



**DEPARTMENT OF PESTICIDE REGULATION
PESTICIDE REGISTRATION AND EVALUATION COMMITTEE
Meeting Minutes – March 18, 2011**

Committee Members/Alternates in Attendance:

Syed Ali, State Water Resources Control Board
Lynn Baker, Air Resources Board (ARB)
David Luscher, Department of Food and Agriculture
Stella McMillin, Department of Fish and Game (DFG)
Jodi Pontureri, State Water Resources Control Board
Ann Prichard, Department of Pesticide Regulation (DPR)
Rebecca Sisco, University of California, IR-4 Program
Charles Salocks, Office of Environmental Health Hazards Assessment (OEHHA)
Patti Tenbrook, U.S. Environmental Protection Agency, Region 9
Gabrielle Windgasse, Department of Toxic Substances Control (DTSC)
Dave Whitmer, California Agriculture Commissioners and Sealers Association

Visitors in Attendance:

Denise Alder, DPR
Kathleen Atencio, Clorox
Brian Bret, Dow AgroSciences
Amy Duran, DPR
Billy Gaither, Pest Control Operators of California
Satoshi Ishimata, Hakureu Agricultural Research Institute
Phil Isorena, State Water Resources Control Board
Anne Katten, California Legal Rural Assistance Foundation
Eileen Mahoney, DPR
Jeanne Martin, DPR
Pat Matteson, DPR
Keith Pitts, Marrone Bio Innovations
Regina Sarracino, DPR

1. Introductions and Committee Business – Ann Prichard, Acting Chairperson, DPR

- a. About 13 people attended the meeting.
- b. No corrections to the minutes of the previous meeting, held on January 21, 2011, were identified.



2. Status of Harmonization Efforts Between U.S. EPA’s Office of Water and the Office of Pesticide Products – Patti Tenbrook, U.S. EPA

Background

Both the U.S. Environmental Protection Agency’s (U.S. EPA’s) Office of Pesticide Programs (OPP) and the Office of Water (OW) assess the effects of pesticides on aquatic ecosystems using high quality data and peer-reviewed methodologies. There are a few key differences in how the two programs do aquatic life assessments. OPP assesses all pesticides during the pesticide registration process. For OW pesticides have to be prioritized among many contaminants that need water quality criteria. Aquatic life assessments done by OPP can be accomplished with less data than is required by OW for criteria derivation.

Stakeholder Concerns

Stakeholders have expressed the need for consistent and timely Federal input to help gauge whether pesticides represent a concern for aquatic life. Most helpful would be numeric criteria, benchmarks, or other type of reference values. Stakeholders would like to see OPP and OW have a consistent and common set of effects characterization methods, and would like the two Offices to use species of similar sensitivity, and/or to include uncertainties about sensitivity in characterizations of potential adverse effects.

One example of why stakeholders are concerned by lack of a common approach stems from differences in the lists of aquatic species used for testing under pesticide registration regulations (40 CFR Part 158) versus the list of species that must be used by water quality agencies to comply with the “no toxics in toxic amounts” provision of the Clean Water Act (CWA). The lists include different species with different sensitivities to pesticides. In the case of the pyrethroid bifenthrin, *Daphnia magna* (submitted for pesticide registration) is orders of magnitude less sensitive than *Ceriodaphnia dubia* or *Hyaella azteca* (CWA compliance testing species).

Progress to Date and Status

In 2009, U.S. EPA issued a scoping document which describes the common effects characterization effort. The goal is to develop a common basis for achieving water quality protection goals established under the CWA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The methodology will focus on data-limited situations, such as when there are sufficient data for risk quotient approach used by OPP, but insufficient data for derivation of OW Aquatic Life Criteria. Potential uses of a common methodology include derivation of benchmarks/criteria/reference values, interpretation of monitoring data, and assessment of uncertainties in interspecies sensitivity. Formal revisions to existing OW and OPP assessment methodologies are not being proposed as part of this process.

U.S. EPA held a series of Regional stakeholder meetings in 2010, including a meeting in Oakland, CA in January of 2010. These meetings were to solicit stakeholder input on U.S. EPA's initial thinking, and to incorporate that input into three draft white papers: 1) Exploration of Methods for Characterizing Effects of Chemical Stressors to Aquatic Animals; 2) Predicting the Toxicities of Chemicals to Aquatic Animal Species, and; 3) Exploration of Methods for Characterizing Effects of Chemical Stressors to Aquatic Plants. In December 2010, EPA held a national stakeholder meeting in Washington, DC, to take comment on the draft white papers. The white papers, developed through the joint efforts of OPP, OW and the EPA Office of Research and Development (ORD), provide overviews of approaches that will be explored in depth in the coming months. U.S. EPA introduced a new term, Aquatic Life Screening Value (ALSV), to describe the values that will be generated by the common effects methodology.

OPP, OW and ORD are currently working to analyze approaches and develop the new methodology. The three white papers will be combined into one document and will be presented to the FIFRA Science Advisory Panel and EPA Science Advisory Board for evaluation (tentatively scheduled for fall 2011).

More Information

Websites:

<<http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/aqlife/cem.cfm>>

<http://www.epa.gov/oppefed1/cwa_fifra_effects_methodology/>

<<http://www.regulations.gov>>

Docket for Regional Stakeholder meetings

EPA-HQ-OPP-2009-0773

Docket for National Stakeholder meeting

EPA-HQ-OW-2010-0818

Contacts:

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Mark Corbin, EPA Office of Pesticide Programs <corbin.mark@epa.gov>

Cindy Roberts, EPA Office of Research and Development <roberts.cindy@epa.gov>

Patti TenBrook, EPA Region 9 <tenbrook.patti@epa.gov>

3. NPDES Permits – Syed Ali, Water Board

Introduction

The State Water Resources Control Board (Water Board) regulates water quality as well as water rights in the State. It implements the federal Clean Water Act (CWA), which applies to point source discharges to surface waters, as well as the State Porter-Cologne Water Quality Control Act, which applies to both point and nonpoint source discharges to both surface and ground waters of the State. The 1972 amendments of the CWA prohibit discharges of pollutants from point sources to waters of the US unless the discharge is in compliance with a National Pollutant Discharge Elimination System (NPDES) permit. In 1989, U.S.EPA granted the Water Board and its nine Regional Water Boards authority to issue NPDES permits. NPDES permits can be specific for a particular point source discharge, such as a refinery, or general Statewide, such as for aquatic pesticides. Pursuant to the Porter-Cologne Act, the State and Regional Water Boards also issue Waste Discharge Requirements (WDRs) or waivers to WDRs for discharges to waters of the State and land.

History of the Aquatic Permits

In March 2001, the Ninth Circuit Court (Court) gave the verdict in the *Headwaters, Inc. vs. Talent Irrigation District* that application of pesticides to waters need NPDES permits. Magnacide (acrolein) used in irrigation canal leaked to fish bearing streams and caused fish kill in this case. Pursuant to this decision, U.S.EPA issued a memorandum to the Regional Administrators in May 2001, stating, “civil water enforcement priorities should not change and enforcement against any direct application of pesticides to waters of the United States in accordance with a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) label will be a low priority until EPA develops a concerted national approach on how to best regulate those activities.” In July 2001, the Water Board adopted an emergency NPDES permit for aquatic pesticides in response to requests from regulated communities (Mosquito Vector Control Association, and Association of Clean Water Agencies).

In November 2002, the Court found that the U.S. Forest Service requires NPDES permits for aerial application of pesticides over rivers and streams as part of silvicultural operations.

The Water Board’s emergency permit expired in January 2004. In May 2004, the Water Board adopted a vector control permit and a weed control permit to replace the expired emergency permit.

In 2005, the Court in the case of *Fairhurst vs Wagner* found that pesticides applied consistent with FIFRA do not constitute “chemical waste” if there is no residue or unintended effects. However, the Court did not vacate the earlier judgment. Based on the 2005 case finding, U.S.EPA in November 2006 adopted the Aquatic Pesticide Rule, which states that FIFRA label applied pesticides do not need NPDES permits for (1) direct water applications (as in

the case of aquatic weed and vector control), and (2) over water and near water (as in the case of aerial application in forestry).

In January 2009, the Sixth Circuit Court in the case of National Cotton Council vs. U.S.EPA found that U.S.EPA did not reasonably interpret CWA and so it vacated U.S.EPA's Aquatic Pesticide Rule. Instead of challenging this decision, U.S.EPA asked the Court to grant a two year stay period to develop a national NPDES permit. In June 2009, the Court granted the stay. U.S.EPA's Aquatic Pesticide Rule remains in effect through April 9, 2011.

On March 1, 2011, the Water Board adopted three permits: (1) vector control permit (for larvicide – direct discharge, and adulticide – indirect discharge), (2) aquatic animal invasive species permit, and (3) spray application for insect control permit. The original weed control permit remains in effect. There are four permits in place for different type of discharges, situations, and pesticides.

On March 2, 2011, a bipartisan group of US congressmen introduced HR 872 to eliminate the requirement of NPDES permits for FIFRA label applied pesticides due to the prohibitive compliance cost and steep fine of \$37,500 per day per violation.

On March 3, 2011, U.S.EPA asked the Court to extend the stay of their Aquatic Pesticide Rule through October 31, 2011, from April 9, 2011. The extension was requested to complete Endangered Species Act (ESA) consultation and develop a database to streamline requests for coverage. U.S. EPA's general permit will cover six states (Massachusetts, New Hampshire, New Mexico, Idaho, Oklahoma, and Alaska), District of Columbia, most U.S. territories, Indian lands and federal facilities. Other states are waiting to review U.S. EPA's permit before taking any action. The states of Texas and Washington may be the only two other states besides California that have aquatic pesticide NPDES permits in place.

California's Aquatic Pesticide NPDES Permits

The four permits do not apply to farmers who use pesticides on their crop lands. These permits apply to special agencies and entities for selected pesticides; such as the pest control permit applies to the California Department of Food and Agriculture and US Department of Agriculture, and the vector control permit applies to public health agencies. The permits deal with biocides and residual pesticide discharges. The permits require: (1) Notice of Intent (NOI), (2) application fee (a one time fee of \$136 for vector control, and an annual fee of \$1,200 plus a 21% monitoring surcharge, for a total of \$1,452 for other permits), and (3) The Pesticide Application Plan (PAP), which specifies what, when, where, how and why a pesticide is being applied. The PAP is posted on the Water Board's website for a 30 day public comment period. Subsequent to this, the Water Board's Deputy Director issues either a Notice of Applicability approving the permit, or a Notice of Exclusion denying the permit

(in which case an individual permit can be issued with more conditions). A discharger can file a Notice of Termination anytime during the life of the permit.

The permits have no effluent limits but include receiving water quality limits where ambient water quality criteria are available, or receiving water monitoring triggers where ambient criteria are not available. For instance the spray application permit has a receiving water limit of 0.1 ug/L for malathion as instantaneous maximum value based on U.S. EPA's ambient water quality criteria. Further, this permit has receiving water monitoring triggers for other pesticides, such as 2.53 ug/L for carbaryl, based on the California Department of Fish and Game's water quality criterion.

The permits should comply with FIFRA labels, have best management practices (BMPs), integrated pest management (IPM), and comply with ESA, California's Endangered Species Act (CESA), and the State Water Board's Antidegradation Policy.

All permits have monitoring and reporting requirements to provide data to insure that water quality is protected and maintained. The water quality monitoring data should answer the following two questions: (1) Does the pesticide residue from the pesticide application result in exceedance of receiving water quality limit or receiving water monitoring trigger?, and (2) Does the pesticide residue, including active ingredients, inert ingredients, and degradates, in any combination cause or contribute to an exceedance of the "no toxics in toxic amount" narrative water quality objective? The Water Board will conduct toxicity testing studies.

4. Status of Neonicotinoid Reevaluation – Denise Alder, DPR

Background

DPR initiated the reevaluation of certain pesticide products containing the neonicotinoids: imidacloprid, clothianidin, dinotefuran and thiamethoxam, on February 26, 2009. The reevaluation was based on adverse effects data submitted by Bayer CropScience for imidacloprid. The adverse effects data included residue studies of imidacloprid use on ornamental plants. Additionally, honey and bumble bee studies were submitted. DPR's evaluation of the adverse effects data noted two critical findings: high levels of imidacloprid in leaves and blossoms of treated plants; and, increases in residue levels over time. The nitroguanidine insecticide class of neonicotinoids includes imidacloprid, clothianidin, dinotefuran, and thiamethoxam. Clothianidin, dinotefuran and thiamethoxam were included in the reevaluation because they are in the same chemical family as imidacloprid. Based on available data, DPR scientists believe these active ingredients would have the same potential residue concerns as imidacloprid. Data also indicate that these active ingredients are similar to imidacloprid in toxicity to honey bees.

Types of Products

Currently, the reevaluation includes 222 products and 41 registrants. Originally, the reevaluation included 282 products and 50 registrants. The reduction in products/registrants is based on registrants choosing to not renew their product's registration or the product fit exemption criteria. Excluded from the reevaluation were certain products such as those formulated as a gel or impregnated in a strip, termiticide, flea control products combined with rodenticide, pet spot applications, ant and roach baits, premise application for control of nuisance pests, and manufacturing use only products. These types of products were excluded as they are unlikely to move into plants that bloom or be a source of forage for honeybee or pollinators. The list of products included in the reevaluation is available on DPR's Neonicotinoid Reevaluation Web page. In February 2009, DPR notified the affected registrants of proposed data requirements and allowed them to provide comments. These comments were considered in concert with the United States Environmental Protection Agency (U.S. EPA) Office of Pesticide Programs (OPP) and Pest Management Regulatory Agency (PMRA) Health Canada before finalizing them in a separate letter to registrants in September 2009.

Data Requirements

DPR's data requirements can be broken into two types: field-based studies and acute toxicity studies. DPR is requiring field-based residue analysis in pollen, nectar, and leaves from specific agricultural orchard and row crops grown in specific soil types for each of the four active ingredients. For products containing imidacloprid, DPR is requiring residue data on almonds, citrus, cotton, cucurbits, fruiting vegetables, pome fruits, and strawberries. For products containing thiamethoxam, DPR is requiring residue data on cucurbits, fruiting vegetables, pome fruits, and strawberries. For products containing dinotefuran, DPR is requiring residue data on cotton, cucurbits, and fruiting vegetables. For products containing clothianidin, DPR is requiring residue data on pome fruits. To determine the crops of focus for data requirements, DPR utilized California's Pesticide Use Reporting (PUR) database. These field-based residue studies collected from representative crops grown in California will assist DPR scientists to better understand the impact of neonicotinoids on honey bees. For the acute toxicity studies, DPR is requiring registrants to conduct an acute dietary concentration (LC₅₀ study) on honey bee brood starting with the larval stage through emergence for each of the four active ingredients. The proposed data requirements listed both LD₅₀ and LC₅₀ values. However, during the comment period, DPR located existing LD₅₀ values and as a result, only LC₅₀ values are required. Depending on the data collected, additional studies may be required including a chronic bee study, honey residue analysis, greenhouse or field toxicity studies. There is a study protocol posted on DPR's Neonicotinoid Reevaluation Web page that was fully vetted by U.S. EPA and United States Department of Agriculture. DPR scientists feel this protocol will yield sufficient LC₅₀ data on the effects to brood and larva.

Project Progress To Date

In 2009, DPR received compliance proposals from the identified data generator registrant for each of the four active ingredients. Shortly thereafter, these four registrants submitted additional information and studies for consideration in satisfying the data requirements of the reevaluation. DPR is communicating with U.S. EPA's OPP and PMRA Health Canada on this reevaluation. Concerns about the effects of neonicotinoid pesticides are not unique to California and DPR, OPP and PMRA are working together to investigate potential effects pesticides may have to honeybees.

Imidacloprid project status:

Field studies:

- Almonds: A keystone commodity for DPR. DPR requested registrants either submit a study protocol or remove its use from all labels. In an email dated March 9, 2011, U.S. EPA provided support by stating, "since US almonds are only grown in California, cancellation in California is a default national action, and the Agency prefers not to have uses exist on paper only."
- Cotton and fruiting vegetable (tomato) residues were collected in August 2010. The registrant collected blossoms and leaves in cotton. In tomatoes, the registrant collected anthers (pollen) and leaves. The requirement for leaf sampling is to ensure that the sample site received an adequate pesticide application to analyze residues in pollen and nectar. DPR anticipates receiving a fruiting vegetable report in the second quarter of 2011, and a cotton final report in the fourth quarter of 2011.
- Citrus investigations are currently being conducted at U.C. Riverside. DPR participated in a Webinar in December 2010, where UC Riverside and Bayer CropScience provided preliminary pollen and nectar data.
- Cucurbit, pome fruit, and strawberry sampling are anticipated to be conducted in the first and second quarter of 2011. The reason for the delay in sampling for these crops was due to problems locating treated fields before the bloom period.

Acute toxicity studies:

- The registrants request to bridge from an existing whole hive study has been denied. DPR anticipates receiving a study protocol in the second quarter of 2011.

Thiamethoxam project status:

Field studies:

- Fruiting vegetable (tomato) blossom and leaf residues were collected in July 2010. The final report is anticipated in mid 2011.
- The registrant is experiencing location challenges for sampling cucurbits. When DPR determined which crop/crop groups to sample, it was based upon the PUR which is a year behind. When the registrant went to locate actual sample sites for

cucurbits, they found that the growers had switched to a different crop for the same location. DPR and the County Agricultural Commissioners are working with the registrant to locate fields for sampling cucurbits.

- Thiamethoxam applications to pome fruit is dwindling.
- The registrant submitted a waiver request from sampling strawberries.

Acute toxicity studies:

- The study is in process utilizing the protocol posted on DPR's neonicotinoid reevaluation Web site.

More information can be found at DPR's Neonicotinoid Reevaluation Web page:
<<http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>>.

5. Public Comment

None received.

6. Agenda Items for Next Meeting

No agenda items were suggested.

The next meeting will be held on Friday, May 20, 2011, in the Sierra Hearing Room on the second floor of the Cal/EPA building, located at 1001 I Street, Sacramento, California.

7. Adjourn