

# Mechanisms to Access and Apply Scientific and Commercial Data to Address the Legal Requirements of FIFRA and the Endangered Species Act

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## ABSTRACT

The FIFRA Endangered Species Task Force (FESTF) is comprised of agrochemical companies and was formed in response to regulatory data requests generated by the EPA's interim Endangered Species Protection Program (ESPP) managed by the Field External Affairs Division (FEAD), within EPA's Office of Pesticide Programs (OPP), and is charged with managing OPP's threatened and endangered species ("T&E species") issues. The project described here is undertaken by the FESTF to meet their regulatory requirements by improving the consistency, quality, availability and use of existing information on T&E species and pesticide use. The foundation of this effort will be the development of access to existing information on T&E species, as well as a mechanism to consistently process the accessed data for use in the registration of pesticides. Consistency in the evaluation of endangered species with respect to pesticide use and impact will be achieved by providing (1) criteria for core elements that should meet minimum standards; (2) types of species data that should meet minimum data standards; (3) the relative ranking of the importance of various data elements or "fields"; and (4) minimum standards to assure a high level of data quality and accuracy.

## PROBLEM STATEMENT

The complexity of agricultural crop protection processes, regulated under FIFRA through EPA, and the dynamic state of listing and monitoring non-target species affected by the ESA (Endangered Species Act) as enforced by USFWS presents tremendous challenges in data assessment. OPP must balance its ability to provide protective mechanisms with the dynamics of local interactions and change while dealing with highly local and variable information sources. Very often, local information is the best source on the relationship between cropping practices and sensitive species, but the mechanisms of law must provide a way to ensure that protective steps are taken where necessary. The problem then becomes that of managing constantly changing information from localized sources so that reliable decisions can be made over time.

## BACKGROUND ON THE PROCESS

EPA OPP is required to assure that its practices comply with the ESA. In the area of pesticide use and assessment, this means that the labels and label language granted by EPA to registrants of these materials must provide for the protection of federally listed threatened and endangered species. However, specific language is impossible to develop for every local situation that might arise. Therefore, an interim communication system, through county bulletins and other mechanisms, has extended the protections provided by the pesticide label when it comes to the interaction of crop cultural practices and sensitive species or habitats. Over time, however, EPA has experienced difficulty in accessing the data necessary to keep such a mechanism current and correct. As a consequence, EPA OPP, through mechanisms available to them under FIFRA, appealed to the registrants to develop data that might assist in their efforts to comply with the ESA.

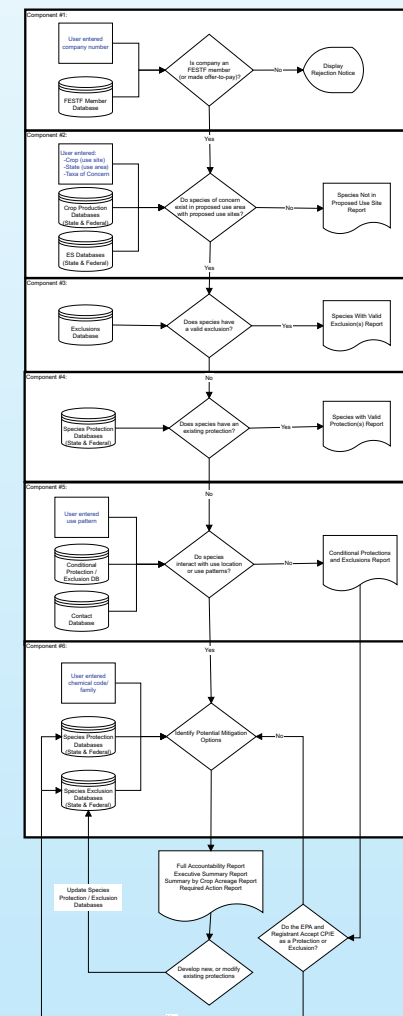
After an extensive research process, including testing data collection and assessment theories through a feasibility study, both EPA OPP and the registrants realized that it was not a one-time collection of data that was important. Instead, what was needed was a means to handle constantly changing data and its use in risk assessments. In short, the development of an expert information management system ("IMS") was conceived as the means by which this challenge could be met.

## COMPONENTS OF THE SOLUTION

Through a series of meetings and workshops, EPA and agrochemical company scientists were able to identify the critical interactions that need to take place in an information management system. Those components include (1) a management system capable of "sifting through" the information sets delivered to it; (2) baseline data and a means to enter new data consistently over time; and (3) quality criteria for the operation of the system and the use of data it accesses. Thus the system becomes a means to house and retrieve data, and run analyses on the relationship between pesticide use and listed threatened and endangered species.

In the flowchart to the right, the IMS is broken down into a series of six conceptual components, each addressing a specific issue that must be addressed in the assessment of an endangered species evaluation. The system provides a feedback mechanism for adding new conditional protections and exclusions.

In the lower left graphic, the distributed concept of the IMS is illustrated. The system will obtain data needed to operate from a number of sources and synthesize the information in a central server system. Users can access the IMS from any remote site through using a standard web browser such as Netscape Navigator or Microsoft Internet Explorer, and by logging in using a valid user name and password.



## PROCESS OF DEVELOPMENT

In the development of any system, the concerns of those affected by it or using it need to be addressed. In this case, state, local and federal regulatory needs and procedures exist, but are not always known from one political jurisdiction to another. Growers are very concerned that their practices are not unduly restricted by overly conservative decisions or by use of inaccurate or untimely data that doesn't take into consideration the specifics of the local situation. The registrant is concerned that products can be used safely, without overly burdensome needs for local data development or label restrictions. OPP, in carrying out its responsibilities under FIFRA and ESA, seeks to be properly protective of the environment and the pesticide user community and is also concerned about its ability to access and utilize high quality data. Once the information management system was generally designed, FESTF attended meetings with growers, the affected industry, state representatives and EPA in a needs assessment process.

Once the needs assessment process was completed, the work of designing the system was subdivided into three sections: "Input", for the review and selection of appropriate data sources; "Output", for the development of system reporting parameters and their design; and "System Design", for the design of mechanisms by which the information management system should combine the "input" to provide the desired "output".

The FESTF is now at the point of implementing the design process for the IMS. This, too, will proceed in stages: first, the building and alpha testing of a model; second the corrections needed for the model to provide the desired output; third, beta testing of the model; and fourth, the installation of a mature system and its use in the assessment process.

A part of the commitment that FESTF has made to OPP includes FESTF's participation in a Cooperative Research and Development Program (CRADA) to be administered by EPA's Office of Research and Development (ORD) in conjunction with EPA's Region 3 Office and the Office of Information and Resource Management (OIRM). The goal of this Agreement is to enable EPA to achieve state by state access to existing T&E species data through the OIRM multi-jurisdictional database (MJD) initiative. The MJD will provide efficient, cost-effective access to the data that are widely recognized as the highest quality, most comprehensive sources of this type of data available. The efforts resulting from this CRADA are intended to provide for the development of procedures to allow participants of this Agreement to have access to high-quality T&E species data, aggregated with the appropriate metadata, in a georeferenced system suitable for the development of risk assessment models and risk reduction measures.

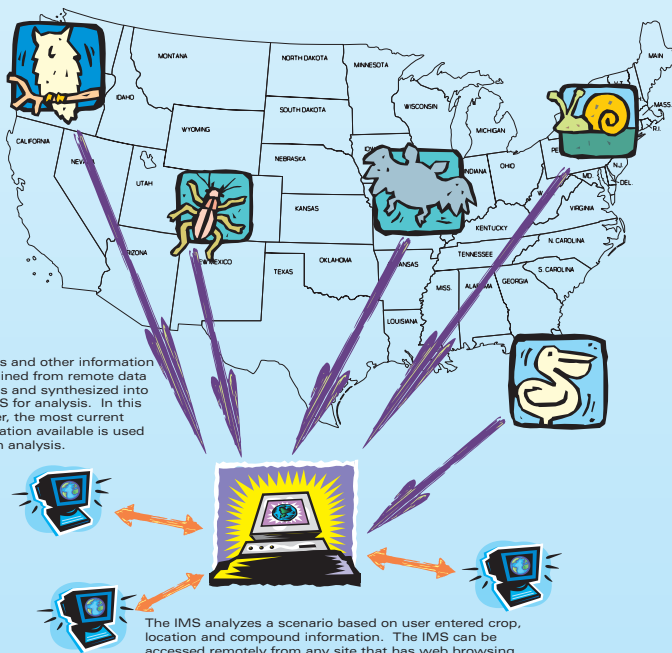
Each participant has different requirements for the use of and access to T&E species data. ORD is involved in ecosystem effects, exposure and risk reduction research requiring access to these data. OIRM is responsible for cost-effective dissemination of data for efforts in assessing the risks of environmental contaminants and other stressors on the Nation's wildlife resources. OPP and the FESTF need access to a given set of T&E species data for the express purpose of enhancing the knowledge base for performing the pesticide risk assessments necessary to meet pesticide registration requirements under FIFRA. While each program is different and encompasses separate analyses, access to an MJD containing T&E species information has been identified as a common need of the participating parties. Provision of a means to meet that common need is the goal of this effort.

Throughout this process, FESTF and OPP desire to have local and state input on how existing resources and data might be used to populate and maintain the accuracy of the analyses that are being conducted. Through this poster, FESTF invites viewer's comment by directly contacting FESTF committee chairs, its project manager, or by making inquiry through our website at [www.FESTF.org](http://www.FESTF.org).

## ADDITIONAL INFORMATION

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

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Species and other information is 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. The IMS can be accessed remotely from any site that has web browsing capabilities. The 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. All data sources used by the IMS are predefined and approved.