



Department of Pesticide Regulation

Gavin Newsom
Governor

Jared Blumenfeld
Secretary for
Environmental Protection

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Acting Director

PESTICIDE REGISTRATION AND EVALUATION COMMITTEE (PREC) Meeting Minutes – July 16, 2021

Committee Members/Alternates in Attendance:

Brian Gress – California Department of Food and Agriculture (CDFA)
Heather Williams – Department of Resources Recycling and Recovery (CalRecycle)
Jaime Rudd – Department of Fish and Wildlife (DFW)
James Seiber – University of California (UC), Davis, Department of Environmental Toxicology
Katherine Sutherland-Ashley – Office of Environmental Health Hazard Assessment (OEHHA)
Lynn Baker – Air Resources Board (ARB)
Patti TenBrook – U.S. Environmental Protection Agency (EPA), Region 9
Rich Breuer – State Water Resources Control Board (SWRCB)
Ruben Arroyo – CA Agricultural Commissioners and Sealers Association (CACASA)
Tom Ineichen – Structural Pest Control Board (SPCB)
Tulio Macedo – Department of Pesticide Regulation (DPR)
Valerie Hanley – Department of Toxic Substances Control (DTSC)

Visitors in Attendance:

Note: Only attendees who identified themselves using their full name are listed below

Anne Katten – California Rural Legal Assistance Foundation
Bill Berti
Darin Cheung
Diala Diab
Eric Lauritzen
James Nakashima – Office of Environmental Health Hazard Assessment (OEHHA)
Jing Tao – Office of Environmental Health Hazard Assessment (OEHHA)
Justine Weinberg
Mike Grieneisen
Mike Zeiss
Niamh Quinn – University of California Agriculture and Natural Resources (UCANR)
Suzanne Hume

DPR Staff in Attendance:

Andrew Turcotte – Pesticide Registration Branch
Ann Schaffner – Worker Health & Safety Branch
Anna Bellini – Worker Health & Safety Branch
Brenna McNabb – Pesticide Registration Branch
Bryan George – Pesticide Evaluation Branch
Carissa Ganapathy – Environmental Monitoring Branch
Eric Kwok – Human Health Assessment Branch

DPR Staff continued:

Gayatri Sankaran – Human Health Assessment Branch
Jason Eiserich – Pesticide Evaluation Branch
Jill Townzen – Pesticide Evaluation Branch
Justin Kroes – Environmental Monitoring Branch
Kara James – Pesticide Registration Branch
Maziar Kandelous – Environmental Monitoring Branch
Minh Pham – Environmental Monitoring Branch
Nan Singhasemanon – Pesticide Programs Division
Nan-Hung Hsieh – Human Health Assessment Branch

1. Introductions and Committee Business – Tulio Macedo, Chair, DPR

- a. Approximately forty (40) people attended the meeting.
- b. DPR will be hosting a pesticide registration workshop for registrants on August 25. This workshop intends to educate registrants on the opposite side of the registration process.
- c. The comment period for the proposed rule-making related to carbon monoxide pest control devices closes on September 8, 2021.
- d. DPR is currently working on the registration fee increase proposal and will be posting it soon. More information can be found on DPR's website on the laws and regulations page.

2. Volatile Organic Compound Emissions from Pesticides: 2016-2019 – Justin Kroes, DPR

In 1963, the United States Clean Air Act (CAA) passed into law, and through subsequent amendments the CAA charged the U.S. EPA with approving state plans to regulate emissions of air pollutants including ground-level ozone or smog. In contrast to ozone in the upper atmosphere, smog is harmful to human and environmental health. Human health effects include increased rates of respiratory infection in healthy individuals, aggravation of existing respiratory illness, and premature death. Ground level ozone forms in the lower atmosphere through a series of chemical reactions, but two of the key chemical precursors are nitrogen oxide and VOCs. VOCs are emitted through many sources including pesticides. Pesticide emissions of VOCs are regulated by two California agencies. The Air Resources Board regulates consumer pesticide products, and DPR regulates agricultural and structural pesticide applications.

In 1994, DPR committed to reducing VOC emissions by a set percentage of emissions in a baseline year (1990) in five nonattainment areas, which are defined as areas that historically did not meet CAA standards. As a part of this commitment, DPR conducts an annual inventory of VOC emissions and publishes the results in an annual report. DPR's VOC inventory focuses on the peak ozone period between May and October of each year. Within that period, VOC emissions are calculated for each pesticide application by multiplying the applied product mass on the field by the fraction of the product assumed to contribute to atmospheric VOCs. For fumigant applications, emissions are further adjusted by a factor that accounts for the effect of

application method on emissions. Calculated emissions are totaled within each of the five nonattainment areas and compared to their emission targets. If committed reductions to emissions are not achieved within the nonattainment area, additional regulatory restrictions may be activated.

DPR has separate regulations regarding fumigants and non-fumigants; fumigant regulations were created in 2008 and non-fumigant regulations went into effect in 2013. Non-fumigant regulations are specific to only the San Joaquin Valley (SJV) nonattainment area, and restrictions on non-fumigant use in this area were triggered in 2015 with the release of the 2013 VOC inventory report. With the release of the draft 2019 VOC report, these restrictions on non-fumigants have been extended through 2022.

The regulations in Title 3 of the California Code of Regulations define VOCs, list VOC emission reductions required in each nonattainment area relative to the base year, and detail the regulatory restrictions available if those reductions are not achieved. Section 6881 mandates the annual VOC inventory report on whether or not these reductions are being achieved. The regulations require emissions to remain below 20 percent of the 1990 emissions for the nonattainment areas, and by 12 percent within the SJV nonattainment area. As of 2019, emissions for each nonattainment area remained below these limits, meaning these areas are achieving mandated reductions. Emissions for a given year are liable to change due to changes in weather patterns, agricultural economics, and other factors. To prevent emissions from rising above regulatory limits in future years, if the VOC report determines that a nonattainment area's emissions exceed 95 percent of its regulatory limit, restrictions on pesticide applications and products are triggered. In the SJV nonattainment area, these restrictions are a general moratorium on the use of so-called high VOC non-fumigant products on any of seven specific crop sites. In the other four nonattainment areas, restrictions are limits on the total fumigant emissions allowed in subsequent years. Fumigant limits are established through individual fumigant allowances, and the ability of counties to deny notices of intent and permits for fumigation within a nonattainment area's boundaries.

The first nonattainment area is the Sacramento Metro nonattainment area. In 2019, this area's emissions were over 1.2 tons per day, below the regulatory limit of 2.2 tons per day. No fumigant limits or restrictions on applications are currently active in this area. The next area is the SJV nonattainment area, and in 2019 emissions in this area were roughly 16.4 tons per day, below the regulatory limit of 18.1 tons per day. Restrictions on the use of certain high-VOC non-fumigant products in this area were instituted in 2015 based on the results of the 2013 VOC report. With the release of the 2019 draft report, restrictions remain in place through the end of 2022. Determination on whether to continue these restrictions beyond 2022 will be made in subsequent inventory reports. In the Southeast Desert nonattainment area, 2019 emissions were over 0.28 tons per day, below the regulatory limit of 0.92 tons per day. No fumigant limits or restrictions are currently active in this area. In the Ventura nonattainment area, 2019 emissions were just under 1.1 tons per day, below the regulatory limit of three tons per day. No fumigant limits or restrictions are currently active in this area. The final of the nonattainment areas in the South Coast. In 2019, emissions for this area were under one ton per day, well below the

regulatory limit of 8.7 tons per day. No fumigant limits or restrictions are currently active in this area.

The draft 2019 VOC emissions inventory report was posted for public comment on July 16th. The deadline for submission of public comments is August 27th. Comments should be sent in writing to:

Maziar Kandelous
California Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, CA 95812-4015

or by email to Maziar.Kandelous@cdpr.ca.gov

[DPR's Air Program site](http://cdpr.ca.gov/docs/emon/airinit/airmenu.htm) is available at <cdpr.ca.gov/docs/emon/airinit/airmenu.htm>

The [Air Monitoring Network page](http://cdpr.ca.gov/docs/emon/airinit/air_network.htm) can be found at <cdpr.ca.gov/docs/emon/airinit/air_network.htm>

[More information on VOC emissions from pesticides](http://cdpr.ca.gov/docs/emon/vocs/vocproj/vocmenu.htm) is available at <cdpr.ca.gov/docs/emon/vocs/vocproj/vocmenu.htm>

Committee Comment

Lynn Baker inquired as to why the status of fumigant emissions in the SJV nonattainment area were not presented. Justin Kroes explained that the area has had trouble consistently meeting its emission goals, and analysis showed that most emissions were coming from non-fumigant usage as opposed to fumigant usage. DPR then determined that non-fumigant restrictions would be more effective in the SJV nonattainment area as opposed to the fumigant restrictions that have been in place in the other four nonattainment areas. Justin added that fumigant emissions are still being tracked, and that the 2013 regulations for SJV still remain in place.

Jim Seiber asked if Justin Kroes could comment on emissions coming from unscheduled non-fumigant applications such as weed control and in dormant sprays as the wildfire season begins to pick up. Justin deferred to the Air Resources Board and stated that they may have more information in regard to tracking such emissions. Lynn Baker stated that the Air Resources Board does have an emission inventory branch, but he is unsure whether those emissions were being tracked specifically.

Public Comment

None to report.

3. Proposed Rulemaking: Spray Adjuvant Ingredient Statement – Bryan George, DPR

The California Food and Agricultural Code (FAC) defines spray adjuvants as any wetting agent, spreading agent, deposit builder, adhesive, emulsifying agent, deflocculating agent, water modifier, or similar agent, with or without toxic properties of its own, which is intended to be used with another pesticide as an aid to the application or effect of the other pesticide, and sold in a package that is separate from that of the pesticide other than a spray adjuvant with which it is to be used (FAC 12758). Spray adjuvants are classified as pesticides in California under FAC 12753, but unlike conventional pesticides, they do not function as pesticides on their own and are similar to inert ingredients found in conventional pesticides. They are registered in California but are not registered or regulated on a federal level, and their labeling is not subject to Code of Federal Regulations Title 40.

The current labeling regulation for spray adjuvants under the FAC differs from conventional pesticides in a few key ways. Principal functioning agents replace “Active” ingredients, and constituents ineffective as a spray adjuvant replace “inert” ingredients. Individual principal functioning agent concentrations do not need to be listed, and only the top three principal functioning agents need to be listed. The purpose of the proposed regulation is to clarify FAC labeling and maintain consistency with California Notice 2020-13 regarding spray adjuvant chemical formulation identity disclosure.

Principal functioning agents are often complex mixtures or polymers without common names. Chemical class simplifies the nomenclature and is more meaningful to end-users. More specific names do not typically provide more useful information about these complex mixtures. The physicochemical properties of class constituents are similar; thus public safety is not comprised by using chemical class in place of more exact names. While chemical class is what’s allowed on the labels, DPR receives the complete chemical composition of these products for the purpose of evaluation.

Siloxanes and silicones, di-methyl, 3-hydroxypropyl methyl, ethoxylated propoxylated is an example of a compound that could be classed as a dimethylsiloxane polymer, which would be more meaningful to end-users. Another example is the chemical class alcohol ethoxylate, which includes a large number of chemicals differing primarily in carbon and ethoxylate chain lengths, but having similar properties. For example, both alcohols, C9-C11, ethoxylated and alcohols, C12-14, ethoxylated could be listed as alcohol ethoxylates. In contrast, a chemical like nonyphenol ethoxylate would be grouped into its own chemical class of alkyl phenol ethoxylates due to the presence of an aromatic phenyl group.

Acids and bases are two exceptions that are not placed under chemical classes, and instead must be identified by chemical or common name. Phosphoric and sulfuric acid, for example, are both mineral acids, but must be listed on a label by their chemical or common name as their physicochemical properties are quite different. Similarly, bases like magnesium hydroxide and sodium hydroxide must not be listed as inorganic hydroxides and instead must use chemical or common name. Another exception to the use of chemical class is for ammonium sulfate, which

must be identified as ammonium sulfate instead of a chemical class or synonym such as diammonium sulfate or sulfuric acid, ammonium salt. This exception makes it easier for pesticide applicators to comply with label guidance regarding ammonium sulfate, as many conventional pesticides recommend tank mixing with spray adjuvants containing ammonium sulfate. Exceptions also exist for ingredients that are not allowed for use on food or feed crops. Precise chemical or common name must be used for these chemicals to prevent inadvertent contamination of food or feed with non-allowable ingredients when other members of the same chemical class may have allowable food uses. The final exception is food allergens, which must use precise chemical or common names. Allergens represent a public health danger to sensitive groups, and they must be identifiable and recognizable to the general public. For example, a product like fish oil must be identified as fish oil instead of a more generic term such as “animal-derived oil”.

This regulation formalizes and clarifies Food and Agricultural Code with language similar to that of California Notice 2020-13. It does not represent a change to current DPR practices and it will not affect currently registered spray adjuvants, only new and amended products.

Committee Comment

None to report.

Public Comment

Diala Diab asked if the exceptions still apply for food allergens with chemical names that may be difficult for the public to recognize, such as artificial additives and colors that are allergens and sometimes carcinogenic. Bryan George responded that DPR looks at these on a case-by-case basis for the time being. He stated that he would look into this further as DPR wants food allergens to be as recognizable as possible.

Mike Zeiss asked if DPR intended to release a glossary of chemical names based on chemical class or vice versa. Bryan George replied that there is no official listing of chemical classes, but DPR encourages registrants to set up pre-registration meetings or email regulatory scientists for issues related to chemical names or classes. Mike also asked if the regulations will increase the amount of information about adjuvants that's available via the California Pesticide Information Portal Application (CalPIP). Bryan replied that the regulations will be consistent with the California Notice 2020-13, but he did not know if there would be any new information available online.

Suzanne Hume asked when DPR would have a glossary for the purpose of recognizing and researching abbreviations. Bryan replied that DPR has no current plan to release a glossary and noted potential confidentiality concerns, but that he would discuss the possibility of a glossary with his manager.

Emily Saad asked for Bryan George to comment on the consistency of DPR's approach with the Washington State Department of Agriculture, as they are another state that registers adjuvants and has a similarly sophisticated registration review approach. Bryan replied that DPR does work with Washington to maintain consistency with their registration practices in an effort to make registration easier for registrants who sell in both states.

Justine Lew Weinberg asked why the number of principal functioning agents on labels is limited at three. Bryan George replied that this rule goes back to statutes in the FAC that are over seventy years old.

4. Funding Available for Ecosystem Monitoring – Jill Townzen, DPR

California's recently signed budget has made new funding available for ecosystem monitoring in fiscal years 20/21 and 21/22. DPR envisions that this funding will be used for one or more research contracts, and the department is open to ideas that anyone may have for ecosystem monitoring. Some potential areas of interest that have already been discussed internally include monitoring impacts to pollinators, monitoring impacts to native plants or restoration projects, and monitoring for pesticides in important environmental compartments. DPR recognizes that these are not the only potential areas of interest for the department, and is interested in hearing from anyone who has ideas for potential projects or contracts. Ideas can be submitted in email to Jill Townzen via Jill.Townzen@cdpr.ca.gov.

Committee Comment

Rich Breuer noted that the potential ideas discussed by DPR were focused around the agricultural environment, and asked if they may be looking at the urban environment as well. Jill Townzen replied that DPR interested in anything that may help inform their pesticide evaluations, and that includes monitoring in urban areas as well. Rich followed up by stating that SWRCB may reach out with suggestions regarding stormwater runoff in urban areas.

Jaime Rudd asked if there was a proposed timeline in which DPR is looking for inquiries and contract/project proposals, and if there was a timeframe in which the allocated funding must be spent. Jill Townzen replied that funding is available for both this fiscal year and next fiscal year, and added that there is an extended encumbrance period which will give DPR more time to choose how to spend the available funds.

Public Comment

An anonymous attendee asked where past ecosystem monitoring projects can be found. Jill Townzen replied that this is the first time funding has been made specifically available for ecosystem monitoring, and there are no past projects. Jill added that the Environmental Monitoring Branch has done similar monitoring programs in the past, but the ecosystem monitoring budget allocation is new.

5. Acephate Human Health Mitigation – Anna Bellini & Kara James, DPR

Acephate is an organophosphate insecticide active ingredient first registered by DPR in 1975. DPR conducted a human health risk assessment for acephate due to its low No-Observed-Effect-Level (NOEL), and possible adverse effects identified in chronic and oncogenic studies. DPR's risk assessment was published in a risk characterization document (RCD) and a subsequent addendum. After completion of the human health risk assessment, DPR updated its exposure assessment policies and transfer coefficients for calculating post-application exposure. In addition, product application rates, use amounts, and seasons in California also changed. As a result, the exposure assessment section in DPR's Human Health Assessment Branch (HHA) updated exposure scenarios and short-term, seasonal, and annual margins of exposure (MOEs) associated with the use of acephate products.

In January 2019, DPR issued a Risk Management Directive (RMD) for acephate. Typically, an RMD defines the scope of mitigation and provides a target number that guides DPR's mitigation efforts of a particular active ingredient. The January 2019 RMD for acephate directed DPR staff to mitigate acute occupational exposure scenarios of concern. Also in January 2019, DPR met with registrants of all currently registered acephate products to discuss generic concerns and potential mitigation options, should a registrant determine their products bared these identified concerns. After meeting with registrants, DPR revised the RMD to include home and garden products and began the process of conducting product label-specific assessments for each of the 25 registered acephate products.

During the January 2019 meeting with registrants, DPR presented the generic exposure scenarios originally identified during the risk assessment process. DPR also requested that all acephate registrants submit their intent to mitigate the concerns outlined in the RMD. After this meeting, DPR evolved its process to be more product-specific, with a greater emphasis placed on the product labels as they are currently registered, and how their registered uses might impact acute occupational exposure. As a part of the evolution to a more product-specific approach, DPR revised the RMD to clarify that both conventional agricultural products, as well as home and garden products, were affected. The RMD directs mitigation of acute occupational exposure and provides the protective goal MOE value. In theory, any home and garden products could be used by a handler in an occupational setting.

In February 2019, memo HSM-19001 was published by DPR. This memo outlines the process for developing mitigation MOEs for non-fumigant pesticides with threshold effects. In this context, a threshold effect is defined as a dose that does not present a health concern. This memo was not just developed for acephate, but for non-fumigant pesticides in general. This memo lays out how to calculate the MOE, which is the No-Observed-Effect-Level (NOEL) divided by exposure. In this case, exposure is calculated by the short-term average daily dose. For acephate, the target acute MOE is 10. Scenarios with MOEs of 10 or above are not considered to be of concern for acute occupational exposure to acephate, because the NOEL identified in the RCD for acephate was based on a human oral toxicity study.

After DPR transitioned from a general assessment presented to registrants in January 2019 to product-specific assessment, the following data were collected to determine if a product bared acute occupational areas of concern: percent of acephate, product formulations, PPE required, maximum application rate, maximum area treated daily, application method, and engineering controls. This assessment informed registrants of specific exposures of concern that need mitigation and fosters development of mitigation options. Each product label had multiple acute exposure scenarios; some had MOEs lower than 10, and some had MOEs that exceeded 10. When coming up with mitigation for their labels, registrants focused on the acute occupational scenarios that had MOEs lower than the target MOE of 10. Scenarios with MOEs that exceeded 10 were not considered to be of concern, and therefore did not need mitigation.

Exposure is expressed as a dose in the 2008 RCD. Acute occupational exposure for acephate is expressed as the Short-Term Average Daily Dose (STADD). The STADD is used to calculate the acute MOE, which is the NOEL divided by the STADD. The NOEL is a constant and is identified in the RCD. The STADD is calculated by taking the sum of the unit exposure rate, multiplied by the absorption factor, multiplied by maximum area treated in a day, multiplied by the application rate, all divided by body weight.

$$STADD = \frac{\sum(\text{Unit Exposure Rate} \times \text{Absorption Factor}) \times \frac{\text{Max Area Treated}}{\text{Day}} \times \text{Application Rate}}{\text{Body Weight}}$$

The bolded expressions in the above equation are fields that can be adjusted and are considered when developing mitigation options. PPE protection factors can also be considered in the unit exposure rate, which is multiplied by the absorption factor.

After determining which products bared acute occupational exposure scenarios with MOEs less than 10, DPR met with each individual registrant and discussed potential mitigation options. Registrants then voluntarily implemented mitigation in the form of label changes that best suited their products. Some mitigation options included the following: adding “Not for use in California” to the label, restricting amount applied per day per handler, requiring chemical-resistant full-body protective suits, clarifying the product is not to be applied by air, requiring an enclosed cab for airblast applications, and extending the reentry interval (REI). One or more of these options helped raise the MOE to 10 or above depending on the product and exposures of concern.

Regarding further steps for the department, the Pesticide Registration Branch (PRB) is monitoring product label amendments as they are approved at the federal level. In addition, PRB will assign all submissions containing acephate to a single point of contact. This will help to ensure that new or amended uses can be evaluated for potential impacts to acute occupational exposure.

Committee Comment

Lynn Baker asked if acute occupational exposure referred specifically to dermal, oral, or inhalation exposure. Lynn also asked if there was concern for non-occupational bystander exposure as well. Dr. Eric Kwok from HHA's Exposure Assessment Section replied that for agricultural workers, dermal and inhalation exposure are the two major exposure sources, and oral exposure isn't usually considered as that is not the common exposure pathway associated with the handler. Eric also replied that bystander exposure is not addressed by the product label, and that any mitigation measure introduced into the product label amendment could potentially affect the bystander exposure assessment. Eric added that by engaging in label-specific mitigation measures, bystander exposure will be affected to some extent.

Public Comment

Anne Katten asked how DPR adjusted for differences between the oral study and dermal and inhalation routes of exposure, and how DPR accounted for the greater range of sensitivities in the general population than those participating in the study. Eric Kwok replied that when the exposure assessment group calculates the internal dose, they apply an absorption factor to account for the absorption from the skin and from inhalation to the lungs. Eric added that the oral dose referred to has already been calculated with an absorption factor, and therefore can be directly compared to internal doses. Eric added that DPR employed acetylcholinesterase (AChE) inhibition in humans as an endpoint in the human health risk assessment, and AChE inhibition is well-established and used by U.S. EPA.

6. Agenda Items for Next Meeting

Tulio Macedo announced that DPR is currently working on making its risk assessment determination drafts available for public comment as per request, as well as on strategies for prioritization of active ingredients that go into risk assessment.

Lynn Baker responded to Tulio Macedo's announcement that the requests were also made to better understand how DPR prioritizes pesticides to enter the risk assessment process, and added that a future meeting could include a presentation by the toxicology group on how that prioritization works.

The next meeting is scheduled for September 17, 2021 at 10:00 a.m. This meeting will be held virtually on the Zoom platform and broadcast live on the [CalEPA webcast page](https://video.calepa.ca.gov/).
<video.calepa.ca.gov/>

7. Adjourn