**ATTACHMENT 2-2. Ecological Incidents**

A pesticide incident is defined as any exposure or effect from a pesticide’s use that is not expected or intended.  Pesticide incidents may involve humans, pets, wildlife, plants, domestic animals and honey bees. Ecological incident reports (those involving wildlife and plants) are typically used by EPA as a line of evidence (in a WoE approach) for making risk conclusions in pesticide risk assessments. Incident data can provide evidence that exposure pathways for a particular pesticide are complete and that exposure levels are sufficient to result in field-observable effects. In short, incident reports provide important information on what can happen to non-target plants and wildlife when a pesticide is used in the ‘real world’, and they can help support or refute risk predictions based on laboratory data.

Because incident data are not typically reported or collected systematically, a lack of reported incidents cannot be used as evidence that incidents could not or do not exist from registered uses of the chemical(s) being considered. Incident reports for non-target organisms normally provide information only on mortality events and plant damage. Except for phytotoxic effects in terrestrial plants, sublethal effects, such as abnormal behavior, reduced growth or impaired reproduction, are rarely reported.

The primary sources of ecological incident information that OPP uses is the Incident Data System (IDS) and the Avian Incident Monitoring System (AIMS) (a database maintained by the American Bird Conservancy). These databases contain information from pesticide incident reports.  The incident reports are derived from a variety of sources [those submitted directly to OPP (*e.g*., by pesticide registrants, the public, and state, federal, and local government agencies) and those available through other sources (*e.g*., the United States Geological Survey’s Contaminant Exposure and Effects – Terrestrial Vertebrate Database, the open literature and media accounts)].

The Incident Data System (IDS) database includes all pesticide incidents of which OPP is aware (*e.g*., those involving humans, wildlife, pets, and other domestic animals). IDS is primarily used by risk managers and staff to track the total number of all incidents (human, wildlife, *etc.*) associated with a particular pesticide active ingredient or product; IDS also contains information on aggregated incident reports. Although pesticide registrants are required to report adverse effect incidents under FIFRA 6(a)(2), the section 6(a)(2) reporting requirements allow registrants to ‘aggregately’ report all ‘minor’ ecological incidents. Incidents that can be aggregately reported include incidents that involve fewer than 200 birds or 5 mammals. The aggregate incident reports lack details including information on effects, specific taxa involved, and descriptions of use. The Avian Incident Monitoring System (AIMS) is similar to IDS, however, it only contains incident data involving birds.

For ecological incidents involving animals in the IDS database, mortality is the most common effect reported. Most of the reports in the IDS database are from incidents that occurred in the United States; however, a small number of foreign incidents are also included in the database. Foreign incidents are included in the database to supplement the available U.S. incidents; they can provide useful information on potential routes of exposure and effects for pesticides also registered in the U.S, although the relevance of foreign incidents depends on the degree to which current labels, formulations, and application practices are similar to those used in the US.

Wildlife incident reports in the IDS database are given a certainty index classification [*i.e*., ‘unrelated’, ‘unlikely’, ‘possible’, ‘probable’, ‘highly probable’– and the relatively new classification of ‘exposure only’ (residues detected but no effects noted)]. The certainty level indicates the likelihood that a particular pesticide caused the observed effects. In general, “highly probable” incidents require residues and/or clear circumstances linking the exposure to the effects. “Probable” incidents include those where residues are not available and/or circumstances are slightly less conclusive than for “highly probable.” “Possible” incidents are those where there was exposure to multiple chemicals, and it is not clear which one was the primary causal factor however, circumstances surrounding the incident and toxicological properties of the pesticide suggest a possible causal relationship. “Unlikely” incidents are those for which evidence suggests that another pesticide or another stressor was the primary cause of the effect, but contribution by the given chemical cannot be completely ruled out. Finally, “unrelated” incidents are those in which evidence clearly indicates that another stressor besides the given pesticide caused the effects. Each incident in the IDS database is also given a legality of use classification [‘registered use’ (the label directions were followed), ‘misuse’ [label directions were not followed; for example, the application involved (accidental or intentional) higher than labeled rates, non-labeled application sites, or the intentional targeting on non-labeled species], or ‘unknown’ (it in not known whether or not the label directions were followed)]**.**

The available incident data are evaluated for relevance based on EFED’s current incident guidance[[1]](#footnote-1)[1].  This evaluation includes decisions on which incidents to exclude from further consideration (*e.g*., because they were determined to be unrelated to a pesticide). An analysis of the combined knowledge obtained from all of the "included" incidents is conducted, along with a characterization of the certainty of the incident information in identifying exposure pathways that lead to risk to plants and/or animals in the field. Factors that are considered in this analysis include the following: certainty level of the incidents; legality determination of incidents; number of incidents; number of animals and/or plants affected in the incidents; evidence of exposure revealed through residues measured in tissue and environmental samples; the agreement of observed incidents with risks predicted by risk assessments; the agreement of observed incidents with risks predicted by laboratory and field studies; patterns of certain types of uses causing certain types of incidents; and evidence that incidents occurred from typical circumstances versus unusual circumstances.  Special emphasis is placed on reported incidents involving any federally-listed species.

1. [1] Guidance for Using Incident Data in Evaluating Listed and Non-listed Species Under registration review. Environmental Fate and Effects Division, Office of Pesticide Programs, US Environmental Protection Agency, Washington, DC.  Oct. 13, 2011.  \\dccx150-opp01\OPP-EFED-SHARE\Information Resources\Websites\policy\_guidance\eco\_risk\_effects.htm [↑](#footnote-ref-1)