PESTICIDE REGISTRATION
AND EVALUATION COMMITTEE (PREC)
Meeting Minutes –September 19, 2014
***AMENDED* –January 16, 2015**

Committee Members/Alternates in Attendance:

Ann Prichard, Department of Pesticide Regulation (DPR)
Charles Salocks, Office of Environmental Health Hazard Assessment (OEHHA)
David Luscher, Department of Food and Agriculture (CDFA)
Eric Lauritzen, CA Agricultural Commissioners and Sealers Association (CACASA)
Lynn Baker, Air Resources Board (ARB)
Rebecca Sisco, University of California (UC), IR-4 Program
Stella McMillin, Department of Fish and Wildlife (CDFW)
Valerie Mitchell, Department of Toxic Substances Control –via webcast

Visitors in Attendance:

Aimee Brooks, CA Cotton Ginners and Growers Assoc./Western Agricultural Processers Assoc.
Andi Cameron, DPR –Pesticide Registration
Anne Katten, California Rural Legal Assistance Foundation
Brian Bret, Dow AgroSciences
Catherine Caraway, OEHHA
Denise Alder, DPR –Pesticide Registration
Eileen Mahoney, DPR –Pesticide Registration
James Nakashima, OEHHA
Jeanne Martin, DPR –Enforcement
Jill Townzen, DPR –Pesticide Registration
Jim Wells, Environmental Solutions Group, LLC
Joe Marade, DPR –Pesticide Programs Division
John Inouye, DPR –Pesticide Registration
Kim Hensley, Environmental Solutions Group, LLC
Kyle Lawson, Lawson and Associates
Leslie Crowl, DPR –Worker Health and Safety
Lisa Ross, DPR –Worker, Health, and Safety
Lori Lim, OEHHA
Margaret Reiff, DPR –Pesticide Registration
Pam Wofford, DPR –Environmental Monitoring
Patricia Matteson, DPR –Pest Management and Licensing
Rachel Kubiak, Western Plant Health Association (WPHA)
Randy Segawa, DPR –Pesticide Programs Division
Rima Woods, OEHHA

1. Introductions and Committee Business –Ann Prichard, Chair, DPR

a. About 32 people attended the meeting.
b. No corrections to the minutes of the previous meeting held on August 15, 2014 identified.

2. Volatile Organic Compounds (VOC) Update –Pam Wofford, DPR

Volatile Organic Compounds (VOCs) and nitrogen oxides react with sunlight to form ozone, causing inflammation and irritation of lungs, increasing risk of premature deaths in elderly people with lung and circulatory diseases, and compromised immune systems. As required by Clean Air Act, the state implementation plan (SIP) describes measures to reduce VOCs and nitrogen oxides to achieve ozone standards. Pesticides contribute to VOCs, but have negligible nitrogen oxide emissions.

The Air Resources Board (ARB) oversees the SIP and requires DPR to develop and maintain an emission inventory to track pesticide VOC emissions for five nonattainment areas based on pesticide use reports while reducing pesticide emissions by specified amounts during May 1 to October 31 (peak ozone season). The five nonattainment areas include Sacramento Metro, San Joaquin Valley, Ventura County, South Coast, and the Southeast Desert. Additionally, DPR implemented "low emission" fumigation methods in 2008, and restrictions on non-fumigant products for the San Joaquin Valley in 2013.

VOC emissions from pesticide products are calculated by identifying the amount of product applied (from pesticide use reports) and the VOC fraction in the product (its emission potential) as determined by thermogravimetric analysis (TGA) or other methods. DPR adjusts fumigants by an additional factor to account for emissions under field conditions. Currently, there is insufficient data to estimate non-fumigant VOC emissions under field conditions. DPR publishes the annual pesticide VOC emissions inventory reports online once the data is analyzed. The reports include identification of whether or not emission levels have exceeded the trigger levels. The preliminary inventory for San Joaquin Valley is now complete and DPR is expecting to release the draft report for all five-nonattainment areas in November 2014.

Preliminary data indicate that pesticide VOC emissions for the San Joaquin Valley have exceeded the SIP goal. The top three pesticide non-fumigant VOC emission active ingredients for the San Joaquin Valley are chlorpyrifos, abamectin, and 1,3-dichloropropene. In 2008, DPR implemented regulations requiring "low-emission" fumigation application methods during May-October in San Joaquin Valley, Southeast Desert, and Ventura. In 2013, DPR implemented additional fumigation methods including using tarps with sixty percent buffer credit (impermeable film, TIF) approved on an interim basis. Furthermore, DPR implemented a backup measure in case the trigger level (95% of SIP goal) is exceeded. DPR is currently drafting a sixth set of VOC regulations. The proposed regulations will add fumigation methods for the use of tarps with a sixty percent buffer credit and revise current methyl bromide regulations.

Proposed Timeline

December 2014	**February 2015**	**December 2015**	**April 2016**
Notice for public comment	Public Hearing	Submission of regulations to the Office of Administrative Law	Regulations in effect

The non-fumigant VOC regulation requires DPR to determine VOC content thresholds to designate certain agricultural products as “high-VOC” or “low-VOC.” The top four active ingredient non-fumigant VOC contributors in the San Joaquin Valley are abamectin, chlorpyrifos, gibberellins, and oxyfluorfen. DPR’s modeling predicted that target values would be achieved by replacing the top non-fumigant high-VOC products with low-VOC products. Furthermore, the use of low-VOC products are a feasible option for most of the uses listed on the top four non-fumigant VOC contributors.

Pesticide dealers selling high-VOC products used in San Joaquin Valley are required to provide VOC information in writing to purchasers pursuant to Title 3 of the California Code of Regulations (3 CCR) §6577 and §6886. Invoices must include a statement that the pesticide dealer provided VOC information to the purchaser indicating that the product may be prohibited under certain conditions. The operator identification number will be used to determine whether the pesticide dealer is located in the San Joaquin Valley.

If VOC emissions exceed trigger levels, growers are prohibited from applying high-VOC products containing the pesticide active ingredients abamectin, chlorpyrifos, gibberellins, or oxyfluorfen to alfalfa, almonds, citrus, cotton, grapes, pistachios, or walnuts in San Joaquin Valley during May through October. The pesticides used on these crops account for over ninety percent of non-fumigant emissions and a University of California study indicates that low-VOC products are available and feasible for these crops. However, under the exceptions listed in regulation, pest control advisors (PCAs) can recommend use of a high-VOC product. Growers must retain all high-VOC recommendations for two years and the recommendation must indicate the exception used. If emissions do not exceed trigger levels, PCAs must still consider low-VOC alternatives (3 CCR 6556 - no changes) when making recommendations.

In conclusion, DPR anticipates high-VOC prohibitions to be in effect for May 2015 to October 2015 and May 2016 to Oct 2016. Low-VOC products will not be prohibited. The final determination will be in March or April of 2015. DPR can lift the prohibitions after two years, if VOC emissions meet specific criteria.

For more information regarding volatile organic compounds, please visit <http://cdpr.ca.gov/docs/emon/vocs/vocproj/vocmenu.htm> or you can subscribe to the e-list at <http://cdpr.ca.gov/docs/dept/listserv/listdesc.htm>. Additionally, you may contact Special Advisor, Randy Segawa by email at <Randy.Segawa@cdpr.ca.gov> or by telephone at (916) 324-4137 or Environmental Program Manager, Pam Wofford by email at <Pam.Wofford@cdpr.ca.gov> or by telephone at (916) 324-4297.

3. <u>FIFRA §24(c) Special Local Need (SLN) Registrations</u> –John Inouye, DPR

Under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) §24(c), states may register an additional use of a federally registered product to meet a Special Local Need (SLN) if registration for such use has not been denied, disapproved, or cancelled by U.S. EPA. Furthermore, under the authority of Title 40 of the Code of Federal Regulations (40 CFR) §162.152, states may register an additional use of a federally registered product, or a new end use product to meet a SLN, if certain conditions exists. This regulation provides additional guidance by stating the definition of terms, state authorization, application requirements, federal disapproval of state SLN, and suspension of state registration authority.

A state may issues an SLN if it determines that there is an existing or imminent pest problem and that an appropriate federally registered product is not sufficiently available. If the pesticide is to be used on a food or feed commodity, tolerances, or exemption from tolerances must be established. Additionally, U.S. EPA must not have previously denied, disapproved, suspended, or cancelled the use, and a determination made that the use will not cause unreasonable adverse effects on man or environment. A SLN may address a new pest, new crop or use site, method or timing of application, or integrated pest management practice in certain crops.

There are two types of SLN registrations: first-party and third-party. The applicant of a first-party SLN is the registrant of the product. The applicant of a third-party SLN is someone other than the registrant of the product (e.g., grower, grower association, county, etc.). To register a SLN, DPR requires submission of a California SLN application form, the federal SLN form, scientific data, and a letter of authorization from registrant (this is only required for third-party registrations). The required data needs to demonstrate the use rates or patterns do not exceed the tolerances set by U.S. EPA. Typically, the required data includes residue, efficacy, and phytotoxicity data. DPR may also request toxicity to fish and wildlife, and worker exposure data on a case-by-case basis.

DPR can register SLNs for up to five years with additional extensions. Currently, there are no state fees; however, there is a $3,250 federal fee for each SLN. On average, the registration process for an SLN takes sixty days with a thirty-day public comment period. Once DPR approves a SLN registration, U.S. EPA has an additional ninety days to respond to DPR's SLN submission. For more information regarding FIFRA §24(c) SLNs, please visit <http://cdpr.ca.gov/docs/registration/sec24/sect24intro.htm>, <http://www.epa.gov/opprd001/24c/>, and <http://www.cdpr.ca.gov/docs/registration/manual/guidance.pdf>. Additionally, you may contact Senior Environmental Scientist (Specialist) John Inouye by email at <John.Inouye@cdpr.ca.gov> or by telephone at (916) 324-3538.

4. <u>FIFRA §18 Emergency Exemptions</u> –Margaret Reiff, DPR

FIFRA §18 authorizes the U.S. EPA to allow an unregistered use of a pesticide or permits the treatment of a crop site, currently not approved, for a limited time if U.S. EPA determines an emergency condition exists. Federal law defines an emergency condition as an urgent, non-routine situation that requires the use of a pesticide to manage the introduction of a new pest, a

pest that will present significant risks to human health, the environment, or a pest that will cause "significant" economic loss. For an Emergency Exemption to be issued there must be no effective registered pesticides and no feasible alternative control practices (e.g., cultural practices) available.

There are four types of Emergency Exemption requests. The majority of requests are Specific Exemptions, which DPR may allow for up to one year. This request intends to avert a significant economic loss or a significant risk to endangered or threatened species, beneficial organisms, or the environment, and growers or scientists identify a pest situation that registered pesticides cannot control. The second type of request is a Quarantine Exemption, which may last up to three years. This request is made to control the introduction or spread of an invasive pest not previously found in U.S. and is justified based on the potential of an invasive species to cause significant economic loss. The third type of Emergency Exemption is a Public Health Exemption, which DPR may sanction up to one year. This request intends to control a pest that will cause significant risk to human health and the request is justified based on the risk to human health from the pest to be controlled. Finally, a Crisis Exemption may last up to fifteen days. DPR issues this request when the time from discovery of the emergency to the need of the pesticide use is insufficient to allow authorization through normal means (i.e., critical imminent pest losses). DPR must receive verbal authorization from U.S. EPA prior to issuance and the applicant must follow up with a Specific, Quarantine, or Public Health Emergency Exemption request.

A pesticide registrant cannot request an Emergency Exemption. Examples of third-parties that can request Emergency Exemptions include the University of California, County Agricultural Commissioners, grower or commodity groups, or private consultants. The applicant must submit a request to DPR. If DPR approves the request, DPR forwards the request to U.S. EPA for further review and authorization. There are no fees, both federal or at the state level, associated with an Emergency Exemption. The application form is located online at <www.cdpr.ca.gov/docs/registration/regforms/sec18/18app3.pdf>.

Applications must include a complete description of the emergency pest problem, knowledgeable expert contact information (to confirm the emergency), an explanation of available alternatives (explaining why currently registered pesticides or cultural practices are not adequate to address pest situation), and Emergency Exemption Use Instructions (label) describing how to apply the product in order to control the pest problem.

Emergency Exemptions require documentation that a significant economic loss has occurred, or is about to occur, due to the pest problem with an economic history of the crop, including annual production, price of commodity, and cost of production. This information must include an estimated average crop loss, not worst-case scenario. The losses can be changes in yield, reduction in quality of product, or an increase of production costs.

Scientific data to support the request must include efficacy, residue chemistry, and phytotoxicity data. If the situation is claiming pest resistance, field data is required and if DPR has never registered the product, acute toxicology and product chemistry data are required. Within DPR,

the scientific data review may take fourteen to thirty days – depending on how complete the application is. DPR's Registration Branch reviews the chemistry, efficacy, phytotoxicity, toxicity to fish and wildlife, and significant economic loss data; the Pest Management and Licensing Branch will review the data for endangered species; the Human Health Assessment Branch will review the data for acute toxicology; and, the Worker Health and Safety Branch will review the data for worker exposure issues.

Additionally, DPR requires a letter of authorization from the product registrant. If the product is not federally registered, the application must also include a draft of the product label and product formulation sheet from registrant. If the product is federally registered, but not registered in California, the application must include a copy of U.S. EPA-accepted label and confidential statement of formula.

Once DPR concludes its review, DPR forwards the application package to U.S. EPA who then evaluates the request within fifty days. U.S. EPA's Risk Integration Minor Use and Emergency Response Branch coordinate review including the Health Effects Division, Biological and Economic Analysis Division, and Environmental Fate and Effects Division. If the exemption involves the treatment of agricultural goods, they will establish a time-limited tolerance corresponding to the time the treated commodities might be found available for sale.

If U.S. EPA approves the Emergency Exemption request, DPR will issue the Emergency Exemption Use instructions, cover letter, and/or the registrant product label (if an unregistered product) to appropriate County Agricultural Commissioner's Office. Furthermore, DPR will notify the applicant (requestor), registrant, and other interested parties such as UC's IR-4 program. The user must obtain a restricted materials permit and follow directions provided by the emergency use instructions and pesticide product label. The County Agricultural Commissioner(s) must file a final use report to DPR upon expiration of the Emergency Exemption.

If chemical concerns exist with a product or safety findings cannot be made (e.g., bystander exposure concerns or chemical risk cup full), U.S. EPA approvals may be impacted. Additionally, to establish a time-limited tolerance, U.S. EPA may take fifty days to four months. Please note the tolerance establishment does not equate to the emergency period. For more information regarding FIFRA §18 Emergency Exemptions, please visit <http://www.cdpr.ca.gov/docs/registration/sec18/sect18s.htm> and for a federal training resource, please visit <http://www.epa.gov/pesticides/regulating/section18_training/>. To view currently issued Emergency Exemptions, please visit <http://apps.cdpr.ca.gov/section18/>. Furthermore, you may contact Senior Environmental Scientist (Specialist), Jill Townzen by email at <Jill.Townzen@cdpr.ca.gov> or by telephone at (916) 445-7230.

5. Committee Comment

Lynn Baker inquired as to when DPR will next update U.S. EPA on the SIP. Randy Segawa stated U.S. EPA is currently reviewing DPR's fumigant regulations. In the next few weeks, DPR will be submitting the non-fumigant regulations to U.S. EPA. Lynn Baker stated U.S. EPA is considering changing the ozone standard, which will change all regulations.

Rebecca Sisco asked if there are specific limits or guidance to PCA recommendations. DPR recommends low-VOC products for PCA recommendations and PCAs are required to look at alternatives before recommending high-VOC products.

Stella McMillin asked if the SLN registrations go through DPR's Notice of Proposed and Final Decisions and Public Reports. John Inouye stated the SLN registration decisions are included in DPR's Notice of Proposed and Final Decisions and Public Reports. DPR posts this report weekly at <http://cdpr.ca.gov/docs/registration/nod/nodmenu.htm>.

David Luscher inquired about U.S. EPA's SLN 90-day review timeframe and whether they have an opportunity to provide a preliminary review of the request before the official submission. John Inouye stated that DPR contacts U.S. EPA ahead of time and discuss the merits of the request and possible concerns DPR may have. This allows U.S. EPA to provide any concerns their scientists may have with issuing a particular SLN. Most SLNs do not undergo a preliminary review by U.S. EPA. DPR typically has discussions with either the company (first-party) or growers association (third-party) when a particular situation occurs to discuss the best option (SLN or Section 18).

David Luscher further inquired if a SLN can treat an unnamed pest not listed on the SLN under FIFRA §2(ee) and if the situation differs if the SLN is a first-party versus a third-party registration. John Inouye stated a SLN can treat an unnamed pest under the authority of FIFRA §2(ee).

Charles Salocks asked how many SLNs are registered per year and if there are any trends with the SLN registrations in the past five or ten years. John Inouye stated in the seventies, there were 150 SLN registrations; this year there have been approximately seven SLNs registered while last year there were approximately fifteen. In the past, DPR issued many SLNs directly to counties. DPR no longer receives such requests due to cost of federal fees. Furthermore, in the past product labels were more specific to individual pests and crops (e.g. lemons), whereas today product labels tend to allow use for an entire crop grouping (e.g. citrus). This has reduced the need for SLNs.

Lynn Baker asked if the Emergency Exemption application requires the applicants to state the method of application to the crop or pest (i.e., aerial, by ground, etc.). Margaret Reiff stated the application is very detailed and requires the applicant to provide items such as the application method, the pesticide type, application rate, application timing, application frequency, additional restrictions, etc.

6. Public Comment

Brian Bret inquired if DPR has received the TGA data requested from certain registrants and if there are any thoughts to adding glyphosate to the prohibited high-VOC list. Pam Wofford stated DPR has not received all the requested TGA data. She further stated that if the current SIP does not bring pesticide emissions below target levels, additional chemicals may be added to the prohibited high-VOC list.

Anne Katten inquired when the product label on the container becomes more restrictive, is there a mechanism to add the same restriction to the SLN registration. John Inouye stated that if a company came out with a more restrictive container label than provided on the SLN, the user has to abide by all precautions, restrictions, and prohibitions listed on the product container label. The SLN is essentially a supplemental label. To use a pesticide product under an SLN registration, the user must have labels - the container label and the SLN label.

7. Agenda Items for Next Meeting

The next meeting is scheduled for Friday, November 21, 2014 at 10:00 a.m. in the Sierra Hearing Room on the second floor of the Cal/EPA building, located at 1001 I Street, Sacramento, California.

The committee anticipates the meeting will include an overview of the pesticide registration process and an update on the Cal/EPA Environmental Health Screening Tool from OEHHA.

8. Adjourn