Draft PPDC Incident Work Group

Meeting Minutes

December 9, 2015

Attendance

Michele Colopy Pollinator Stewardship Council, Inc.	Capt. Geoffrey Calvert, Centers for Disease Control and Prevention
Nichelle Harriott Beyond Pesticides	Robyn Gilden, PhD, RN University of Maryland School of Nursing
Valentin Sanchez Oregon Law Center	Donnie Taylor Agricultural Retailers Association
Marylou Verder-Carlos, Ph.D., DVM, MPVM California Department of Pesticide Regulations	Virginia Ruiz Farmworker Justice
Cindy Palmer American Birds Conservancy	John Peckham**,** Program Manager Minnesota Department of Agriculture
Lisa Arkin, Executive Director Beyond Toxics	Meghan Sadlowski U.S. Fish and Wildlife Service
Cheryl Cleveland BASF Corp	Lacey Babnik Wild Care
Kaci Buhl, MS National Pesticide Information Center	Jeffrey Rogers Virginia Department of Agriculture and Consumer Services
Steven Coy Coy Bee Company	Will Heeb, Manager of Pharmacovigilance Bayer HealthCare
Gary Wilkinson Scotts	Rick Kingston SafetyCall
Julie M. Spagnoli JM Specialty Consulting, LLC	Chelly Richards Farmworker Justice
Margaret Jones EPA Region 5	OPP people in room Jackie Mosby, Melissa Panger, Nick Mastrota, Shanna Recore, Bob Miller, Rich Dumas

1. Jackie Mosby gave some introductory remarks concerning the purpose and goal of the work group. The question was then posed to the group whether after completing review of the human health data elements we should (1) continue the review data elements for other types of incidents or (2) discuss the results of the ranking exercise for human health before moving on to the next group. The group expressed favor for completing review of all of the data elements, and then discussing the ranking exercise at the end.

2. Rick Kingston of SafetyCall asked for some clarification on how the tasks assigned to the work group fit into the "big picture" of how the EPA will use incident data. Melissa and Rich mentioned that this topic was discussed at the first meeting, and referred Rick and anyone else interested to review the presentation that was made at that meeting, which is available on the PPDC Incidents Workgroup page on the OPP PPDC website.

3. Rick also noted that there has been a lot of progress by various groups in collecting of incident data since the EPA regulations were written in 1998. He emphasized the importance of harmonizing the way we categorized data such as age, routes of exposure, and symptoms with standards established by other groups. Melissa noted that the first stage is to discuss and agree upon the data elements, and discussion of the way that the data are collected will take place

after that. Nick Mastrota said that any information on established standards for categorizing data can be brought up while the data elements are discussed, and we will note it and take it into consideration in our later discussions.

4. Cheryl Cleveland noted that it is difficult to divorce discussing what the data elements should be with how they are collected and recorded, as they are sometimes intertwined. Rich concurred that these factors are clearly related, but stated that reaching agreement on what we want to collect is critical before we get into how we collect the elements. Again, how we collect the data is definitely an area for which we need advice.

5. The group then proceeded with discussion of the data elements for human health incidents, picking up where we left off last time with the "misuse" attribute.

I. Human Health Incidents

Subgroup	Data Element	Description	Comments
Discussed during October 20, 2015 meeting			
Contact Information	Submitter Name	Name and title of the individual submitting the incident report to the EPA.	Some incident reporters would like to allow anonymous reporting as some (e.g. farm workers) may not feel comfortable providing their name. This would mean making this field optional, or allowing submitter to identify themselves by entering a general title (e.g., "farm worker") when they don't want to give their name.
	Submitter Organization	For 6(a)(2) reporting, the name of the registrant submitting the incident report. For other reporting, name of the entity (e.g., government agency, nonprofit organization, or academic institution) that is submitting the incident report to the EPA. If it is a private citizen, enter "private citizen."	OK
	Submitter Category	Category of the entity submitting the report. ("Registrant" for 6(a)(2) reports)	OK
	Submitter Address	Address of the individual reporting the incident to the Registrant or Registrant Agent.	For all contact information fields: You need to be very cautious about collecting names of individuals. CDC does not collect names and contact information of individuals (PPI) because of privacy concerns.
	Submitter Phone Number	Phone number of the individual reporting the incident to the Registrant or Registrant Agent.	OK
	Submitter Email	Email of the individual reporting the incident to the Registrant or Registrant Agent.	OK
	Report Date	Date that the incident report was prepared.	Will not be captured electronically? Submission date is automatic. Report may be prepared some time before it is submitted, so report date may be different than submission date.

Subgroup	Data Element	Description	Comments
			Make sure that you do not record duplicate records for the same incident.
	Contact Name	Contact information for a person, other than the submitter, who may be contacted for obtaining further information on the incident. This may be the complainant, a physician, a veterinarian, or a wildlife biologist.	1. You need to be very cautious about collecting names of individuals. CDC does not collect names and contact information of individuals (PPI) because of privacy concerns. 2. You may want to not capture PPI of contacts in this database, but instead rely on the submitter to hold that information. The user would then contact the submitter if when they need this private contact information. 3. You may want to restrict this to public information, such as contact information for the office of a physician's practice.
Incident Data	Incident Type	Human.	OK
	Reporter's Case Number	Non-OPP case number from submitter for the incident (if exists).	OK
	Incident Location	The location where the pesticide exposure is believed to have occurred. Location fields will include Town/City, County/Province, State, and Country.	Location data may pose a problem because of privacy concerns. For CDC cases, some incident reporters are unwilling to provide location information any more specific than the state level.
	GPS Coordinates	Latitude and longitude coordinate of the incident location.	1. Make optional. May have major privacy concerns for human incidents. 2. May not be important for human incidents as for ecological incidents. 3. May want to keep this out of the database for humans and rely on the submitter to keep this information, if it is needed.
	Exposure Date (Start)	Date of the exposure, or if more than one day, the start date of the exposure.	1. State reports usually don't include exposure date, only the incident date. 2. CDC records exposure date as well as incident date. It is important since health effects may occur well after exposure.
	Exposure Date (End)	End date range of the exposure.	OK
	Incident Date (Start)	Date of the observed adverse effects, or if more than one day, the start date of the observed adverse effects.	OK
	Incident Date (End)	End date of the observed adverse effects.	End date may not be applicable to human health incidents. The date when people no longer suffer adverse effects is generally unknown.
	Date Comment	Use to provide information about the timing of the incident when exact dates are not known. (Example: "Early April"). May also be used for comments concerning the start and end dates.	OK

Subgroup	Data Element	Description	Comments
	Incident Awareness Date	Date when the registrant, or registrant agent, became aware of the incident. Not applicable to non-6(a)(2) incident reporting.	OK
	Notification (Yes/No)	Indicates if the incident was reported to a government agency other than the EPA, such as a state government office.	OK, but you may also want to know if it was reported to a nongovernment organization (NGO), such as the Poison Control Center. May want to modify the description to include notification to NGOs
	Notification (Text Field)	Identifies the federal, state, or regional government office (other than EPA) that was notified of this incident.	1. The database should capture the date of notification and the case number as well. 2. Should include reporting to NGOs, such as the poison control center, as well as government agencies. 3. It would be important to know if an incident was reported to a health department.
	Part of a Study?	Indicates if the incident part of a larger study? An example is ongoing worker exposure studies.	1. Seems unlikely that you would get many of these incidents. 2. Does not seem like critical information. 3. If one answers "yes", then you probably would want to prompt a text field to enter a description of the study.
	Status (New or Update)	Indicates if the report is for a new incident or an update to a previously submitted incident.	OK
Number Affected	Number Affected	The number of persons having the adverse effect. Enter the exact number.	It was noted that a relational database structure is needed. Much of the following fields are for a single individual. Therefore if there is more than one person affected, you would need a one-to-many relationship to capture the health data for each individual affected.
Pesticide Information	EPA Registration No.	EPA Product Registration Number. Include the 1-6 digit manufacturer number and the 1-5 digit product identification number. Separate the two numbers with a hyphen. Distributor's number, if applicable, is entered separately.	1. The product name may be more available than the EPA Reg. No. Needs to be optional since some reporters will not know the Reg. No. 2. Product names can be ambiguous; different products sometimes have the same name. 3. The Reg No. is preferred because incident reporters do not always report the full, precise product name. 4. It is important to know the exact label of the product used because different labels may have different labels use instructions. 5. Farm workers would find it easier to record the Reg. No. than the product name. They can get the Reg. No. from the pesticide use records.

Subgroup	Data Element	Description	Comments
	Canadian Reg. No.	Canadian product registration number (for Canadian incidents only)	OK
	Product Name	Product name. Should include the complete trade name, including codes describing the formulation, and any description of pesticide type. Example: "Propazine 80W Herbicide"	1. Is very critical to identify the product when known. 2. The database will need relational structure to allow more than one product to be entered. 3. You may want to instruct people to enter the pesticide type when the exact product is unknown (e.g.; “herbicide” or “rodenticide.”) Alternatively, you may want to have a separate field for pesticide type.
	Product Formulation	Formulation type of the product as purchased.	OK
	Formulation as Applied	Formulation type of the product when it was applied (e.g. diluted solution, granule, dust, etc.)	OK
	Active Ingredient	Common name of the active ingredient to which the affected person or other organism was exposed.	Will want to make the input system auto-populate or give default values when possible. For example, once you enter the product, the active ingredients should populated automatically.
	Active Ingredient Comment	Information on the identity of the active ingredient when the specific ingredient cannot be identified or is not on the drop-down list. Enter the ingredient name if known but is not on the list. If the ingredient identity is unknown, enter the known or suspected chemical class or classes (e.g., "carbamate" or "anticoagulant rodenticide") or enter "unknown."	OK
	Toxicity class	Signal word (Danger, Warning, or Caution) for acute oral toxicity class of the active ingredient.	Suggested added field. Should be obtained from a look-up table based on the ingredient ID. Do we want to record the signal word or the toxicity class (I, II, III, or IV)?
	Restricted Use Product	Indicates if the product is a restricted use product	OK
Application Information	Application Site Category	General category of application site (Agricultural, Residential, Commercial, etc.)	1. Consider adding additional categories, such as “Golf Course” or “Right-of-way” (We may want to add “Recreational” for sites such as golf courses, and “Municipal” or “Government” for right-of-way sites such as roads) 2. Consider adding “Labor Camp”
	Worker Protection Standard	Does the person affected fall under the worker protection standard (yes/no)	Suggested new field. You can enter a default value of “No” if the *Application Site Category* is not “Agricultural.”
	Application Site	Description of the site where the pesticide product was applied. If it is an agricultural site, identify the crop. If an accidental	OK

Subgroup	Data Element	Description	Comments
		exposure, enter the site of the exposure. If applied to an animal, enter "Animal treatment".	
	Application Method	Description of method used to apply the pesticide. Examples include aerial spraying, ground spraying, granular application, and bait placement.	1. Recommend being more specific on this to include the general type of equipment used (e.g. boom sprayer, backpack sprayer, etc.) 2. We may want to use Smart Label fields for this. They have has one field for general method type and a second field for more specific type.
	Application method specific	Description of the specific type of method used to apply the pesticide, indicating the general type of equipment used.	Suggested added field.
	Application Rate	Rate of the application of product, if known. Enter value and units.	1. Add "as applied" to definition. 2. Note that this is sometimes not applicable, for example with spills or pesticide loading exposure. Modify the definition accordingly.
Discussed on December 9, 2015			
	Misuse	Yes/No/Uncertain. Indicates if the manner the product was used was in violation of the label.	For human health, person reporting may not have good judgement of misuse. May not be qualified. More useful when reported by registrant or state lead agency. Question if it is worth including on form filled out by general public. May need to qualify this field as "misuse as reported."
	Misuse Comment	For misuse cases, comment on evidence indicating misuse of the product.	Important
	Applicator Certification	Yes/No. Indicates if product was applied by, or under the supervision of, a certified applicator.	OK
Incident Description	Incident Description	Description of what happened, including a general description of the suspected pesticide exposure and the adverse effects/symptoms observed. Also may include other important details not captured by the other data fields.	OK. Very important
	Incident Site or Exposure Site	Description of the site where the person or organism was exposed to the pesticide, or if unknown, enter where symptoms, mortality, or other adverse effects were observed.	Remove "or organism" for human health. Consider renaming "exposure site" Site where effects happened is also important.
	Site of Effects	Description of the site where the where symptoms, mortality, or other adverse effects were observed.	Disagreement about how important this element is. For example, if symptoms began "at the mall," is that important?
	Route of Exposure	Primary the route of exposure of individuals affected (e.g., oral, dermal, inhalation, or ocular)	OK
	Exposure Pathway	The route of transport of the pesticide from the site of application to the affected	Change "organism" to "person"

Subgroup	Data Element	Description	Comments
		organism (e.g., spray drift, run-off, volatilization, secondary exposure).	
Lab Report	Lab Report Title	Title or description of the laboratory report(s) that the submitter attaches or encloses with the incident report submitted to the EPA.	OK
	Lab Report Number	Report number for the laboratory report.	OK
Demographic Information	Case ID	ID used in the incident report to identify individuals affected. If none are given, sequential numbers will be assigned.	OK
	Age	The age of the individual exposed. Enter number and unit, or a general description (e.g., young adult)	OK
	Sex	The sex of the individual exposed.	OK
	Occupation	If the incident was occupationally related, state the occupation of the individual involved.	Also want to capture type of industry associated with the occupation.
	Suicide/homicide	Yes/No. Indicate if the incident was the result of a suicide or homicide.	OK
	Pregnancy Status	Pregnancy status of individual exposed.	OK
Exposure	Exposure Activity	Description of how the product was being used at the time of the reported incident, or what the exposed individual was doing when the exposure occurred.	OK Uncertain if this is separate from Incident Description.
	Circumstances of Exposure	Description of the event that caused the pesticide exposure.	Uncertain if this is separate from Incident Description.
To Be Discussed			
	Exposure to Concentrate	Yes/No. "Yes" indicates the product is sold in a concentrated form and the incident involves exposure to the concentrate prior to dilution.	
	Protective equipment (Yes/No)	Indicates if any personal protective equipment (PPE) was used by the affected person(s) at the time of the incident.	
	Protective equipment	Description of the type of personal protective equipment (PPE) and protective clothing that was used or worn by the affected person(s) at the time of the incident.	
	Workdays lost	Number of workdays lost due to the incident, if known.	
	Time to Symptoms	Indicate how long after the incident occurred that the first signs and symptoms were noted.	
Adverse Effects	Medical Care	The type of medical care or consultation sought. Examples include none, clinic, hospital emergency department, private	

Subgroup	Data Element	Description	Comments
		physician, PCC (Poison Control Center), hospital inpatient.	
	Symptom Type	Classification of the type of symptom(s) observed. May select more than one.	
	Symptoms Comment	Optional field to provide a more detailed description of the symptoms that correspond to the symptom type.	
	Case Outcome	Characterization of the current status or final outcome of adverse effects.	
Lab Results	Lab Test Results	Results of laboratory tests, such as blood test or urine analysis.	
Residential (non-ag)	Indoor or Outdoor	Indicates if the product was used indoors or outdoors	
EPA Fields	PC Code	PC Code(s) of the active ingredient(s) to which the affected person or other organism was exposed.	
	Certainty	EPA's conclusion on the certainty that the ingredient caused or contributed significantly to causing the observed adverse effects. Entered for each ingredient.	
	Certainty Discussion	A brief discussion of the evidence supporting the certainty level that EPA assigned to the ingredient.	
	Legality	EPA's categorization on the legality of the pesticide use. Legality categories are "Registered Use," "Suspected Misuse," "Known Misuse," and "Malicious Intent." ["Malicious Intent" used for intentional targeting of affected person or non-target organism.]	
	Exposure-Severity Code	Code that indicates the type of incident and the severity level of the incident.	