

US EPA 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 40CFR 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 managers 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 40CFR 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

ACKNOWLEDGEMENT:

Pyrethrins/Pyrethroids Workgroup

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NPIC "Reporting Pesticide Problems"

Frank Davido, ITRMD

National Pesticide Information Center - Reporting Pesticide Problems

http://npic.orst.edu/reportprob.html

npic NATIONAL PESTICIDE INFORMATION CENTER

Reporting Pesticide Problems

Pesticides have a wide range of uses. For example, pesticides help farmers and food processors to maintain a safe and plentiful food supply. They can prevent infections from being transferred in our water and hospitals, prevent property damage from mold, termites and other pests, and protect family pets from tick and flea infestations. The [US Environmental Protection Agency \(EPA\)](#) is responsible for the registration of all pesticides within the United States. The EPA aims to protect human health and the environment by regulating pesticides, in part, by the collecting of adverse effects reports and re-evaluating pesticide products regularly. This page explains the types of adverse effects that should be reported, and how you can report them.

Select the type of report you want to learn about from the list below:

- [Reporting a Human Exposure or Illness](#)
- [Reporting an Animal Exposure or Illness](#)
- [Reporting an Environmental Incident](#) (wildlife, air, soil or water)
- [Reporting an Illegal Pesticide Application or Activity](#)
- [Reporting Problems with a Pesticide Container or Label](#)


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.
2. 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.
3. Consider reporting the incident to the product's [manufacturer](#). Manufacturers are [required by law](#) 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 [Medical Case Profile](#) on [Pesticide Incident Reporting](#). 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 [Food and Drug Administration \(FDA\)](#).

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Follow these steps to report an animal exposure or illness:

1. If your animal needs medical attention right now, consider calling your local veterinarian, a local emergency clinic, or calling the [National Animal Poison Control Center](#) at 1-888-426-4435. A \$60.00 credit card fee may apply.
2. 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.
3. Consider reporting the incident to the product's [manufacturer](#). Manufacturers are [required by law](#) to submit reports of adverse effects to the US 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 \(FDA\)](#).

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1.800.858.7378

OSU Oregon State University

EPA United States Environmental Protection Agency

NPIC "Reporting Pesticide Problems"

National Pesticide Information Center – Reporting Pesticide Problems
http://npic.orst.edu/reportprob.html

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npic NATIONAL PESTICIDE INFORMATION CENTER


Follow these steps to report an animal exposure or illness:

1. If your animal needs medical attention right now, consider calling your local veterinarian, a local emergency clinic, or calling the [National Animal Poison Control Center](#) at 1-888-426-4435. A \$60.00 credit card fee may apply.
2. 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.
3. Consider reporting the incident to the product's [manufacturer](#). Manufacturers are [required by law](#) to submit reports of adverse effects to the US 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 \(FDA\)](#).

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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.
3. Also, consider reporting the incident to the product's [manufacturer](#). Manufacturers are [required by law](#) to submit reports of adverse effects to the US EPA.


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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 of [illegal pesticides](#).

1. Call the National Pesticide Information Center (NPIC) to report pesticide activities that are concerning or 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.
2. 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.


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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.

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NPIC Ecological Reporting Portal

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

NPIC Ecological Reporting Portal

Ecological Pesticide Adverse Effects Reporting

Event Description

Contact saved successfully.

Please provide a general description of the adverse effect event. More detailed information will be requested in subsequent screens based on entries made here.

Required fields are shown as **green text on a light background**.

Type of Incident: (click to select a type)

State where incident occurred:

County:

Overall number of affected entities:

Overall magnitude of affected entities:

Starting date of observed adverse effects:

Ending date of observed adverse effects:

Brief abstract of overall event:

Please be brief, and provide a general overview and evidence for the overall event. Areas for providing additional details about specific affected entities, including the ability to upload a lab report or other supporting documentation, will be available on later screens.

Description of choices:

- Terrestrial:** Incident involving **only** terrestrial animals. This includes all mammals, birds, reptiles, and air-breathing stages of amphibians and insects, *other than bees*.
- Aquatic:** Incident involving **only** aquatic animals. This includes all fish, aquatic invertebrates, and aquatic stages of amphibians and insects.
- Terrestrial and Aquatic:** Incident involving **both** terrestrial **and** aquatic animals.
- Plants:** Incident involving plants **only**. This includes all plants, terrestrial and aquatic.
- Bees:** Incident involving **only** bees.

Save and go to Next Screen

Cancel and go back to Page 1

NPIC Ecological Reporting Portal

Ecological Pesticide Adverse Effects Reporting

Pesticide Product Information

Description saved successfully.

Please provide as much information as possible about the product involved in this event. The EPA Registration Number is the best piece of information you can give us about the product. **If you don't have the EPA Reg. Number, please provide both the product's name and active ingredient(s) instead.**

Pesticide Registration Number:

Product Name:

Active Ingredient:

[click to add more ingredients...](#)

Active Ingredient %

Use Site:

Type of pesticide:

Formulation:

The pesticide registration number, a.k.a. "EPA Reg. Number," is the best piece of information about a product you can give us. The EPA Reg. Number provides a unique identifier for a specific product.

You should be able to find the EPA Reg. Number on the product label, usually in fine print close to where the active ingredients are listed.

The number will usually have at least one hyphen in it -- be sure to enter the number exactly as shown, including any hyphens, e.g. 12345-67 or 12345-67-89

Save and go to Next Screen

Cancel and go back to Page 2

Save and Add Another Product

NPIC Ecological Reporting Portal

Summary

The following is a summary of the report you are submitting. Please review this summary and click the appropriate buttons to make changes if necessary. Click the "Save" button at the bottom of the screen when done, or you can skip this review and [Save immediately](#).

You may want to print this page for your records.

Report ID: NPICEREP4131007

Contact Information (page 1)

Change Contact Information

Name: John Smith
Title: Professional
Clinic/Company: John's Company
Street Address 1: 1234 Any Street
Street Address 2: Suite 2
City: Anytown
State: OR
Zip Code: 98765
Phone: (541) 123-4567
E-mail address: john@nowhere.net

Event Description (page 2)

Change Event Description

Type of Incident: Terrestrial
State where incident occurred: OR
Total number of entities: 5
Magnitude of event: moderate
Starting date: 3/3/09

PMRA Incident Data Reporting Website

Mandatory Incident Reporting

 Health Canada Santé Canada





Health Canada
www.hc-sc.gc.ca

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Mandatory Incident Reporting

In accordance with the [Pest Control Products Incident Reporting Regulations](#), pesticide registrants and applicants are required to report to the Pest Management Regulatory Agency (PMRA) all incidents associated with their products effective April 26, 2007. For details on the reporting requirements, such as the type of incidents that must be reported and the time frames for reporting them, please refer to the Regulations and related Guidance Document.

To report an incident to the PMRA, please use the electronic Incident Report Form provided below. The PMRA is also providing the XML Schema of its Incident Report form for registrants that would prefer to render their Incident Reports from their proprietary systems. Please contact us to receive an electronic copy of the XML Schema.

Should you require further information please contact the [Pest Management Information Service](#).

If you are a member of the public and wish to report a pesticide incident, please see the [Voluntary Incident Reporting](#) section.

Form and User Guide

- [Incident Report Form for Registrants and Applicants - Version 1.02](#)

Examples of completed Incident report forms can be found in the [Public Registry](#).

Incident Report Form User Guide - Version 1.1

To obtain an electronic copy of the document, Incident Report Form User Guide - Version 1.1, please contact publications@hc-sc.gc.ca.

Should you require further information please contact the [Pest Management Information Service](#).

The following document provides the Registrant and Application the functional and technical information needed in order to complete the Incident Report (IR) form and submit it to the Pest Management Regulatory Agency (PMRA).

Additional Resources

- [Evaluation of Pesticide Incident Report 2008-5998](#)

Related Resources

- [Pest Control Products Act \(PCPA\) - Department of Justice \(2002\)](#)
- [Pest Control Products Incident Reporting Regulations - Canada Gazette, Part II, November 15, 2005](#)
- [Guidance Document for the Pest Control Products Incident Reporting Regulations](#)

Questions or Comments?

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