PPDC Incident Work Group

Meeting Minutes

April 14, 2016

Attendance

Michele Colopy Pollinator Stewardship Council, Inc.	Dr. Matthew Keifer Marshfield Clinic National Farm Medicine Center
Tom Delaney National Association of Landscape Professionals	Beth Law Consumer Specialty Products Association
Nichelle Harriott Beyond Pesticides	Virginia Ruiz Farmworker Justice
Jeanette Klopchin Division of Agricultural Environmental Services Florida Department of Agriculture and Consumer Services	Jeffrey Rogers Virginia Department of Agriculture and Consumer Services
Valentin Sanchez Oregon Law Center, Farmworker Program	Kaci Buhl, MS National Pesticide Information Center
Michel Oriel CA Department of Pesticide Regulations	Will Heeb, Manager of Pharmacovigilance Bayer HealthCare
Cindy Palmer American Birds Conservancy	Chelly Richards Farmworker Justice
Lisa Arkin Beyond Toxics	Julie M. Spagnoli JM Specialty Consulting, LLC
Jack Arthur (BASF) for Ray McAllister CropLife America	Margaret Jones EPA Region 5
Gary Wilkinson Scotts	OPP people in room: Melissa Panger, Nick Mastrota, Bob Miller, Rich Dumas, Marietta Echeverria , David Miller, Shanna Recore, Bo Davis, & Julie Breeden

Enhanced Reporting

1. Rich: Today we will be discussing enhanced incident reporting on pet spot-on products.

2. Julie Breeden (RD) gave background information on the registration actions EPA has done in response to reported adverse effects caused by pet spot on products. Included in this was requiring enhanced quarterly incident data.

3. David Miller (HED) discussed the enhanced reporting project. They have developed a draft set of standard elements for reporting on these pet incidents. They got input from NPIC, SafetyCall, and PVWorks (?). A main goal was to make the data to be easily downloaded into an Excel spreadsheet. OPP staff has talked to Animal Health Institute about the enhanced reporting template, and they were supportive of the approach. OPP staff also plan to meet with FDA on April 18th to discuss the proposed template.

4. In early May, OPP plans to seek up to nine volunteer registrants to submit pet spot-on incidents using the new template for a one-year pilot. At the end of the pilot, OPP will consider modifying reporting requirements for the enhanced pet spot-on incidents and encourage reporting using the enhanced template.

5. Rich: What is on the form? I expect the elements would be similar to our proposed elements for pets. David: Breed, weight, if first time use, symptom onset duration, and other standard information. They will be use standard VEDDRA terms for describing symptoms. The same vocabulary was also recommended to be used for our *Symptom Type* field.

6. Melissa: We plan to take advantage of the pilot to learn lessons that we may apply to our project.

Other Comments

1. Have created ballots that list all data elements discussed, along compilation of comments. Please do your ranking of 1 (low importance), 2 (nice but not essential), or 3 (essential), along with your comments. Ballots were sent in an email yesterday, plus are attached to the meeting invitation. Please complete and submit your ranking by the end of next week.

2. Comments may be used to indicate how an element could be important for some types of incidents, but not for other types.

3. Will discuss elements that don't have a good consensus on rank at next meeting (April 28). We will also want to discuss preparation of the presentation and final report of the team to the PPDC. We will need to have volunteers by next meeting. Please send Rich a note if you are interested in volunteering.

4. Next phase will be discussion of how we will collect the information and design the reporting forms.

5. Discussion of "parking lot" issues. Topics that we will need to address as we move forward in building an improved system for collecting and sharing incidents data.

    a. Tom Delany, how do we identify if the incident is verifiable or not? Rich responded that before we can have a usable public system, we will need to address that issue as well as which data need to stay internal (i.e.; private information).

    b. Julie Spagnoli: What is the expected timing of the revision of the rules? Rich and Melissa: Rule change would only be needed for required 6(a)(2) elements. Any rule change may take a while. In the meantime, we cannot add "required" elements not already required without a rule change, but could still identify "highly desired" fields.

    c. Documenting if an incident is verified is important.