EPA/OPP & Human Incident Data: Process & Data Sources

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EPA/OPP & Human Incident Data: Process & Data Sources

Presentation Overview

1. Introduction: Overview of OPP & Human Incident Data
2. Human Pesticide Illness Data Sources Used by OPP
3. Tier I & II Incident Data Reviews

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1. Introduction: Overview of OPP & Human Incident Data

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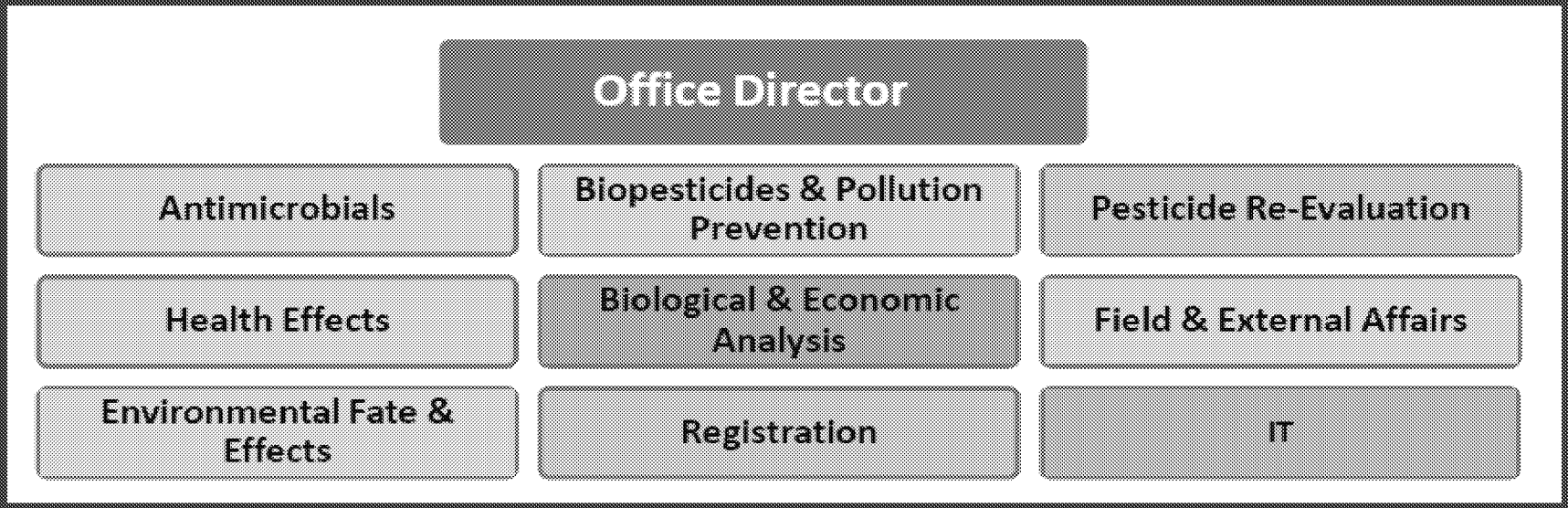
EPA's Office of Pesticide Programs



- Registers pesticides for agricultural, residential, and public health applications
- Evaluates safety of pesticides by assessing exposure and associated risks
- Establishes legal limits (aka "tolerances") for residues of pesticides in/on agricultural commodities

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Introduction

- EPA's Office of Pesticide Programs' mission is to protect human health and the environment from unreasonable effects of pesticide use.
- FIFRA gives EPA authority to:
  - Register pesticides
  - Require chemical, toxicological, environmental and residue studies
  - Develop pesticide product labeling requirements based on these studies
  - Collect adverse event incidents from registrants

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Introduction

- New pesticide products must be reviewed and registered prior to marketplace availability
- Before registering a pesticide, OPP conducts human health and environmental risk assessments to determine if the pesticide can be used without resulting in adverse effects
  - OPP may require ~100 studies
    - acute and chronic toxicity
    - developmental toxicity
    - pesticide mobility and persistence

- EPA registration numbers assigned to approved products
- Safe use requirements are reflected on the label
- The Label is the Law

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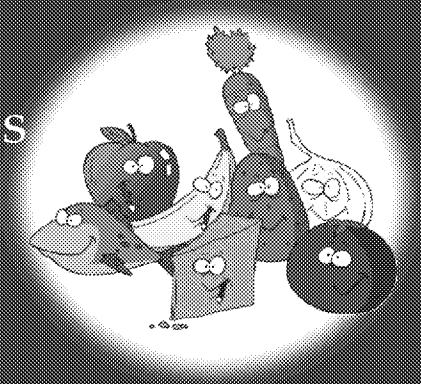
Introduction

OPP provides regulatory oversight of existing pesticide products:

- Registration Review
- Residue monitoring programs
  - Pesticide Data Program (PDP)- USDA
  - FDA- residue monitoring
- Worker Safety Regulations
  - WPS and Certification/Training
  - Pesticide Safety Outreach Activities
- Epidemiological Data (e.g., AHS)
- Incident Data (IDS & SENSOR)



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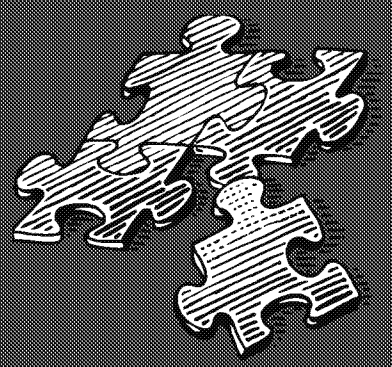
Human Incident Data

- Incident data can be an important source of feedback for OPP regulatory decision-making
  - But… causation cannot be determined based solely on incident data.
- Patterns and trends may signal the need for further investigation of a particular pesticide a.i. or product

Human Incident Data

Human incident data helps OPP

- Characterize risks
- Evaluate exposures
- Identify patterns and trends



"Incident data can be useful for confirming real world risks that are predicted by lab-generated toxicity and exposure data modeling"

OPP Report on Incident Information

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OPP's HED Incident Data Team

- Human Incident Reviews conducted OPP's Health Effects Division (HED) Toxicology and Epidemiology Branch (TEB)
  - Toxicovigilance and Epidemiology
- TEB incident analysis process:
  - Tier I "scoping" documents review human pesticide illness data and epidemiological findings in the Agricultural Health Study (AHS) for docket openings
  - Tier I "update" documents review human pesticide illness data and AHS findings for Human Health Risk Assessments
  - Tier II reviews incidents and epi findings when warranted
    - more in-depth reviews
    - primarily determined by high frequency/severity of incidents

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2. Human Pesticide Illness Data Sources Used by OPP/HED

- EPA's "6a2" Incident Data System (IDS)
- CDC/NIOSH-led SENSOR-Pesticides
- National Pesticide Information Center (NPIC)
- California's Pesticide Illness Surveillance Program (PISP)

Incident Data System (IDS)

- EPA collects incident data through Section 6(a)(2) of FIFRA
  - FIFRA 6(a)(2) mandates registrants to submit information about adverse outcomes resulting from exposure a pesticide for which they hold a registration.
- EPA receives ~ 90,000 incidents per year
  - Human incidents account for ~ 20,000 incidents
    - 20% -25% of all IDS reports
    - ~ 90% of these human incidents per year are minor
  - IDS also encompasses ecological/wildlife incidents, pet incidents, crop/turf/tree damage, etc.

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Incident Data System (IDS)

Where Do IDS Cases Come From?

- Mandatory registrant reporting of any adverse outcome (~ 95%)
- Federal and state health and environmental agencies
- Individual consumers

- Cases often contain Personally Identifiable Information, not available to the public
- IDS data may be obtained via FOIA

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Incident Data System (IDS)

There are 2 IDS Datasets:

- Main IDS:
  - Includes human incident reports of moderate severity and higher
  - Incident narratives and details are available via hardcopy
    - May include lesser severity cases when narrative/detail provided
- Aggregate IDS:
  - Includes human incidents of low severity and incidents with unknown or unspecified severity
  - Counts only
    - No narratives available for incidents reported into Aggregate IDS

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IDS Human Severity Codes*

Main IDS & Aggregate IDS both contain information on incident severity

H **Human** **(D= Domestic Animal)**

Main

- **H**A Human fatality (H-A)
- **H**B Human major incident (H-B)
- **H**C Human moderate incident (H-C)

Aggregate

- **H**D Human minor incident (H-D)
- **H**E Human incident - symptoms unknown or not specified (H-E)

*codes defined in 40 CFR 159.184 (c) (5) (i)

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Incident Data System (IDS) – Main and Aggregate

Limitations:

- Cases are not validated or otherwise verified- no certainty index is applied
- Narratives are not electronically entered into a searchable database
- Most IDS reports are received in paper format and the hardcopies have to be reviewed to obtain case detail
- System does not consistently capture details such as occupational exposure circumstances or medical outcome

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SENSOR-Pesticides

- The Centers for Disease Control's National Institute for Occupational Health (CDC/NIOSH) manages the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides.
- Participating states (12) are: California, Florida, Iowa, Louisiana, Michigan, Nebraska, New Mexico, New York, North Carolina, Oregon, Texas and Washington
  - Illinois is in the process of joining SENSOR-Pesticides
- Current dataset includes 1998 – 2013
- SENSOR-Pesticides webpage: http://www.cdc.gov/niosh/topics/pesticides/overview.html

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SENSOR-Pesticides

- Strict Coding/Definitions
  - Case requires two or more symptoms to meet case definition
  - Case classification matrix includes (complex) criteria for determining strength of case (definite, probable, possible, or suspicious) based on combined evidence of:
    1. Documented exposure
    2. Documented health effects and
    3. Causal relationship between 1 & 2
  - NIOSH-organized Training Sessions to ensure coding consistency across SENSOR states

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SENSOR-Pesticides

- Searchable by over 200 variables such as:
  - Case activity at the time of exposure
  - Product name
  - Active ingredient
  - Registration #
  - Symptoms
  - Prevention codes
  - Violation information
- Provides occupational case characterization
  - It is important to reflect the occupational exposures that are not well represented in IDS.
- Detailed narratives/descriptions provided

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SENSOR-Pesticides

- The SENSOR-Pesticides program is most useful in the timely identification of emerging pesticide problems.
- SENSOR-Pesticides strengths include:
  - Depth of detail about confirmed cases of pesticide incidents
  - Strict definitions/requirements & inter-state consistency
  - Case ascertainment from a variety of sources including
    - direct reports from local poison control centers
    - workers' compensation reports
    - physician reports
  - Participating states include important agricultural states

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SENSOR-Pesticides

NIOSH/SENSOR-Pesticides alerts EPA in a timely manner when a "high priority event" is identified. A high priority event meets one or more of the following criteria:

- events that result in a hospitalization or death
- events that involve 4 or more ill individuals
- events that occur despite use according to the pesticide label
- events that indicate the presence of a recurrent problem at a particular workplace and/or employer

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National Pesticide Information Center (NPIC)

- NPIC is a pesticide public health information service funded through an EPA grant with Oregon State University
- NPIC's primary purpose is to provide information to the public on pesticides
- NPIC functions nationally during weekdays from 8:00 am to 12:00 pm Pacific Time through a toll-free telephone and online at: www.npic.orst.edu
- NPIC includes a veterinary portal for veterinarians to report pet incidents

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National Pesticide Information Center (NPIC)

<u>NPIC criteria for immediate reporting to EPA</u>:

- Any incident involving a given set of limited number of high-concern chemicals
  - (*e.g.* paraquat, phosphine, Al phosphide, fumigants)
- Any incident involving schools/schoolchildren
- Any incident involving death or major severity
- Any incident involving more than 3 people exposed simultaneously
- Any moderate incident involving misuse or faulty applications
- Any incident requiring home evacuation

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California Pesticide Illness Surveillance Program (PISP)

- California's Department of Pesticide Regulation runs the Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries.
  - http://www.cdpr.ca.gov/docs/whs/pisp.htm
- Case reports are received from physicians and via workers' compensation records.
- Data is available publicly through 2013.
- The County Agricultural Commissioner investigates circumstances of exposure.
- PISP has limited coverage (only California)
- PISP does not conduct severity coding for cases.

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3. Tier I & II Incident Data Reviews

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Levels of Incident Review: "Tier I Scoping"

During the problem formulation/scoping phase of Registration Review, standard OPP practice is for the HED Incident Team to conduct a "Tier I Scoping" incident analysis.

- Tier I Scoping memos summarize incidents reported to IDS and SENSOR-Pesticides in terms of frequency and severity of incidents.
  - Example Tier I Scoping memo :
    - methyl bromide
  - If there are deaths or incidents classified as of "major" severity, a review of the more detailed narrative reports on these incidents is performed.

Levels of Incident Review: "Tier I Update for Draft Risk Assessments"

- Developed after docket opening for EPA risk assessment in preparation for Draft Risk Assessment
- Provides further detail on incidents involving the active ingredient under review for risk assessment
  - Includes root cause analysis and product-specific analysis
  - Considers IDS, SENSOR-Pesticides and may also include other datasets (described later)
- Example "Tier I Update for DRA" memos:
  - Aldicarb
  - Diquat dibromide

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Levels of Incident Review: "Tier II"

- Tier II analysis of the pesticide may be triggered based on high frequency and/or severity of incidents in the results of the Tier I scoping
- A Tier II analysis will include searches and analysis of the following incident databases:
  - EPA/OPP Incident Data System (IDS)
  - SENSOR-Pesticides
  - The National Pesticide Information Center (NPIC)
  - The California Pesticide Illness Surveillance Program (PISP)
  - The American Association of Poison Control Center Annual Reports (AAPCC)
- Trend analyses and summaries/root cause analysis with respect to incidents is conducted, as well as additional analysis on a product-specific (rather than a.i.) basis.

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Levels of Incident Review: "Tier II"

- Closer review of the descriptive analyses/narratives are performed with moderate and higher severity cases.
- Medical case reports from the literature involving the a.i. may be summarized.
- Some recent Tier IIs :
  - Glyphosate, docket posting March 2017
  - Diazinon, docket posting December 2016
  - Acephate, docket posting December 2016
  - 2,4-D, docket posting December 2016

Future Directions in AER at OPP

- Improve incident memos with use of developing information resources, including:
  - Smart Label
  - REJV/GRETF use survey information
- Better define IDS incident severities through discussion with and guidance for registrants
- 6(a)(2) rulemaking updates to clarify/improve adverse event reporting requirements
  - PPDC/OPP Incident Workgroup
- Funding SENSOR-Pesticides for expansion
- Spot-On Pilot Template + "Lessons learned"

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Conclusions

- HED human pesticide illness incident and epidemiological reviews follow the OPP chemical review schedule and are included in human health risk assessments / dockets
- IDS and SENSOR-Pesticides are the primary incident data sources reviewed
  - IDS and SENSOR strengths and limitations were summarized
  - These 2 datasets provide EPA with different incident perspective:
    - IDS: registrant-reported homeowner cases from all states vs.
    - SENSOR : 13 state Depts. of Health with agricultural occupational focus
- These distinct yet complementary databases allow for identification of pesticide incident patterns/trends

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Linked Source Citations

- Agricultural Health Study (AHS)
- EPA/OPP Incident Data System (IDS)
- SENSOR-Pesticides
- The National Pesticide Information Center (NPIC)
- The California Pesticide Illness Surveillance Program (PISP)
- The American Association of Poison Control Center Annual Reports (AAPCC)

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Web Addresses for Source Citations

- AHS [slide 10] : https://aghealth.nih.gov/
- IDS [slides 12-16] : https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants
- SENSOR-Pesticide [slides 17-21] : http://www.cdc.gov/niosh/topics/pesticides/overview.html
- NPIC [slides 22-23] : http://npic.orst.edu/
- PISP [slide 24] : http://www.cdpr.ca.gov/docs/whs/pisp.htm
- AAPCC [slide 28] : http://www.aapcc.org/annual-reports/

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Web Addresses for Regulatory Citations

- Methyl bromide Tier I Scoping [slide 26] : https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0269-0005
- Aldicarb Tier I Update [slide 27] : https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0161-0024
- Diquat Dibromide Tier I Update [slide 27] : https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0846-0027

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