OPP Report on Incident Information: The Baseline

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OPP REPORT ON INCIDENT INFORMATION: THE BASELINE

Introduction

The U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs' (OPP) mission is to protect human health and the environment from unreasonable effects of pesticide use. This responsibility applies not only to the review and licensing of pesticides prior to their marketing in the U.S., but to stewardship of existing pesticides and pesticide products.

Prior to registering a pesticide, OPP conducts human health and environmental risk assessments to determine the conditions under which a pesticide can be used without resulting in adverse effects. These conditions are reflected in the pesticide's label. In conducting these assessments, OPP may require upwards of 100 studies in areas such as acute and chronic toxicity, developmental toxicity, and pesticide mobility and persistence.

Similarly, when reviewing an existing pesticide OPP has the ability to require data to fill in any gaps in existing knowledge. The Office has nearly completed its reregistration process, a major review of existing pesticides and their tolerances (maximum legal amounts of the pesticide allowed to remain on food and feed). Reregistration is being replaced with a process called Registration Review, which will entail the periodic review of all pesticides to ensure that their registrations continue to meet current scientific standards.

OPP's statutory authority requires the Office to consider the benefits of pesticides as well as the potential risks. This does not override the responsibility to protect human health and the environment but means that where a pesticide's use provides benefits, OPP considers means to ensure that the risk is acceptable. For human health concerns, this may take the form of restrictions on the time or amount of application or the use of personal protective equipment when applying the pesticide. For environmental concerns, OPP may place restrictions on where a pesticide can be applied (e.g., away from water bodies) or how application may occur (e.g., no aerial application).

In reaching regulatory decisions on new or existing pesticides, OPP uses a "line of evidence" approach, considering all available data to ensure that decisions are both protective and sensible. Animal test data are used to characterize what the hazard of a pesticide may be, or what risks are associated with its normal use, and to estimate exposure levels above which those hazards may occur. To supplement testing data, OPP reviews available field data. These data may be formal monitoring to determine a pesticide's effects on the environment, or may consist of human or ecological incident data collected from governmental and non-governmental sources, reported by medical professionals, or submitted by pesticide registrants.

In 2006, OPP committed to developing a series of reports on incident information. In this, the first of those reports, the focus is providing an overview of the main sources of incident information currently used by OPP. To understand incident numbers, it is important to understand the data sources that provide those numbers. The report is divided into five sections. Following this first, introductory, section the remainder of the report is structured as follows:

Section 1 - Overview of Incident Data.

This section contains basic information on questions regarding what constitutes a pesticide incident and how OPP collects incident data. This section summarizes and profiles pesticide incident data sources, and discusses practical considerations associated with those sources

Section 2 – How OPP Uses Incident Data.

This section discusses how incident data is considered in OPP's regulatory process, including risk assessment and risk management, risk communication, performance accountability, and enforcement. There is also discussion of the limitations of pesticide incident data.

Section 3 – What Does Incident Data Tell Us?

This section provides insight on the difficulty in using incident data to reach conclusions on pesticide exposures, and how OPP deals with that issue.

Conclusion

Section 1: Overview of Incident Data

What is a pesticide incident?

Pesticides are used in a variety of settings every day. Bug sprays are used in gardens and homes, bait traps are put out to control mice, disinfectants insure that surgical tools are safe to use, herbicides are applied to corn to control grasses and weeds, and kitchen countertops are wiped down using sprays containing antimicrobials. With this amount of use, it is not surprising that there are incidents associated with pesticide use.

What exactly is a pesticide incident? A simple way to define it is that an incident is any effect of a pesticide's use that is not expected or intended. For relatively rare incidents adversely affecting humans, such as spills, leaks, pesticide movement off-site, or chronic exposure to sensitive people or those with pre-existing diseases, symptoms may include head aches, nausea, a breathing problem, or more severe symptoms. In extreme situations, systematic effects, serious illness, or death may occur. For an incident affecting the environment, impacts may include fish or bird kills or damage to plants. In addition, incidents may occur to domestic animals or wildlife. Incidents may be occupational, residential, or ecological.

How is Incident Data Collected?

Sources of incident data are as varied as the type of incidents. Under OPP's primary statute, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), once a pesticide is registered a registrant is required to notify EPA if it becomes aware of "factual information regarding unreasonable adverse effects on the environment of the pesticide". In addition, the Agency obtains reports of pesticide incidents from private citizens, poison control centers, states, and other government and non-governmental organizations.

OPP utilizes a variety of incident data sources since no one source completely addresses the program's data needs. OPP takes a two-pronged approach to incident data: (1) utilize all available incident information to the extent possible, recognizing the strengths, weaknesses and limitations associated with each data source; and (2) work to improve incident information used for decision-making. Table 2.1 lists OPP's primary sources of incident data, and includes information on the baseline year (how long the data source has collected data), as well as the source and scope of data collected.

In addition to the sources listed in Table 2.1, OPP: conducts open literature searches on case reports and relevant pesticide epidemiology studies; reviews periodic surveys and studies, such as the National Agricultural Workers Survey, the Washington State Human Bio-Medical Monitoring Studies on Pesticide Handlers, and the National Cancer Institute-led interagency Agricultural Health Study (AHS). Finally, OPP draws upon continuous bio-monitoring studies of pesticides from all routes of exposure in the National Health and Nutrition Examination Survey (NHANES).

Table 1.1 – Summary of Incident Data Sources

Name	Baseline Year	Source of Data	Scope
Data Sources with both Human and Ecological Incident Data			
Incident Data System (IDS)	1992, but includes earlier incidents	Registrants (under FIFRA §6(a)(2), general public, and governments; international incident reports	All types – occupational, residential, ecological
Data Sources with Human Incident Data			
National Poison Data System (NPDS)	1983; later expanded to cover 100% of U.S. population	Primarily public reporting, through Poison Control Centers	All types (national in scope)
National Pesticide Information Center (NPIC)	1978	Predominantly public reporting, with some physician reports	All types (national in scope)
Sentinel Event Notification System for Occupational Risk (SENSOR)	1998	State coordinators receive reports from physicians, emergency room records, workers' compensation claims, Poison Control Centers, State Ag. Depts.	Occupational and non-occupational
Cal. Pesticide Illness Surveillance Program (PISP)	Standard collections from 1982; updated 1992	Physicians reported medical records, or through review of worker compensation reports	Occupational and residential pesticide incidents (California only)
Data Sources with Ecological Incident Data			
Ecological Incident Information System (EIIS)	~ 1970	Registrants, public literature, public news reports, voluntary reports from a few states	Ecological
Avian Incident Monitoring System (AIMS)	~ 1970	EIIS, Fish & Wildlife Service enforcement cases, some state reporting, reports from wildlife rehabilitation centers	Ecological (incidents related to birds)
U.S.G.S. Nat'l Wildlife Health Cent. Mortality Reports	1995	Wildlife mortality reports gathered quarterly by field teams	Ecological (all wildlife – national in scope)

Profiles of Incident Data Sources

When considering a data source it is important to understand its purpose. The following are thumbnail sketches of each data source. In addition to divergent purposes, data sources differ in key definitions and in how data are obtained and maintained. Understanding these differences is critical to understanding what the data represent and the strengths and limitations of those data for OPP purposes.

Incident Data System (IDS)

IDS is maintained by OPP and incorporates data submitted by registrants under FIFRA section 6(a)(2), as well as other incidents reported directly to EPA. FIFRA allows the aggregation of individual events in some circumstances. IDS includes information on incidents involving humans, plants, wild and domestic animals where there is a claim of an adverse effect, as well as detects of pesticides in water. The vast majority of reports are received in paper format. IDS entries act as a pointer to copies of original reports, retained on microfilm and scanned images in OPP's Information Service Center. Many companies use standardized, industry-developed Voluntary Incident Reporting Forms. While IDS reports are broad in scope, the system does not consistently capture detailed information about incident events, such as occupational exposure circumstances or medical outcome. In most cases data going into IDS is not validated or verified, though some reports are collected from calls to contract poison control centers.

Strengths – Centralized system; data "owned" by OPP
Limitations – low to uneven levels of detail, lack of fully automated system - difficulty of working with data (need to review hard copies instead of electronic searches)

Sentinel Event Notification System for Occupational Risk (SENSOR)

The Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health, with some funding from EPA for pesticide poisoning surveillance, maintain the SENSOR database which covers all occupational injuries. In part via competitive funding to states, SENSOR is used to monitor trends in occupational health related to acute exposures to pesticides, to identify emerging pesticide problems, and to build and maintain state surveillance capacity. SENSOR is a state-based surveillance system, with most poisoning incident cases collected from Department of Labor workers' compensation claims when reported by physicians, reports from State Departments of Agriculture, or from poison control centers. Depending on state reporting laws, cases may also come from State Departments of Health based on reports by physicians suspecting pesticide exposure. A state SENSOR contact specialist does follow-up with workers and obtains medical records to verify symptoms, circumstances surrounding the exposure, severity, and outcome. Using standardized protocol and case definitions, derived from poison center reporting, SENSOR coordinators at State Departments of Health enter the incident interview description provided by the worker, medical report, physician and patient into the SENSOR data system, accessible to participating states and EPA.

Strengths – Most comprehensive system for occupational incidents
Limitations – Only 12 states participate, and a large % of data comes from California and Washington State

California Pesticide Illness Surveillance Program (PISP)

The State of California maintains the PISP database and shares data with EPA on request. Pesticide-related illness and injury data from PISP are used to validate the effectiveness of California's Department of Pesticide Regulation exposure control measures and identify potential areas for improvements to state regulations. Physicians must report suspected cases of pesticide exposure in order to be paid in worker compensation cases and worker's compensation claims are reviewed and entered into PISP. County agricultural commissioners are notified to follow-up with investigations.

Strengths – Unique infrastructure for follow-up; strong baseline information; longest history of record keeping for tends; and, all types of pesticides are included
Limitations – Limited to California; occasional lag time between incident and report

Poison Control Centers National Poison Data System (NPDS)

NPDS, formerly the Toxic Effects Surveillance System (TESS), is maintained by the American Association of Poison Control Centers (PCC), with funding from several federal agencies. NPDS is a computerized information system with geographically specific and near real-time reporting (for bioterrorism detection purposes). While the main mission of Poison Control Centers is helping callers respond to emergencies, and not collecting specifics on incidents, NPDS data helps identify emerging problems in chemical product safety. Hotlines at 61 PCC's nationwide are open 24/7, 365 days a year with many bilingual centers in high Spanish speaking areas, and 80 language translation capability. Hotlines are staffed by specially trained nurses to provide poisoning information and clinical care recommendations to callers with a focus on triage to give patients appropriate care. Using computer assisted data entry, standardized protocols, and strict data entry criteria, local callers report incidents that are retained locally and updated in summary form to the national database. Since 2000 nearly all calls in the system are submitted in a computer-assisted interview format by the 61 certified Poison Control Centers, adhering to clinical criteria designed to provide a consistent approach to evaluating and managing pesticide and drug related adverse incidents. Information calls are tallied separately and not counted as incidents. The PCC system covers nearly all the US and its territories and is undergoing major computer enhancements post 9/11.

Strengths – National in scope
Limitations – System is clinically oriented and large (with over 1.5 million records) and primarily represents residential settings (not currently designed to collect detailed occupational incident data). A recent pilot in Colorado is addressing this gap and could prove to be a National example of improved reporting. It is difficult to interpret trends in PCC data without statistical know how.

National Pesticide Information Center (NPIC)

NPIC is funded by EPA to serve as a source of objective, science-based pesticide information in response to inquiries and to respond to incidents. NPIC functions nationally during weekday business hours, under a cooperative effort between Oregon State University and EPA. Similar to Poison Control Centers, NPIC's primary purpose is to provide information and not to collect incident data. NPIC does collect information about incidents from inquirers and reports that information to EPA. The Center's main role is to provide information to inquirers on a wide range of pesticide topics, and direct callers for pesticide incident investigation and emergency treatment.

Strengths – National in scope
Limitations – System not designed to collect detailed occupational incident data; limited # of calls. Although the main objective is not to obtain incident data, NPIC's recording of calls is guided by Standard Operating Procedures and the ability to retrieve and use data for such cases is adequate, and has proven useful. About 10% of NPIC's annual calls are considered "incident" related.

Ecological Incident Information System (EIIS)

EIIS is an OPP database with 89 distinct fields within 13 data tables and provides more detailed information on IDS incidents involving effects to wild non-target animals and plants. When available, EIIS includes date and location of incident, type and magnitude of effects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and results of any chemical residue and cholinesterase activity analyses conducted during incident investigation. EIIS incidents are categorized according to the certainty that the incident resulted from pesticide exposure.

Strengths – Detailed information related to ecological impacts
Limitations – Limited number of reported incidents; difficult to prove cause of mortalities

National Wildlife Health Center (NWHC) Quarterly Mortality Reports

The U.S. Geological Survey's National Wildlife Health Center (NWHC) produces quarterly mortality reports detailing wildlife mortality events throughout the U.S. These reports are compiled from a database of wildlife mortality events maintained at NWHC. Data are gathered by Field Investigations Team personnel collaborating across the country, at the federal, state and local levels. Information is most complete post-1975, but some data are available from earlier years.

Strengths – Data collected by field personnel, so it is reliable; national in scope
Limitations – Low level of detail; no determination of probability that pesticide caused effect; difficult to locate carcasses. Data is primarily limited to effects on migratory birds and endangered species.

The Avian Incident Monitoring System (AIMS)

The Avian Incident Monitoring System (AIMS) was created by a cooperative program between the American Bird Conservancy (ABC) and EPA, and is now maintained by ABC alone. Through AIMS, ABC seeks to collect, store, and report data on pesticide poisoned birds, and improve identification, investigation, and laboratory analysis related to bird poisonings. The AIMS database serves as a centralized public source for field data on lethal and sub-lethal effects of pesticides on birds. These data can be used to develop pesticide usage recommendations, while providing a means to identify risks posed by current usage recommendations and label instructions. AIMS facilitates more systematic identification, diagnosis, and reporting of pesticide-related bird incidents, and enables better sharing of information on incidents among government agencies.

Strengths – High level of detail; data is reliable; national in scope
Limitations – Small number of cases that are not available from other sources; only contains avian incidents

Data Source Practical Considerations

Each data source has strengths and weaknesses, particularly as it relates to OPP's needs. The next section (How OPP Uses Incident Data) contains a more detailed discussion of those issues and how they are addressed by the program. Several considerations must be taken into account in deciding whether to routinely use a data source, including completeness of data, accessibility, and ability to search the database. In addition, as mentioned in the thumbnail sketches of Poison Control Centers and NPIC, many of the incident data sources were developed as public health surveillance tools to observe trends in health or environmental concerns and not for arriving at point estimates of pesticide incidents.

Table 1.2 reviews some of the key features for each data source. These features provide a context for how useful the information provided may be to OPP. For example, the level of detail provided by SENSOR and PISP, which are primarily designed to collect data on pesticide incidents, differs from NPIC whose primary purpose is to assist the public in obtaining information about pesticides and pesticide exposure. Table 1.2 also indicates the volume of reports generated by each data source. While this may vary from year to year, this information allows a comparison between data sources. Finally, Table 1.2 indicated the relative cost for each data source. This cost is not the total cost for operating the data source, but rather the cost to OPP. Where OPP staff time is required (IDS and EIIS) this figure is indicated as well. It should be noted that the costs listed for both IDS and NPIC are for all incident data collected, not just human incident data.

Table 1.2: Key Features of Incident Data Sources

Name	Key Features	# Reports/Yr.	Cost/Yr.
Data Sources with both Human and Ecological Incident Data			
IDS	• Mainly industry generated, many using standardized, voluntary format • Most reports on paper, indexed electronically by EPA registration number/incident case number • Two-tiered search capability (tabular summary of ecological and minor human incidents, full summaries of moderate/major human incidents) • Database contains the summaries, but full reports are available • Database is fully searchable by experts	~ 60,000, aggregated from all reports	~$200 K (2 staff)
Data Sources with Human Incident Data			
NPDS (formerly TESS)	• Open 24 hours/day, 365 days a year • Bilingual in Spanish speaking areas, instant access to 80 other languages • Specialized nurses supported by toxicologists • Computer assisted data entry using standardized protocols and data entry criteria • Searchable by experts w/ database knowledge	89,361 (05), 90,341 (06)	~$45 K
NPIC	• Toll-free service that provides a variety of information about pesticides • Information provided includes pesticide product information, toxicology, recognition and management of pesticide poisonings, safety practices, clean up and disposal • Staffed by pesticide specialists with toxicology and environmental chemistry training • Operates daily from 6:30 – 4:30 Pacific Time	3,190 (05)	~ $1.6 M (total cost for NPIC operation, not just cost associated with the reporting of incidents)
SENSOR	• Fully computerized w/ common case definitions • Data owned by participating states (12 currently) • Capacity to identify new hazards/provide rapid state follow-up and inter-state communication • Fully searchable by knowledgeable experts	~1,000 (@ ½ of which are occupational	~$350 K
PISP	• History of cooperation with EPA • Product specific use/usage info. by county • Computerized link to workman's compensation claims data/requirement for physicians report prior to payment of workman's comp claim	~1,000	None

Name Key Features # Reports/Yr. Cost/Yr.

Data Sources with Ecological Incident Data

EIIS		Ranges from ~150 to ~675	~150 K; (1 staff)
AIMS		Rangers from ~40 to ~225	None
NWHC Mortality Reports		~ 6-7	None

Section 2: How OPP Uses Incident Data

Section 1 provided an overview of available sources for incident data, and provided some insight as to the strengths and limitations of each. This section will discuss the ways in which OPP utilizes incident data. As was discussed earlier, no single data source provides perfect data for OPP's purposes. In addition, as will be discussed in this section, some incident data has severe limitations and must be properly considered. While incident data may help provide perspective, it may not be of sufficient quality or quantity to be appropriate for use in risk assessments for every chemical. OPP's approach is to utilize all available data, accounting for both strengths and limitations.

There are several ways in which incident data may help inform OPP's pesticide regulatory process. For example, incident data may be:

- considered when reviewing applications for registration of new pesticides that are chemically similar to existing pesticides;
- used as an indicator of relative risk or unusual exposure situations during deliberations on risk management decisions;
- reviewed to determine trends that may indicate potential problems with an existing pesticide and to track improvements when mitigation measures are applied.

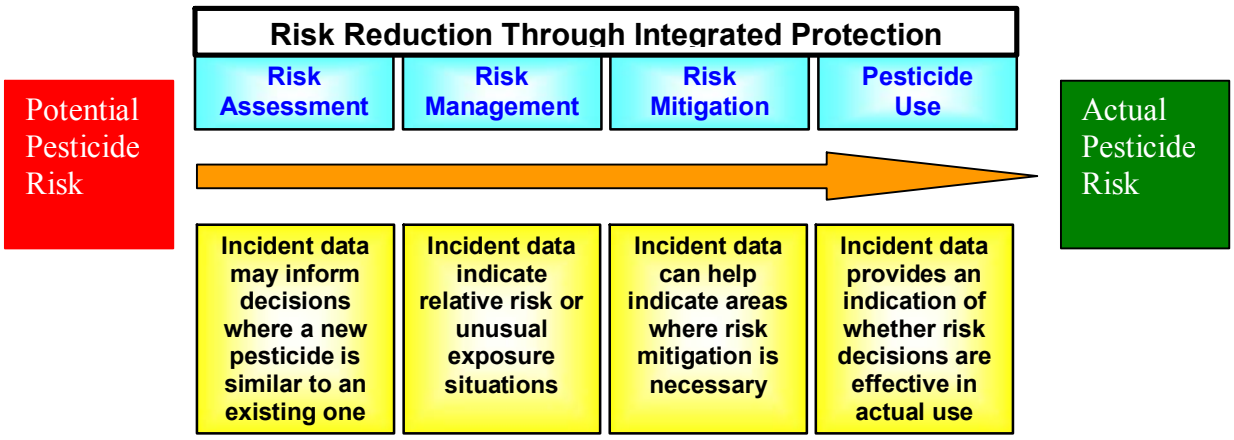
OPP uses incident information for four primary purposes. First, incident data is used to inform risk reduction through risk assessment/risk management activities. For example, incident information can indicate a need for new risk management measures and can help assess the success of risk mitigation actions after they are implemented. Second, incident data may be used in risk communication to portray nature, extent and severity of incidents to decision-makers, stakeholders and the public in general. Thirdly, incident information is an integral part of OPP's performance accountability system. Last, but not least, incident information can be useful in targeting enforcement activities and can serve as a source for information on compliance with incident reporting regulations.

Risk Reduction through Risk Assessment and Risk Management

The pesticide regulatory system can be seen as an integrated program designed to ensure that decisions on pesticide products are translated to actual protections in the field (Figure 1). The first step is an assessment of a pesticide's risks, using a battery of scientific studies and exposure models. Second, EPA conducts risk management where measures are introduced where needed to allow for the safe use of a pesticide. Third, risk management decisions are conveyed through label directions so that potential risks may be mitigated at the point of use. Lastly, effective risk communication ensures that individuals who use pesticides have the knowledge to use them properly.

Incident data can help strengthen the links in this integrated program both by helping OPP make better decisions in addressing potential pesticide risks and by responding to situations where the goal of safe and beneficial use is being compromised. This feedback is important in ensuring that regulatory decisions are sufficiently protective.

Figure 1 – EPA's Pesticide Regulatory System



EPA's risk assessment - risk management paradigm (Figure 2) helps illustrate how OPP utilizes incident data. The paradigm includes four basic risk assessment elements: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Data used in hazard identification, dose-response, and some exposure assessments are based on laboratory data or data generated by models.

Incident data can be useful for confirming real world risks that are predicted by "lab-generated" toxicity and exposure data modeling. For example, an incident of mortality of fish in a pond following exposure to an insecticide would confirm a prediction of high risk based on laboratory toxicity data and exposure modeling. In addition to confirming predicted risks, incident data may show an effect not evident in toxicity tests or help OPP compare the risks of a specific pesticide with other products approved for the same use.

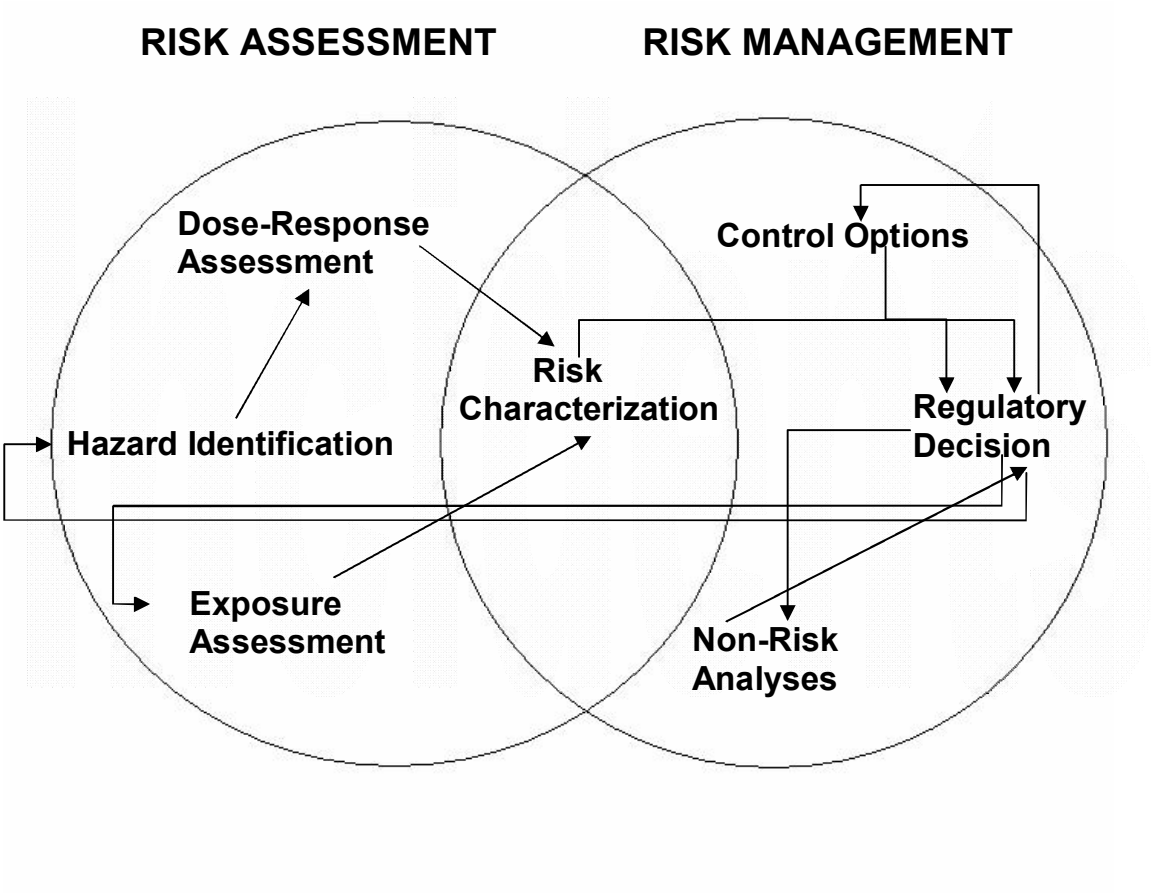
Once a risk assessment is completed, it is used to make risk management decisions on a product-by-product basis, if product specific information Is consistently captured, as in many IDS and NPDS incidents. If the risks are considered too high, risk management techniques can be employed to reduce exposure or the hazard from the pesticide in order to reduce the risk. Many of these techniques are implemented through the product's label. Examples of risk management techniques utilized by OPP include, but are not limited to:

- Restrictions on who can use the product and when and how it can be used;
- Changing product formulation;
- Changing Restricted Entry Intervals (REIs) for workers;
- Reducing application rates;
- Using spray drift control technology;
- Increasing personal protective equipment (PPE);
- Adding engineering controls (e.g., water soluble bags or closed mixing/loading systems);

- Canceling uses;
- Setting buffer zones;
- Training for those using the pesticide to ensure proper usage.

As this figure indicates, incident data may help inform OPP's activities in any of these areas. While incidents, and incident data, are not generally a determining factor, on occasion they do indicate trends or areas that need greater attention.

Figure 2: The Risk Assessment – Risk Management Paradigm



In addition to the product-by-product decisions, OPP utilizes incident data as an aid to assess risks and decide on appropriate risk management techniques during rulemaking. For example, in drafting worker protection regulations, OPP considered all available incident information.

The risk assessment and risk management process provides the means and methodology to ensure that pesticides can be used safely, and that public health and the environment are protected from any unreasonable adverse effects of that use. The ability to determine details concerning pesticide exposure is critical in developing protective risk management strategies. Analyzing pesticide incident data can provide an important feedback mechanism. Specifically, human health incident data can target

field program direction and focus outreach and training to reduce pesticide exposures and provide impetus to pursue regulatory change. Similarly, ecological incidents involving a pesticide may confirm a risk that was predicted by effect and exposure models, or it may indicate that the actual risk is greater than that predicted by the model.

On occasion, incident data has been of enough concern for EPA to initiate action against a pesticide. Residential use restrictions were applied to both diazinon and chlopyriphos, action was taken to control drift for methyl bromide, better packaging was required for malathion, and personal protective equipment was required for thiram. Some additional cases are outlined in Table 3.1.

Table 2.1: Selected Cases Where Incident Data Informed Regulatory Action

Pesticide	Incidents of Concern	Agency Action	Result
Mevinphos	Worker exposure	Initiated process to cancel all uses	Registrant voluntarily cancelled all uses
Carbofuran	Bird kills	EPA responded to incidents associated with use of granular formulations	Granular formulation use severely reduced by elimination of uses and limits on amount allowed for sale
Allercare (trade name) selected products	Residential exposure (asthmatic reactions, respiratory problems)	Request for registrant to cancel/recall products	Registrant stopped sale and recalled existing products

Risk Communication

In addition to risk assessment and risk management, incident information can be useful in risk communication. Information on the nature, extent, and severity of incidents is valuable in communicating with Congress, the Office of Management and Budget, the general public, and stakeholders. Incident information can provide insight on the magnitude of problems identified which provides critical information to managers involved in resource allocation. Several OPP public communication efforts have been initiated to directly respond to situations where incidents have occurred, including:

- "Lock it Up" – To raise awareness of how to prevent poisonings and exposure to household cleaners and pesticides, EPA produced posters encouraging parents to safely store pesticides – poster displayed on several mass transit systems;
- "Ten Tips to Protect Children from Pesticide and Lead Poisoning" – brochure produced in English/Spanish, providing steps to limit pesticide exposure to children;
- "Read the Label First" – community action kit, containing training materials for use in heightening awareness about pesticide poisonings. In addition, posters, magnets, and bookmarks were produced;

- National Hispanic Outreach Initiative - Launched in 2004, focused on reducing risk in Latino communities by providing pesticide safety information through mass communications - TV, radio and press, including segments broadcast nationally on the three major networks (Univision, Telemundo, CNN en Espanol. Reached about 63 million Hispanics in the U.S. and 16 million households in Latin America in 2006.

Performance Accountability

Accountability mechanisms, such as performance measures, are important to ensure good program management and provide an objective means to determine if a program's intended outcomes are being met. Incident data help measure the effectiveness of risk management actions that OPP has taken to protect human health and the environment.

For example, in EPA's 2006 -2011 Strategic Plan, there are two measures dealing with human incidents under Goal 4, Objective 1, Sub-objective 3:

> By 2011, improve the health of those who work in or around pesticides by reaching a 50% targeted reduction in moderate to severe incidents for 6 acutely toxic agricultural pesticides with the highest incident rates: chlorpyrifos; diazinon; malathion; pyrethrins; 2,4-dicholorophenoxyacetic acid (2,4-D); and carbofuran. [Baselines established using PCC-TESS (NPDS) data for 1999 – 2003 and updates through 2004-2005 with 2006-2007 data expected in early 2008.]
>
> Through 2011, protect those occupationally exposed to pesticides by improving upon or maintaining a rate of 3.5 incidents per 100,000 potential risk events. [Baselines established using data from PCC-TESS (NPDS) as of May 2007, and EPA's earlier 1992 Regulatory Impact Analysis for the Worker Protection Standard and U.S. Department of Labor updates]

The first measure is meant to gauge OPP's efforts to improve the health of those who work with or around six acutely toxic pesticides with the highest incident rates. It is OPP's intent to realize a 50% reduction in the number of moderate to severe incidents for these six acutely toxic agricultural pesticides by 2011 as a result of the risk management decisions that OPP has made and is implementing for these pesticides. Reviews of the number of occupational incidents for these six chemicals will help OPP determine if the risk reduction actions taken in the reregistration process have had the intended effect and to take additional action if appropriate.
While OPP is intent upon reducing the incidents associated with these six pesticides, it is also important to monitor all other incidents to make sure that the number of incidents overall does not increase. The first measure listed from the Strategic Plan is intended to monitor the rate of occupational incidents to ensure that the established level of protection is maintained or improved upon over time.

Enforcement

Enforcement data are useful in providing information on incidents that have previously been reported and, in some less frequent situations, to identify incident trends. In the first instance, if an incident is the result of a suspected violation of FIFRA, an inspection may be requested. This inspection can provide additional details concerning the incident, including verification of the cause-effect linkage, more information about the magnitude of the exposure or the resulting adverse effect.

It is also possible for a series of investigations to point towards incidents that have not been previously reported. For example, an investigation resulting from a complaint about spray drift may uncover adverse effects that were previously unreported in any incident reporting system. Through collection and review of incident information, OPP can help EPA's Office of Enforcement and Compliance Monitoring target inspections where there are potential compliance problems, which may lead to breaking the non-compliance/ incident cycle. Improvements to near real-time NPDS pesticide incident reporting for bioterrorism control purposes, reduced use of the most risky chemicals, and increased emphasis on prevention of a wider range of more subtle health end points in an increasingly aging population will make possible a new generation.

Limitations of Incident Data

As discussed in this section, appropriate use of incident data can assist OPP in a number of ways. It is important, however, to note the limitations associated with incident data. This underscores the importance of the lines of evidence approach used by OPP – where available, incident data is considered along with other data and is given the proper consideration.

So what are some of the problems with incident data as it is currently available? Some of the more notable limitations include:

Underreporting – There is undoubtedly some degree of underreporting in every incident database regularly used by OPP. This underreporting is the result of a number of factors including, but not limited to:

- The lack of a universal, mandatory legal duty to report;
- No central reporting point for all incidents;
- No requirement for active monitoring for incidents;
- Symptoms associated with pesticide poisonings are often vague or mimic other causes leading to incorrect diagnoses;
- Physicians may also misdiagnose due to a lack of familiarity with pesticide effects;
- Incidents are often not investigated adequately enough to identify the pesticide that caused the observed effects;
- Difficulty in identifying and tracking chronic effects;
- Reluctance or inability to report;
- Limited geographic coverage for individual databases; and

- For ecological incidents, difficulty in observing carcasses of animals poisoned in the wild (mortality often occurs under dense vegetation or in sparsely populated areas or scavengers scatter or devour the carcass before it is discovered).

It is difficult to determine the magnitude of underreporting. Clinical follow-up studies in several locations have shown that 4-25% of human pesticide poisoning cases are reported to poison control centers. OPP recognizes that as a significant issue that may only be addressed with significant additional investments that are not currently feasible.

Double Counting – It might seem as though it would be possible to simply add or subtract incident numbers from different data sources to determine the total number of incidents. This seemingly logical method is actually misleading because the same case could be reported in multiple data sources and, in many cases, specific information recorded in the database is not adequate to determine whether a particular case in one database is the same case or merely a similar case in another database. Since data sources have different purposes and geographic coverage, it is generally assumed that cases are not duplicative, unless conclusively shown to be so by date, place and particular circumstances of exposure. While it may be possible to make this determination routinely for SENSOR, California data, NPDS data, and clinical cases reported in the open literature, it is more difficult for IDS and NPIC. When available, NPIC does record name, address, and phone number of the affected individual, the EPA registration number, name, and active ingredient of the product, and the circumstances of the incident.

Resources – Collection of incident data, particularly ecological data, takes significant resources. This leads to a limited number of incidents being reported per year, even in the best system. In addition, limited resources at the federal level have hindered OPP's efforts to improve data collection and use and in providing funding for existing incident data sources.

Completeness/Usefulness of Data – This is a general category that covers a variety of shortcomings with much of the available incident data. As mentioned earlier, several sources of incident data are primarily designed to disseminate information on pesticides and not to collect pesticide incident data. As a result, the data from these sources may be lacking in sufficient detail. In many cases, when an incident is reported useful information such as the exact product that was the source of the exposure, the amount of pesticide involved, or the circumstances are omitted. In many cases there is not enough information to determine if the adverse effects noted were in fact the result of pesticide exposure and not another contributing factor.

Section 3: What Does Incident Data Tell Us?

For the reasons listed above, it is very difficult to reach precise conclusions based on incident data. For example, estimating how many occupationally-related pesticide poisoning incidents occur in the United States results in numbers as varied as the data sources themselves. National data from the American Association of Poison Control Centers indicates that the answer may be 1000 – 2000 for 90,341 consumer reported exposures in 2006. The range reaches between 1500 - 6000 if looking at SENSOR data on handlers and agricultural workers extrapolated to the entire U,S,

When the U.S. Department of Labor's 1999 National Agricultural Workers' Survey (NAWS) asked workers if they had been poisoned by pesticides in the previous year and 1.4% of the estimated 1.8 million farm workers (or 25,200 workers) said "yes." However, the number was 10,000 - 40,000 when OPP estimated agricultural worker poisonings in the 1992 Worker Protection Standard Regulatory Impact Analysis. As has been noted, each estimate has limitations. For example, OPP's analysis is hampered by the inadequacy of national pesticide poisoning surveillance, which has been criticized on several occasions by the Government Accounting Office. These considerations do not make a particular answer to the "how many?" question wrong or right, but perhaps more or less useful depending on the intended use for the answer

All of this serves to point out the complexity of determining the number of pesticide-related incidents, whether they are occupational or residential in nature or whether they impact human health or the environment. Although OPP would prefer to have a precise number of incidents in every category of interest, the fact is that the program's success is not dependent upon this precision. More important than the precision of this number is an understanding of the magnitude of the problem.

Along with the magnitude, reliable trend information is also arguably more important than greater precision. For example, assume there were 20 incidents reported last year. Is this number down from 100 five years ago or up from 5 incidents two years ago? These different trends would no doubt lead OPP to different risk management decisions. Precisely counting incidents is not OPP's goal; rather, the ultimate goal is to minimize the occurrence of incidents. Every incident avoided furthers OPP's mission of protecting human health and the environment.

The practical implication is that OPP must perform a balancing act with limited resources. OPP must balance the resources spent on gathering and managing incident information to increase the precision against the resources needed to prevent or mitigate potential future incidents. The two performance accountability measures OPP included in the Strategic Plan reflect this balancing act (see Section 2's "Performance Accountability" section).

Conclusion

OPP is currently considering how best to manage and utilize incident data. This process includes examining internal processes, data sources, and current procedures. The program will continue to periodically update its stakeholders on our activities in this area.