano et al. (1993, <http://www.cdpr.ca.gov/docs/emon/pubs/ehapref/atrzne.pdf>) illustrated the effectiveness of limiting percolating water on the movement of atrazine, a well-known and studied pesticide ground water contaminant, in coarse sandy soil with very low organic carbon content. Limiting downward soil movement also resulted in faster degradation of atrazine residues. Results should be similar for iodide.

Another example of laboratory and field differences relate to comments that indicated relatively long estimates for the soil half-life of methyl iodide, which was reported in an indoor study conducted by Gan et al. (1996). Since the study attempted to isolate the effect of soil on the degradation rate of methyl iodide, soil was held in sealed vials and either methyl bromide or methyl iodide was injected into the soil. The results did indicate a slower rate of degradation for methyl iodide on the coarse-textured Greenfield sandy loam soil, but loss of methyl iodide from soil by volatilization was minimized because of the sealed vials. In contrast, half-lives for methyl iodide determined from the TFD studies conducted in the field in California and Florida indicated a dissipation half-life of around 5 days for both sites. Soil in the California study was sandy loam with 1.3 percent organic carbon and in Florida was loamy fine sand with 1.2 percent organic carbon. Volatilization from the soil was an important route of dissipation in both field studies. A 14 day reentry interval required by the imposed mitigation measures would allow longer time for dissipation of soil residues, especially for continued off-gassing rather than by degradation.

The assertion that MeI is likely to move deeper in soil than MeBr relies upon data generated and reported by Yates (1996). This study was an early attempt to determine fate of MeI using only a modeling procedure. In the publication, the author cautions in the last paragraph, "Although this gives a first glimpse into the behavior of MeI in soils, the effect of numerous model simplifications need to be investigated before making any conclusions using the figures above." We are not aware if the author has revisited these modeling results in light of the environmental fate data that has been generated since the publication of this short article in 1996.

Lastly, evidence to support the statement that MeI leaches even several days after fumigation and aeration was based on the indoor study reported by Guo et al. (2004). Again, this laboratory study measured soil movement in packed soil columns and those results have not been observed under field conditions. For more detail see the memorandum to the Central Coast Regional Water Quality Control Board at < http://www.cdpr.ca.gov/ docs/registration/mei_pdfs/ccrwqcb_memo.pdf >. As indicated previously, the TFD data indicated rapid dissipation of MeI, primarily through volatilization, and the potentially rapid transformation of iodide degradation product to other oxidized forms. These results imply low potential for leaching of MeI or iodide to ground water in vulnerable soils. The further restriction of irrigation water additions to 133 percent of crop

need after removal of the tarp will provide further restriction to movement of residues out of the upper layers of vulnerable soils.

18. COMMENT: DPR did not have sufficient information to guarantee no risks to ground water (PAN).

At the Sept. 24–25, 2009 meeting of the SRC, DPR clarified to the SRC that the department did not have sufficient information to guarantee that methyl iodide would not contaminate groundwater. In fact, the physical properties and reactivity of methyl iodide in groundwater are similar to those of DBCP, a fumigant that pollutes many wells in the Central Valley, making them unusable for drinking water. DPR's response to the SRP's questions indicated that once a groundwater problem was noticed, the department would know how to handle it because of their previous experience with DBCP.

The DPR staff report evaluating potential for methyl iodide contamination for groundwater pointed out that in terrestrial field dissipation studies conducted by Arysta, the soil recovery of iodide appeared very low in relation to the theoretical transformation of the estimated amount of iodomethane in soil, as calculated from mass balance. Staff concluded that "potential explanations for the lack of iodide recovery are that the analytical methodology was not adequate, or that iodide existed in either another chemical form such as iodate or reacted with soil components." In light of these findings, DPR staff recommended as conditions of registration that soil sampling be conducted after applications of methyl iodide to coarse textured soil sites that are vulnerable to leaching to assess the concentration distribution of methyl iodide and breakdown products. In addition, it was recommended that analytical techniques for measurement of iodide and iodate be developed to facilitate analysis of methyl iodide transformations in the environment. DPR management has not proposed imposing any of these conditions on the registration of methyl iodide.

RESPONSE: The comment mischaracterizes DPR's presentation on ground water at the September 24 SRC meeting. As documented in the transcript of the SRC meeting (DPR 2009, <http://www.cdpr.ca.gov/docs/risk/mei/mei_wkshp.pdf>, DPR staff stated that "contamination of surface water was very unlikely. Ground water contamination by the parent methyl iodide was also unlikely, but that the ground water contamination potential by the iodide an[d] ion breakdown product was uncertain due to lack of data." DPR also stated that "the model repredicted (sic) essentially zero ground water contamination, zero concentration of the parent compound." As summarized in Volume III of DPR's Risk Characterization Document, DPR staff conducted ground water modeling of several fumigants, including DBCP and methyl iodide (Dias and Clayton 2008, <http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/analysis_memos/2086_grndwtr.pdf>. For the worst-case modeling scenario, predicted concentrations of DBCP were approximately two orders of magnitude higher than actual concentrations measured in well samples, demonstrating that the modeling overestimated ground water concentrations. Using the same worst-case scenario, DPR estimated that the ground water concentration of methyl iodide would be approximately 11 orders of magnitude lower than DBCP and several orders of magnitude less than the nominal detection limit.

The difference in use patterns for soil fumigants previously found in ground water, e.g. DBCP, from other currently registered fumigants and those that will be required for MeI, provide additional support for the conclusion that the use of MeI as restricted by the California label presents a lower risk for movement to ground water. Even though DBCP was identified as a soil fumigant, the major method of application was directly to irrigation water and to plants that were actively growing. Most of the applications were to furrow irrigation where large amounts of percolation water are produced at each event, moving residues below the crop rootzone. The use pattern for methyl iodide is application to bare soil prior to planting. This difference minimizes the downward movement in soil with water and maximizes the processes of dissipation associated with surface soil layers.

By implementing mitigation measures to prevent ground water contamination by the iodide breakdown product, DPR management chose a health-conservative approach that does not require the submission of additional data. In addition, as part of its obligation to continuously evaluate all registered pesticides, DPR will conduct ground water sampling in areas with high methyl iodide use to monitor the effectiveness of the mitigation measures.

19. COMMENT: Subchronic exposure becomes problematic when fumigations are broken up into smaller application blocks.

DPR has not addressed the very real threats that longer-term exposure to methyl iodide from smaller application blocks, including increased cancer risks and thyroid disruption.

RESPONSE: DPR has addressed the situation of smaller application blocks and discussed why the regulatory approach taken will not lead to harmful longer-term exposure. To repeat, repetitive exposures of bystanders residing adjacent to a 40-acre field were considered by DPR to be a worst-case situation. Smaller fumigated parcels, separated from each other by their respective non-overlapping buffer zones, would likely produce lower air concentrations of methyl iodide, both on an acute and repetitive exposure basis, than the worst case scenario DPR selected. The map included with the comment to show bystander exposure to multiple sources does not appear to take into account a prevailing wind direction, nor does the map indicate the label-required, non-overlapping buffer zones which must separate treated fields.

20. COMMENT: DPR Has Failed to Comply with CEQA by failing to evaluate a range of alternatives.

To satisfy CEQA, DPR "must consider a reasonable range of alternatives to the project... which (1) offer substantial environmental advantages over the project proposal . . . and (2) may be feasibly accomplished in a successful manner, considering the economic, environmental, social and technological factors involved." (Citizens of Goleta Valley v. Board of Supervisors (1990) 52 Cal. 3d 553, 566, italics deleted.) One of the alternatives analyzed must be the "no action" alternative. (Cal. Code Regs., tit. 14, § 15126.6, subd. (e)(1).)

The Public Report prepared by DPR in connection with its proposed registration decision, which purports to act as a functional equivalent document under CEQA, fails to consider any

alternative to the proposed action. Instead, DPR states that "[a]n alternatives analysis . . . is beyond the scope of this process." Pub. Rpt. at 4. This claim is unfounded. CEQA provides specifically that an agency operating in a certified regulatory program must analyze alternatives to the proposed action. (Pub. Res. Code § 21080.5, subd. (d)(3)(A)). DPR's regulations implementing the pesticide registration certified regulatory program likewise require a thorough analysis of alternatives (Cal. Code Regs., tit. 3, § 6254.), and the Food & Agriculture Code requires DPR to refuse to register any pesticide "for which there is a reasonable, effective, and practicable alternate material or procedure that is demonstrably less destructive to the environment." Food & Agr. Code § 12825.

RESPONSE: When DPR takes action to register a pesticide product, that action is considered a "project" under CEQA. DPR follows the process that has been certified by the Resources Agency as the functional equivalent of an environmental impact report (EIR) required for an action by a state agency that may impact the environment. See Title 14 CCR § 15251(i). The registration process certified as the functional equivalent of an EIR is found in 3 CCR §§ 6253-6255. It requires that a proposed registration decision be noticed for public comment for 30 days (3 CCR § 6253) and that a Public Report be prepared that describes the proposed project that includes a statement of any adverse environmental effect that can reasonably be expected to occur, as well as "a statement of reasonable mitigation measures that are available to minimize significant adverse environmental impact" (3 CCR § 6254) of the decision. Under these regulations, the Director "shall not approve an activity which would cause a significant adverse environmental impact if there is a feasible alternative or feasible mitigation measure available which would substantially lessen any significant adverse impact which implementation of the proposal may reasonable be expected to have on the environment." See 3 CCR § 6254(a).

The project in this instance is not time and place specific, but the issuance of a general license allowing use the product in the state. In fact, whether the product will actually be used, and to what extent is unknown.[1] The only alternative to the "project" of product registration is to refuse to register the product if there are no adequate mitigation measures to substantially reduce any significant adverse impact on the environment that could reasonably be expected to occur. In the context of a registration decision, if the proposed action incorporates mitigation that substantially reduces the significant adverse impact that might otherwise have been reasonably expected to occur, discussion of any alternative (which can only be refusal to register or the "no project" alternative) or further mitigation is not required. In this instance, a description of the mitigation measures that are part of the project, and which support the determination that a significant adverse impact is not expected to occur, is included in the Public Report. Not only were those mitigation measures set forth in the Public Report, but the specific criteria that guided that mitigation are identified.

[1] One of the mitigation measures included in this proposed decision, is that these products would be made restricted materials that require a permit issued by the county agricultural commissioner before that could be used. A further CEQA analysis is required when that permit is issued when the exact location, time, crop, application method, rate of application, and pest are known before the application is allowed under the permit.

21. C0MMENT: DPR has failed to comply with CEQA by not analyzing the cumulative impact of registering methyl iodide.

In order to truly understand the full impact of its decision to register methyl iodide for use in California, DPR must analyze how the combination of methyl iodide use with the effects of other related environmental impacts are cumulatively significant. DPR's Public Report fails to provide such an analysis.

For example, all of the MIDAS products intended for field use contain chloropicrin in amounts ranging from 2–67% of the product by weight. Chloropicrin is a severe irritant, a glutathione depletor, and a potent carcinogen. Yet DPR did not consider the cumulative health and environmental impacts of using both methyl iodide and chloropicrin even though the agency just finalized a risk assessment of chloropicrin showing that it is a highly potent carcinogen.31 It can reasonably be assumed that the combined presence of chloropicrin and methyl iodide will at least enhance cancer risk and glutathione depletion and may possibly exacerbate other effects. The net result of this enhancement is that toxic effects will be observed at lower doses than those determined in a risk assessment that accounts for exposure to only a single chemical.

RESPONSE: For a certified regulatory program, the obligation to consider cumulative impacts does not flow from the specific criteria set for an EIR, but from obligation to adhere to the general policy of CEQA. In this context, the assessment of the cumulative impacts resulting from a number of projects is guided by standards of practicality and reasonableness. As noted above, the "project" of registration is the granting of license that allows use of the product without any knowledge of the amount that will be used, at what location, and during what time period. It is not known if the registration of the product will increase the amount of pesticides used, replace other pesticides used, or decrease other pesticide used in a specific area. In recognition of the unique aspect of this "project", DPR's certified program includes the obligation to continuously evaluate the environmental impact of registered products (Food and Agricultural Code §12824, 3 CCR §§ 6210-6226). Further, for restricted use pesticides such as these, an additional environmental review is required through the permit process based upon the proposed use of the registered product that is specific as to place, time, and amount.

CEQA requires an environmental analysis of activities of government agencies that cause a reasonably foreseeable change in the environment. Chloropicrin is an active ingredient by itself and in combination with other active ingredients in currently registered pesticides. As discussed above, it is not practical or reasonable to analyze how the registration of these products may change the environment in any specific context. Toxicity evaluation of the formulated product is part of the registration process, and the methyl iodide formulations were evaluated as such. However, as common practice, risk assessments are conducted only on active ingredients. Protocols and procedures in conducting risk assessments on a combination of chemicals are not available at this time.

For this proposed registration decision, DPR believes that the mitigation to reduce any significant adverse impact from the use of methyl iodide provides a margin of safety that

would reduce any impact from the use of the combined product. The restrictions on the use of the methyl iodide products are more stringent than any other fumigant product including those combined with chloropicrin.

22. COMMENT: DPR has failed to comply with CEQA by not adequately justifying or documenting the proposed regulatory target levels.

In its final risk assessment for methyl iodide, DPR concludes that exposures to workers, bystanders, and residents from use of methyl iodide in California would result in highly significant acute health risks, one of the regulatory factors to be given "special attention," pursuant to Cal. Code Regs., tit. 3, § 6158. In the risk assessment, DPR scientists set the reference concentrations (RfCs) for acute health risk of neurotoxicity at 35 ppb for workers, 12 ppb for adults in the general public, 7 ppb for children, and 6 ppb for infants. For fetal death (the most sensitive endpoint), DPR set the RfC at 0.8 ppb for workers and 0.3 ppb for the general public (Risk Assessment at 9). The RfCs are, by definition, the maximal target exposures that DPR determined would protect human health from these toxic health effects. Yet, without explanation, DPR management has proposed allowable exposures of 96 ppb for workers and 32 ppb for the general public. DPR's April 30, 2010 Notice of Proposed Decision (page 5) merely states that:

[The] exposure target level was based on the no-observable effects level (NOEL) of 2 parts per million identified in the RCD for the most critical endpoint of fetal loss (effect seen after a short duration inhalation exposure to the chemical). Following standard scientific practice, the RCD relied exclusively on animal studies. Additional consideration of animal-to-human ratios of breathing rates and hours and days of exposure resulted in a calculation of the human-equivalent concentration (HEC). The exposure estimates were calculated using a very conservative (that is, health-protective) approach since it assumes that exposures occur directly downwind at the edge of the field, 8 or 24 hours a day for workers and bystanders respectively. The target level also takes into consideration interspecies and intraspecies uncertainty factors accounting for the differences between humans and animals, and consideration for sensitive individuals within the human population.

The Notice of Proposed Decision to Register Pesticide Products Containing Methyl Iodide and Public Report do not contain sufficient information for the public to know how DPR management arrived at the proposed regulatory target levels. Missing from DPR's analysis are at least the following:
1) The value of the HEC used in the calculation
2) The uncertainty factors used in the calculation (the target MOE)
3) Justifications for using the selected values
4) Explanations for how, exactly, the mitigation measures would work to keep exposures below 96 ppb and 32 ppb for workers and bystanders. This failure to provide adequate information to evaluate the basis of DPR's decision is a violation of CEQA.

RESPONSE: DPR's proposed decision to register methyl iodide and Public Report meets the requirements of CEQA by providing a description of how management to arrived at the

regulatory target levels and provided the exact POD (NOEL of 2 ppm) and a description of the analysis used to arrive at the two regulatory levels. The numbers used for the adjustment of that starting point were no different than in the risk assessment, and would be known or assumed by any person who knows enough to want this kind of detail. The animal-to-human ratios of breathing rates used in each instance was 0.54/0.28. The adjustment used for the hours and days of exposure for bystanders was 6/24 and 7/7, and 6/8 and 7/7 for workers. The value of the human-equivalent concentration resulting from these calculations for the bystander regulatory target level was 0.965 ppm while the value of the human-equivalent concentration for the occupational regulatory target level was 2.89 ppm. Additionally, the uncertainty factor or target margin of exposure used to calculate the regulatory target levels was 30. As stated in the report, this uncertainty factor was used to account for interspecies and intraspecies uncertainty factors accounting for the differences between humans and animals, and consideration for sensitive individuals within the human population and is consistent with U.S. EPA's risk assessment document <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2005-0252>. As reflected in the Public Report, there was no uncertainty factor applied for the lack of a developmental neurotoxicity (DNT) study. The reason for not requiring such a study is discussed earlier in this document.

DPR risk managers concluded that the uncertainty factors applied in the risk assessment producing a factor higher than 30 were not needed because accompanying exposure calculations already overestimated potential exposure (thereby providing an inherent safety margin).

23. COMMENT: DPR has failed to comply with CEQA because the Public Report does not include other sufficiently detailed analyses of the impacts of registering methyl iodide.

CEQA provides that a functional equivalent document must contain "environmental information" and include mitigation measures to minimize "any significant adverse effect on the environment." (Pub. Res. Code § 21080.5(a), (d)(3)(A).) The report prepared by DPR in connection with its proposed registration decision fails by this measure. The seven-page document is bereft of information regarding the impact that registering MeI will have on the environment. DPR provides only a conclusory statement that "no direct or indirect significant adverse environmental impact is anticipate from . . . registration." Pub. Rpt. at 3-4. The report fails to explain the basis for this determination. It likewise fails to summarize the main points of scientific disagreement. Ultimately, the report is not sufficient as an informational document.

For instance, the DPR Public Report does not disclose that the SRC recommended far more stringent regulatory exposure levels than those proposed by DPR, much less explain how DPR determined its regulatory exposure target levels. The Public Report does not provide information on how DPR was able to set "acceptable" exposure levels when critical toxicity data are missing and mandatory health studies, such as a developmental neurotoxicity study, were not available. Furthermore, DPR fails to explain whether, and if so, why it has disregarded the SRC's recommendation of an additional 10-fold uncertainty factor to

account for data gaps regarding toxicity and other developmental effects. There is also a glaring lack of analysis or explanation for the choice of any of the mitigation measures and DPR's proposal does not identify how any of the proposed mitigation measures control the identified risks sufficiently to reduce those risk—even to the inadequate regulatory target levels identified, never mind the levels that DPR scientists and the SRC say are actually required to protect the health of workers, bystanders, and residents near a fumigated area. DPR has also failed to adequately explain how proposed mitigations will prevent ground water contamination, especially in light of the Office of Environmental Health Hazard Assessment's conclusion:

"Given the potential volume of use, even if 90-95% of applied MeI evaporates within a few days, the residual remaining in soil could eventually contaminate ground water because the compound is readily mobile in soil. In our opinion, the potential adverse effects of iodine and MeI contamination of surface and ground water on humans and ecological receptors should be evaluated." (Risk Assessment, Volume IV - Part 1 at 15).

DPR cannot rely on hidden calculations and conclusory statements of "no impact" to justify registering methyl iodide. The agency must disclose its analysis and provide adequate information on every aspect of its decision in order to fulfill its duty under CEQA.

RESPONSE: The Public Report described how the regulatory target levels were reached that were used to establish mitigation measures to keep exposure levels below those that would be harmful to workers or bystanders. Under the certified regulatory program, the report is required only to have a statement that the agency's review of the project found that it will not have significant adverse effects and a check list to show the possible effects that the agency examined in reaching this conclusion (Title 14 CCR section 15252). The Public Report in this case references both its risk characterization document as well as that of U.S. EPA as documents used in reaching its decision to register based upon its determination that no direct or indirect significant adverse environmental impacts are anticipated. It states that acute inhalation exposure is the primary area of concern, noting that dermal exposure and dietary exposure were determined not to be significant. It also notes the potential for ground water contamination in susceptible soils. The mitigation measures listed in the report to be required for registration, and evaluated further in this document, address acute inhalation exposure as well as ground water concerns. This process complies with our certified regulatory scheme. For a more detailed summary of all California mitigation required contrasted with Federal requirements, see <http://www.cdpr.ca.gov/docs/registration/mei_pdfs/mei_table_label.pdf>.

During the comment period on the proposed decision and Public Report, extended to 60 days in this case, the public can question whether the restrictions on the registration decision support the determination that a significant adverse environmental impact is not expected to occur. The regulations, certified as the functional equivalent of an EIR, include the provision that the final action to register include a written evaluation of any significant adverse environmental points raised during the evaluation process [3 CCR § 6254 (b)]. Points raised by the initial staff evaluations have been addressed and can be reviewed at <http://www.cdpr.ca.gov/docs/registration/mei_pdfs/eval_midas_products.pdf>. In addition, this document evaluates the points raised by the comments submitted in response to the

Notice of Proposed Decision to Register Pesticide Products Containing Methyl Iodide and Public Report. This satisfies the requirement of 3 CCR § 6254(b) and completes DPR's obligation under CEQA in connection with its registration decision.

24. COMMENT: A number of commenters expressed concerns that methyl iodide residues would remain on fresh produce, particularly strawberries.
For example, "I love strawberries but I read that soon they will be poisoned with this pesticide. What other crops will be poisoned by this chemical? I need to know so I can stop buying and eating them." Another commenter said, "No one I know would eat strawberries with methyl iodide on them and any thinking parent would not feed their children seemingly beautiful strawberries with an invisible layer of poison." These comments were typical of hundreds of others.

RESPONSE: Methyl iodide when used is injected into bare soil before planting. If the fumigant is not allowed to break down completely in the treated soil, it will cause plant toxicity therefore crops cannot be planted until it dissipates. Methyl iodide breaks down to iodide which is a common, naturally occurring component of all soils, plants and animals and as such there is an existing background level of iodine and iodide in the environment which varies depending on the naturally-occurring sources of iodine chemicals in the region. Plant metabolism studies on strawberries and tomatoes showed that Iodide levels in the raw commodities were comparable to background levels found in control samples.

Field studies showed that methyl iodide is extensively metabolized and incorporated into plant constituents, primarily carbohydrates. Additionally, those studies demonstrated that methyl iodide could not be detected in harvested fruit, therefore U.S. EPA considered it a nonfood use chemical, and food tolerances were not needed. In short, methyl iodide use does not present a food safety concern.

REFERENCES:

Andrews, C., and Patterson, G. 2000. Interim guidance for selecting default inhalation rates for children and adults. HSM-00010 Sacramento, CA Worker Health and Safety and Medical Toxicology Branches, Department of Pesticide Regulation, California Environmental Protection Agency. http://www.cdpr.ca.gov/docs/whs/memo/hsm00010.pdf

Barry, T. 2010. Duration of Tarping for Methyl Iodide Applications. Memorandum to John Sanders, dated April 29, 2010. Department of Pesticide Regulation. http://www.cdpr.ca.gov/docs/registration/mei_pdfs/mei_tarp_duration_4-29-10.pdf.

Barry, T. and R. Segawa. 2010. Methyl Iodide (Iodomethane) Mitigation Evaluation and Options. Memorandum to John Sanders, dated April 29, 2010. Department of Pesticide Regulation. http://www.cdpr.ca.gov/docs/registration/mei_pdfs/mitigation_options_4-29-10.pdf.

Bowman, R.S. 1984. Evaluation of some new tracers for soil water studies. Soil Sci. Soc. Am. J. 48:987-993.

Dias, J. and M. Clayton. 2008. Updated Evaluation of the Ground Water Contamination Potential of the Regulations to Reduce Volatile Organic Compounds by Controlling Field Fumigant Emissions. Memorandum to Randy Segawa, dated October 6, 2008. Department of Pesticide Regulation.
http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/analysis_memos/2086_grndwtr.pdf

DPR. 2009. Transcript of the Methyl Iodide External Peer Review Panel Workshop, September 24, 2009. Department of Pesticide Regulation.
http://www.cdpr.ca.gov/docs/risk/mei/mei_wkshp.pdf

Frank, J. P. 2008. Default Inhalation Retention/Absorption Values to be used for Estimating Exposure to Airborne Pesticides. HSM-08011. Worker Health and Safety Branch, Department of Pesticide Regulation, California Environmental Protection Agency. September 18, 2008. http://www.cdpr.ca.gov/docs/whs/memo/hsm08011.pdf.

Fuge. R. and C.C. Johnson. 1986. The geochemistry of iodine – a review. Environ. Geochem. Health 8:31-54.

Gan, J., and S.R. Yates, S.R. 1996. Degradation and phase-partitioning of methyl iodide in soil. Jouranal Agricultural and Food Chemistry. 44:4001-4008.

Guo, M., W. Zeng, S.K. Papiernic, and S.R. Yates. 2004. Distribution and leaching of methyl iodide in soil following emulated shank and drip application. Journal of Environmental Quality 33:2149-2156.

Layton, D. W. 1993. Metabolically consistent breathing rates for use in dose assessments. Health Phys 64:23-36.

Santschi, P.H. and K.A. Schwehr. 2004. 129I/127I as a new environmental tracer or geochronometer for biogeochemical or hydrodynamic processes in the hydrosphere and geosphere: the central role of organo-iodine. Sci. Tot. Environ. 321:257-271.

Sheppard, M.I. and D.H. Thibault. 1992. Chemical behaviour of iodine in organic and inorganic soils. Appl. Geochem. 7:265-272.

Spencer, J.R., A.M. Welsh, B.Z. Hernandez, C. Benson, S. Fredrickson, and V. Quan, 2006. An observation of crop advisors' activities, project 0202. HS-1858. Sacramento, CA: Worker Health and Safety Branch, Department of Pesticide Regulation, California Environmental Protection Agency.
http://www.cdpr.ca.gov/docs/whs/pdf/hs1858.pdf

Troiano, J., C. Garretson, C. Krauter, J. Brownell, and J. Hutson. 1993. Influence of Amount and Method of Irrigation Water Application on Leaching of Atrazine. J. Environ. Qual. 22: 290-298.
http://www.cdpr.ca.gov/docs/emon/pubs/ehapref/atrzne.pdf.

U.S. EPA. Benchmark Dose Methodology, (n.d.) Retrieved from http://www.epa.gov/ncea/bmds/bmds_training/methodology/intro.htm.

U.S. EPA. 2006. Iodomethane: Revised HED Human Health Risk Assessment. U.S. Environmental Protection Agency, Washington, D.C. EPA/HQ/OPP/2005-0252-0005. http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2005-0252.

U.S. EPA, 2007. Pesticide Fact Sheet for Iodomethane, New Chemical Registration. U.S. Environmental Protection Agency, Washington, D.C., EPA/OPPTS/7505.

U.S. EPA, 2008. Child-Specific Exposure Factors Handbook (Final Report). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-06/096F.

U.S. EPA, 2009a. Exposure Factors Handbook 2009 Update (External Review Draft). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-09/052A.

U.S. EPA, 2009b. Metabolically Derived Human Ventilation Rates: A Revised Approach Based Upon Oxygen Consumption Rates (Final Report) 2009. U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-06/129F.

Verder-Carlos, M, Final Evaluation of Midas Products. Memorandum to Ann Prichard, dated November 24, 2010. Department of Pesticide Regulation. http://www.cdpr.ca.gov/docs/registration/mei_pdfs/eval_midas_products.pdf.

Warmerdam, M, Response to the Central Coast Regional Water Quality Control Board Comments Dated June 10, 2010 Regarding Methyl Iodide Registration Decision. Memorandum to Roger Briggs dated December 1, 2010. Department of Pesticide Regulation. http://www.cdpr.ca.gov/ docs/registration/mei_pdfs/ccrwqcb_memo.pdf

Yates, S.R. 1996. Methyl iodide as a replacement for methyl bromide: Environmental implications. Agricultural Research Service, U.S. Department of Agriculture, October 15, 1996.

Yates, S.R. 2009. Update of Film Permeability Measurements for USDA-ARS Area-wide Research Project. Presentation at the 2009 Annual Research Conference on Methyl Bromide Alternatives and Emissions Reductions. Methyl Bromide Alternatives Organization. http://www.mbao.org/2009/011Yates.pdf