

Department of Pesticide Regulation

Gavin Newsom

Jared Blumenfeld
Secretary for
Environmental Protection

PESTICIDE REGISTRATION AND EVALUATION COMMITTEE (PREC) Meeting Minutes – March 18, 2022

Committee Members/Alternates in Attendance:

Brian Gress – California Department of Food and Agriculture (CDFA)

Garrett Keating – Department of Industrial Relations (DIR)

Jaime Rudd – Department of Fish and Wildlife (DFW)

Katherine Sutherland-Ashley – Office of Environmental Health Hazard Assessment (OEHHA)

Ken Everett – Department of Pesticide Regulation (DPR)

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)

Visitors in Attendance:

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

Alex Harper

Anne Katten – California Rural Legal Assistance Foundation

Bridgit McKay

Cameron Blackford – Compliance Services International, California

Cathy Fisher – Santa Barbara County Agricultural Commissioner, Sealer

Christopher Finarelli – Household & Commercial Products Association (HCPA)

Fabiola Estrada – U.S. Environmental Protection Agency (EPA), Region 9

James Nakashima – Office of Environmental Health Hazard Assessment (OEHHA)

Jennifer Stafford

Jing Tao – Office of Environmental Health Hazard Assessment (OEHHA)

John Bottorff – CleanEarth4Kids.org

Kevin Graulich – California Division of Occupational Safety and Health (Cal/OSHA)

Marcia Trostle - Nutrien

Michael Barber – SBM Life Science Corp

Michael Zeiss

Michele Brunlinger

Pat Dinnen

Paula Thompson

Pepe Martinez-Villela

Rebecca Baskins – KSC

Suzanne Hume – CleanEarth4Kids.org

Vicki Quinn Ghaffarzadeh

Vikram Kanmukhla

DPR Staff in Attendance:

Aisha Iqbal – Pesticide Registration Branch Alicia Scott – Enforcement Headquarters Branch Alyssa Knudsen – Pesticide Registration Branch Andrew Turcotte – Pesticide Registration Branch Aron Lindgren – Pesticide Registration Branch Brenna McNabb – Pesticide Registration Branch Brittanie Clendenin – Pesticide Registration Branch Francie Bishop – Pesticide Registration Branch Jessica Teague – Enforcement Headquarters Branch Joseph Damiano – Enforcement Headquarters Branch Kara James – Pesticide Registration Branch Laurie Brajkovich – Enforcement Headquarters Branch Lucia Graham – Worker Health and Safety Branch Michel Oriel - Worker Health & Safety Branch Morgan Thai – Pesticide Registration Branch Nan Singhasemanon – Pesticide Registration Branch Savannah Hadley – Pesticide Registration Branch

1. Introductions and Committee Business - Ken Everett, Chair, DPR

- a. Approximately seventy-seven (77) people attended the meeting.
- b. Last Friday, March 11, 2022, the Department of Pesticide Regulation (DPR) issued California Notice 2022-06, announcing the agenda for the public hearing of the Pesticide Contamination Prevention Act (PCPA) review for imidacloprid. The public hearing will commence on Tuesday, March 22, 2022 and can be watched on the CalEPA Webcast page. Please direct all questions to PCPA@cdpr.ca.gov. DPR continues efforts to adopt control measures to protect pollinator health in an agricultural setting based on the findings of the July 2018 California Neonicotinoid Risk Determination for the insecticides imidacloprid, clothianidin, thiamethoxam, and dinotefuran. On February 25, 2022, DPR published a Notice of Proposed Regulatory Action, at which time a sixty-day public comment period began. A public hearing is scheduled for 9:30 AM on April 25, 2022, to receive oral or written comments regarding the proposed regulations. The comment period ends 5:00 PM on April 26th. Please direct all questions to Neonics@cdpr.ca.gov. DPR recently posted the 2022 Rulemaking Calendar. Four County Agricultural Commissioners announced a voluntary partnership with the DPR to launch pilot projects to support DPR's development of a statewide pesticide application notification system. Riverside, Santa Cruz, Stanislaus, and Ventura County pilot projects will launch between February and July 2022 and will help inform the design and implementation of the state's statewide notification system. Submit questions and comments to ProjectNotify@cdpr.ca.gov. Congratulations to the 2021 DPR IPM Achievement Award Winners. To learn more about the five winning organizations and their IPM accomplishments visit DPR's website. If you missed the ceremony, you can watch the ceremony, winner, and legislative videos on YouTube.

2. <u>Pesticide Illnesses Involving Antimicrobials Used in the Workplace – Lucia Graham, DPR</u>

The Department of Pesticide Regulation (DPR) is one of six different departments within the California Environmental Protection Agency (CalEPA). DPR is charged with regulating the sale and use of pesticides in California. DPR's mission is to protect human health and the environment by regulating pesticide sale and use by fostering reduced-risk pest management.

In California, physicians are required to report suspected or confirmed pesticide related illnesses to their local health officer, similar to communicable diseases such as Tuberculosis and COVID. These reports are then forwarded to DPR. DPR has a contract with the California Poison Control System (CPCS), when a healthcare provider contacts poison control for advice to manage the patients care, poison control will offer to submit a pesticide illness report (PIR) on their behalf in order to meet their reporting responsibility. Though there are other reporting sources, those will not be discussed in detail in this presentation; CPCS is the main source of DPR's cases. The PIRs are then forwarded to the County Agricultural Commissioner (CAC) where there is a memorandum of understanding with the 58 counties to conduct the illness investigation and document the circumstances of exposure. The CACs complete their investigation and submit the report to us so we can evaluate and extract information to enter into the PISP database. We collect over 120 different variables to capture this information and analyze the data to determine the association between exposure and symptoms reported.

Our program is the oldest and most comprehensive compared to the 11 other states in the United States that have a similar program, however, those are housed in the state's health departments where we are in a regulatory agency. The data we use can be used to identify emerging problems that could result in reformulation, label revision, permit conditions, product reevaluation and outreach. For example, several years ago we noticed a number of incidents involving insecticides containing the active ingredient fenpyroximate. These incidents occurred in different counties throughout California, but all of the affected individuals reported an odor and described it using similar words. We looked further into these incidents and discovered that although there were multiple products containing fenpyroximate, all of these incidents involved one specific product that contained an inert ingredient that was not in the other products. DPR reached out to the registrants, informed them on our analysis and they have since changed their formulation. Since then, we have not received pesticide illness reports involving field workers exposed to this specific product.

Our program also collaborates with internal and external stakeholders. We generate an annual report that covers the different sources of pesticide illness reports mentioned earlier. The data is also available to the general public using our online query portal called CalPIQ capps.cdpr.ca.gov/calpiq/calpiq_input.cfm. CalPIQ contains the most requested variables such as activity and type of exposure.

The data discussed will cover the years 2009 through 2018, 2018 being the most recent publicly available year. Most of California's associated pesticide-related illnesses are from non-

agricultural use at 84 percent. Non-agricultural use is defined as incidents in which the pesticide involved was not used for the production of an agricultural commodity. For example, restaurants, schools, hospitals, and structural pest control. With regard to agricultural incidents, there have been a number of regulations in place to protect agricultural workers and applications of agricultural use pesticides which may explain the proportion differences. Of the individuals exposed, 36 percent were at work when exposed to non-agricultural use pesticides. Of those occupational cases, 72 percent were exposed to antimicrobials such as sanitizers and disinfectants, while the other majority were exposed to conventional pesticides such as herbicides, insecticides, and rodenticides. A big portion of workers are exposed to antimicrobials. The non-occupational cases account for about two thirds, which are the individuals not at work at time of exposure such as tenants, homeowners, and customers at restaurants.

Over 50 percent of the non-agricultural cases occur in retail, service, or wholesale establishments, and hospital or medical facilities. The retail, service, and wholesale establishments are grouped together because they have very similar sanitizing requirements. Although antimicrobials are considered a pesticide, both industries can opt to follow Title 8, which is enforced by the Department of Industrial Relations (DIR). They do still have to create and implement an Illness and Injury Prevention Program and Hazard Communication.

Antimicrobials come in multiple formulations and 62 percent of these incidents involved liquid formulations. This would be a liquid concentrate where dilutions are required prior to use which is the easiest to use. Eight percent of incidents involved impregnated materials such as sanitizing wipes. Of the workers exposed to the impregnated formulation, 33 percent used sanitizing wipes at a hospital or medical facility. This analysis is highlighted in the 2018 annual report.

At time of exposure, two thirds of the workers were handling non-agricultural use antimicrobials. Those workers were typically mixture loaders, applicators or workers handing or working on contaminated equipment. Individuals whose activity has an increased risk of pesticide exposure accounted for 26 percent and was grouped as 'Other'. For example, lifeguards, non-handlers at a water treatment plant or food processing facility.

Handlers who had direct contact exposure with antimicrobials such as a spill on the hands, splashes in the eye, or having hands immersed in the solution made up 71 percent. To a lesser extent, there is offsite movement which would include spray, mist, vapors, particulates, or odor that's carried from the target site during the application. The bystander's route of exposure, who are at work but not working directly with the application, varies greatly with about one third of offsite movement.

The most common type of illness reported for handlers based on the type of exposure they experienced were eye and skin as well as the bystanders following a similar pattern in addition to respiratory and systemic. Of workers exposed, 17 percent had at least one disability day due to the exposure.

Out of the violations that occurred, 52 percent of the cases had identified a contributory violation, 31 percent did not, and 17 percent of the cases could not be determined if a violation occurred. When looking at the types of violations, 67 percent of the individuals were not wearing the label required personal protective equipment (PPE), 23 percent of the individuals had other misuse such as mixing incompatible products or use above the label rate. The data suggests lack or improper training in the use of the product contributed to their exposure.

Based on the analysis, data indicates failure to wear label required PPE, lack of proper training, and misuse of the product can lead to pesticide-related illnesses and injuries. Generally, in the most common incident settings such as food facilities, workers are unaware that antimicrobials are a type of pesticide and training does not include ensuring that PPE is worn or reading the label. Employers have the option to follow Title 8-3 CCR 6720(c) (DIR) for antimicrobial use. In certain industries such as retail and food facilities, they do not specify the use of registered antimicrobials for sanitizing. For example, the California Retail Food Code (Cal Code) only has requirements on the concentration to use to sanitize food contact surfaces, but it does not say that you have to use a registered sanitizer. Another example would be Title 22 which regulates the recreational health swimming pool and that is also enforced by the local environmental health, they do not specify the use of registered antimicrobials. When analyzing the hospital impregnated materials, we found that there were some sanitizers involved that required PPE only when handling or sanitizing for biological waste.

There are overlapping jurisdictions when it comes to antimicrobial because it is multifactorial. For example, DPR, regulating the sale and use of pesticides, the Department of Industrial Relation (DIR) and Division of Occupational Safety and Health (CalOSHA), overseeing, administering, and enforcing workplace safety and health, and the Environmental Health group (EH), enforcing state and local health codes. This overlap makes it difficult to enforce.

Several years ago, DPR collaborated with the California Conference of Directors of Environmental Health (CCDEH) to perform outreach to educate about the safe use of sanitizers in retail food facilities. This is an example of how DPR is educating and performing outreach in hopes to mitigate and reduce the number of illnesses. DPR also created educational flyers with the help of local environmental health specialists to be distributed when the specialists inspect restaurants throughout the state. Data will be analyzed to see if there is a decrease in number of cases at these establishments post outreach. DPR consulted with the Office of Environmental Health Hazard Assessment (OEHHA) to begin developing a protocol to quantify occupational exposures to quaternary ammonium compounds.

As mentioned earlier, 63 percent of non-agricultural incidents that are not occupational are home use situations. DPR created the top ten safety tips for using pesticides safely in the home and distributed them at community outreach fairs. The County Agricultural Commissioners (CAC) distribute them when they conduct their illness investigation. All the flyers mentioned are available on DPR's Web site <cdpr.ca.gov/docs/whs/sanitizersafety/index.htm>.

Committee Comment

Garrett Keating stated being with CalOSHA and being in a pandemic, Garrett assumes there is a lot more aggressive sanitization going on. Garrett asked is this being tracked in the CalPIQ database, though it was just noted the data has only been released through 2018. Lucy Graham replied that it is too early to tell, most of the cases are from poison control and yes, during covid there was an increase in antimicrobials and sanitizers but there has been a decrease in number of people going to urgent care and emergency rooms. Considering that is our main source, the number of incident reports from poison control did go down.

Garrett Keating also asked if the CCR section where it sites employers can opt into Title 8 instead of Title 3, do they still have to do the reporting through the CACs in regard to illness reports. Lucy Graham answered, employees who are taken for care, physicians are still required to report that. That's under Health and Safety Code section 105200 regardless of occupational or non-occupational. For occupational, the doctors will also complete the doctors first report and that is then submitted to DIR, which subsequently will be routed to CDPH and DPR.

Patti TenBrook asked given that so many people still don't recognize disinfectants as pesticides, is there a sense of how underreported this stuff is and are those outreach materials provided to doctor's offices to hand to people? Lucy Graham stated it is hard to know what is underreported because we have passive surveillance. DPR has assisted OEHHA to conduct physician outreach on their reporting requirements and there were handouts for them. Michel Oriel added that physician outreach falls under jurisdiction of OEHHA but we do work closely with them to assist with that.

Public Comment

Mike Zeiss stated regarding under-reporting, isn't it correct that in the past, DPR has contracted for an external audit to estimate under-reporting? If that is correct, when was the last year such an audit was conducted? Lucy Graham stated, I'm not aware of an audit, there was a study conducted by Louise Mehler that looked at possible under reporting before there was a contract with poison control. She found that for agricultural cases, our database contained a high proportion of those incidents that occurred; here there was a lack of reporting was the non-agricultural home use. Since our contract with poison control the number of non-agricultural cases have gone up. It is difficult to know what we don't know.

Mike Zeiss replied, okay, so would it be useful for DPR to fund a study similar to Mehler's previous study? Lucy stated, yes, we could certainly look into that as a potential project

Emily Saad stated DPR is proposing regulations concerning the Medical Supervision Program. One of the impacts of the proposed action is to clarify that the physician contracted with an employer to act as a medical supervisor must be registered with OEHHA. Are you able to provide any background into this revision to the regulations? It appears that the regulation change is to be consistent with the requirement in the Health and Safety Code, but it's unclear

when and why this requirement was first implemented. Lucy Graham responded, Health and Safety Code section 105206, that was revised recently, states OEHHA is to register physicians who would like to be a medical supervisor under the Medical Supervision Program. The proposal 3 CCR 6728 is to make that consistent with 105206 where it currently states an employer is in contract with a physician to be medical supervisor. We want to clarify that the physician the employer contracts with as their medical supervisor has to be registered with OEHHA. The proposal is to ensure the language is the same, and that both the employer and physicians understand the requirements.

3. Special Local Need Registrations – John Inouye, DPR

When referring to the Special Local Need (SLN) program you will hear the term 'SLN' or Section 24(c) and those are referencing the Special Local Need Registration process that takes place in California. This program starts at the federal level with the Federal Insecticide Fungicide Rodenticide Act (FIFRA) of 1947. It gives the states the authority to regulate pesticides but also states may register an additional use of the federally registered pesticide product to meet a special local need if registration for such use has not been denied, disapproved, or cancelled by the U.S. Environmental Protection Agency (U.S. EPA).

The U.S. EPA creates and implements the law and created 40 Code of Federal Regulation (40 CFR) section 162.152 which provides guidance through regulations to the states. This provides guidance and defines terms, authorizes the states application requirements, and can disapprove a state's SLN if need be. If states are not implementing the programs as such, they can suspend state registration authority to issue 24(c) registrations.

Within 40 CFR, additional information is defined giving additional information, similar to FIFRA law, that states may register an additional use of a federally registered pesticide product, or a new end use product to meet a special local need, if certain conditions exist. The biggest criteria reviewed in the application is the Special Local Need and the condition.

The Special Local Need, based on U.S. EPA's determination, is when the state determines there is an existing or imminent pest problem, and an appropriate federally registered pesticide product is not sufficiently available. The conditions are broken down into four areas: existing or imminent pest problems, food or feed uses tolerances or exemption from tolerances, registration for same use has not been denied, disapproved, suspended, or cancelled, and the registration is in accord with the purposes of FIFRA. There are two types of SLNs, first party and third party. First party SLNs are associated with the registrant of the pesticide. The third party would be anything other than the registrant, for example agency of public health or county association.

SLNs may address new pests, new crop or use site, method or timing of application, or integrated pest management (IPM) program. An IPM program may try to integrate another chemical to try and mitigate resistance management.

When the Department of Pesticide Regulation (DPR) receives a Section 24(c) or Section 18 application, we want to make sure that it is not circumventing Section 3 registration process. It is understood that at times special regulatory tools such as a SLN may be warranted. This information is reviewed and data may be requested from an unbiased opinion such as a UC Extension specialist that has a more broad view of the information. Though we do require third party support letters and DPR will reach out to question the validity of those support letters, more information may be requested for the application. The 24(c) does go through a stringent process of review to ensure that DPR is carrying out the program's intentions in the eyes of the U.S. EPA.

The state SLN application form consists of a few different components. Within that form there are labeling and use directions that cover the use rates, directions, and methods. Depending on the site and situation, we may incorporate some additional use directions to mitigate issues such as drift issues or exposures to aquatic sites for example. The 24(c) label is more broad than the Section 3 label. Included in the application is a federal form that must be completed and signed, data to show it supports 24(c), and if it is a third party, a letter of authorization from the registrant must also be included. There are very few cases where the third party submits a letter from the registrant that did not support 24(c).

The data that is required in the application needs to include multiple areas. Residue data is required to demonstrate that the use rate and or methods will not exceed the established tolerances, or the data presented shows that they are exempt from tolerances. Efficacy and phytotoxicity data are required to be submitted to make sure that it is efficacious to mitigate the pest and that it is not toxic to the site. The phytotoxicity is to address additional nearby crops that may be sensitive. On a case-by-case basis, it may be required to submit data looking at fish and wildlife on target issues and worker exposure depending on use. Additional data may be requested after initial review to further understand the mitigation measures needed.

The 24(c)s have expiration dates and can be approved up to five years. Though it is not a requirement by the U.S. EPA, it is a state requirement because the U.S. EPA recommends expiration dates for 24(c)s. This is in efforts to motivate 24(c)s to become incorporated into the Section 3 product label though it does not happen very often. Extensions can be requested past the 5 year if needed.

The 24(c)s are always issued to the primary registrant's label. In California, supplemental registrations or distributor registrations are always associated with a primary or basic registration. Within the regulation that the U.S. EPA set out, it is always based on the primary registrant's label. The distributor products may be used under the primary registrant's SLN label. The enforcement letter dated October 6, 2003 addressed to the state, that if a SLN is associated with a basics registrants label and the distributor label has a unique U.S. EPA registration number associated to that basic label, then they use their product under that SLN label. That gives them the authority to develop a SLN label off the basics label.

Currently, there are no state fees but there are federal fees. For each SLN, it is four thousand dollars but depending on the registrant, they can request a waiver for that federal fee. When it comes to third party SLN fees, DPR pushes the third party to try and see if the basic will carry it because that fee may be a burden to a third party.

DPR has a 60-day timeframe once it reaches an environmental scientist desk for review, 30 days for the required public posting for formal review for a total 90 days. If everything is approved the SLN will be approved for immediate use. DPR is required by law to submit the SLN submission to the U.S. EPA and then they have 90 days to respond. After those 90 days, it becomes a Section 3 registration though the U.S. EPA and the U.S. EPA still has the ability to cancel the SLN.

Table 1: SLNs and Section 18 Emergency Differences.

Section 24(c) Special Local Need	Section 18	
Tolerance or exemption already established.	No tolerance established. U.S. EPA will	
	establish a time-limited tolerance.	
To meet a special local need (regional or	For limited use to treat sudden and limited	
statewide)	emergency pest infestations.	
Justification and lack of alternatives must be	Emergency situation must be well	
documented.	documented and not a historical pest problem.	
	Economic and lack of alternatives must be	
	verified.	
Must be posted for a 30-day public comment	Can be used during the 30-day public	
period before use is allowed.	comment period.	
DPR issues without U.S. EPA review,	Request through DPR and issued after U.S.	
although U.S. EPA has 90 days to comment.	EPA approval.	
U.S. EPA request expiration date. May be	Expiration date not to exceed 1 year, except	
inactivated by applicant, DPR, or U.S. EPA.	for Quarantine exemption (up to 3 years).	
	Renewable if the emergency recurs or	
	persists, although renewal is difficult after	
	third year.	
Applicant – First party is registrant of	Applicant – must be someone other than the	
product.	manufacturer.	
Applicant – Third part is someone other than		
product manufacturer.		
Fees – U.S. EPA maintenance fee, no state	Fee – No federal or state.	
fee.		
Use requires a restricted materials permit,	Always requires a restricted material permit	
only if the product is a restricted material.	(CCR 6400)	

For more information, please visit the links included below.

http://www.cdpr.ca.gov/docs/registration/manual/guidance.pdf

https://www.cdpr.ca.gov/docs/registration/sec24/sect24intro.htm

https://www.epa.gov/pesticide-registration/guidance-fifra-24c-registrations

Committee Comment

Lynn Baker asked in a typical year, how many requests does DPR receive for special local needs. John Inouye stated that it varies by year. Amounts received and issued vary as well, about 95 percent get approved. This year's amount received have been low and a large portion are approved.

Jaime Tudd stated when these get approved are any other agencies notified by the requested applicant or by DPR that these have passed and to be on the lookout if there is something going on in the environment? John Inouye replied no, DPR will normally post on the website. If it goes through a formal review and is posted for public comment, then it will be released through DPR's public notice as well. Many of the public agencies belong to the public notice so they will get copies of those public actions.

Public Comment

James Nakashima inquired how long does it take for DPR to approve a SLN? John Inouye answered there are two areas observed, the initial critique on the front end with the intake process and the back end with the formal evaluation. The formal evaluation takes some time but the intake review may take even longer due to gathering additional information to substantiate the need for that SLN. The only time it is somewhat easier on the front end is with an export SLN because that commodity is not going to be converted into the channels of trade in the U.S.

An anonymous attendee asked if 24(c) or Section 18 are a way to provide emergency use patterns if the Neonic proposed regulations were to be put into effect? John Inouye answered that the current environment, the database, and the issues that are surround that active ingredient were observed. DPR will consult with the U.S. EPA to discuss the issues with that active ingredient. 24(c)s do not get around those kinds of issues such as pollinator, ground water, surface water, or air concerns.

James Nakashima queried if a product can be approved by the SLN process if they have not completed the usual state registration process? John Inouye replied SLNs have to be associated with a product and has to be registered federally and in the state of California.

Anne Katten asked if there is a notification of each application of an SLN on the DPR website through a listsery so that members of the public know that comments are being accepted? John Inouye answered that he is unaware if there is one available for that. If it went through a formal comment process afterwards then there is a listsery for that process.

4. Section 18 Emergency Exemption Program – Morgan Thai, DPR

For those unfamiliar with the Section 18 program, Section 18 of (FIFRA) authorizes the U.S Environmental Protection Agency (U.S. EPA) to allow an unregistered use of a pesticide for a limited time if the U.S. EPA determines that an emergency condition exists. There are a few different factors associated with Section 18 Emergency Exemption requests that set them apart from other registration actions. Foremost, these products are exempt from registration for a limited period of time. Section 18 Emergency Exemptions allow for the unregistered use of the products being requested. In order for these exemptions to move forward, the emergency condition must be found to exist and be justified. This is meant to act as a stopgap allowance for people to only utilize in emergency situations and is not meant to be a long-term solution. Section 18s cannot have tolerances established at the time that the Section 18 is being requested and there must also be no known exemption from tolerances. Specific exemptions, quarantine exemptions, public health exemptions, and crisis exemptions are the four different types of Section 18s that can be requested and the individual exemption type requested will differ based on each emergency situation.

Specific exemptions are the most frequent exemption requests received. They are generally used to avert a variety of issues. The most common are significant economic losses. Occasionally, they can be requested to mitigate significant risks to endangered or threatened species, significant risk to beneficial organisms, or significant risks to the environment. With specific exemptions, it is required that growers or scientists verify that there are no currently available pesticides that can mitigate the pest of concern. This is necessary to justify the emergency condition. These exemptions requests can be authorized for up to one year with a possibility of extensions.

Quarantine exemptions, in comparison, are used to control the introduction or spread of an invasive pest not previously found in the United States. Justification is based on the potential of the invasive species to cause significant economic loss. These may be authorized for periods of up to three years.

The other emergency exemption that can be requested is public health exemptions which are meant to address a pest that could cause significant risk to human health. Justification for these types of exemptions are geared toward mitigating such a risk. These can be authorized for up to one year.

Crisis exemptions, unlike the other exemption categories, act as a temporary allowance for the issuance for the Section 18 Emergency Exemption in which an unpredictable emergency situation has developed. The need is immediate and there isn't time to put together a more stringent, formal emergency exemption request. Basic information is still required to move forward with the request but due to the fact that the application submitted is not as thorough, DPR must receive verbal authorization from U.S. EPA prior to issuance and these requests are only authorized for up to 15 days. Along with the initial crisis request, DPR additionally requires

that a formal application also be submitted for whatever specific, quarantine, or public health emergency exemption is being requested before the end of the 15-day authorization period.

Table 1: Section 18 Timelines

Types	Conditions	Time limits
1. Specific	Economic loss	Up to 1 year
2. Quarantine	Invasive pest	Up to 3 years
3. Public Health	Human health risk	Up to 1 year
4. Crisis	Immediate Need	15 days

The types of emergencies resulting in the submission of a Section 18 request are defined as having been caused by an urgent, non-routine critical pest situation that has developed, and the unregistered use of a pesticide is needed to control the pest. These requirements have to be met in order for a situation to be defined as an emergency situation. A previous Section 18 submission that highlights this requirement was the use of bifenthrin to control leaffooted bug infestations in pomegranate orchards. When there is a high enough pest load to cause a great deal of damage, as was the instance in this case, emergency exemptions are used to try and mitigate the potential destruction caused by the pest of concern.

There are a couple of different conditions that have to be met in order for a situation to be defined as an emergency condition. As previously mentioned, in order for the request to move forward, there have to be no effective registered pesticides or any feasible alternative control practices available. The other aspect that has to be considered is whether or not the pest poses significant risk to human health or the environment or if it will cause significant economic loss. Emergency conditions develop from a variety of different causes that have to be disclosed such as the introduction of a new pest, if pests have developed resistance, loss of registered products, or unusual weather patterns such as drought.

DPR requests that someone other than the pesticide company apply when requesting a Section 18 Emergency Exemption. For example, University extension personnel, County Agricultural Commissioners, grower or commodity groups, or private consultants are all acceptable parties to do so. Applications are available on DPR's website on the Section 18 page cdpr.ca.gov/docs/registration/sec18/sect18s.htm and need to be submitted back to DPR. There is no state or federal fee required for Section 18 exemption requests. The applicant must include information such as the complete description of the emergency pest problem and the contact information of knowledgeable experts who can confirm the problem. Also required is any available significant economic loss information. The application requires documentation showing the economic history of the crop in question, evidence that significant loss has occurred or is about to occur due to the pest of concern. Additionally, scientific data (efficacy data, acute toxicity/chemistry data, etc.) is also needed.

Once an application is received, DPR will evaluate and investigate the claims and general information. Once the investigation is complete, DPR will edit the application as needed and

submit the application to the U.S. EPA. The process can take anywhere from 15 to 60 days. The U.S. EPA will determine if there is adequate justification and supporting data to authorize the exemption. This process can take between 50 to 60 days.

To summarize, Section 18s are exempt from registration, but they are not meant to be permanent solutions. Tolerances must have not been established at the time of submission, as Section 18 Emergency Exemptions are reserved for products that do not have an established tolerance. For a Section 18 to be approved, an emergency situation must exist. There are four types of emergency exemptions that can be requested: specific, crisis, quarantine, and public health. Specific exemptions are most common and are usually requested to avert significant economic loss. Once a request is received, DPR evaluates and validates the request before sending the submission to the U.S. EPA. The U.S. EPA makes the final decision whether to authorize an emergency exemption. DPR must receive U.S. EPA's authorization before issuing a Section 18.

Committee Comment

Lynn Baker asked when you submit the potential application for review, is EPA Region 9 involved with that, or is that solely review done by U.S. EPA headquarters? Morgan Thai responded that it is done solely by U.S. EPA headquarters.

Public Comment

Suzanne Hume with CleanEarth4Kids.org asked how many exemptions are applied for a year. how many are denied, and how many are extended? Morgan Thai answered that it varies year by year. There have been years where multiple Section 18 requests have been denied. Morgan added that the majority of Section 18 requests are reissuance requests.

Mike Zeiss commented though Ms. Thai said they are "emergency stopgaps", it's not uncommon for the same Section 18 use to be renewed year after year. Recent examples include bifenthrin to control leaf-footed bug on pomegranate, and methoxyfenozide to control armyworm on rice. Each of those were renewed for 4 years. What is DPR's policy about allowing registrants to renew the same Section 18 for multiple years? Morgan Thai replied that one of the hallmarks of requesting a Section 18, in order for it to move forward is that the registrant has to be making adequate progress towards full federal registration. Morgan added that DPR requests, with every reissuance request, that they provide that proof. As long as they are doing that and that there is still a pest issue, DPR will consider a Section 18 request for reissuance.

John Bortoff with CleanEarth4Kids.org asked how many exemptions every year are public health vs economic? We don't see a lot of public health requests and the ones that have come through have not been authorized. Significant economic loss is usually primary reason for requesting.

James Nakashima stated regarding the Section 18 Emergency Crisis Exemptions, can you provide any recent examples? Francie Bishop provided an example stating methoxyfenozide on rice was a crisis in the first year received around 2015.

John Bortoff with CleanEarth4Kids.org asked who applies for the exemption? Individual farmers, farmer organization, County Ag Commissioner, or pesticide manufacturer? Morgan Thai responded that DPR does not allow the pesticide registrants applying but all the other mentioned are acceptable for applications.

Due to time constraints, the following questions were not answered live.

John Bortoff with CleanEarth4Kids.org also asked who can apply, how are you checking that "private consultants" aren't working for industry? Isn't the farmer, AG commissioner, etc. making the request based on pesticide industry information? How else do they know what pesticide to ask for?

Morgan Thai answered via email:

DPR thoroughly vets individuals that have submitted a request for a Section 18 emergency exemption to prevent this. Private consultants need to represent a third party, not the company of the pesticide product. The County Agricultural Commissioner is required to sign the Section 18 application confirming the validity of the requested situation. Additionally, contact information for experts knowledgeable with the "urgent, non-routine" nature of the emergency situation (e.g., non-registrant personnel such as University researchers, commodity groups, etc.) are questioned and extensive documentation is required, including an explanation of all registered pesticide and non-pesticidal alternatives. The pesticide registrant is involved only in that they write a letter of support for the proposed product's use and to attest they have enough stock of the product on hand, but beyond that they shouldn't be involved in the Section 18 emergency exemption request process.

As to your other concern, the County Agricultural Commissioners or growers derive a great deal of their information about what pesticide product to request from UC Researchers and UC Cooperative Extension Specialists as well as IR-4 Research Programs that are ongoing. A lot of times in research situations, if a product is already used in a similar crop system to control the pest in question (or a very similar pest), researchers will investigate if that product might have similar efficacy in other applications, such as the one being requested under a Section 18. The research derived from these projects is often how applicants know what to request. At grower industry events, these research projects are often presented, which is how they learn about them.

John Bortoff with CleanEarth4Kids.org asked what toxicity data do you have for a product that isn't even registered?

Morgan Thai answered via email:

In most cases, products that come in for consideration under a Section 18 emergency exemption have toxicity data in place for similar crops/use sites and, if possible, DPR will bridge to those components if the scientific evaluators find it applicable. There are also instances in which the data has already been prepared for the use site/crop in question, but it simply has not received federal approval yet. However, it is available for DPR to review.

If bridging toxicity data is not possible, DPR will not be able to move forward with a Section 18 emergency exemption application if all required toxicity data is not received. A Section 18 application for a new active ingredient may take just as long to review as the Section 3 process. This is because the data has never been reviewed by DPR before, so a full review is required.

Patti TenBrook with U.S. EPA Region 9 asked are all Section 18 Emergency Exemptions exempt from federal tolerances?

Morgan Thai answered via email:

No, as briefly covered in John's presentation, U.S. EPA may establish a time-limited tolerance such as for proposed food uses. Alternatively, if a tolerance is not established U.S. EPA will consider this in their decision and may elect to exempt.

Suzanne Hume with CleanEarth4Kids.org commented concern about the pesticides used in California and the United States. Do you have a list or check the other countries where the pesticides are banned? Legal is not safe in the U.S.! The U.S. only bans 15 pesticides, China bans 51 pesticides. The European Union bans 175 pesticides. The eight-part article in the Intercept lists names of U.S. EPA members and others that deleted information and harm of pesticides. Also, the OPP's record is terrible. Chemical company insiders sit on agencies and committees. Please see Part 1- Part 8.

Suzanne Hume with CleanEarth4Kids.org stated that the U.S. EPA's pesticide office approved 89 percent of 972 industry requests to waive toxicity tests between 2011 and 2018. Senator Richard Blumenthal, D-Conn., is quoted in the article: "These findings are profoundly alarming and point to a troubling pattern of disregard at the EPA's Office of Pesticide Programs."

Mike Zeiss commented that whenever Registration is asked questions about approval rates, it seems clear that Registration does not track that statistic. I would encourage Registration to begin tracking number of applications, and rate of approval or denial, for all categories of registrations. For example, it would be useful to know if approval rates are going up or down over the years.

5. <u>Certification and Training of Pesticide Applicators (C&T) Regulations Update –</u> Jessica Teague, DPR

In 2017, the U.S. Environmental Protection Agency (U.S. EPA) revised Title 40, Code of Federal Regulations Part 171 (40 CFR Part 171). The revisions to 40 CFR Part 171 set stronger standards for people who use and supervise restricted use pesticides (RUPs). 40 CFR Part 171 details the minimum requirements state agencies, who certify applicators of RUPs must meet. In California, RUPs include state restricted materials (RMs) and due to the state's unique regulatory framework, the revisions to 40 CFR Part 171 impact users of both RMs and general use pesticides. California is required to meet the revised standards of 40 CFR Part 171 set by U.S. EPA.

The first key change is the new commercial applicator fumigant categories. Two new commercial applicator categories are being adopted: The new Soil Fumigation Category, Category L, and the new Non-Soil Fumigation Category, Category M. Commercial applicators who use soil and/or non-soil fumigants must obtain the appropriate fumigation categories by January 1, 2024 to remain in compliance with the new regulatory standards.

The second key change being introduced is aligning commercial applicator categories with the federal categories and competencies. The Department of Pesticide Regulation (DPR) is aligning all commercial applicator categories with those listed in the revised 40 CFR Part 171. As a result, this will eliminate the existing commercial applicator subcategories of Sewer Line Root Control (Subcategory N), Wood Preservation (Subcategory L), Anti-fouling Tributyltin (Subcategory M), Microbial Pest Control (Subcategory P), and Field Fumigation (Subcategory O). Pest control activities currently conducted under these subcategories will need to be conducted under one of the new fumigant categories, if applicable, or under an existing category.

The next key change being introduced is the expansion of private applicator competencies. The revised 40 CFR Part 171 includes expanded competency standards for private applicators. All private applicators must meet these revised competency standards. As a result, all existing private applicator certificate holders must take and pass an examination that includes the revised competencies. This examination is required to be taken at a private applicator's time of renewal. This will be conducted over a three-year period to make sure these individuals are in compliance with the competency standards; this approach is also consistent with the private applicator three-year renewal cycle.

In connection to California's private applicator certificates, there is going to be a new private applicator burrowing vertebrate pest certificate option. This certificate option is for private applicators using fumigants labeled for the control of burrowing vertebrate pests and will be called the Burrowing Vertebrate Pest Fumigation Certificate. Individuals who possess a private applicator certificate may apply for this additional certificate. This certificate option is in addition to a private applicator's existing certificate. A private applicator who uses fumigants labeled for the control of burrowing vertebrate pests must obtain the correct certification by January 1, 2024 to remain in compliance.

In connection to the new Burrowing Vertebrate Pest Fumigation Certificate option for private applicators, is the limitation of fumigant activities conducted under a private applicator certificate. Private applicators conducting fumigant activities, other than those using fumigants labeled for the control of burrowing vertebrate pests, must obtain a commercial applicator license or certificate in the appropriate categories; Soil Fumigation (Category L) and/or Non-Soil Fumigation (Category M). If a private applicator is conducting any other fumigant activities other than for the control of burrowing vertebrate pests, they would need to get a commercial applicator certificate or license. To remain in compliance, this requirement must be met by January 1, 2024.

The last private applicator topic is the amendment to the Title 3 California Code of Regulations (3 CCR) private applicator definition for 'householders.' U.S. EPA has requested that DPR align California's private applicator definition with the federal private applicator definition. As a result, the definition of 'householder' is being removed from the 3 CCR private applicator definition. Individuals currently conducting 'householder' activities under a PAC must obtain a commercial applicator certificate or license by January 1, 2024 to remain in compliance.

40 CFR requires states to adopt continuing education (CE) standards that ensure the quality, content, and quantity of CE is appropriate and that the state has a process in place to verify CE has been completed. As a result, changes to DPR's CE program are being adopted, including requirements for monitoring course attendance and participation, interactive online and webinar formatted courses, identity verification, submission of CE records of attendance by course sponsors to DPR, a maximum 8-hour course time, and elimination of correspondence-formatted courses.

There are a few important miscellaneous new changes being introduced. The first is a new minimum age requirement. Applicants for a commercial applicator license or certificate or private applicator certificate must be a minimum age of 18 years old and must provide valid government-issued identification as proof of age and identity to be able to take an exam and be certified or licensed to use pesticides. Handlers must also be a minimum of 18 years old. Additionally, there are some increased handler training requirements included in these regulatory changes. Those include how to identify if a product is a restricted use pesticide or California restricted material and that only certified applicators or those under their supervision use the product, how to identify information on product labeling applicable to safe pesticide use, such as required PPE and precautionary statements about human health hazards, having immediate and direct communication with the supervising certified applicator, identifying where on the label physical presence of a certified applicator is required, and knowing that the certified applicator is responsible for providing site-specific instructions prior to pesticide use.

In May 2022 the C&T regulatory changes are scheduled to be published for public comment. Then in July 2023 the C&T regulatory changes are scheduled to be approved and finalized by the Office of Administrative Law (OAL). Approximately between July 2023 and January 2024 DPR will work to get commercial and private applicators in compliance with new regulatory

requirements and provide outreach and examinations. January 1, 2024 is when the C&T regulatory changes become effective.

The best way to be involved is to sign up for the listserv, <u>Notice of Proposed Regulatory Action</u>, <cdpr.ca.gov/docs/dept/listserv/listdesc.htm> and encourage participation in the public comment period starting in May 2022.

Committee Comment

Rich Breuer stated some of the work being done recently with DPR has to do with storm water and pesticides. One of the things observed is that urban applicators are doing this work, so they are working under one license for a particular spraying company. Are there any changes in requirements for urban applicators or is it just for those with licenses? Jessica Teague answered stating in terms of specific changes for urban applicators, all of the application categories for commercial applications are setting specific. They would need the certificate for the setting that is most appropriate to the setting. In terms of the requirements of 40 CFR part 171, urban applicators would fall under the Qualified Applicator License (QAL) or Qualified Applicator Certificate (QAC) category but would depend mainly on the setting. The biggest changes for commercial applicators are the adoption of the new soil fumigation categories.

Rich Breuer also asked if those requirements were getting tighter. Laurie Brajkovich, Program Manager for the Licensing and Certification program, helped to answer stating that that is not going to be changing in this package. Workers can still work under a supervisor which has always been the case.

Public Comment

John Bottorff with CleanEarth4Kids.org stated that all that has been discussed in the training is pesticides, what training is done on alternatives to using pesticides, using biological controls, etc? The programs don't appear to move away from using pesticides. Laurie Brajkovich answered that the package being presented focuses specifically on aligning the program with the federal requirements that changed with certification for pesticide applicators. The focus of the federal regulations were on restricted use pesticide users and this regulatory package is to ensure California is in compliance with those new stricter federal standards for certification and training of pesticide applicators.

John Bottorf also asked what about education on the health risks of pesticides? There are many studies linking exposure to pesticides to cancer, etc. Laurie Brajkovich answered there is required continuing education in California to renew your license and use of pesticides and pesticide safety and effects of pesticides is part of that training. Those are courses that applicants would go to as part of that required continuing education that they have to complete in order to renew their license/certificate.

Ann Katten inquired is it correct that minimum age for agricultural applications is already 18 and this will make the minimum age 18 for all other types of commercial application? Laurie Brajkovich replied that yes, this aligns with the worker protection standard which changed a couple years ago. This specific package is changing the age for those who are getting certified, specifically requiring us to check identification before letting those into a certification exam.

James Nakashima asked does the increased oversight of trainings and dropping the correspondence courses reflect an adjustment to all the virtual trainings and challenges in verifying training information? Jessica Teague responded that the adoption of the changes are to ensure that attendees are completing the entire course and to verify they are completing the entire amount of required time and continuing education. Yes, it is to monitor that the course is done appropriately.

6. Agenda Items for Next Meeting

Patti TenBrook requests an agenda item to be added to the next meeting to discuss the recently U.S. EPA approved genetically-engineered mosquitoes.

The next meeting is scheduled for May 20, 2022 at 10:00 a.m. This meeting will be held virtually on the Zoom platform and broadcast live on the <u>CalEPA</u> webcast page. <video.calepa.ca.gov/>

7. Adjourn