

MEMORANDUM OF UNDERSTANDING
BETWEEN
CALIFORNIA
DEPARTMENT OF PESTICIDE REGULATION
AND
DOW AGROSCIENCES LLC
REGARDING AN
UPDATED PROGRAM TO MANAGE THE APPLICATION OF
PRODUCTS CONTAINING 1,3-DICHLOROPROPENE

This Memorandum of Understanding (MOU or Agreement) between the California Department of Pesticide Regulation (DPR or "the Department") and Dow AgroSciences LLC (DAS) (sometimes referred to collectively as "the Parties") establishes a new Updated Management Program for the distribution and application of the agricultural soil fumigant known as 1,3-Dichloropropene (1,3-D).

BACKGROUND

Pesticide products that contain 1,3-D are used in California to fumigate soil before planting crops such as almonds, grapes, walnuts and strawberries, and other fruits, nuts and vegetables, to control the growth of nematodes, plant pathogens and other soil-borne pests that damage the root structures of these plants and trees and hinder the growth of these valuable agricultural commodities. DAS is the primary registrant and sole producer of 1,3-D that is used to produce all of the 1,3-D soil fumigant products that are used in California.

The sale and distribution of 1,3-D for the uses listed above and similar uses on other agricultural crops are regulated by the United States Environmental Protection Agency (US EPA) pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and by the Department of Pesticide Regulation (DPR or Department) under the California Food and Agricultural Code (FAC). The use of 1,3-D in a manner inconsistent with instructions for use on its labeling, which is reviewed and approved by US EPA and DPR, is unlawful and punishable by US EPA and the Department under FIFRA and the FAC, respectively. In addition, 1,3-D is designated under the FAC as a restricted material and may be applied only pursuant to permits issued by the County Agricultural Commissioner ("CAC") in each county. 1,3-D also is

included on the list of chemicals "known to the state to cause cancer" for purposes of California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). DPR has designated 1,3-D as a toxic air contaminant because it is listed as a hazardous air pollutant under the Federal Clean Air Act.

PURPOSE OF AGREEMENT

The purpose of this Agreement is to establish and memorialize an Updated Management Program to manage the application of products containing 1,3-D consistently with the laws referred to above and with the Risk Management Directive and Mitigation Guidance for Cancer Risk from 1,3-Dichloropropene issued by DPR on October 6, 2016 (Risk Management Directive) (Attachment A) and the Risk Characterization Document Inhalation Exposure to Workers, Occupational and Residential Bystanders and the General Public (Risk Characterization Document) published by DPR on December 31, 2015.

UPDATED MANAGEMENT PROGRAM

The following Updated Management Program shall become effective in January 2017 and will remain in effect unless and until revisions are agreed upon by the Parties. The only exceptions that DPR will consider approving are for uses associated with alternatives research, quarantine, or other special applications. For these very limited circumstances, DPR will only accept requests for exceptions to the township limit from DAS in writing.

IMPLEMENTATION OF UPDATED MANAGEMENT PROGRAM THROUGH CAC PERMIT PROCESS FOR RESTRICTED MATERIALS

The Updated Management Program will be implemented through the permit system for restricted materials operated by the CAC of each county where 1,3-D is used, in the manner summarized below. In each township¹ where 1,3-D is used, there shall be a limit of 136,000 adjusted pounds per year.^{2,3} DAS hereby agrees to take certain steps, identified below, to manage

¹ A township is an area of 6 x 6 miles, as designated by the Public Lands Survey System.

² For purposes of calculating allocations and limitations and usage, the amount in which 1,3-D is used is calculated as "adjusted pounds," using Application Factors specified in DPR's Pesticide Use Enforcement Program Standards Compendium, Volume 3.

³ No township currently has an average annual use over 136,000 adjusted pounds, except for Township 7S/11E in Merced County. The limit for Township 7S/11E will be 115,000 adjusted pounds in 2017 to bring its

the application of its 1,3-D products or products that contain 1, 3-D manufactured by Dow so that the township caps are not exceeded. The tasks and duties that are to be discharged by DAS may be conducted by a contractor managed by DAS.

1. Products containing 1,3-D will be applied only upon the recommendation of a licensed pest control advisor (PCA) approved by DAS and the issuance of a restricted materials permit by the office of the CAC in the county where the application is to take place. Such recommendation shall be presented to DAS or a contractor employed by DAS no more than fourteen days prior to the anticipated date of application.
2. Upon the presentation of a recommendation by a PCA for the application of 1,3-D consistent with a valid and current restricted material permit, DAS or a contractor employed by DAS shall review the recommendation for consistency with the use sites, target pests and application rates and methods on the product label.
3. DAS or its contractor will calculate or verify the number of adjusted pounds of 1,3-D requested under the recommendation, taking into consideration factors such as the total weight of the product in pounds, the density of the product and the percentage of active ingredient contained therein, and application factors described in DPR's Pesticide Use Enforcement Program Standards Compendium, Volume 3.
4. DAS or its contractor will ensure before the PCA recommendation is approved that the amount of 1,3-D to be applied pursuant to the recommendation will not cause the township limit of 136,000 adjusted pounds per year to be exceeded.
5. If the amount requested will not cause the township limit to be exceeded and other conditions of the PCA recommendation are consistent with instructions

overall average annual usage down to 136,000 adjusted pounds or below. After 2017, usage in Township 7S/11E will be limited to 136,000 adjusted pounds.

on the product label, then DAS or its contractor may approve the PCA recommendation.

6. If a sufficient amount does not remain available to allow application of the amount of 1,3-D recommended without exceeding the township limit, then DAS or its contractor will not approve the request and will display a response to the electronically submitted recommendation that indicates the amount that may be applied before the township limit is exceeded, and that a modified application in that amount or less may be approved.

7. If the PCA recommendation indicates that an application is planned for November or December, a note will be displayed in the response explaining that that applications in December are prohibited and that applications approved for November that do not take place in November may not be extended into December.

8. DAS or its contractor will advise PCAs that their Pesticide Use Reports for 1,3-D products should include the fumigation method code for all 1,3-D applications to allow verification of compliance.

9. In the event that a producer or registrant or other person other than DAS introduces a 1,3-D soil fumigant product in California that is produced from 1,3-D not manufactured by DAS, then DPR will require that producer or registrant or other person to discharge the same tasks and duties for its product that are to be discharged by DAS under this Agreement.

10. In the event that any of the actions described above become impossible, commercially impractical, or infeasible for any technical, economic or other reasons, the Parties agree that DAS's responsibilities can be discharged through alternative means that are reasonably consistent with the terms and purpose of this Agreement subject to approval by DPR.

DAS REPORTING REQUIREMENTS

DAS or its contractor will continue to provide to DPR annually a report that includes the total number of adjusted pounds of 1,3-D applied in the State, including a summary by

township and detailed data that includes the adjusted pounds for each application. DAS will provide the detailed data in "csv" format. In order to allow DPR to match the data for each application to its corresponding Pesticide Use Report, the report will include for each application the following information.

1. Transaction Type
2. Date Posted
3. Date Applied
4. Month Applied
5. County
6. Meridian/Township/Range/Section – in a single field, with the same formatting used by pesticide use reports: no spaces, and a single leading zero for single-digit township and range values (e.g., 'M 2S 8E' would become 'M02S08E')
7. Report Identification Number
8. Acres
9. Application Rate
10. Application Factor
11. Application Method
12. Fume Code
13. Commodity Name
14. Commodity Code
15. Pest
16. Product Name
17. Product Registration Number
18. Application Company

19. Grower Name
20. Pest Control Adviser
21. Permit Number
22. Site Identification
23. Amount of Product Used
24. Unit of measure
25. Pounds of Product Used
26. Pounds of Active Ingredient Used
27. Adjusted Total Pounds of Active Ingredient Used

ENFORCEMENT OF UPDATED MANAGEMENT PROGRAM

The Parties acknowledge that provisions of the Agreement above may be construed as rules, regulations, limitations or conditions for permitting within the meaning of FAC Section 14027, and that a violation of any requirement, limitation or prohibition may result in the initiation of an action against the violator for a civil penalty pursuant to Section 14027. In this regard, a violation of a requirement, limitation or prohibition by an applicator, registrant or other person other than DAS or its contractor shall not be construed as a violation by DAS. In addition, if the Agreement is not carried out effectively, DPR may exercise its authority to instruct CACs to suspend the further issuance of restricted material permits for 1,3-D until another equally effective management plan can be implemented or, if the Department concludes that the continued use of 1,3-D results in serious uncontrollable adverse effects to the environment, to initiate a proceeding to cancel the registration(s) pursuant to FAC Section 12824.

FOR THE DEPARTMENT OF PESTICIDE REGULATION

Date: Dec 16, 2016 Agreed: Brian R Leary

FOR DOW AGROSCIENCES LLC

Date: DEC 15, 2016 Agreed: Ramnath Subramanian

Ramnath Subramanian
Global Regulatory Affairs and Product Stewardship





Department of Pesticide Regulation



Brian R. Leahy
Director

MEMORANDUM

Edmund G. Brown Jr.
Governor

TO: Marylou Verder-Carlos
Assistant Director

George Farnsworth
Assistant Director

FROM: Teresa Marks *Teresa Marks*
Chief Deputy Director
916-445-4000

DATE: October 6, 2016

SUBJECT: RISK MANAGEMENT DIRECTIVE AND MITIGATION GUIDANCE FOR
CANCER RISK FROM 1,3-DICHLORPROPENE (1,3-D)

In December 2015, the Department of Pesticide Regulation (DPR) completed a Risk Characterization Document (RCD) for 1,3-D. This document outlines DPR's management decisions based upon the RCD to set the regulatory target concentration necessary to initiate and guide the development and adoption of mitigation measures to address cancer risk to bystanders (nearby workers and residential/public). Risk management decisions to address cancer risk to handlers of 1,3-D (workers involved in the application), as well as acute, seasonal, and chronic (non-cancer) exposures identified in the RCD will be issued at a later date after further analysis and consideration.

Background

1,3-D is a fumigant used to control nematodes, insects, and disease organisms in the soil. 1,3-D has major uses in California in fruit and nut trees, strawberries, grapes, carrots, and a host of other food and non-food crops. It is commonly used as a pre-plant treatment that is injected into soil. It may also be applied through drip irrigation. Regardless of the application method, the possibility of offsite transport of this fumigant due to volatilization may subsequently cause human exposure through inhalation. Dermal exposure is expected to be minimal; therefore, use restrictions are aimed at mitigating risk from inhalation.

DPR and other agencies have evaluated the cancer risk potential of 1,3-D. In 1997, DPR assessed the risk and implemented mitigation measures. In 1986, the U.S. Environmental Protection Agency (U.S. EPA) issued a Special Review of 1,3-D based on cancer concerns for workers. This review involved a data call-in requiring additional residue chemistry, inhalation exposure, and environmental fate data. In December 1998, U.S. EPA published a Reregistration Eligibility Decision (RED) for 1,3-D. Following publication of this Reregistration Eligibility Decision, additional mitigation measures through label modifications were put in place including lower maximum application rates, closed loading requirements, additional personal protective equipment, an increased restricted entry interval, and a buffer from occupied structures.



U.S. EPA updated the human health assessment for 1,3-D in 2007, but no new mitigation measures specific to 1,3-D were required. In 2007, U.S. EPA classified 1,3-D as “likely to be carcinogenic to humans” based on animal studies. The International Agency for Research on Cancer categorized 1,3-D as a group 2B carcinogen (“possibly carcinogenic to humans”). 1,3-D is listed under Proposition 65 as a chemical known to the State of California to cause cancer.

1,3-D is listed as a Hazardous Air Pollutant under the Clean Air Act, and is therefore designated as a Toxic Air Contaminant in California.

Updated Cancer Risk Estimate and Goal

DPR scientists evaluated a range of scenarios for the 2015 estimates of cancer risk. In other words, DPR evaluated different assumptions about when and how people are exposed to 1,3-D as well as about 1,3-D’s cancer potency. Using this information, the scientists estimated the risk of people contracting cancer for each set of assumptions. This analysis indicated a need to implement certain risk management measures to reduce cancer risk in exposed populations. For this purpose, DPR concluded that a cancer risk goal of 1×10^{-5} for a 70-year lifetime exposure was a reasonable objective for mitigation. DPR used the same target in 2001 when it previously adopted mitigation measures for 1,3-D. A cancer risk goal of 1×10^{-5} for a 70-year lifetime exposure means that the risk of contracting cancer should be no more than 1 individual for every 100,000 people. The risk level and exposure period are consistent with the [Proposition 65](#) standards for notification of carcinogenic risk and with the U.S. EPA non-dietary cancer risk policy, which states that U.S. EPA will seek to reduce risks in the 10^{-4} to 10^{-6} range (Barolo D. Non-Dietary Cancer Risk Policy, Office of Pesticide Programs and Toxic Substances, U.S. EPA, August 14, 1996).

Regulatory Target Concentration to Address Cancer Risk

DPR needs to establish a regulatory target concentration to achieve the 1×10^{-5} risk goal. However, there are uncertainties in estimating the air concentration that meets this risk level including the following:

- *Mode of action*: The 2015 RCD indicates that 1,3-D may cause cancer by two possible mechanisms: portal of entry or systemic modes of action. DPR scientists evaluated both mechanisms and concluded that the weight of the evidence favored a portal of entry mode of action based on currently available studies.
- *Residency duration and time away from residence (mobility)*: People generally do not live in one place throughout their lifetimes, and if they do, school, work, and other activities occur away from their residence. The 2015 risk document considered several options to estimate

years of residency in one place and time spent away from a residence. DPR concluded that a low-mobility scenario and 70-year lifetime exposure would be health protective in this case.

- *Additional uncertainty factor for age sensitivity:* The draft RCD was sent for peer review to the Office of Environmental Health Hazard Assessment (OEHHA). One of their comments addressed the variations of human sensitivities based on age as recommended in U.S. EPA and OEHHA guidance documents for carcinogens. DPR scientists favored not including an additional uncertainty factor for age sensitivity because a direct portal of entry mechanism bypasses the metabolic differences that can result in increased sensitivity in early life. However, DPR scientists recognized that there is remaining uncertainty involving age-related sensitivity due to other potential susceptibilities such as the rapid growth and development of the lung in early life, and the longer latency period during which cancer could develop. For this reason, DPR will use an age sensitivity factor to derive a concentration level that will trigger additional evaluation and consideration of further mitigation.

To account for the uncertainties and achieve a risk goal of 1×10^{-5} , DPR will set a regulatory target concentration of 0.56 parts per billion (ppb). This concentration is a 70-year average that should be achieved at least 95 percent of the time, and is based upon:

- the conclusion that the mode of action is portal of entry,
- assumption of 70-year residency time, and
- assumption of low mobility.

The 95 percent probability of protection is consistent with previous risk management directives. This means that DPR will implement limits on use and other restrictions so that there is at least a 95 percent probability that the average air concentrations for 70 years will not exceed 0.56 ppb. Although the RCD did not consider the age sensitivity factor necessary, adding an additional uncertainty factor to account for age sensitivities can be considered a health protective goal. This additional factor would result in an average lifetime target concentration of 0.27 ppb. As described below, if any one-year average concentration reaches this level, DPR will require additional evaluation. The 0.27 ppb trigger recognizes that science evolves and provides an expedited process to implement more stringent mitigation measures if they become necessary.

The regulatory target concentration of 0.56 ppb is higher than the previous target of 0.14 ppb. The target is higher because DPR has determined that it is appropriate to use a portal of entry mechanism as opposed to the systematic mechanism that was selected previously. This resulted in the use of differences in lung surface area instead of body weight to extrapolate data from animal studies to humans.

Measures to Achieve Regulatory Target Concentration

After several revisions, the following control measures have been in effect since 2002 with the goal of achieving the 2001 regulatory target concentration of 0.14 ppb. DPR has required Dow AgroSciences (1,3-D manufacturer and registrant) to limit the use in each township (6 x 6 mile area). Under this township cap program, each township was allocated 90,250 adjusted total pounds¹ of 1,3-D per year. If less than 90,250 adjusted total pounds was used in the township during the year, the excess was placed in a “bank” for future use in that township. If a sufficient amount was available in the bank, up to 180,500 adjusted total pounds could be used in a township during a year.

Concerns were raised, however, about the “bank” for both scientific and practical reasons. The bank was based in part on the fact that 1,3-D had not been used in California from 1991-1995. Since 1,3-D is now used regularly in California, there is a concern that high use, potentially up to double the cap, would result in one-year concentrations above the proposed regulatory concentration levels. Additionally, the banking system requires a level of recordkeeping that is disproportionate to any benefit it may confer.

DPR will revise the township cap program to meet the new regulatory target concentration of 0.56 ppb. While this is a 4x increase of the 2001 regulatory target concentration, the township cap will not increase by 4x because DPR has acquired additional data and developed more refined methods to relate air concentrations with use levels. DPR staff developed two methods to determine the township cap level.

- Using air monitoring and pesticide use data, DPR staff evaluated the relationship between the amount of 1,3-D applied and air concentrations, and arrived at a use level that would meet the 0.56 ppb regulatory target concentration. See attached [Tao document](#).
- Using the SOil Fumigant Exposure Assessment (SOFEA) computer model that has been developed and refined over a number of years, the 0.56 ppb regulatory target concentration would be met at levels inconsistent and usually higher than the ones estimated using air monitoring and use data. See attached [Barry and Kwok document](#).

There are several possible reasons why the two methods produce different township cap levels. One reason is the difference in time periods of the evaluations. The air monitoring data could only be evaluated as one-year average air concentrations, while the SOFEA modeling estimated 70-year average air concentrations. Using one-year data instead of 70-year data results in a lower

¹ 1,3-D allocations and use are “adjusted total pounds” using application factors that vary from 0.3x to 2.3x of pounds applied depending on fumigation method, month, and region. The application factors account for differences in emissions and air concentrations associated with different application methods, field conditions, and weather conditions.

township cap. Another possible reason is uncertainty in estimating December air concentrations. Monitoring data shows higher air concentrations during December than other months. The higher December concentrations are likely due to long periods of calm conditions at night. Computer modeling may not accurately estimate concentrations under calm conditions, so December air concentrations are more uncertain compared to other months. Additionally, the December monitoring data potentially indicates unacceptable seasonal exposures compared to the subchronic reference concentration in the 2015 RCD. DPR selected the air monitoring and pesticide use data method, which results in a township cap that is lower than the SOFEA method.

Effective January 1, 2017, DPR staff will make the following revisions to the township cap program to achieve the regulatory target concentration of no more than 0.56 ppb.

- The township cap will be 136,000 adjusted total pounds each year, based on 1,3-D air monitoring and use data described in the attached [Tao document](#).
- The banks of unused 1,3-D for all townships will be discontinued due to the potential for repeated high air concentration over several years.
- 1,3-D applications during December will be prohibited to address air concentration uncertainties and potentially high seasonal exposures.

These restrictions mean that if:

- 100,000 people lived in a 6 x 6 mile township for 70 years; and
- 136,000 adjusted pounds of 1,3-D were applied in the township every year for 70 years; then
- there is less than a 5 percent chance that 1 person in the township would develop cancer from exposure to 1,3-D.

DPR has determined that this will reduce emissions sufficiently so that the public will not be exposed to levels that may cause or contribute to significant adverse health effects.

Continued Evaluation of Mitigation Measures

To verify that the regulatory target concentration is achieved 95 percent of the time, DPR will continue to evaluate the effectiveness of the township cap and other mitigation measures, including the following.

- *Continue air monitoring:* As specified in the Budget Act for 2016-2017, DPR and the Air Resources Board (ARB) will continue to expand the air monitoring network by conducting year-round monitoring for 32 pesticides (including 1,3-D) in eight communities. The eight communities will include the top three regions for 1,3-D use, or DPR and/or ARB will conduct additional monitoring to capture the top three regions.
- *Continue to evaluate computer model:* DPR will continue to evaluate the SOFEA model. The modeled air concentrations will be compared to the air monitoring data network of DPR and

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George Farnsworth
October 6, 2016
Page 6

ARB to verify that the SOFEA model can accurately simulate long-term air concentrations in all high-use areas.

While the regulatory target concentration is a 70-year average, DPR will measure the effectiveness of its mitigation measures on an annual basis as an additional margin of safety. Monitoring that shows one-year average air concentrations less than 0.27 ppb will indicate that no changes are needed to the revised mitigation measures. DPR will evaluate and consider more stringent mitigation measures if air monitoring shows one-year average air concentrations that are between 0.27 and 0.56 ppb. The evaluation will include an analysis of measured air concentrations relative to 1,3-D use near the monitoring stations. The mitigation measures that DPR will evaluate and consider include, but are not limited to, a lower township cap amount, different township cap amounts in different regions, additional application date restrictions, additional application method restrictions, application factor revisions, and larger buffer zones. DPR will implement more stringent mitigation measures if one-year average air concentrations exceed 0.56 ppb.