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FIFRA Endangered Species Task Force: Information Packet

October 2005

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Dow AgroSciences, LLC

DuPont Crop Protection
FMC Corp., Ag. Products
ISK Biosciences Corporation

Monsanto Co.
Nichino America, Inc.
Nissan Chemical Industries, Ltd.

Nufarm Americas, Inc.
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Valent USA Corp.

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Regulatory Requirements

EPA Pesticide Registration Notice 2000-2

**The FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) Endangered
Species Task Force**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 17, 2000

Pesticide Registration (PR) Notice 2000-2

**NOTICE TO MANUFACTURERS, PRODUCERS,
FORMULATORS AND REGISTRANTS OF PESTICIDE
PRODUCTS**

ATTENTION: Persons Responsible for Federal Registrations and Reregistrations of Pesticides

SUBJECT: The FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) Endangered Species Task Force

I. Introduction

This PR Notice announces an industry-wide Task Force that has been formed in response to EPA data requirements related to the potential impact of pesticides on threatened and endangered species ("endangered species"). This Notice also contains an EPA contact and a Task Force contact for persons wanting further information.

II. Summary

The FIFRA Endangered Species Task Force (FESTF) was formed in December, 1994 to share in the cost of developing data required by EPA of applicants or registrants, some of whom are member companies of the FESTF, relative to the potential impacts of pesticides on endangered species. FESTF has been organized to develop information sufficient to address FIFRA data requirements imposed on registrants. The work product to be accomplished by the Task Force may provide necessary information for many pesticide product reregistrations in the United States. The Task Force's work likely will address certain new product registration data requirements as well. Because of the wide cross section of pesticide registrants who could potentially benefit from this endeavor,

EPA by this notice informs all pesticide registrants of the existence of the FESTF.

III. A Task Force to Satisfy Data Requirements

EPA as part of the registration and reregistration process, reviews pesticide products to assure that pesticides meet FIFRA and ESA requirements to protect endangered species. The Agency intends to impose data requirements on endangered species locations as part of each registration and reregistration action wherever appropriate based upon the properties and proposed uses of the pesticide in question. Pesticide registrants who have conditions of registration, or have received a Data Call-In Notice requiring endangered species locality information for their product(s) have the option of addressing these data requirements through participation in FESTF. In addition, any pesticide registrants or applicants who have not yet received a specific request from EPA for endangered species locality information but who believe they will have to satisfy such requirements in the future also have the option of addressing these data requirements through participation in FESTF. If the registrant or applicant elects to participate in FESTF's efforts to satisfy an appropriate data requirement(s), then the registrant or applicant must inform the agency of its election of this option when notified of the data requirement and provide evidence of its membership in the Task Force or evidence that it has complied with the applicable data compensation requirements of FIFRA.

IV. Joining the FESTF

The Agency is not a participant in the Task Force but is available as the Agency deems appropriate to provide regulatory and technical guidance and assistance relating to the development of the work product the Agency is requiring from FESTF. The following information was supplied to EPA by the FESTF for the benefit of registrants and applicants interested in joining the Task Force. The FESTF is organized under a FIFRA joint data development and limited liability company agreement with costs shared equally by all participants. Membership is available for a period of six months from the date of issuance of this PR Notice by means of a payment of all prior member assessments, adjusted for interest. Thereafter, membership is available by paying all assessments, interest, and certain late fees. Each participating company has the right to appoint one representative to each of the Administrative and Technical Committees of FESTF. Those desiring further information on the Task Force may contact the following persons:

Harold Himmelman, Counsel, Beveridge & Diamond, P.C. (202) 789-6012

Jennifer Shaw, Zeneca Agricultural Products, Technical Chair (302) 886-1225

V. What the FESTF will do.

The work product expected to be developed and submitted by and through FESTF consists of three elements:

- the development and submission by FESTF of an Information Management System (IMS) that EPA can use to screen pesticide applications when their applications trigger

- potential endangered species issues;
- funding by the FESTF through a Cooperative Research and Development Agreement (CRADA) of a state by state species access program to be undertaken by EPA that will enable EPA to access high quality species locality data to validate the IMS;
- a quality test of the IMS, based in part upon information collected by EPA pursuant to the CRADA.

If a registrant or applicant must satisfy endangered species locality requirements, it may (a) join the FESTF; (b) cite to FESTF's work and offer to share costs with FESTF; or (c) submit its own information providing the information is of sufficient quality to meet FIFRA and ESA requirements.

Because the Agency views each of the elements of FESTF's work as essential to the creation of a high quality endangered species Information Management System, applicants and registrants citing to the work of the FESTF should be aware that any offer of compensation made that cites to the work of FESTF will extend to all three elements of FESTF work. Accordingly, applicants who cite to FESTF's work may be obligated to pay compensation for all three elements of FESTF's work. In accordance with FIFRA, in the event that the FESTF and a non-member who cites to FESTF's work are unable to reach a cost-sharing agreement, the terms and amount of compensation shall be determined by arbitration, as provided in sections 3(c)(1)(F) and 3(c)(2)(B) of FIFRA.

It is possible that certain atypical use patterns, uncommon formulations, or other situations may arise for which EPA might require separate data from an applicant or a registrant that would not be available through the work performed by the Task Force.

Participants in the Task Force individually and separately assume the responsibility of complying with the data requirements for their various products by the deadlines set by the Agency, and must understand and accept the risk involved in the possible failure of the Task Force to meet those deadlines, or to provide a satisfactory work product to address applicable requirements. Any deadline extensions and waivers for any of the relevant data requirements must be requested from the Agency individually by applicants and registrants on a case-by-case basis.

This PR Notice is issued by the Agency for the sole purpose of informing pesticide registrants of the formation of the FIFRA Endangered Species Task Force. It is not intended to define or restrict the terms of or subsequent amendments to the joint data development agreement and its operation.

V. For Further information

For questions or further information regarding formation of the FESTF, please contact Larry Turner at (703) 305-5007.

/s/ Marcia Mulkey, Director
Office of Pesticide Programs

Regulatory Requirements

Federal Register Notice of March 11, 2005 (70 FR 12276)

Environmental Protection Agency 40 CFR Parts 152 and 158 [OPP-2004-0387; FRL-6811-2] RIN 2070-AC12 – Pesticides: Data Requirement for Conventional Chemicals. Proposed Rule (*excerpt relevant to endangered species data*)

[Federal Register: March 11, 2005 (Volume 70, Number 47)]
[Proposed Rules]
[Page 12276-12353]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr11mr05-29]
[[Page 12277]]

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Parts 152 and 158
[OPP-2004-0387; FRL-6811-2]
RIN 2070-AC12

Pesticides; Data Requirement for Conventional Chemicals

AGENCY: Environmental Protection Agency (EPA).
ACTION: Proposed rule.

SUMMARY: EPA proposes to update and revise its data requirements for the registration of conventional pesticide products. These data requirements and those already codified in part 158 of title 40 of the Code of Federal Regulations (CFR), are intended to provide EPA with data and other information necessary for the registration of a conventional pesticide chemical. Since the data requirements in part 158 were first codified in 1984, information needed to support the registration of a pesticide chemical has evolved as the general scientific understanding of the potential hazards posed by pesticides has grown. Over the years, updated data requirements were developed by EPA using a process that involved public participation and extensive involvement by the scientific community, including peer review by the FIFRA Scientific Advisory Panel (SAP). Most of the data requirements contained in this proposal have been applied on a case-by-case basis to support individual applications, or imposed via Data Call-In (DCI) on all registrants of similar products. Although the data requirements imposed have progressed as scientific understanding and concerns have evolved, the codified data requirements have not been updated to keep pace. This proposal involves changes to the codified data requirements that pertain to product chemistry, toxicology, residue chemistry, applicator exposure, post-application exposure, nontarget terrestrial and aquatic organisms, nontarget plant protection, and environmental fate. Coupled with updating data requirements, EPA proposes to add a few new studies, reformat the requirements, and revise its general procedures and policies associated with data submission. By codifying existing data requirements which are currently applied on a case-by-case basis, the pesticide industry, along with other partners in the regulated

community, attain a better understanding and are better prepared for the pesticide registration process. This proposed rule does not apply to the data requirements for the registration of antimicrobial pesticide products; inert ingredients for pesticide products; spray drift, product performance (efficacy); or biochemical, and microbial pesticides.

EXCERPT FROM PAGES 12292 – 12293 OF THE NOTICE

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C. Data Requirements Specific to Endangered Species Assessments and Determinations

Over the last several years, the Agency has been requiring, on a case-by-case basis for certain pesticides, data demonstrating specific geographic location(s) of threatened and endangered species (listed species), which can then be compared with areas of potential pesticide use. These data have been required when EPA determined that the estimated environmental concentration of the pesticide when applied according to the labeling appears to exceed the Agency's numeric concern levels for listed species. The specific species for which location information was needed, has been determined on a case-by-case basis based upon the use pattern of the pesticide and the sites on which it may be used. These special data are currently not required by part 158, and have only been requested on a few occasions; however, the Agency anticipates that they may be requested in the future in connection with other registration and reregistration actions. In response to a Data Call-In notice for data on the location of all listed species, an industry task force is working to develop a database that may partly fulfill Agency needs, i.e., geographic locations where potentially affected species are thought to occur. Access to the task force data by other registrants who may be required to provide such data in the future would be made available through appropriate data sharing mechanisms. Although the anticipated expanded burden on registrants is not large since it does not entail experimental or laboratory procedures, it is nevertheless not likely to be inconsequential. Consequently, the Agency is requesting comment on its utility and appropriateness.

In addition, through discussions about methods to evaluate the potential risks of pesticides to listed species, EPA and the Fish and Wildlife Service and the National Marine Fisheries Service (jointly referred to as the Services) identified several aspects of EPA's current approach for which there is some scientific uncertainty. While the Services agreed that EPA was using the best available scientific and commercial information to assess risks to listed species, the Services and EPA also agreed that where uncertainties existed, further research and investigation might help to develop improved risk assessment approaches. The Agency recognizes that such research also could lead, in the long run, to additional data requirements for registration. Accordingly, the Agency seeks input on research areas that may be necessary to effectively

characterize potential risks to listed endangered species from pesticide use. These include research to address the following types of uncertainties:

- Product use information by geographic location below the state and county levels
- Toxicity data and environmental fate measurements/exposure model predictions with end use products
- Toxicity data from surrogate species that quantify dose-response relationships for effects relevant to critical life stages of endangered species
- Measured or estimated values of physiological, biochemical, and morphological characteristics of endangered species and surrogate species to refine chemical-specific interspecies toxicity extrapolations
- Toxicity, exposure, uptake and elimination data to better determine any differences in interspecies sensitivity of non-target and endangered plant species exposed to herbicides
- Toxicity data to characterize potential effects to freshwater mussels
- Toxicity data to characterize potential effects to reptiles and amphibians.

The Agency seeks comment on:

1. The relative value of each of these research areas in better refining assessments of potential risks to listed species.

[[Page 12293]]

2. Input on specific research directions in these areas, including methodologies, protocols etc., that would be appropriate and useful in assessing the potential risks to listed species.
3. Other types of research that would be of value in refining potential risks of a pesticide to a listed species.
4. The extent to which potential research areas reflect uncertainties that apply to pesticides generically; to chemical stressors generically, or to types of pesticides or chemicals stressors.

Task Force Information

FIFRA Endangered Species Task Force Overview

(August 23, 2005)

FIFRA ENDANGERED SPECIES TASK FORCE: OVERVIEW

August 23, 2005

1. What is the FIFRA Endangered Species Task Force?

The FIFRA Endangered Species Task Force (FESTF) is a limited liability company composed of 15 agrochemical companies who are meeting EPA-imposed pesticide registration requirements under the Federal Insecticide, Fungicide and Rodenticide Act. Membership in FESTF is open to those companies affected or potentially affected by endangered species pesticide registration requirements under FIFRA and the Endangered Species Act. Additionally, some registrants have met their data requirements by relying on task force data and meeting their data compensation obligations owed FESTF. Under this structure:

- *Registrants with and without specific data requirements are participating in FESTF*
- *Registrants have agreed on strategic and technical positions to meet EPA-OPP data requirements using a spirit of cooperation and the best management of corporate and environmental resources*
- *Non-member registrants who have met their data compensation obligations to FESTF can utilize or rely upon task force data for endangered species assessments*

2. Why was the FESTF formed?

As part of its pesticide registration process, EPA-OPP must consider the potential impacts of pesticide use on federally-listed threatened and endangered (T&E) species. In response to requirements from EPA-OPP generated under the authority of FIFRA, FESTF was formed out of a work group that was initiated through the American Crop Protection Association (now CropLife America, "CLA") in 1993. The FESTF was formally incorporated as an LLC in 1997. Between the group's first work under CLA until the EPA issued a PR Notice in April 2000, FESTF investigated and worked with EPA's Office of Pesticide Programs (EPA-OPP) to establish a means of meeting FIFRA endangered species requirements that would result in minimal disruption to the pesticide user community. To reach what would be a meaningful product for EPA-OPP, FESTF

- *Could not meet the original request by EPA-OPP for species location data to assess potential pesticide use and potential endangered species exposure, because the specific deliverable was unclear.*
- *Defined that its goal was to provide EPA with useful data.*
- *Conducted a Feasibility Study and submitted it for EPA review. Using this and other resources, EPA defined the data requirements for FESTF, as outlined in PRN 2000-2.*

- *Met throughout the process with EPA. Both EPA and FESTF also have met with agricultural and environmental stakeholders to discuss their concerns about endangered species and related data.*
- *Submitted IMS 1.1, IMS 2.0 and provided access to NatureServe biological data on species and spatial data on species locations*

3. What is FESTF doing to meet endangered species protection requirements?

After nearly four years of research on endangered species protection mechanisms and subsequent exploration of protection alternatives with EPA-OPP, FESTF developed a program by which FIFRA and ESA requirements will be met by pesticide registrants with a minimal impact on the pesticide user community while still providing the necessary species benefits. The principle of the approach is the development of access to existing information on T&E species locations, so that these locations can be compared to potential pesticide use at the county level of resolution. This approach has been agreed upon by FESTF and EPA-OPP.

The program undertaken by the FESTF to meet its members' regulatory requirements is described in Pesticide Registration Notice 2000-2 dated April 17, 2000. There are three deliverables described in the PR Notice:

1. An Information Management System (IMS),
2. A Cooperative Research and Development Agreement (CRADA), and
3. A quality test of the IMS.

The key component of the second deliverable is access to best available data on listed species, directly provided by an FESTF contract with NatureServe rather than through a CRADA. As a result of an unresolved delay in EPA offices concerning the CRADA (which was intended to be the mechanism to access data from NatureServe) the FESTF instead accessed the data directly from NatureServe, in order to meet the second deliverable without further delay.

The components of the PR Notice produce a unique combination of tools designed to allow the application of new information technologies to the management and protection of endangered species. The deliverables discussed in the PR Notice and since submitted¹ improve the consistency, quality, availability and use of existing information on T&E species for assessing pesticide use. FESTF has developed these deliverables for EPA in a manner that fits EPA's risk management needs.

- *FESTF Subcommittees were established invested many hours in the development and implementation of the project, and met with EPA to seek their guidance*

¹ MRID 46325901: FESTF Information Management System (IMS): Documentation of Structure and Function of IMS 1.1 (submitted to EPA on July 19, 2004); MRID 4648301: FESTF Task Force Information Management System (IMS): Beta-Tested IMS 2.0 and Access to NatureServe Data – Final Report (submitted to EPA on March 1, 2005)

- *Workshops were arranged at key phases of project development to enable subcommittees to make progress on their initiatives. These involved the entire team from FESTF, and work products were presented to EPA for their input and review*
- *A Core Group of individuals from the FESTF maintained communication with EPA to assure the task force's understanding of EPA's intent for implementation of the data requirements*
- *While the workshop format provided an environment of "roll up your sleeves and figure this out," communication with EPA-OPP on a regular basis provided agency feedback on the manner in which data requirements should be met and applied.*
- *Since the submission of IMS 2.0, individual, on-line and group training sessions have been undertaken and will continue as needed.*

5. What are the characteristics of the tools FESTF has developed?

The first tool, and central component of the FESTF-EPA agreement, is an FESTF-proprietary Information Management System (IMS) which accesses and collates existing high quality data on federally-listed endangered species with those data extracted by EPA's risk assessment process on individual compounds. The design of the system allows for it to be periodically updated, assuring the consistent application of the best available scientific data to endangered species protection decisions. The system also provides a mechanism for adding to and reporting on protections in use, as well as capturing spatial or temporal relationships that define whether or not there is a need for the further development of protections. Access to existing high quality data on endangered species is provided through FESTF's contract with NatureServe. Because the IMS is a complex tool, it will not simply be submitted and left in isolation for EPA-OPP:

- *FESTF and EPA-OPP are using the IMS in a case study. The case study will provide detailed information on how the IMS will actually be used by registrant risk assessors and by EPA-OPP risk assessors, endangered species assessors and risk managers to facilitate its implementation and use.*

6. What is this effort expected to produce?

The outcome of this effort will provide reliable access to and quality control of datasets that can then be managed within OPP for the assessment needs of FESTF members (and non-members who properly cite to and offer to compensate the FESTF work products) through the application of the FESTF Information Management System. The work products allow the registrant to collect, archive and submit data and species assessments, while preserving EPA-OPP's authority over if and how that information will be used. As EPA-OPP further develops data access, both with and independently from the NatureServe data, and adopts protection measures for T&E species, the Information Management System will classify new information as provisional if not reviewed and accepted by EPA-OPP, or as final ("valid") if accepted or developed independently by EPA-OPP. Consequently:

- *The designed tools allow registrant input but preserve EPA-OPP's authority, a combination that capitalizes on the resources and regulatory duties of both parties.*

- *In combination with the registration process and the proposed county bulletin development process, all stakeholders have full opportunity to comment on the final action of local species protection under a nationally administered program.*

Task Force Information

FESTF: Summary of Levels of Data Reliance

(July 15, 2005)

**FESTF: Summary of Levels of Data Reliance
(July 15, 2005)**

Level One: Full Membership

Full membership in FESTF may be obtained under the terms of the FESTF LLC agreement, which calculates cost of membership using the total of assessments made per member adjusted by accumulated interest and a risk factor.

Member Rights:

1. Active participation in the conceptualization, design, submission and implementation of data to address EPA FIFRA endangered species data requirements
2. Access to NatureServe data
3. Complete access to www.FESTF.org, an archive of FESTF and key endangered species documents.
4. Input to the National Council for Air and Stream Improvement's (NCASI) evaluation of biodiversity data.
5. Access and contribution to NCASI reports on NatureServe data.
6. Complete access to and use of all FESTF work products for any purpose allowed in underlying agreements.
7. Voting rights on all actions requiring member approval.
8. Representation on the FESTF Administrative and Technical Committees.
9. Ownership rights to all FESTF-generated data.
10. A share in all incoming revenue from data citation or other sources.
11. Complete and direct access to the FESTF submitted FIFRA Data Matrix.

Member Obligations:

1. Responsible for data development.
2. Responsible for submission of FESTF data to EPA and obtaining acceptance by EPA including further supporting work if EPA so requires.
3. Active defense of FESTF data in data compensation matters.
4. Payment of additional assessments should the membership approve them.
5. Accountability for the performance and goals of the LLC.

Level Two: Hired Use of the IMS for a Non-Member Company's Assessments

Level Two Rights and Benefits:

1. Access to the IMS through an FESTF-certified agent for any company assessment need.
2. Reliance on the IMS when it is used for any assessment completed by another company.
3. Provides expedient conduct of an endangered species assessment by allowing reliance on accumulated data and system use experience.

4. Allows use of all knowledge and risk mitigation decisions accumulated in and retrieved by the FESTF IMS for any use to the benefit of the company's product assessment.
5. Removes the hurdle of collecting public data manually and repeatedly under an approach that may vary from the standard EPA has established through expectation of use of the IMS.
6. Gives added assurance that the investment in an endangered species assessment will be acceptable to EPA.

Level Two Obligations:

1. Independent conduct and support of active ingredient assessments.
2. One time payment to FESTF for access to and reliance on the IMS.

Level Three: Relying upon the IMS for a Completed and Submitted Assessment

Level Three Rights:

1. Citation to the IMS for a completed assessment.

Level Three Obligations:

1. One time payment to FESTF for data reliance.

Task Force Information
Description of FESTF Work Products
(November 18, 2005)

Description of FESTF Work Products

INTRODUCTION

The goal of the program undertaken by the FESTF centers around meeting its members' regulatory requirements to support registration and reregistration of their products under FIFRA by improving the consistency, quality, availability and use of existing information on threatened and endangered species and pesticide use. The foundation of this effort is the development of access to existing information on threatened and endangered species and pesticide use information. Existing information that is compiled includes data from pesticide labels, usage information, FWS/NOAA-Fisheries, states and those data provided through EPA's access to the NatureServe network. This information is managed by a software system that is able to consistently process the accessed data for use in the registration and reregistration of pesticides (an information management system, or "IMS"). FESTF work products will be used as a component of the EPA process for conducting ecological risk assessments and species-specific risk refinements for endangered species (effects determinations). Use of the FESTF IMS allows the registrant and EPA to:

- Provide better accountability, organization and communication of endangered species risk assessments
- Support a uniform implementation of the ecological risk assessment process outlined in the proposed rule and described by EPA in their Overview Paper.
- Record outcomes at each step of an EPA effects determination so that a warehouse of data are built and available for future reference in new or revised assessments
- Assist in the transfer of information from risk assessors to risk managers

Why is an information management system necessary? The task of assessing the effects on endangered species for pesticide products is enormous. There are more than 900 active ingredients used in more than 19,000 formulated products registered under FIFRA. Each product is registered for one to potentially many different uses. Each pesticide use site and its specific use pattern have different potentials to affect a listed species or its critical habitat, and in each situation this potential must be evaluated. This means that more than 1,200 listed species in one or more of over 2,000 counties throughout the USA must be compared with many different pesticide use sites, making the burden of the assessment daunting in the absence of a tool like the IMS to manage it. The IMS provides this comparison, together with systematic and thorough documentation of results on each potential overlap of a pesticide use site and a species location or critical habitat. The FESTF IMS can systematically process the necessary information related to an endangered species assessment, utilize past decisions and existing information on protections and exclusions for listed species, and provide flexible reporting functionality supported by through documentation.

HOW FESTF DATA ARE USED IN THE RISK ASSESSMENT AND PROPOSED COUNTERPART REGULATION PROCESS

The EPA Overview Document² demonstrates the complexity of the ecological assessment and species-specific refinement process in place at EPA. However, neither the Overview Document nor existing regulations clearly describe the sequence of events that work together in the screening-level risk assessment process. With its knowledge of assessment and data needs, and through a sound development and EPA communication process, FESTF has followed the flow of emerging requirements in order to implement processes associated with the data requirements in a manner that will provide consistency over time. Currently, EPA is projecting that it will wrap species evaluations into the Registration Review process, beginning in 2006 and ending the first round of review in 2021.

Such a detailed and lengthy process is well-served by the manner in which FESTF has met endangered species data requirements. Task force work products are the FESTF Information Management System (Figure 1) and access to spatial and biological data on endangered species (Figure 2) through utilizing data licensed from NatureServe, a non-profit organization that houses the best available aggregated database on biodiversity in the United States.

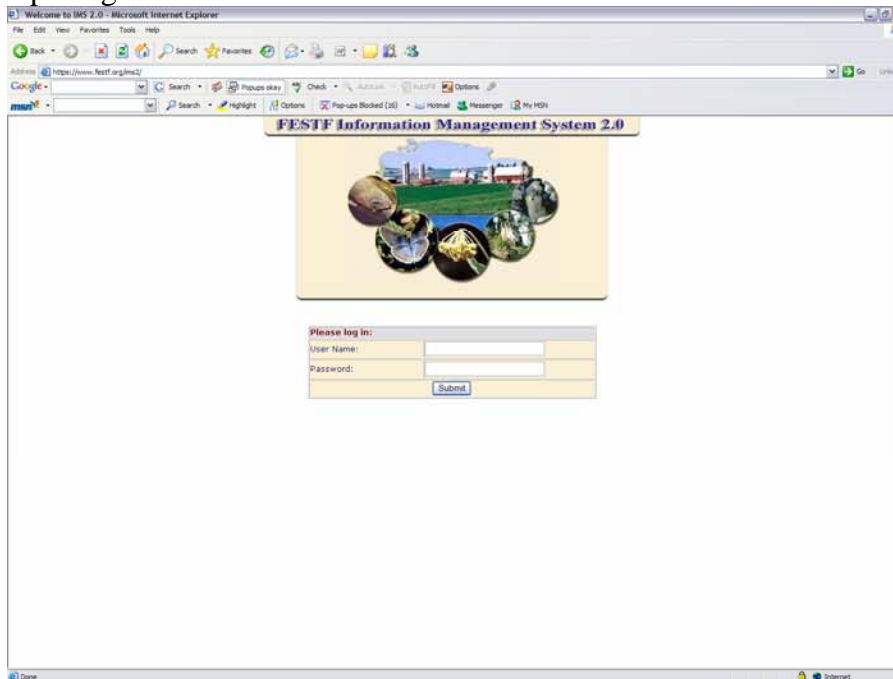
Taken together, the Overview Document and the new counterpart regulation³ describe the sequential process leading through an effects determination to either risk management decisions that avoid effects on threatened and endangered species or to the formal consultation process. EPA must formally consult with another branch of government, the Services, if on their own they cannot reach what is called a “no effect” or a “may effect, but not likely to adversely affect” determination. In simple form, the process leading up to formal consultation, should it be necessary, is shown in Figure 3. The basic role of the IMS is to document and capture registrant research or recommendations and subsequent EPA risk management decisions that arise from the process described by Figure 3. In this way, all intersections of crop, endangered and threatened species and pesticide use are

² *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, US Environmental Protection Agency, Endangered and Threatened Species Effects Determinations.* Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Washington, D.C. January 23, 2004.

³ *Joint Counterpart Endangered Species Act Section 7 Consultation Regulations.* 50 CFR Part 402

Figure 1. Opening pages of the FESTF Information Management System. Note requirements for entering a user name and password and upon entering the system the requirement for agreement with the terms of use of the system. The system is web based and maintained by FESTF.

Opening screen:



Warning statement upon entry of valid password:

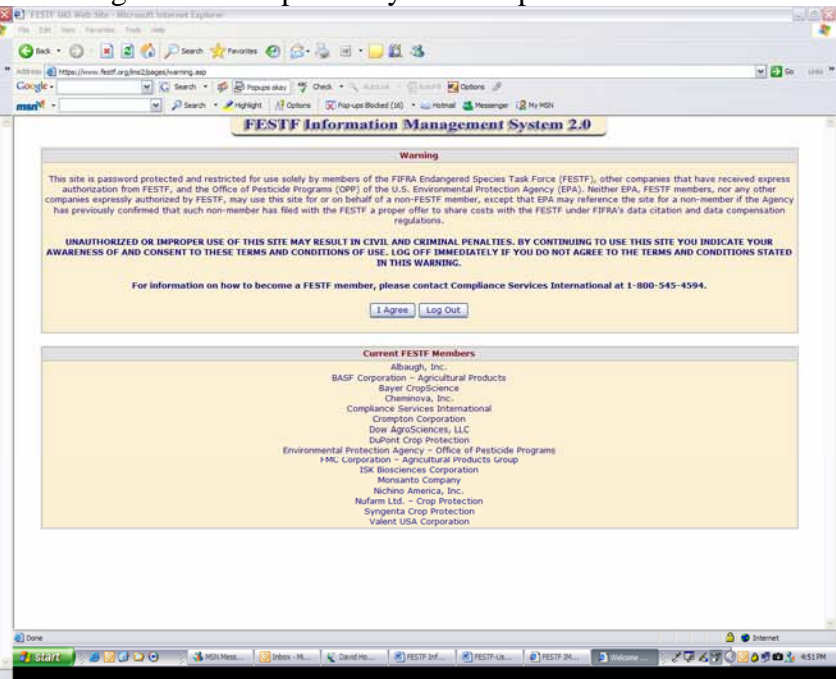
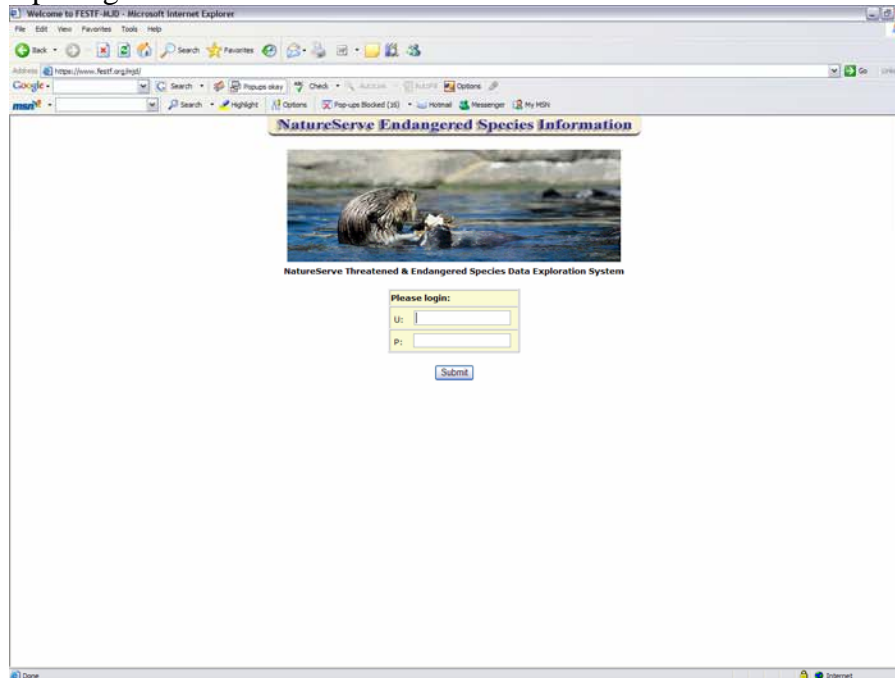
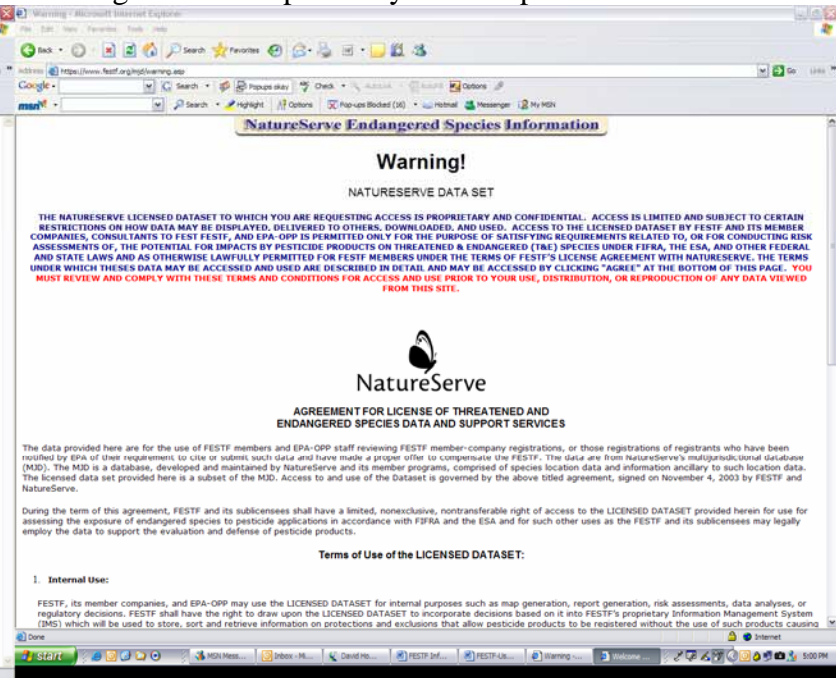


Figure 2. Opening pages of the NatureServe Data Access System. This password protected system provides access to endangered species biological and spatial data licensed from NatureServe. The terms of the license agreement are repeated for the user when the system is accessed.

Opening screen:



Warning statement upon entry of valid password:



documented with respect to their findings: “no effect,” “may affect but not likely to adversely affect” and “may effect.” Not only is the status documented within the context of an assessment, but also the reason a conclusion is reached on a given species is captured, along with the stage of assessment in which the conclusion is drawn. In other words, the IMS documentation includes the status of the evaluation within the context of an assessment; the reason a conclusion was reached on a given species and the stage of the assessment in which the conclusion was drawn.

At the end of the screening-level risk assessment (Figure 3), EPA may use additional data for a species-specific refinement. Such data may include monitoring data, incident data, higher-tiered species or site-specific risk assessments and more refined use data, as explained in the Overview Document. As such data are submitted and documented through the IMS, decisions are made using these data, and the decisions and the information supporting them will then be documented in and retrievable through the IMS. It is important to note that the EPA will demonstrate the process described in the Overview Document, the main flow of which is shown in Figure 3, when they start to routinely conduct and document explicit effects determinations. Two initial IMS-based assessments have been submitted and reviewed by EPA and EPA plans to conduct 12 assessments of a similar nature in 2006.

The IMS provides a clear method for tracking each overlap of an endangered or threatened species, crop and pesticide use, and recording how that intersection was evaluated, or if necessary, mitigated to below a level of concern. Figure 4 demonstrates the full accountability that the IMS brings to the assessment process by following the overlaps analyzed by each step of a sequenced risk assessment, moving from the set-up or problem formulation stage, through the screening-level assessment and on to a series of refined evaluations that end in complete species assessment and protection or the identification of remaining specific overlaps that would enter formal consultation. Figure 4 presents an Analysis Plan, a critical component of the problem formulation stage of any ecological risk assessment.

Given the complexity of ecological risk assessment and specifically the evaluation of endangered species on a location-centric basis, and the large number of potential overlaps that must be systematically analyzed, the IMS eases the burden of the analytical process by taking advantage of applied information technology. Rather than simply assisting in county-level comparisons, the IMS will also house EPA’s decisions, and the basis for making them, as they are made, bringing greater documentation and efficiency to species assessments – two goals central to the appropriate execution of the proposed counterpart regulation and key to fulfilling data requirements. Sample pages from the IMS are included in Figure 5 to show the depth of functionality the system offers.

The IMS is not a model that requires value-oriented input and statistically derived output. Instead, it takes existing factual information and provides a mechanism for those *data* to be converted to more useful *information* that is more supportive of the needs of the assessor and risk manager, allowing them to synthesize and draw conclusions more quickly because the relationships of pesticide use, species and existing mitigations are

retrievable in context. The IMS has distinct user roles for EPA and the registrant, each with differing functionality. Each company has the option of retaining the privacy of their assessments or sharing certain findings with others should they choose to do so. Only EPA has the authority within the IMS to validate the species and crop overlaps that are related to reaching “no effect” or “may effect but not likely to adversely affect” determinations. Those overlaps left outstanding at the end of the process are then readily available for possible elimination from concern through the findings of further research or by implementing additional label or local restrictions.

The IMS is not designed to evaluate the characteristics of a chemical; that process is an integral part of EPA’s responsibility in the risk assessment *per se*. Because the IMS is a “data warehouse” and not a predictive model, decisions on endpoints are outside its functionality, but information gathered and opinions expressed can be captured as species are evaluated and the impact of site- and species-specific refinements are made. The IMS stores and compares data on species locations, crop locations and previous or existing management decisions so that they can be readily retrieved and compared to assessments about to be initiated or currently underway. This brings a dimension of consistency to assessments because past decisions and discoveries are immediately available to the next review that may touch upon the same crop, species or geographic area.

Certain fields of data are constructed as tables within the IMS and provide a basis for its functionality. These data are regularly updated using existing public sources such as crop statistics (as referred to in Section VI.D.1 of the Overview Document), FWS published county-level location data for threatened and endangered species, and EPA’s county bulletins. They are stored and arrayed in the IMS in such a way as to be more useful to the problem formulation and decision-making process.

The IMS starts with the information EPA has collected and builds additional functionality and resources into a software program not only to refine geographic proximity evaluations, but also to provide information on species biology and habitat as it is collected through the types of resources mentioned in the first paragraph of section VI.D.2 of the Overview Document (Services’ species listing status, designated critical habitat, species recovery plans, status reviews, benchmark studies, species profiles and those additional details brought by access to NatureServe data). The IMS will also house the expert opinion resources and references as they are identified and collected (as described in section VI.D.3 and 4 of the Overview Document) and will provide a means to compare data of the types mentioned in sections VI.D.5 through 8 of the Overview Document as the data are collected or provided by registrants.

In discussing endangered species data requirements and evaluation, EPA references the importance of spatial and temporal relationships: this is at the heart of IMS functionality. Tools are not currently available to allow EPA to make the county level comparisons that are possible in the IMS. Currently, there are no other tools available to EPA to provide this rigorous level of documentation of all species and crop overlaps that occur for a given use. EPA is taking steps to require all pesticide registrants with endangered species assessment needs to either cite FESTF data or develop their own data. Conditions are

being placed on new and amended uses that are directed toward fulfilling these requirements. Consequently, this evaluation process, or one like it, will be available consistently to EPA in their risk assessment process for pesticides. The general specifications of the IMS are summarized in Table 1.

Figure 3. Responding to Endangered and Threatened Species Data Requirements and the Overview Paper's Assessment Process

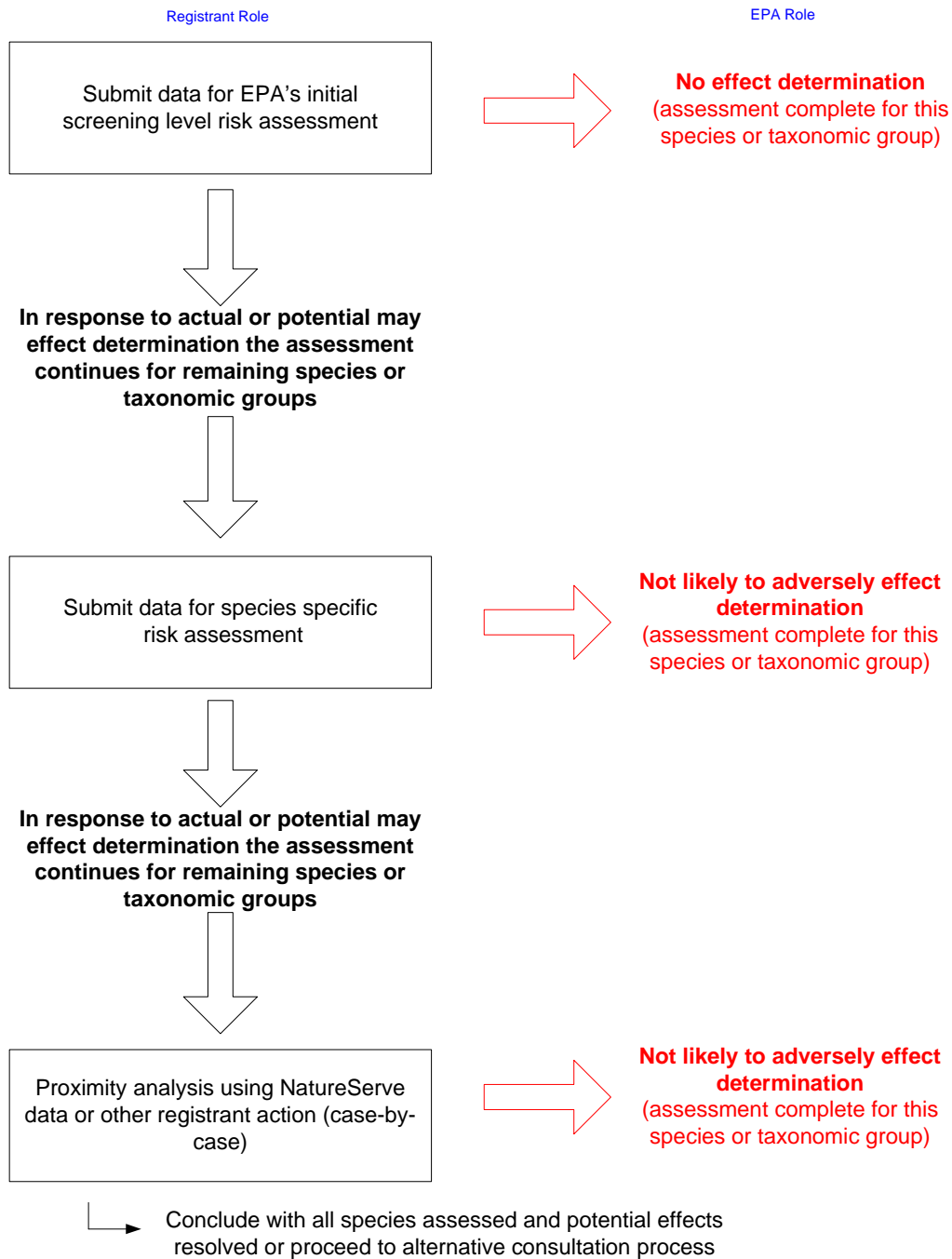


Figure 4. Detailed Flowchart on the Sequential Documentation in the IMS of Endangered Species Assessment: Example of the Assessment and Documentation Process

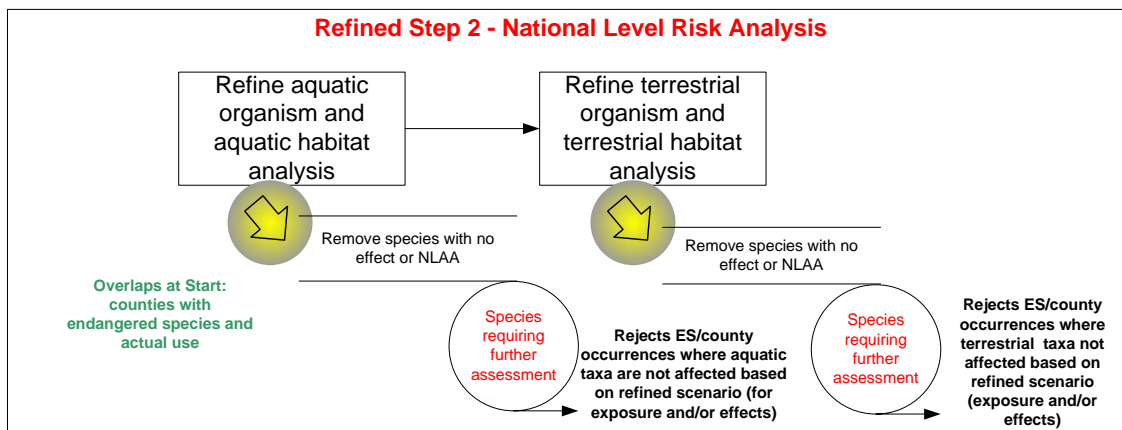
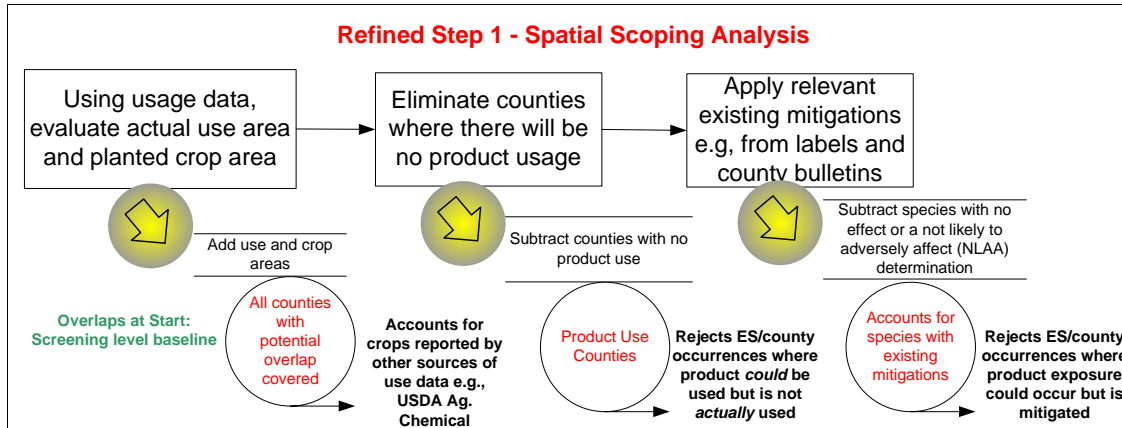
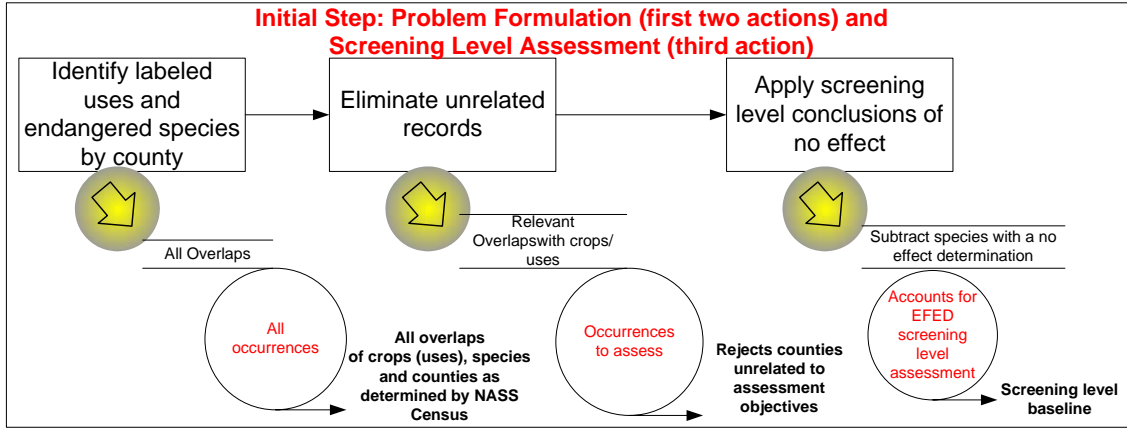


Figure 4 (continued). Detailed Flowchart on the Sequential Documentation in the IMS of Endangered Species Assessment: Example of the Assessment and Documentation Process

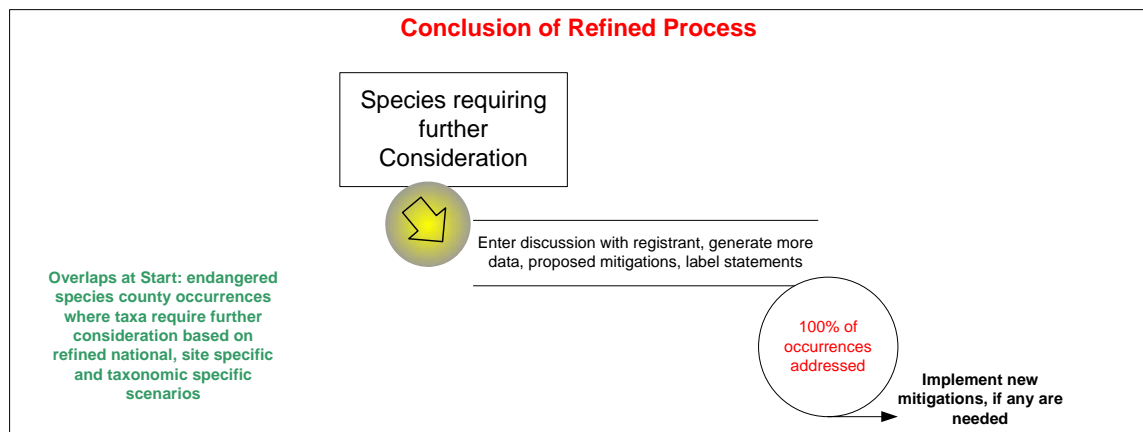
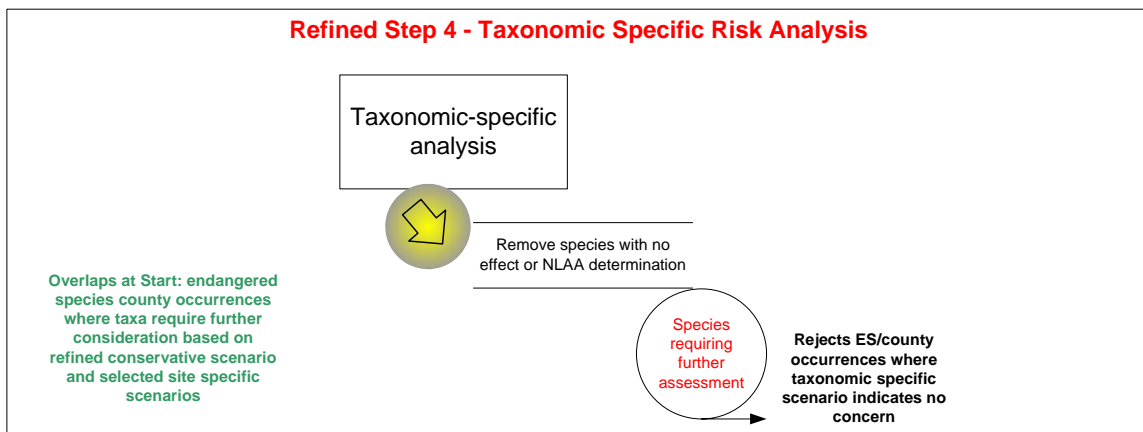
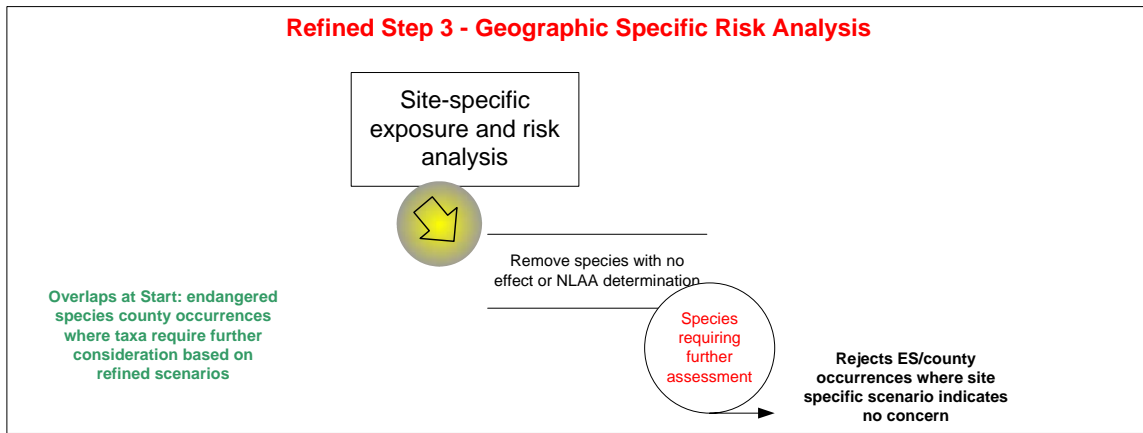


Figure 5a. Documentation supporting the assessment (taken from non-confidential group exercise - for example only)

FESTF Information Management System 2.0
 Home | Setup | Analysis | Submission | Exploration | Logout

Edit Assessment

Current Settings [Show](#)

Basic Details

Assessment Title:

Created By: Tom Priestler
 Company: Compliance Services International
 Creation Date: 6/22/2005 10:01:43 AM
 Last Modified Date: 10/25/2005 4:27:49 PM
 EPA Submission Status: Not released
 Product: Microban(TM) Roundup(R)
 Description: 1919 characters still available. Evaluation of the use of BDM-Test Product in Cotton when used as an aerial spray.
 Personnel: 1960 characters still available. Group effort by all.
 Other Comments: 1903 characters still available. BDM-Test Product is also used in cotton via ground spray. See separate assessment on ground uses.

Runs

| Run Title | Type | Created By | Creation Date |
|--------------------|---|----------------------|--------------------------|
| Conventional Crops | Set as Current Full Data Release | Location Priester | 6/22/2005 10:24:38 AM |

Documentation

Uploaded Documentation

| File | Date Uploaded | Comments |
|--------|---------------|----------|
| Upload | | |

Figure 5b. Example of how data are matched (intentionally exhibit no matches here to protect data)

FESTF Information Management System 2.0
 Home | Setup | Analysis | Submission | Exploration | Logout

Matching Exclusion Associations

Current Settings [Show](#)

Species Status Record Selected for Matching

Active Ingredient: Glyphosate, potassium salt
 Class: Amino Acid Derivatives
 No Data have been returned

Exclusion Associations for Current Assessment

| Exclusion Association ID | Exclusion Group Title | Match Type Count | Match Count | Active Ingredient | Species | Site | Location | Application Method Type |
|--|-----------------------|------------------|-------------|-------------------|---------|------|----------|-------------------------|
| No matching Exclusion Associations available for the current Assessment. | | | | | | | | |

[Return to Species Status Records for Run](#)

EPA Exclusion Associations

| Exclusion Association ID | Exclusion Group Title | Match Type Count | Match Count | Active Ingredient | Species | Site | Location | Application Method Type |
|---|-----------------------|------------------|-------------|-------------------|---------|------|----------|-------------------------|
| No matching EPA Exclusion Associations available. | | | | | | | | |

[Return to Species Status Records for Run](#)

Other Exclusion Associations

| Exclusion Association ID | Exclusion Group Title | Match Type Count | Match Count | Active Ingredient | Species | Site | Location | Application Method Type |
|---|-----------------------|------------------|-------------|-------------------|---------|------|----------|-------------------------|
| No other matching Exclusion Associations available. | | | | | | | | |

[Return to Species Status Records for Run](#)

Figure 5c. Documentation showing number of associated records (7175 species status records – for example only)

The screenshot shows the 'Documentation' section of the FESTF Information Management System 2.0. It includes a table for 'Runs' and a 'Species Status Record Summary' table.

| Run Title | Type | Created By | Creation Date |
|--------------------|----------|------------|-----------------------|
| Conventional Crops | Location | tpriester | 6/22/2005 10:24:38 AM |

| File | Date Uploaded | Comments |
|--------------------------|---------------|---|
| RED_glyphosate.pdf (7MB) | 6/23/2005 | EPA has expressed no concerns other than frogs. |

| Number of Species Status Records: | 7175 |
|-----------------------------------|------|
| Status: | |
| Valid: | 0 |
| Conditional: | 0 |
| Rejected: | 0 |
| Available: | 0 |
| None Available: | 7175 |

Figure 5d. Example of grouping to expedite review (non-confidential group exercise - for example only)

The screenshot shows the 'Exclusion Group List' section of the FESTF Information Management System 2.0. It displays a table with columns for Exclusion Group Title, Comments, Number of Referencing Exclusion Associations, Created By, Creation Date, and Last Modified Date.

| Exclusion Group Title | Comments | Number of Referencing Exclusion Associations | Created By | Creation Date | Last Modified Date |
|-----------------------------|---|--|------------|-----------------------|-----------------------|
| af-WA_high_altitude | | 1 | arose | 5/12/2005 12:38:22 PM | 5/12/2005 12:38:22 PM |
| BK_Cranes_Birds | Can we exclude cranes? | 1 | bkenyon | 5/12/2005 12:38:24 PM | 5/12/2005 12:38:24 PM |
| BDM_Exclusion_eagle | species not present | 1 | dmayfield | 5/12/2005 12:38:19 PM | 5/12/2005 12:38:19 PM |
| DH-DL | Exclusion Group for delisted species | 1 | dhowes | 5/12/2005 12:38:17 PM | 5/12/2005 12:38:17 PM |
| Fish_in_NC - proximity | | 0 | thall | 5/12/2005 12:38:04 PM | 5/12/2005 12:38:04 PM |
| JMS_delisted | Species no longer on TAC list | 1 | jpiddings | 6/12/2006 12:38:24 PM | 6/12/2006 12:38:24 PM |
| JRW_T & E delisting | No longer threatened | 1 | hwirtz | 5/12/2005 12:38:26 PM | 5/12/2005 12:38:26 PM |
| KE - Test | exclude the XX for the XX because of XX | 0 | keberhart | 5/12/2005 12:38:19 PM | 5/12/2005 12:38:19 PM |
| mgd - species cave dwelling | | 1 | mdobbs | 5/12/2005 12:38:21 PM | 5/12/2005 12:38:21 PM |
| ml_0002 | | 1 | mleggett | 5/12/2005 12:38:14 PM | 5/12/2005 12:38:14 PM |
| ph_not_near_habitat | Fish species are marine, no | 1 | phavens | 5/12/2005 12:38:01 PM | 5/12/2005 12:38:01 PM |

Table 1. General description of the system specifications for the FESTF Information Management System

| Parameter | General Features |
|------------------------------|---|
| System Platform | Centrally stored as a single program operable via a secure web page |
| System Access | Controlled by passwords issued to match the functionality allowed a given user |
| User Roles within the System | <p><u>Member Superuser and Member User</u> has access to a given member’s assessments, all shared data, and all risk management decisions released by EPA. Superuser controls the accounts for a given member.</p> <p><u>EPA Risk Assessor, EPA Endangered Species Assessor</u> have access to member-released assessments, EPA assessments, all shared data and all risk management decisions. Only the Endangered Species Assessor can accept or “validate” a mitigation or species status finding that is suggested by a member user or an EPA risk assessor.</p> <p>EPA Product Manager, Services Read-Only Users have the ability to review assessments and insert comments, but cannot alter assessments.</p> <p><u>Data Administrator</u> is a user designated to issue passwords, upload new content data and maintain the operations of the system</p> |

| Parameter | General Features |
|---|--|
| System Content Data | <p>ESA-Listed threatened and endangered species and those formally proposed for listing (described at all taxonomic levels)</p> <p>State and county identities (accompanied by standard geographic references)</p> <p>Active ingredients and active ingredient codes used by EPA</p> <p>Tables of formulation types, timings, and methods</p> <p>USDA-NASS crop statistical data</p> |
| System-Captured Data (tied to individual assessments or to individual co-occurrences of a use, product and species) | <p>Uploaded PDF or other file types containing support data</p> <p>Research findings characterized as “exclusions” (reasons the species can be excluded from being of concern) or “protections” (mitigations at a local level that can protect the species)</p> <p>User comments, reviews, management decisions, labeling details, refined risk assessment findings, etc.</p> <p>Assessment dates, management decision dates and other time-related “date-stamped” information</p> |
| System Output | <p>Exported detailed documentation (to Excel format spreadsheets)</p> <p>Summary reports standardized to reflect parameters EPA wishes to see in a submitted report</p> |
| Other System Features | <p><u>Data Exploration</u>: A search engine allowing exploration of all data (within the permissions of the user’s password)</p> <p>Expert Contact Database: A dynamic and searchable database to aid the user in finding a species or state expert.</p> |

THE SPECIFIC ROLE OF NATURESERVE DATA

The counterpart regulations also state that EPA is to utilize “species profiles” as provided by the Services. These profiles are not always available to EPA in a timely manner. The registrant can enhance the data available to EPA by supplementing it with NatureServe habitat and species information made accessible through FESTF. NatureServe has indicated, in fact, that much of their data are the basis for Services analysis and output.^{4,5}

NatureServe was established by The Nature Conservancy in 2000 as an independent, international non-governmental organization. NatureServe encompasses a network of natural heritage programs and conservation data centers, the first of which was established by The Nature Conservancy in 1974, along with regional and central offices. The network’s information on species and ecological communities comes from numerous sources, including museum collections, published literature, unpublished reports, outside expert consultants, and field surveys.

NatureServe central and regional offices were created to improve the quality and uniformity of data managed by the network, through the creation and distribution of standardized, universally applicable scientific methods and products and through a formal process of data exchange with the member programs. Additional depth of data on species and species locations come to FESTF members and EPA through their access of the NatureServe multi-jurisdictional database. Providing a means for EPA to access them directly assures that the abundant species data in that system are readily available to EPA and can be easily accessed for assessment purposes. Examples of data are shown in Figure 6. NatureServe data are a second component of FESTF’s deliverables and they directly address EPA’s requirement for “location data.”

⁴ In a draft report partially supported by the National Council for Air and Stream Improvement, Inc. (NCASI), NatureServe notes “The U.S. Fish and Wildlife Service and the U.S. Forest Service are particularly significant public users of NatureServe’s information and tools. NatureServe’s conservation status assessments, along with information from other sources, help guide the selection of species for consideration for listing under the U.S. Endangered Species Act.” (NCASI Technical Bulletin No. 885, “Managing Elements of Biodiversity in Sustainable Forestry Programs: Status and Utility of NatureServe’s Information Resources to Forest Managers.” August 2004)

⁵ The FWS itself has noted the importance of these data: “Given the Service’s budgetary constraints and ever-increasing workloads, the Service can no longer afford to duplicate these efforts . . . Many Agencies, such as the USFS, BLM, and DOD, are working with The Nature Conservancy’s (TNC [now NatureServe]) Heritage system . . . One of the most comprehensive information sources on rare or imperiled species is the Natural Heritage Central Database, developed by TNC and the network of State Heritage Programs.” (61FR64481 (12/5/96))

Figure 6a. Spatial data access for FESTF Members Only (spatial data display (read-only) under development for EPA)

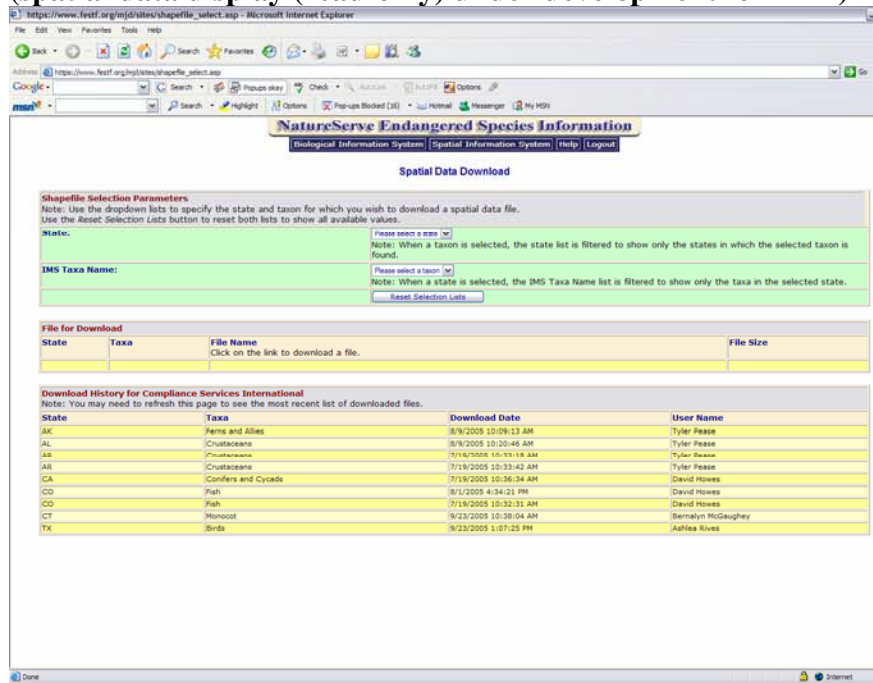
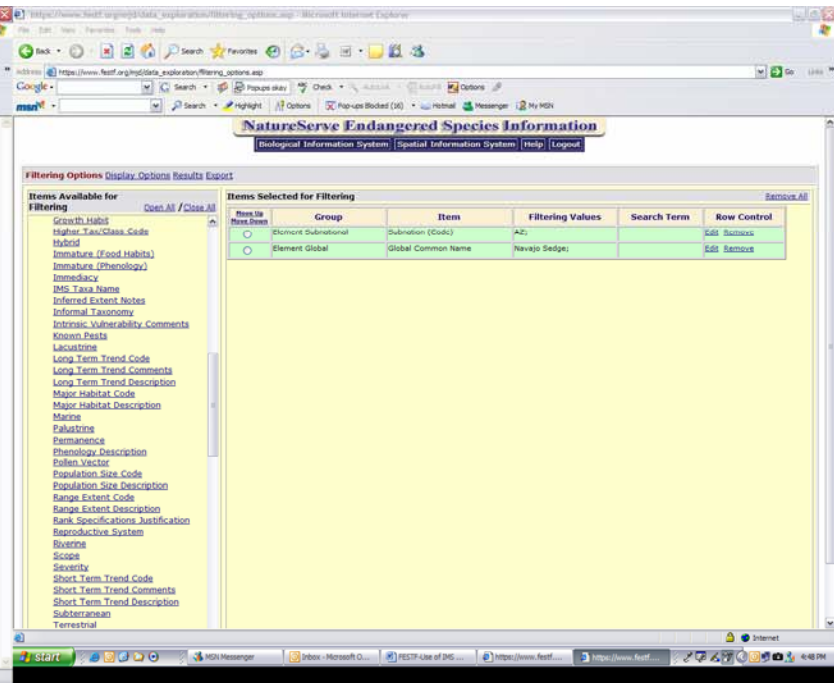


Figure 6b. Biological data access for FESTF and EPA



CONCLUSIONS

FESTF began an exploration of how FESTF could meet the data requirements of FIFRA for endangered species assessment more than 10 years ago, and the data developed and now in implementation are directly responsive to needs expressed by EPA. In absence of the use of such tools, a large part of the efficiency and effectiveness of the assessment and species evaluation process is lost. Data requirements cannot fully be addressed without these tools or the development of something that could be used to replace them. Because the IMS and access to NatureServe data are something that has evolved and been developed over a period of 10 years, it is unlikely that a registrant could develop a robust and EPA-acceptable program within a reasonable time period.

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Task Force Information

FIFRA Endangered Species Task Force Limited Liability Corporation Agreement

FESTF LLC Agreement