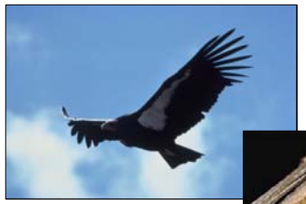

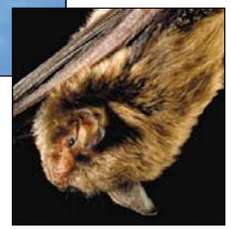

ENDANGERED SPECIES AND PESTICIDE USE: DOCUMENTING RISK MANAGEMENT DECISIONS AND THEIR SUPPORTING SCIENTIFIC ASSESSMENTS

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ABSTRACT

The Endangered Species Act requires that every agency taking an action ensure that in so doing it does not harm endangered species. For actions on pesticide registrations, the scope of which potentially includes all pesticide actions, this is a complicated process. The evolving science, driven also by evolving regulations, has been the subject of several previous SETAC presentations. The Counterpart Regulations, defining how EPA and the Services interact in this process, and EPA's Overview Document on the risk assessment process, describe the documentation standards of the risk assessment/risk management process. At SETAC 2005, a poster was presented on how the assessment was done; this presentation gives information on how documentation standards are met. Pesticide risk management decisions are complex, drawing on extensive scientific testing, interpretation and extrapolation. Therefore, consistency in and retrievability of those decisions and the information supporting them are critical to the understanding and success of the subsequent programs implemented in the field. The FIFRA Endangered Species Task Force (FESTF) has developed an Information Management System (IMS) that can be used to thoroughly document the species assessment process, so that conclusions and the uploaded documentation on which they are based can be stored, interactively reviewed during the action evaluation process, and historically retrieved. The IMS is critical to achieving the clarity and documentation goals of endangered species assessment with respect to pesticide registration. We demonstrate here how an assessment is approached and documented using FESTF's Information Management System and species data, which, when submitted electronically, then support EPA-OPP endangered species risk assessment and risk management decisions.

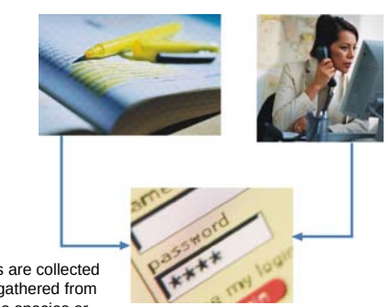
ASSESSMENT APPROACH: RESEARCH AND SYNTHESIS

The endangered species analysis process begins with problem formulation and also defines the action taken and action area. The findings on which an endangered species analysis is based are drawn from a screening level risk assessment that is responsive to EPA-OPP's Overview Document. The initial pesticide risk assessment serves as a screen to determine the need for a national level endangered species analysis. The national level analysis will evaluate threatened and endangered species and their critical habitat found to be potentially at risk in the screening level exercise. The national level analysis refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, or other species, use or location attributes. If there are exposure concerns that cannot be resolved in the national level risk assessment, those species-use-location combinations may be subject to further, in-depth location or species-specific risk assessment to better characterize risk or exposure.

The relationship of the use site and species of interest is evaluated and conclusions are explained and recorded in the IMS

ASSESSMENT DOCUMENTATION: RECORDS AND REFERENCES

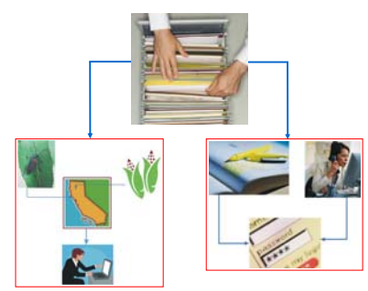
The IMS allows the user to record analytical thought as well as references and full, uploaded documentation supporting the analysis. Output from the basic functionality of the IMS on species locations, pesticide use locations and existing management decisions are documented. Information documented can include any information provided by an Agency, expert, registrant, or publicly available resource. For example: use labels for the product under evaluation can be uploaded, allowing the reviewer to ensure which version of labeling is relevant to the assessment. Other helpful records include screening-level or refined assessment values; EPA-OPP reviews that offer risk management strategies; PDF files from web page references; and published articles. In the specific comments relevant to the uploaded document, the user of the IMS can insert document-specific and general comments to explain why the references are useful and how they were interpreted or applied in the evaluation process. The final result is a manageable and accessible documentation of analyses that support risk management decisions.



As resources are collected or opinions gathered from experts on a species or area, details and reference documents are recorded in or uploaded to the IMS.

ASSESSMENT CONSISTENCY: RETRIEVAL AND REPEATED USE

EPA-OPP has set goals in endangered species assessment that will help achieve transparency, clarity, consistency and quality of endangered species analyses. While this is an emerging process, it is well supported by the IMS because the information gathered during and recorded by the specific assessment process is available, when relevant, for application in the next visitation of data relevant to a particular species, location and use. The IMS recalls data and informs the user of its points of relevancy so that an informed decision can immediately be made regarding the use of existing research in new assessment conclusions. Such recall and accumulated knowledge in a readily retrievable form contributes to the expediency, consistency and depth of an endangered species analysis when an assessor using the IMS moves from one situation to a subsequent, similar circumstance.



Using the accumulated data in IMS, the assessor can recall relevant data and immediately evaluate it for relevancy to risk management decisions in similar use, location and species situations.

CONCLUSIONS

The IMS brings structure, efficiency and quality to the endangered species effects determination process for pesticides:

- Consistent access to quality data
- Efficient and transparent support to assessments and decisions
- Rigorous documentation of the assessment and decisions based upon it
- Efficient and effective use of resources
- Continual improvement of utility through increasing value with each use

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