Identification, Selection and Use of "Best Available Data": Building a Regulatory Data Inventory for an Expert System to Assess Threatened and Endangered Species Protection Requirements for Pesticides

Authors: Tilghman Hall (Bayer Corp.); Mike McKee (Monsanto Company); Bernalyn McGaughey, Matt Kadlec (Compliance Services International)

FESTF FIFRA Endangered Species Task Force

ABSTRACT

The FIFRA Endangered Species Task Force, LLC (FESTF) is comprised of more than a dozen agrochemical companies and was formed in response to regulatory data requests generated by the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP). Within the OPP, the Field and External Affairs Division (FEAD) is charged with managing threatened and endangered (T&E) species issues. The work undertaken by the FESTF is designed to meet regulatory requirements described in Pesticide Registration Notice 2000-2, dated 17 April 2000. Uniform delivery of the review elements required by the Notice will improve the consistency and quality of information available on T&E species for making decisions on pesticide use. The information presented here projects progress since SETAC 1998. The fundamental effort continues to be development of access to existing information on status, location, and protection of T&E species. Construction of an Information Management System (IMS) has taken place. The IMS software enables pesticide registrants and the EPA to process T&E species data for use in the registration of pesticides. The system was conceived to provide a constantly refreshed but quality-controlled data source so that users comply with the "best available data" requirement of the Endangered Species Act (ESA). Methods used in locating, compiling and assessing the "best available data" for T&E species are described here. FESTF continues in its commitment to develop access to existing information on T&E species, providing for uniform evaluations of potential pesticide use on a county-wide basis.

INFORMATION MANAGEMENT SYSTEM (IMS)

IMS Process

Simplified Process Chart for IMS

Purpose: The IMS is intended to provide a more efficient, effective, and uniform method of species protection related to agricultural pesticide use.

Usages: By making the registration process more transparent and uniform for all parties involved, the IMS assists pesticide registrants and the EPA in assuring that potentially exposed species are protected, and provides a mechanism to build sound new protections where needed.

- EPA-OPP will use the IMS to evaluate products belonging to Task Force members.
- Member companies will use the IMS to evaluate their own products prior to sending them to EPA for independent evaluation.
- The system can be used to determine which species of vulnerable tax in proposed locations are at risk and how they currently are or can be protected (see "Threatened & Endangered Species Risk Report" screen).
- EPA-OPP user privileges are built into the system that protect individual Company data, and EPA's ability to control the validity of decisions "accepted" in the IMS.

"Create Use" Screen

"Create Use" screen allows users to select conditions for assessment of a pesticide product to selected T&E species.

BACKGROUND

Pesticide Registration Notice 2000-2
The Notice, directed to manufacturers, producers, formulators and registrants of pesticide products, announced the formation of an industry-wide Task Force in response to EPA data requirements concerning the potential impact of pesticides on threatened and endangered species.

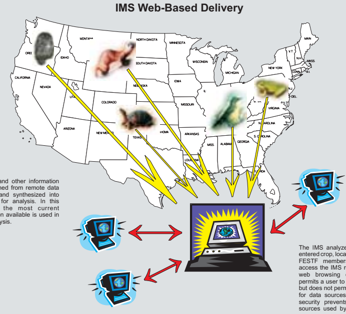
As part of the pesticide registration and re-registration process, EPA requires supporting data to assure that the pesticide under review meets T&E species protection requirements under the FIFRA and ESA. Where appropriate, EPA can require data on T&E species locations as part of the registration process. Such requests are primarily based on the properties and proposed use(s) of a given pesticide.

Pesticide registrants who have: (1) existing conditions on a registered compound; (2) received a Data Call-In Notice; or (3) believe they will have to satisfy T&E species locality information requirements for their product(s) now have the option of addressing these data needs through participation in FESTF.

If the registrant or applicant elects to participate in FESTF's effort to satisfy any appropriate data requirement(s), then the registrant or applicant must inform EPA of its decision. In addition, the applicant must provide evidence of its membership in the FESTF or evidence that it has complied with the applicable data compensation requirements of FIFRA.

The IMS Database
The IMS is a relational database containing over 70 different tables. Existing information was gathered as "content data" for insertion into several tables. Other types of data are "system", which are generated by the IMS, and "product", which will be entered by users as they evaluate products.

IMS Web-Based Delivery



Species and other information are obtained from remote data sources and synthesized into the IMS for analysis. In this manner, the most current information available is used in each analysis.

The IMS analyzes a scenario based on user-entered crop, location and compound information. FESTF members and EPA-OPP users can access the IMS remotely from any site that has web browsing capabilities. Remote access permits a user to use the IMS from any location, but does not permit the user to "browse the web" for data sources for the IMS to use. System security prevents unauthorized use. All data sources used by the IMS are predefined and

THREATENED & ENDANGERED SPECIES PROTECTIONS TABLE

Protections Tables
A Protection is a method used to protect vulnerable T&E species from a pesticide product. There are currently **103 Protections** used in one or more counties, for one or more AIs, to protect one or more T&E species associated with one or more crops. These multiple relational layers in the table have produced a total of more than **150,000 Protection records** compiled from a variety of sources.

An Exclusion is a regulatory acknowledgment that a T&E species is not present or not reasonably expected to be present in the intended use site either permanently or during the time pesticide application or persistence occurs. Some examples of Exclusions are:

- Exclusion of restriction if application is soil-incorporated.
- If acceptable formulation is used, formulation restriction does not apply.
- Agricultural land use exclusion.

Exclusion and Lack-of-Impact decisions that have actually been made by EPA-OPP in their assessment process will be added later. Addition of such data as a "valid" decision will only be possible by authorized EPA staff.

Among the fields contained in the table are:

PE_Desc Description of the protection. Required if the Option Type is not a Generic Restriction Code (GRC*).

Appl_Meth_Type An application method classification. Example values are: Ground, Aerial, Both, Other, Any.

Formulation_Type A pesticide formulation classification. Example values are: Granular, Non-Granular, Either.

Status_Cd Valid status names are: Conditional, Valid, Rejected. Status is the assessment response entered by the EPA Endangered Species Assessor.

- Valid (Protection approved by the EPA after review. Examples: County Bulletins, Habitat Conservation and Recovery Plans.
- Conditional (Protection proposed by a company or EPA user, but not yet EPA approved. Examples: Results of a Risk Assessment, Results of a GIS analysis examining species/crop interaction)
- Rejected (Protection rejected by the EPA Endangered Species Assessor)

Status_By Unique name assigned to the user who entered the status_cd.

Status_Date Date that the status_cd was set.

Recommendation_Cd Values are RA for Recommend Approval; RR for Recommend Rejection; RM for Recommend More. This is the assessment response entered by the EPA Risk Assessor.

Recommendation_By Unique name assigned to the user who entered the recommendation_cd.

Expert_Contact_ID Generated identifier for the Expert Contact if an expert assisted in creating this P/E.

Released_Sw A Y/N/Null switch indicating whether the PE has been released. Released means that a company has released a Label Use Set to the EPA. This is done when a Company has decided they are ready to let EPA-OPP see information for a new product so that EPA-OPP can begin its review.

Release_Date Date the PE was released to EPA for approval. For EPA, this is the date that the PE was released for viewing by the company.

EPA_Gen_Sw Whether this PE was generated by the EPA or not.

Concentration_Desc An informational-only field to describe the concentration range of the AI in the pesticide formulation for which this PE is valid.

Application_Rate_Desc A free form field to describe the application rate or range of rates covered by this PE.

Prot_Cd An EPA ID for the Protection Code. Required if the Option Type is GRC.

Option_Type_ID IMS generated ID.

Copied_From_PE_ID IMS generated identifier for the protection that this P/E was copied from.

Data_Src_Name Name of the data source. Example is 'Wallowa County, OR County Bulletin'.

Data_Src_Date Date the PE data source was issued/approved.

Data_Src_URL The URL to access this document via the Internet.

Data_Src_Desc Description of this data source.

Date_Modified Date and time the record was inserted or changed. Example is 1999-10-07 09:59:00.130 meaning Oct 7, 1999 just after 9:59 am.

Modified_By The User Name of the person who inserted or last modified this record.

Deleted_Sw Whether this PE has been logically deleted. Valid choices are Y and N. A PE can also be physically deleted under certain circumstances.

*Two examples of Generic Protection Codes

Protection Code	Description
32a	Do not apply this pesticide on rights-of-way in the species habitat (described under the Shading Key).
33	Do not apply within one-quarter mile of species habitat.

An example of another type of Protection

Ca31	Use is prohibited from October 1 through April 30, EXCEPT: a) in cultivated areas, or b) on the water side of water supply channels.

THREATENED & ENDANGERED SPECIES TABLE

The Protections table is linked to several supporting tables that contain data on T&E species and other information. One example is the Biological Classification table. The **Bio_Class table** has information used in identifying the species, genus, taxa, etc. Some of the fields are described below:

Bio_Class_Type Type of biologic classification. Choices are S for Species, G for Genus, and T for Taxa.

Scientific_Name The scientific name for this biological classification. For example *"Haliaeetus leucocephalus"* for the species Bald Eagle.

Common_Name The common name for this biological classification. For example Bald Eagle as a species.

Lifeform Aquatic, terrestrial, or both. Required for species only.

Date_Entered Date the record was originally created.

Date_Modified Date and time each record was inserted or changed. Example is 1999-10-07 09:59:00.130 meaning Oct 7, 1999 just after 9:59 am.

Modified_By The User Name of the person who inserted or last modified this record.

Deleted_Sw Whether this biological classification has been deleted. Valid choices are Y and N.

Bio_Class_ID IMS generated identifier for a biological classification.

EPA maintains a current list of T&E species as well as proposed, withdrawn, and delisted species. Where available, EPA has county-specific location data for these species. To prepare this list for the IMS and to establish referential integrity from it to the Protections table, FESTF identified the correct scientific binomial and associated common names for each species using information from the U.S. Fish & Wildlife Service (USFWS), Code of the Federal Register (CFR), and Integrated Taxonomic Information System (ITIS). This list was corrected by adding missing information.

The final list was edited to remove species considered by the EPA to be wide-ranging species. These are species whose protections will be managed outside of the IMS, although some wide-ranging species such as migratory birds will be included for consideration in the IMS.

Threatened & Endangered Species Risk Report

THREATENED & ENDANGERED SPECIES LOCATION TABLE

Each species location (by county), scientific name, common name, lifeform, and taxon are listed in the database. The most current EPA-OPP species-locations data set was used to provide information to the IMS. Problems were corrected in this list in order to establish referential integrity. The list was then formatted to make it compatible with the IMS. The Bio_Class_Location table has the location (county level FIPS) of each species. The following information was provided:

Bio_Class_ID IMS generated identifier for a biological classification.

FIPS_cd The FIPS code for the location. The code is a 5 digit number. The first 2 digits represent the state. The last 3 digits represent the county within the state. Examples are 00000 for the United States as a whole, 08000 for Colorado as a whole and 08069 for Larimer County, Colorado.

The Bio Class and Bio Class Location data are accessed using the IMS and are displayed like this:

T&E Species Search

CROPS-RELATED TABLES

The term "Site" is used to denote a place where a pesticide would be applied. The IMS uses Site information to discover where T&E species may need to be protected or to find where they are already protected by restrictions to pesticide applications.

Data on what, how much, and where various agricultural crops occur are periodically gathered by the USDA National Agricultural Statistics Service (NASS). The NASS surveys growers, then reports crop locations by county and acreage of crops. These data are used in the IMS. The names of some of the data fields as used in the IMS are:

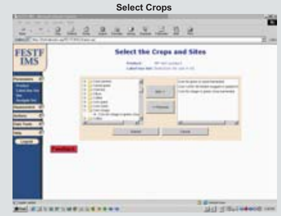
Site_Desc Example, "Durham wheat"

Acres The quantity of land (acres) planted or harvested or irrigated area reported for each crop

FIPS_cd The location (county) for each crop item given using the five-digit County location code

These data are primarily contained in the **Site** and **Use Site Acres** tables in the IMS, which are linked to the Protections table for a few defined crops. However, most Protections do not discriminate between crops, and so apply to all crops.

Select Crops



IMS allows users to select from a list of "Sites" to what crops a pesticide might be applied.

CONCLUSIONS

An Information Management System (IMS) is being developed which provides ready access to a number of databases relevant to evaluating risk of pesticides to threatened and endangered (T&E) species. The best available data on species location, species biology, existing protections, expert contacts, crop information, formulation types and application methods, have been included in the IMS.

The USDA National Agricultural Statistics Service periodically provides county location and crop acreage updates. The U.S. EPA-FEAD (Field and External Affairs Division) maintains county location data of T&E species through consultation with the USFWS and regional experts. Both of these databases are integral to the functioning of the IMS.

The ultimate goal of the project is to provide timely and equitable assessments of potential risks from pesticides during the registration process.

The IMS not only provides access to relevant databases, but also integrates information and facilitates evaluation of endangered species concerns. The IMS assists in assuring that T&E species that could be potentially exposed to pesticides are protected, and provides a mechanism to build sound new protections where needed.

ADDITIONAL INFORMATION

For further information on the FIFRA Endangered Species Task Force, please contact the following individuals:

Administrative Chair
Mike McKee
Monsanto Company
800 North Lindbergh Blvd. C2SE
St. Louis, MO
Ph: 314-694-883863167
Fax: 314-694-4028
Michael.J.McKee@Monsanto.com

Technical Chair
Tilghman Hall
Bayer Corporation
17745 S. Metcalf Ave.
Stilwell, KS 66085
Ph: 913-433-5362
Fax: 913-433-5389
tilghman.hall.b@bayer.com

Project Manager
Bernalyn McGaughey
Compliance Services International
1112 Alexander Avenue
Tacoma, WA 98421
Ph: 253-272-6345
Fax: 253-272-6241
BMcGaughey@ComplianceServices.com

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FESTF Company Members

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