US ERA ARCHIVE DOCUMENT



OPP Incident Data Update

April 22, 2009

Agenda

- OPP Overall Strategy Regarding Incident Data
 - Anne Overstreet
- Pets
 - Kimberly Nesci
- Pyrethrins/Pyrethroids
 - Mary Manibusan
- National Pesticide Information Center (NPIC) New Portal
 - Frank Davido
- PMRA Incident Data Reporting Website
 - Anne Overstreet

OPP Incident Data Workgroup Background

- 2006 OPP committed to presenting a series of reports on incident information to the PPDC.
- October 2007- the Agency presented the first report which provided an overview of the main sources/limitations of incident data, how the Agency currently utilizes the information in risk communication, performance accountability and enforcement.
- June 2008 an OPP-wide Incident Data Workgroup was formed to build on past work and develop a strategic plan to improve the Agency's management and utilization of incident data.
- October 2008- a report on the charge and objectives of this group presented to PPDC

OPP Incident Data Workgroup Goals

- Develop an improved electronic system for reporting, tracking, managing and analyzing incident data.
- Create an internal system to pull together various data sources currently available to OPP into a single database.
- Improve outreach with other federal agencies, states, regions, and stakeholders in order to obtain more robust incident data.
- Rewrite of the 4oCFR to include non-aggregate and electronic reporting.

Progress Since October 2008 PPDC Meeting

- October 2008 a reporting portal was launched for veterinarians relating to pet incidents via the National Pesticide Information Center (NPIC)
- March 2009 PMRA demonstrated incident data reporting site to the Incident Workgroup and mangers within OPP. Ideally, OPP would like to harmonize reporting systems for mutual benefit.
- May 2009 launch of a second incident portal to facilitate the reporting of bee incidents and other types of ecological incidents.

OPP Incident Data Workgroup Ongoing Work

- External database
 - Continue to develop an overall electronic web-based reporting portal for all incident data specifically focusing on the reporting of registrant submitted 6(a)(2) data.
 - OPP continues to share dialogue with Canada PMRA
- Internal database improvements
 - Continue to develop a single database to pull together various data sources currently available to OPP
- Preliminary work to rewrite the 4oCFR regarding reporting requirements and submission format
 - To require non-aggregate and electronically formatted data
 - Will registrants voluntarily report 6(a)(2) incident information into a database prior to promulgation of a new Rule?

Pet Incidents

Kimberly Nesci, Registration Division

Advice

 Released an advisory statement on April 16, 2009 at the same time as a similar statement from Health Canada.

Investigation - Ongoing

- Conducting an analysis/evaluation of the incidents
- Identifying products that may need further regulatory action
- Reviewing premarket testing to determine if the domestic animal safety studies are adequate to protect pets
- Meeting with the registrants the week of May 4th
- Determining whether further restrictions are necessary to protect the health of pets

Agency Response/Action

Pyrethrins/Pyrethroids

Mary Manibusan, Health Effects Division

Overview

- Center for Public Integrity (July 30, 2008) reported an association between pyrethrins/pyrethroids and asthma and allergies
- USEPA/OPP initiates review on pyrethrins/pyrethroids to determine whether a relationship exists between exposure and asthma and allergies
- OPP Workgroup to explore this relationship via integration of animal and human data to determine an evidence based conclusion
- Publicly release USEPA findings of this detailed analysis

Center for Public Integrity reported:

- Pyrethrins and pyrethroids human incidents have increased 300% over the past decade
- This class makes up approximately 26% of all fatal, major, and moderate incidents in 2007
- Total of 50 fatalities are associated with pyrethrins/pyrethroids since 1992, with 20 occurring between 2003 and 2007
- Poison Control Center data shows human incidents increasing 63% between 1998 and 2006

^{*}Note: EPA performed an analysis of these findings and could not verify these conclusions, with the exception of this class making up 26% of all fatal, major and moderate incidents in 2007. EPA does not support an evaluation of incident data based on numbers of cases reported, but rather a integrated scientifically based analysis of all the available human and animal toxicology data.

Objective:

 To determine whether an association exists between human exposure to pyrethrins and pyrethroids and asthma and allergies

Definitions:

- Pyrethrum is an extracted form of Chrysanthemum, a known dermal and respiratory allergen
- Pyrethrins are refined forms of pyrethrum
- Pyrethroids are synthetic insecticides that have been modified to increase their environmental stability and their insecticidal properties
- Asthma is a chronic inflammatory disease of the airways characterized by reversible airway constriction upon exposure to a provoking agent
- Allergy is an immunologically mediated adverse reaction to a chemical resulting from previous sensitization

Incident data is more than a number...

- Evaluation of Human Incident Data must be "biologically evidence based "and not a simply a number count
- Criteria for Evaluation:
 - Consistency
 - Reproducibility
 - Temporal and Dose Concordance
 - Biological Plausibility

"Weight-of-Evidence" Approach

- Animal Toxicology Data
 - Acute oral, inhalation, dermal, dermal sensitization studies
 - Dose Response data at site of toxicity
 - Pharmacokinetic data on absorption, distribution, metabolism and excretion
 - Mode of Biological Action: Human relevance

"Weight of Evidence"

- Human Data
 - Human Studies Sensitive subpopulations
 - Population level studies Human variability
 - Epidemiology Studies Prospective cohort study
 - Human Incident Data 6(a)(2)
 - Various sources PCC, NPIC, AERS, California PISP
 - Biological effects profile comparison

Additional Data:

- Other Federal Regulatory Agency's findings for pyrethrins and pyrethroids
 - USFDA pediculicides (e.g., lice shampoos)
 - USEPA/OAR: Indoor air and asthma
- Previous and published reviews on this potential relationship
- Research needs, uncertainties and variability
 - Additional follow-up on human incident cases

Communication:

- Pyrethrins/Pyrethroids website
 - Link to pyrethrins/pyrethroids docket where this analysis will be located
 - Pyrethrins/Pyrethroids registration review docket
 - Emerging issues (e.g., total release foggers, etc.)
 - Fact sheet on pyrethrins/pyrethroids and asthma and allergies

Timeline:

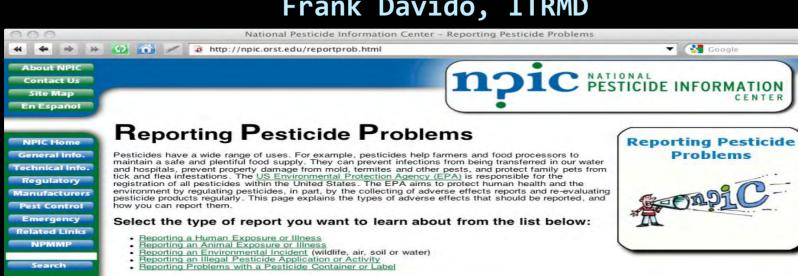
- Finalization of analysis late Spring 2009
- Develop website early Summer 2009
- Outreach to Stakeholders early-mid Summer 2009

ACKNOWLEGEMENT:

Pyrethrins/Pyrethroids Workgroup Authors:

Sarah Winfield, HED Yung Yang, HED Audrey Galizia, Detail to <u>HED</u> Molly Clayton, SRRD Cathyrn O'Connell, SRRD Jacqueline Guerry, SRRD

NPIC "Reporting Pesticide Problems" Frank Davido, ITRMD



Follow these steps to report a human exposure or illness:

- 1. If you need medical attention right now, call the Poison Control Center at 1-800-222-1222.
- Call the National Pesticide Information Center (NPIC) to report the pesticide exposures or illnesses. NPIC
 provides these reports to the EPA under a cooperative agreement. NPIC is open seven days per week from
 6:30am 4:30pm PST. Our phone number is at the bottom of the screen.
- Consider reporting the incident to the product's <u>manufacturer</u>. Manufacturers are <u>required by law</u> to submit reports of adverse effects to the US EPA.

Attention Physicians and Health Care Providers: By law, pesticide-related illness is a reportable condition in several states. If you are a health care provider treating a pesticide related incident, consider reading our <u>Medical Case Profile</u> on <u>Pesticide Incident Reporting</u>. NPIC has a medical toxicologist on staff who is available to provide information and consult with physicians about non-emergency pesticide exposure cases. Call the number below for assistance

Note: Some products applied to humans or animals are considered drugs (pharmaceuticals). Adverse reactions to pharmaceuticals should be reported to the <u>Food and Drug Administration (FDA)</u>.

Return to Top

Follow these steps to report an animal exposure or illness:

- If your animal needs medical attention right now, consider calling your local veterinarian, a local emergency clinic, or calling the <u>National Animal Poison Control Center</u> at 1-888-426-4435. A \$60.00 credit card fee may apply.
- Call the National Pesticide Information Center (NPIC) to report the pesticide exposures or illnesses. NPIC provides
 these reports to the EPA under a cooperative agreement. NPIC is open seven days per week from 6:30am 4:30om PST. Our phone number is at the bottom of the screen.
- Consider reporting the incident to the product's manufacturer. Manufacturers are required by law to submit reports
 of adverse effects to the LIS EPA

Attention Veterinarians: If you are a veterinarian, your report about pesticide-related illness will help improve the quality of all animal incident data received by the EPA. Please submit reports using our quick and easy Veterinary Pesticide Adverse Effects Reporting portal.

Note: Some products applied to humans or animals are considered drugs (pharmaceuticals). Adverse reactions to pharmaceuticals should be reported to the Food and Drug Administration (FDA).

Return to Top



NPIC "Reporting Pesticide Problems"



Emergency

Related Links

NPMMP

Follow these steps to report an environmental incident (wildlife, air, soil or water):

- 1. If a pesticide incident has occurred involving wildlife, air, soil or water, contact your State Environmental Agency to report the problem.
- 2. Next, call the National Pesticide Information Center (NPIC) to report the incident, NPIC provides these reports to the EPA under a cooperative agreement. Trained pesticide specialists are available to document the incident and provide information that could be helpful in your unique situation. NPIC is open seven days per week from 6:30am - 4:30pm PST. Our phone number is at the bottom of the screen.
- Also, consider reporting the incident to the product's manufacturer. Manufacturers are required by law to submit reports of adverse effects to the

Return to Top

Adverse Effects Reporting portal.

to the Food and Drug Administration (FDA).

Follow these steps to report a concerning or illegal pesticide application or product:

The types of situations you may want to report include reports of pesticide drift, applications where label directions or local regulations are not followed, applications of restricted-use pesticides by unlicensed applicators, and the sale

- 1. Call the National Pesticide Information Center (NPIC) to report pesticide activities that are concerning or may be may be illegal. Laws vary from state to state, so first contact one of our trained specialists who will ask questions, evaluate and document your situation, and help you determine if you need to consult with your state's authorities that enforce pesticide laws.
- If the NPIC specialist determines the pesticide application could have been made improperly or illegally, or that a pesticide product may be an illegal product, NPIC specialists will help you report the situation to your state pesticide regulatory agency for possible enforcement action.

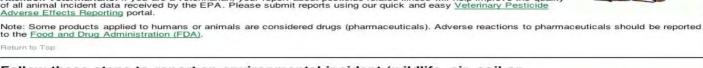
Return to Top

How to report problems with faulty pesticide containers or pesticides with misleading or faulty labels:

First, call the National Pesticide Information Center (NPIC). Some problems with pesticide products should be reported to the state pesticide regulatory agency, while others should be reported to the product's manufacturer. Our trained specialists will ask you questions to help you determine who needs to be notified. NPIC is open seven days per week from 6:30am - 4:30pm PST. Our phone number is at the bottom of the screen.

Return to Top



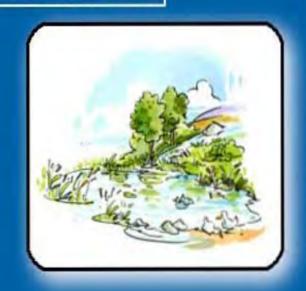




Ecological Pesticide Adverse Effects Reporting

Welcome to NPIC's Ecological Pesticide Adverse Effects Reporting portal.

The purpose of this system is to gather information from environmental and agricultural officials and similarly-qualified professionals. Use of this system by the public is strongly discouraged and may result in the termination of this service.

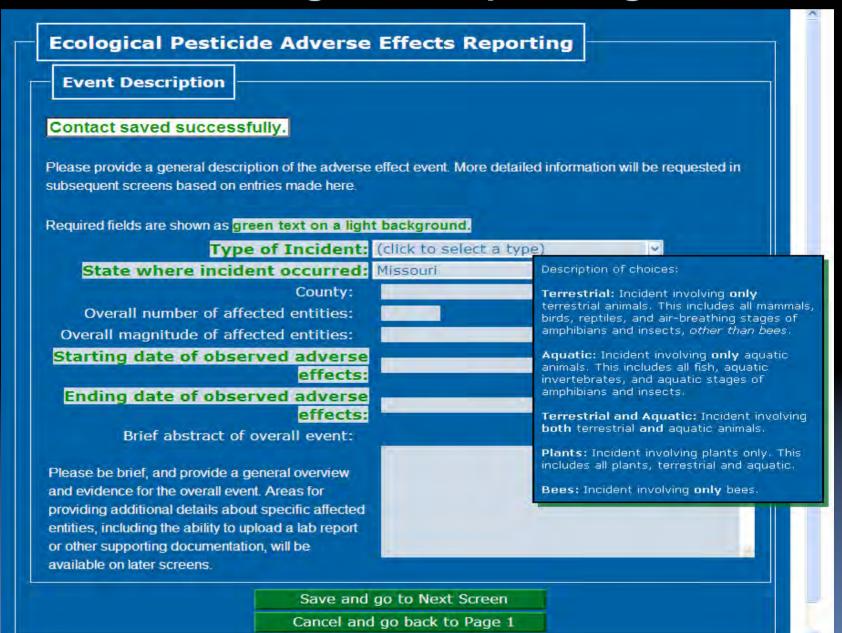


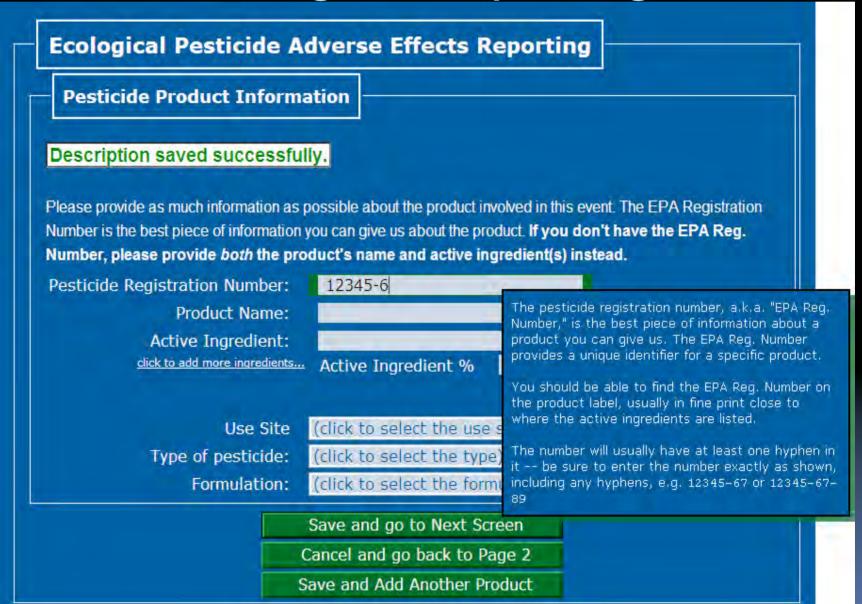
If you are not a professional, but would like to report an adverse effect of a pesticide, please call NPIC at 1-800-858-7378 and we will take your report over the telephone.

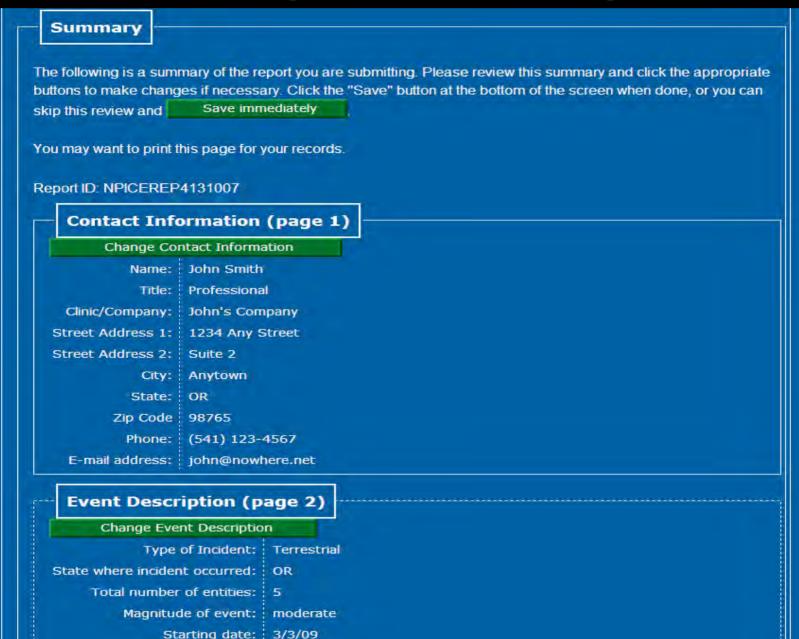
Click the appropriate button below if you would like to submit a report

Yes, I Am A Professional

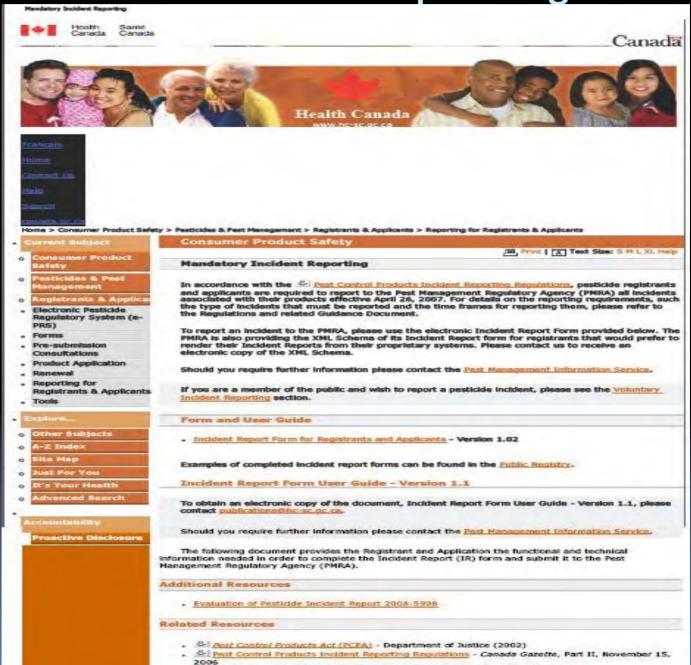
No, I Am A Member of the Public







PMRA Incident Data Reporting Website



Guidance Document for the Fest Control Products Incident Reporting Regulations

Questions or Comments?

- Anne Overstreet
- Special Review and Reregistration Division
- **(703) 308-8068**
- Overstreet.anne@epa.qov
- Kimberly Nesci
- Registration Division
- **(703) 308-8059**
- Nesci.kimberly@epa.gov
- Mary Manibusan, Chief
- Toxicology and Epidemiology Branch
- Health Effects Division
- **(703) 308-0025**
- Manibusan.mary@epa.gov
- Frank Davido
- Information Technology Resources Management Division
- **•** (703) 305-7576
- Davido.frank@epa.gov