United States Department of the Interior
FISH AND WILDLIFE SERVICE
UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

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Dear Ms. Hazen:

This letter provides an evaluation by the U.S. Fish and Wildlife Service and National Marine Fisheries Service (collectively referred to as the Services) of an approach to assessing the ecological risks of pesticide products, which has been developed by the Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP), under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U. S. C. §136 et seq. (FIFRA). This approach is set forth in a document prepared by OPP entitled Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Environmental Protection Agency (January 2004) (Overview).

After careful consideration, the Services have concluded that this approach, as understood and reflected in this letter, will produce effects determinations that reliably assess the effects of pesticides on endangered and threatened species (listed species) and critical habitat pursuant to section 7 of the Endangered Species Act (ESA) and implementing regulations. The Services have further concluded that the approach used by OPP should produce effects determinations that appropriately identify actions that are not likely to adversely effect listed species or critical habitat, and that are consistent with those that otherwise would be made by the Services. This approach also will produce all information necessary to initiate formal consultation where appropriate.

I. Historical Background

Examination of OPP's risk assessment process was undertaken to assist the Services in considering whether and how to develop counterpart regulations creating new ESA section 7 consultation procedures for FIFRA actions taken by EPA. In an Advance Notice of Proposed Rulemaking published on January 24, 2003, EPA and the Services announced their intent to promulgate counterpart regulations. 68 Fed. Reg. 3786 (Jan. 24, 2003). The goals of these counterpart regulations are to improve interagency cooperation for regulatory actions under

FIFRA involving pesticides, and provide optional, alternative approaches to consultation on pesticide actions that better integrate the consultation process under §7 of the ESA with the processes for pesticide regulatory actions taken by EPA under FIFRA. By doing so, the Services expect the administration of the ESA and FIFRA will better protect threatened and endangered species and critical habitat.[1]

While interagency examination of OPP's risk assessment process has been ongoing for a number of years, the Services initiated this specific review in the Fall of 2002. As part of this review, the Services looked at voluminous documentation furnished by OPP explaining its approach to making ecological risk assessments. This documentation included supporting materials addressing specific components of OPP's process, together with information supporting the analytical underpinnings and statistical reliability of its approach.

In addition to reviewing the above documentation, program and technical personnel from the Services, EPA and the United States Department of Agriculture (USDA) have met extensively to

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[1]Examination of OPP's risk assessment process also was intended to facilitate future consultations between EPA and the Services. For the past several years, EPA and the Services have been engaged in a proactive conservation review under the authority of section 7(a)(1) of the ESA. This review has sought in part to clarify EPA's approach to risk assessment and the consultation requirements imposed on EPA by the ESA. The Services' review reflects multi-year interagency efforts to evaluate OPP's approach to assessing ecological risks and to enhance the efficiency and effectiveness of future consultations involving pesticide actions taken by EPA under FIFRA.

The importance of this review and need to facilitate future consultations was underscored by a judicial Order issued in July 2002, EPA is under a court-ordered schedule to make effects determinations and consult where appropriate on 55 pesticide active ingredients, and the effects they pose to 26 salmonid ESUs in the Pacific Northwest. *See Washington Toxics Coalition, et al, v. Environmental Protection Agency, et al , No. C01-132C (W.D. Wash. 2002)*. In separate litigation, EPA has entered into a Consent Decree in which it has agreed to make effects determinations and where appropriate request consultation on the use of pesticide products: a) containing 18 active ingredients, and the effects their use may pose to 26 salmonid ESUs; and b) containing eight active ingredients, and the effects their use may pose to 33 species of listed plants. *See Californians for Alternatives to Toxics, et al, v. Environmental Protection Agency, et al, No. C00-3150 CW (N.D. Calif. 2002)*. To date, EPA has submitted consultation requests on approximately 27 active ingredients addressed in these two lawsuits. Beyond the pesticides addressed in the above litigation, EPA has informally acknowledged that it likely will need to make effects determinations and where appropriate consult on literally hundreds of additional pesticide actions. Given the number of pesticides for which future effects determinations and consultations will be required, the Services determined it appropriate to ensure that EPA effects determinations reliably produce effects determinations that satisfy the ESA and implementing regulations.

discuss OPP's risk assessment process. The Services and EPA held two large interagency workshops, once in November 2002, in Portland, Oregon, and again in February 2003, in Arlington, Virginia. These multiple day workshops, which were attended by scientists, program personnel and lawyers from each agency, were designed to build relationships and educate each other on the FIFRA and ESA processes. Subsequent to these workshops in the Spring of 2003, the Services and EPA established a smaller interagency working group comprised of technical personnel from each Agency. This group was tasked with conducting a more searching review of OPP's risk assessment process and the extent to which it will produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations. This interagency group met approximately 20 times from late February, 2003 through early May, 2003.

In October 2003, the Services and EPA created a second interagency group comprised of senior scientists and program specialists from the Services, EPA and USDA to explore specific issues identified by the first interagency technical working group. Over a three month period of time, this group of experts met 21 times, for over 65 hours of discussion, to examine specific issues identified by the original working group. Specifically, the interagency group evaluated OPP's approach to risk assessment in the context of the following issues:

* OPP's approach to capturing and using the best scientific and commercial information available.

* OPP's approach to assessing risks to listed species and critical habitat through its use of: a) surrogate species as a means of assessing risks to listed species and critical habitat; c) established exposure pathways; c) established "levels of concern" which trigger further investigation of potential adverse effects.

* OPP's approach to assessing risks posed by inerts, formulations, mixtures and degradates.

* OPP's approach to appropriately: a) determining the environmental baseline; b) assessing sublethal, indirect and cumulative effects; c) assessing effects to critical habitat; and d) addressing uncertainty when making effects determinations.

Throughout these discussions, the Services conducted a probing analysis to fully understand OPP's risk assessment approach. When evaluating OPP's approach, the Services were mindful that there is no single correct approach to evaluating ecological risks. Organizations often use different, yet analytically defensible methodologies that are capable of producing sound, scientifically based effects determinations.

As a product of this comprehensive dialogue between OPP and the Services, OPP has prepared a document entitled, Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Environmental Protection Agency (January 2004). The Overview discusses

the collective processes used by OPP evaluate ecological risks associated with pesticide use. The Overview includes a bibliography of: a) 81 supporting documents that describe specific components of EPA's process in greater detail; and b) 26 reference documents. Within the Overview, OPP describes a particular approach, primarily used by OPP's Environmental Fate and Effects Division (EFED), and Field and External Affairs Division (FEAD), to evaluate the ecological risks associated with use of a pesticide, including the potential risks to listed species and critical habitat. Where appropriate, the Overview includes recommendations provided by the Services during the course of interagency discussions.

The Services' have carefully reviewed the approach to risk assessment used by EFED and FEAD, (which we collectively refer to in this letter as the OPP approach to risk assessment).[2] Review has focused upon whether this approach will, "produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations." In order to satisfy this standard, the Services determined that OPP's approach to risk assessment must:

* Address, where applicable, the informational and analytical requirements set forth at 50 C.F.R. 402.14(c);

* Rely upon the best scientific and commercial data available; and

* Analyze the best scientific and commercial data available by using sound, scientifically accepted practices for evaluating ecological effects.

Through this analysis, the Services also have examined:

* Whether OPP's approach to risk assessment produces effects determinations that appropriately identify actions that are not likely to adversely affect listed species or critical habitat. As a corollary to this criterion, the Services have examined whether OPP's approach produces effects determinations consistent with those that otherwise would be made by the Services. While this corollary is not a requirement of the ESA, the Services have evaluated OPP's approach from this perspective in order to appropriately determine whether and how to develop counterpart regulations that would in part authorize EPA to conclude, without informal consultation or Service concurrence, that certain FIFRA actions are not likely to adversely affect listed species. The Services understand that legitimate professional differences of opinion may from time to time cause EPA to produce an effects determination that differs from that which a Service biologist might reach with the same information, just as two Service biologists may

[2] The Services understand that OPP's approach to assessing ecological risks may vary depending upon the nature of the FIFRA action at issue. The Services' assessment focuses on and is limited to the approach to assessing risks described in the Overview, that primarily is used by EFED and FEAD.

disagree on the interpretation of scientific data. In the main, however, EPA's effects determinations should be comparable to those that would be produced by Service biologists.

* Whether OPP's approach to risk assessment produces all information necessary to initiate formal consultation where appropriate.

II. Overview of OPP's Risk Assessment Approach.

The following discussion is a summary of OPP's risk assessment process, as OPP has described it to the Services. It is based upon the Services' review of the Overview document furnished by OPP, together with all supporting attachments, and the many interagency discussions that have taken place over the past year.

In deciding whether to authorize the use of a pesticide product under FIFRA, EPA considers, among other things, the potential risks to non-target species posed by use of a pesticide product. This examination helps EPA fulfill its responsibilities under FIFRA, which authorizes registration and reregistration of pesticides that will not cause "unreasonable adverse effects to the environment," when performing their intended function or when used in accordance with widespread and commonly recognized practices,. See 7 U.S.C. 136a(c)(5); 7 U.S.C. 136a-1(a).

Ecological risk assessments associated with pesticide registration and reregistration are conducted by EPA's OPP. While several divisions within OPP assist in this process, risk assessments are principally conducted by two divisions: EFED and FEAD.

* EFED is a division which conducts initial and refined screening level assessments which assess the ecological risk to non-target species, including listed species. EFED is comprised of a cadre of biologists, chemists, environmental engineers, agronomists and hydrologists, most of whom possess Masters of Science and Doctorate degrees. EFED reviews, evaluates and validates data submitted by registrants and data from other sources. Based upon this data, EFED examines the properties and effects of pesticides, and assesses and characterizes ecological risks associated with varying pesticide exposure scenarios.

* FEAD is a division that administers and coordinates the field implementation of OPP's Endangered Species Protection Program. FEAD also is responsible for conducting refined species-specific and habitat-specific risk assessments in the event EFED initially concludes through its screening level assessment, and associated conservative exposure and effect assumptions, that a "no effect" determination can not be made for specified pesticide use pattern.

Over many years, OPP has developed and refined extensive processes and systems to evaluate the potential ecological effects of pesticide usage on non-target species. These OPP processes

and systems, which are designed to promote sound scientific assessments, include: a) Pesticide Assessment Guidelines, which provide testing and reporting procedures to support registration and reregistration; b) Standard Evaluation Procedures (SEP), which ensure comprehensive and consistent review of scientific data submitted; c) internal information systems and databases, including OPP's Ecotoxicity Database, Ecological Incident Information System, and Environmental Fate Database; d) internal procedures which subject all risk assessments and characterizations to peer review by task teams comprised of scientists from multiple disciplines; and e) external review processes, including the FIFRA Scientific Advisory Panel (SAP) which reviews, as appropriate, existing and new scientific tools and methodologies. These collective processes are consistent with larger agency-wide guidelines designed to promote sound scientific decisions, including EPA's Guidelines for Ecological Risk Assessment and EPA's Risk Characterization Handbook.

Both FIFRA and regulations promulgated by EPA seek to ensure that risk assessments are based upon the best scientific and commercial information available. Under FIFRA, EPA is authorized to require production of data to support the registration or reregistration of a pesticide product. Pursuant to this authority, EPA has published regulations establishing data requirements registrants must satisfy to support registration. These requirements, which are found at 40 C.F.R. Part 158, require registrants to submit the following data: a) a series of laboratory and field studies characterizing the environmental fate of both the active ingredient(s) in a pesticide product and any significant degradates or metabolites; and b) a suite of laboratory toxicity studies examining the effects of the active ingredient(s) in a pesticide product on multiple species of birds, fish, aquatic invertebrates, non-target insects, and plants. In addition to information furnished by registrants, OPP reviews, as appropriate, toxicological and biological information contained within internal databases and within the open literature

The initial phase of OPP's risk assessment process is conducted by EFED, which performs a "screening level assessment" on the pesticide. This assessment involves combining the results of a series of computer simulation models that examine estimated environmental concentrations (EEC) of an active ingredient and any significant environmental degradates with information about the toxicity of the product to non-target organisms. These simulation models have been developed and refined using actual field monitoring data and have undergone extensive external peer review.

When conducting a screening level assessment, EFED first examines the likely fate and transport of an active ingredient and any significant environmental degradates or metabolites. To do so, EFED relies upon the following categories of data:

* Pesticide Composition and Use Patterns
  EFED's examines the pesticide at issue and how it will be used, based upon information contained on the product labeling. Information of significance includes: a) the type of formulation (bait, granule, wettable powder, concentrate); b) the concentration of the active ingredient in the product; c) application rates; d) approved crops and target pests;

e) geographic and other limitations; f) application methods; g) application timing; and h) application frequency.

* Pesticide Fate and Transport Data
  EFED then examines the likely fate and transport of an active ingredient and any significant degradates or metabolites once the product is introduced into the environment. As part of this examination, EFED reviews mandatory laboratory and field studies submitted by registrants that address factors bearing upon the fate of an active ingredient including hydrolysis, photolysis, aquatic and soil metabolism and terrestrial dissipation. EFED also will examine other sources of data, including non-guideline studies submitted by the registrant or other scientific literature. From this information, EFED is able to predict: a) how fast and by what process(es) an active ingredient will degrade; b) chemical moieties (components) that result from the degradation process; c) the mobility of the active ingredient and significant degradates or metabolites from the application site into the soil, water and atmosphere; and d) levels of active ingredient and significant degradates or metabolites that will accumulate in the environment.

With these data, EFED then conducts exposure modeling to determine the EEC of an active ingredient or any significant degradate or metabolite. EFED uses a variety of exposure modeling techniques that are tailored to each taxonomic group evaluated.

* For aquatic exposures, the initial screening model is GENEEC2 (GENeric Estimated Environmental Concentration). The model is not site specific, but rather estimates concentrations of an active ingredient in a generic water body located adjacent to land subjected to maximum pesticide application. GENEEC2 is used as a rapid screen to separate low risk pesticides from those requiring more refined assessments. If "levels of concern" (LOC) for aquatic species are exceeded using GENEEC2 (discussed below), EFED uses a second model known as PRZMS-3, which determines more site and use-specific levels of pesticide in surface runoff. These runoff estimates are then further evaluated using a third model known as EXAMS II, which simulates the dissipation and degradation processes that occur in the water body to estimate daily pesticide concentrations.

* For terrestrial species, EFED primarily evaluates the effects of pesticides resulting from dietary exposure. Given this, EFED determines exposure levels by considering both pesticide residue levels on food items and estimated levels of dietary intake. Separate approaches are used for spray applications, and for granular, bait and treated seed applications. For granular, bait and seed applications, EFED uses a screening method based on pesticide mass per unit of treated area as an index for all potential exposure routes.

EFED's exposure models rely upon conservative assumptions designed to reduce the possibility of understating exposure levels. For example, EFED's screening level exposure models assume

pesticide is applied at maximum rates, at the highest frequency, and with the shortest interval in between applications authorized by the label. The model also assumes species subject to exposure reside exclusively within the exposure area, and will be exposed to the maximum EEC, with no variation in exposure levels. For aquatic species, the assessment model also utilizes fate and transport assumptions that would create upper bound concentration levels within a water body adjacent to a treated field as a result of the pesticide application.

Having determined conservative exposure levels by way of modeling (levels unlikely to understate actual exposure), EFED determines the potential effect exposure levels may have on non-target species. To do so, EFED reviews toxicity studies submitted by registrants that address the toxic effects of an active ingredient on non-target species as well as any relevant information gathered from the open literature.

EFED's screening level assessment typically relies upon the use of "surrogate species" within eight broad taxonomic groups to characterize the risks to a large array of non-target species that may be affected by pesticides. Testing for some taxonomic groups is required to include multiple surrogate species (e.g., the category "freshwater fish" includes bluegill sunfish, rainbow trout, and fathead minnows), while other groups rely upon a single surrogate species (e.g., the category "mammals" relies upon laboratory rats, and the category "estuarine/marine fish" generally relies upon the sheepshead minnow).

For each taxonomic group, EFED establishes one or more "assessment endpoints." Typical assessment endpoints for aquatic and terrestrial animals are survival and reproductive fitness. "Measures of effects" for these assessment endpoints (i.e., mortality, growth, hatch rate, embryo survival) are derived from short-term (e.g., 4-day) toxicity studies as well as partial life cycle, full life cycle, and multi-generational studies, depending on the class of organism. For terrestrial plants the assessment endpoint concerns the status of non-target plant populations, whose responses to pesticide exposure is evaluated from toxicity studies that quantify seedling emergence and vegetative vigor. For non-target aquatic plants the assessment endpoint is concerned with the maintenance and growth of standing crop or biomass, which is evaluated based on toxicity studies that quantify algal and vascular plant growth rates and biomass production. Within each of these broad taxonomic groups, acute and chronic dose levels are selected from the most sensitive tested species, based on a review of available test data that meet data quality requirements.

EFED then conducts a "risk characterization," integrating the results of its exposure and toxicity data, to evaluate the likelihood of adverse effects to non-target species. This risk characterization is expressed mathematically as a "risk quotient" (RQ), which is calculated by dividing the EEC (as estimated by exposure modeling) by acute and chronic toxicity assessment endpoints. The resulting RQ is then compared against established LOCs. LOCs are conservative RQs, which if not exceeded would generally lead EFED to conclude that pesticide usage has no effect on non-target species.

* The acute LOC for listed aquatic animals is an RQ of .05, which, depending on the dose-response values observed in toxicity testing, translates into a risk of mortality ranging from one in 200, to less than one in 10^{16}. For a pesticide with an average slope of 4.5, the estimated risk is around one in 417,000,000. For listed terrestrial wildlife EFED's acute LOC is an RQ of 0.1, which translates into a risk of mortality ranging from one in 50 to less than one in 10^{16}. For a pesticide with an average slope of 4.5, the estimated risk is around one in 300,000. Acute LOCs for listed species are a fraction of those established for non-listed species.

* The chronic LOC for listed animals is an RQ of 1, which represents an exposure equivalent to a level producing no observed adverse effects.

* The listed plant LOC is an RQ of 1, which represents an exposure equivalent to either a level producing very limited effects (EC05) or no observed adverse effects depending upon the availability of effects data.

When LOCs for listed species are exceeded, typically following an initial refinement of exposure assumptions by EFED, a "species specific" assessment generally is conducted by FEAD. A species specific assessment is a more refined examination than the screening level assessment. While the screening level assessment uses data on surrogate species to predict the effects on listed species together with a series of conservative assumptions about exposure, the species specific assessment may make adjustments in exposure estimates to reflect actual site specific conditions and whether the product will be used in areas where it is likely to result in exposure to listed species. The goal of species specific assessments is to better estimate the actual potential for exposure of listed species. Where feasible, FEAD may suggest changes in pesticide usage that reduce potential exposure so that established LOCs are not likely to be exceeded. Use modifications proposed by FEAD are examined by EFED through a modified screening level assessment, to determine whether alternate usage will trigger LOCs for listed species. Alternately, FEAD will characterize risks, determining whether effects are likely to adversely affect listed species or critical habitat.

As part of a species specific assessment, FEAD first determines whether listed species or critical habitat are found in or near areas subject to pesticide application. To assist in this review, FEAD searches "DANGER", a computerized database populated with county level information on both listed species distribution and crop occurrence. Listed species information is derived from listing notices and recovery plans published by the Services, and from other documentation and staff communications. Crop distribution information is extracted from the most recent U.S. Department of Agriculture Census, together with updated information based upon outreach with state and county representatives. Where an initial search identifies counties in which listed species and pesticide usage may co-occur, FEAD may examine whether unique geographical considerations within those counties is likely to preclude crop production or the presence of listed species, thereby eliminating the risk to listed species within those counties. FEAD also

determines the existence of potentially affected critical habitat by reviewing designated critical habitat listings.

Where pesticide application and listed species/critical habitat co-occur, FEAD attempts to predict the level of exposure likely to occur. FEAD examines the screening level assessment methodology used by EFED, to determine whether the conservative assumptions used within those models are appropriate given regional geography and actual use patterns. OPP maintains a suite of exposure scenarios that address most major crops and several regions, that may be used to better determine actual exposure levels. FEAD also examines the biological characteristics and habits of concerned species, to determine likely exposure pathways.

FEAD then examines whether exposure levels may result in direct and indirect effects to listed species or critical habitat. If effects are identified, FEAD will determine if the effects identified are likely to adversely affect any listed species. FEAD's assessment is based upon the screening level assessment performed by EFED, any additional information gathered during the species specific assessment, and FEAD's professional judgment about the significance and likelihood of the effects. FEAD's conclusions and supporting analysis are then documented in a written effects determination.

As EPA weighs acceptable levels of risk to non-target species by taking into account the economic, social, and environmental costs and benefits of any pesticide, FEAD evaluates those risks against the "not likely to adversely affect" standard established in 50 C.F.R. Part 402. In instances where acceptable risks are likely to adversely affect listed species or critical habitat, FEAD will engage in formal consultation with the Services to ensure that acceptable levels of risk are managed in a way to avoid jeopardy, or in rare circumstances provide justification for seeking an exemption from the requirements of section 7.

III. Evaluation of OPP's Risk Assessment Process

The Services have reviewed OPP's approach to risk assessment as described in the Overview, to determine whether this approach will produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations. The Services also reviewed OPP's approach to determine whether it should: a) produce effects determinations that appropriately identify actions that are not likely to adversely effect listed species or critical habitat; and b) produce all information necessary to initiate formal consultation where appropriate.

Attention is directed toward those issues identified by the interagency working group which met last Spring, and which were discussed extensively by a second interagency working group which met this Fall. The Services believe these issues go to the heart of whether OPP's approach will produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations. While the following discussion focuses upon those specific issues, it is important to note that the Services

review has examined OPP's entire risk assessment approach, and its ability to produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations.

1. *Best Scientific and Commercial Data Available*

The ESA requires that determinations relative to section 7 be based upon "the best scientific and commercial data available." 16 U.S.C. 1536(a)(2). As previously discussed, both FIFRA and regulations promulgated by EPA seek to ensure that pesticide risk assessments are based upon the best scientific data available. OPP gathers and considers a wide array of relevant information including:

* Data from laboratory and field studies submitted by registrants addressing the environmental fate of active ingredients and the toxic effect of such ingredients upon surrogate species. Studies conducted to generate data are subject to Good Laboratory Practice requirements, ensuring that results are reliable and of high quality.

* Information maintained in two EPA databases, which provide additional information on the toxic effects of pesticides. OPP reviews incident reports contained within its Ecological Incident Information System. This database includes: a) reports submitted under section 6(a)(2), which requires registrants to submit any factual information related to unreasonable adverse effects to the environment caused by a pesticide; and b) investigative reports voluntarily submitted to EPA from various state and federal agencies that oversee agriculture, wildlife, natural resources and environmental quality. OPP also reviews information contained in its Environmental Fate Database. This database contains a variety of environmental fate studies submitted by pesticide manufacturers in support of registration and reregistration.

* Information gathered by FEAD in order to better predict actual exposure levels associated with pesticide usage, and the likelihood exposure will affect listed species. Information includes: a) data from EPA's database DANGER, which provides information relevant to the possible co-occurrence of pesticide exposure and species presence on a county-by-county basis; b) refined exposure scenarios addressing major crops in several regions; and c) county specific information concerning local geography and pesticide application practices.

At the recommendation of the Services, OPP also will routinely search the open literature for relevant data on the toxic effects of pesticides subject to a FIFRA action. OPP will use ECOTOX as its search engine. The ECOTOX database is maintained by EPA's National Health and Environmental Effects Research Laboratory, Mid-Continent Ecology Division (MED) in EPA's Office of Research and Development (ORD). The database is populated through a broad search strategy designed to locate worldwide aquatic and terrestrial effects literature. Specifically, the ECOTOX database is populated with publically available literature located using Cambridge Scientific Abstracts; the Science Direct database, which provides access to

hundreds of scientific and technical journals; DIALOG, which provides access to the environmental databases BIOSIS and CAB abstracts; and Current Contents, which searches the tables of contents from current issues of leading journals in the sciences. Relevant sources are also identified from benchmark documents and review papers, and online ecotoxicology databases such as the USGS Wildlife and Contaminants Online website and the Canadian Wildlife Services Reptile and Amphibian Toxicology Literature database. At the present time, ECOTOX includes over 455,000 toxic effect records abstracted from over 19,000 references. It includes lethal and sublethal effects data and bioconcentration and bioaccumulation data on more than 10,000 chemicals, including data for pesticides on over 6,000 aquatic and terrestrial species.

OPP will utilize broad search strategies to ensure retrieval and review of all relevant information as more fully defined and discussed in other sections of this letter. The Services agree that the search strategies used by MED to identify information for potential inclusion into the ECOTOX database will retrieve the vast majority of relevant literature on the toxic effects of pesticides to listed species.

The Services expressed concerns as to whether all relevant data identified by these search strategies is actually included in ECOTOX database and retrieved by OPP. Through interagency discussions, the Services concluded that apparent gaps in the amount of information available from the publicly accessible component of ECOTOX were likely due to two considerations. First, there typically is a time lag between when information is initially identified through the MED search process, and when it is included in the ECOTOX database. Second, in an effort to populate ECOTOX with reliable and relevant information, MED rejects for inclusion into ECOTOX certain information initially identified through its broad search strategies. Though rejected, MED archives this rejected data and codes the basis for rejection. To ensure that all information relevant to the risk assessment will be obtained, OPP will request that MED: a) search its holding files for any relevant information identified through its search strategies, but not yet reviewed by MED and included in ECOTOX; and b) provide the titles (and abstracts and/or papers, if available), and rejection codes, for those articles not selected for coding and inclusion in the publically accessible component of ECOTOX.

Where established LOCs for listed species are exceeded during the screening level assessment, OPP also will review relevant biological, ecological and critical habitat information. Such information could include: a) species biology, physiology and biochemistry; b) species life history; c) species ecology (i.e., how a species life history unfolds in the environment in which it lives); d) status and trends; e) species incident data; and f) small and declining population dynamics. Sources for such information could include, as appropriate, status reviews, listing documents, recovery plans, critical habitat designations, and when available, species and critical habitat profiles (which are prepared by the Services for EPA and other Federal agencies and represent a summary of best available information).

When reviewing relevant biological, ecological and critical habitat information, OPP will employ appropriate and increasingly comprehensive search strategies to identify, understand and potentially rule out possible effects. OPP will typically begin with species and critical habitat profiles prepared and provided by the Services, if they are available. If a risk assessment proceeds beyond the screening level and to the extent initial information indicates potential effects or pathways leading to effects on listed species, OPP will employ appropriate and increasingly comprehensive search strategies. OPP search strategies will be tailored to address specific biological, ecological or critical habitat information relevant to identified uncertainties and potential effects. At the appropriate stage in OPP's review, the Services' lead Field Offices or Lead Recovery Coordinators will provide OPP a list of all current relevant benchmark documents, and other relevant and scientifically-reliable literature, identified by the Services since any status review was published, to facilitate OPP's ability to access specific biological, ecological or critical habitat information required to adequately address any potential effects identified as relevant for a given risk assessment and associated pesticide use scenario.

The Services have concluded that information collected by way of the above data requirements and search strategies, will capture information that will enable EPA to make effects determinations based upon the best scientific and commercial data available.

2. *Surrogates/Species Extrapolation*

The suite of laboratory toxicity studies required to be submitted by registrants necessarily involves a finite number of species, which serve as surrogates for other, untested species, including listed species. The species used in these required tests represent eight taxonomic groups, and are species deemed to be appropriately representative of other species within that group. Review of the current process noted that required tests do not include any surrogate species from four categories: amphibians, reptiles, marine mammals, and freshwater mussels. Interagency discussions examined OPP's use of surrogate species to ensure that use of test data from surrogate species represent the toxicological sensitivities of untested species, and especially species of these four categories.

Where no other data is available, the Services agree that the toxicity tests on surrogate species constitutes the best available information to analyze the toxicological sensitivities of untested species. In certain instances, OPP will have substantial information tending to demonstrate that the test species appropriately represents the sensitivity of another species. However, in other instances, frequently concerning the use of a surrogate species outside the class of the listed species, information demonstrating that the tested species appropriately represents the listed species is limited or inferential. The Services note that for some uses of surrogate species, the trend in data may indicate that the tested species is likely to be at least as sensitive as the untested class of species, but the analytical confidence in any conclusions drawn from these studies currently is limited. First, the confidence may be limited due simply to the small number of the studies. Second, the confidence may be limited due to the potential, and unknown, range of toxicological sensitivity among different species within the untested class, especially given the potential variability regarding most sensitive life stages or age classes among different

species. Consequently, while this surrogate information is the best available toxicological data, OPP's analysis will discuss species extrapolation uncertainties to ensure that scientific judgments using this data are made in a transparent manner. The Services and EPA will work cooperatively to develop methods in the future to increase confidence in the use of surrogate species test data, such as determining whether new safety factors may be identified, or exploring opportunities for testing additional species.

OPP will use methods described earlier concerning "Best Scientific and Commercial Data Available" to ensure that any additional information is obtained. Consequently, the Services and OPP also discussed when and how additional toxicological data, outside of the tests required of registrants, may be incorporated into OPP's risk assessment process. It was first noted that, if a test were conducted on an additional relevant species using the same protocols as the required tests, the results of the additional test would be compared to the results of the test on the standard surrogate species. If the standard surrogate species were shown to be more sensitive, then data from that test would continue to be used. If the standard surrogate species were shown to be less sensitive, however, then the test data from the additional species would be incorporated into the analysis.

Other tests on additional species may exist that were not conducted using the protocols similar to those for required studies. In these cases, OPP will review the test to determine the level of scientific reliability of the resulting data. For some tests, OPP may determine that the data is sufficiently reliable that it may be used in the same manner as a test conducted using required protocols. At the other end of the spectrum, results from some studies would be essentially impossible to quantify, leading OPP to conclude that the data from the study could not be used in the consideration of the toxicological effects on the species tested. If OPP determines that an available study addressing the toxicological sensitivity of a species will not be incorporated into analysis of the quantified risk assessment, OPP will nonetheless acknowledge the study and identify the reasons that its data was not incorporated as part of the analysis.

Other toxicity tests may be available, using appropriate protocols for a taxonomic class of organisms, for chemical compounds thought to be similar to the pesticide being analyzed at the time and for which such data is unavailable. The Services explored the possibility that such data could be used to estimate toxicity values in these instances. Due to a lack of externally peer reviewed information or analytical tools to credibly ascertain the similarities or differences between chemical compounds in this context, the ability of OPP to consider any test of one compound when reviewing a different compound is very limited. Consequently, it is unlikely that OPP would incorporate such a test into its risk assessment. However, to the extent that information does exist, and to the extent OPP has a documented basis for extrapolating from a test of one compound to the possible effects of another compound, OPP would consider such information as appropriate. Other programs within EPA are currently developing potential analytical models that may increase the likelihood of this capability.

The Services and OPP also discussed how surrogate data is used to address chronic and sublethal effects and to develop No Observed Effect Concentration (NOEC) levels for untested species. Once again, the data from tests on surrogate species would generally be the best available information. Also, as with data on acute effects, in those cases where other chronic or sublethal effects tests have been performed on species not included in the required tests, OPP will review the test and incorporate the information to the extent it is deemed sufficiently reliable, and will identify why the study data is not used if the information is deemed inappropriate to incorporate into the analysis. It was noted that due to the inherently longer-term nature of chronic effects, combined with the varied developmental processes of some untested classes of species (such as amphibians), the uncertainties in the chronic effects surrogate data may be greater than the uncertainties when extrapolating acute effects data from surrogate species. Consequently, the Services anticipate future joint discussions to explore methods to address these unknowns for chronic effects.

In each case, therefore, OPP will use the best available information to review acute or chronic effects on listed species, and when such data is limited to surrogate tests on species of a different class, OPP will discuss the uncertainty in the use of the data. Consequently, the Service believes this is an appropriate method and use of the best available data. As additional data becomes available in the future, including data from outside tests or input from the Services, OPP will continue to revise its characterization of any uncertainties that may be inherent to the process.

3. *Potential Exposure*

The models used by OPP to calculate potential exposure to pesticides are developed to represent conservative estimates, and to avoid underestimations of the actual exposure. Nonetheless, there are certain types of exposure that are not fully represented in the available models. Consequently, the Services and OPP discussed what potential gaps may exist in the information obtained through these models, and how OPP uses available information to address these potential gaps.

The current model used to estimate aquatic exposure is intended to establish a "worst case" scenario, and therefore an upper bound exposure. Nonetheless, there are some unique scenarios in which even this model may underestimate exposure, due to specific circumstances (e.g. potential that a vernal pool may develop unpredicted high concentrations due to evaporation). Although there are no currently-established models that fully address these unique situations, OPP has developed proposals for aquatic exposure models for puddles, run-off, or similar exposure. The Services agree that these proposals could possibly be more effective at estimating some of these unusual exposure scenarios, and support OPP's intentions to incorporate these models in the near future, pending a favorable external peer-review by the FIFRA SAP. In addition, the Services are developing information that may be used in the future to further refine these models. In the meantime, however, the Services agree that the existing model necessarily represents the best available approach currently producing data for estimating aquatic exposure.

OPP's assessment uses different screening-level assumptions in PRZMS/EXAMS for the percentage of applied pesticide drift to estimate exposure through drift from ground spraying or from aerial spraying. The current assumption for drift associated with ground spraying (1%) is consistent with or greater than modeled drift predictions. The current assumption for drift associated with aerial spraying (5%), however, has the potential to underestimate drift in certain scenarios of droplet size and distances down field from application. Consequently, when the risk assessment indicates that drift may be a substantial component of overall exposure and risk, the risk characterization will present additional risk estimates based on alternative spray drift assumptions, when necessary to account for instances where the 5% assumption potentially underestimates exposure.

Current analysis of terrestrial exposure either focus exclusively on dietary exposure, or expresses exposure on a generalized potential bioavailable mass of pesticide on a per unit area basis. The Services agree that the dietary exposure analysis is appropriate as a means of estimating dietary exposure. Potential exposure through inhalation or dermal contact currently constitutes an unknown for which the risk assessment provides no available information. OPP has developed proposals to analyze inhalation and dermal exposure for birds in such a way that it may be added to dietary exposure, and thus used in the development of a risk quotient. Similar proposals for other classes of species are expected in the future. The Services support the development and implementation of these proposals, following external peer-review by the FIFRA SAP. Pending this, however, the data on dietary exposure remains the best available quantified information provided through existing models.

In each case above, of course, the information incorporated from these existing models constitutes the best available data only if no alternative and superior data exists from a specific outside test or study. OPP will use methods described earlier concerning "Best Scientific and Commercial Data Available" to ensure that any such information is obtained. If data from an additional test is available, OPP would review the test to determine the extent to which it is scientifically reliable and identifies a quantitative measure of exposure potential. Relevant data may include new tests on exposure pathways already considered by existing models; tests on new pathways such as inhalation; pesticide residue monitoring data; analysis of practical application scenarios that do not meet existing models; or toxicological data suggesting alternate exposure pathways for listed species. If OPP does not believe other relevant data provide a demonstrable basis from which to draw conclusions about exposure, OPP will identify the data and explain why it was not used. OPP has noted that monitoring data are seldom relevant, quantifiable, and reliable for risk assessment purposes because model-generated values represent possible exposure scenarios not likely evaluated through monitoring and because model values are usually higher. However, in situations where monitoring exposure data is relevant, quantifiable, and reliable, OPP would change its EEC values. In addition, EFED, in providing the risk quotient for review by the risk manager, would use the information to identify any potential uncertainty the new data creates in the calculated risk quotient. This uncertainty would be highlighted, and if the risk manager determines that no adjustment needs to be made from the exposure levels otherwise estimated despite the highlighted uncertainty, this decision would be

explained in the record of the risk assessment. By this method, OPP ensures that all available information will be considered, and date that are relevant, quantifiable, and reliable will be used.

Finally, as noted above in Section II of this letter, the species specific assessment of risks conducted by FEAD may make adjustments to EFED's exposure estimates to reflect actual site specific conditions and whether the product will be used in areas where it is likely to result in exposure to listed species. The goal of species specific assessments is to better estimate the actual potential for exposure of listed species. Consequently, this portion of the assessment will frequently consider label use restrictions, state laws or regulations, or county bulletins when considering actual potential for exposure. Similarly, as discussed in Section II, FEAD may suggest changes in pesticide usage to limit exposure. The Services' review of EPA's approach assumes that any analysis of pesticide exposure based on use limitations will involve limitations that can be enforced as legal restrictions on the pesticide use, and therefore it is reasonable to expect them to represent the likely actual exposure. In the same light, the Services' review assumes that any use restrictions that would be purely voluntary would not be the basis for a conclusion by OPP that pesticide exposure would not occur.

4. *Levels of Concern*

The toxicological levels of concern for acute effects developed through OPP's risk assessment process are developed by applying a factor to the median lethal dose ("LD50 or LC50"), calculated from the toxicological dose-response tests (the median lethal dose being the dose at which there is a one-in-two probability of individual mortality). The data used to calculate the median lethal dose can also be used to estimate the point at which the probability of mortality is negligible, and the fraction of the median lethal dose that equates to that negligible effect can then be determined. The fraction of the LC50 currently used for listed aquatic species is 0.05. For mammals, the factor is 0.10 of the LC50 or LD50. Both are an estimate of a dose which has a negligible probability of mortality. This terrestrial animal factor was originally established using an average of the available dose-response test data, which indicated that 0.10 of the median lethal dose would have a one-in-300,000 probability of individual mortality and the aquatic animal factor of 0.05 would have a one in 400 million probability of individual mortality. However, the test data from any given species, or any given test, may indicate that the actual likelihood of mortality is different – that is, the probability of mortality from 0.05 of the LC50 may be higher or lower than one in 400 million. Thus, the actual probability of individual mortality may be higher or lower than the probabilities discussed above.

The Services and OPP discussed potential ways of selecting specific effect probabilities as the LOCs, consistent with the intent of the currently employed LC50 and LD50 endangered species factors. One option would take advantage of the actual data from the acute and chronic effects tests that form the bases of the LC50/LD50 values actually used for the chemical in question. This option would be expected to result in higher levels of concern in some instances, and lower levels of concern in other instances. However, both the Services and OPP acknowledge that implementation of such an option will require further development and external peer review, and anticipate future discussions to assess the propriety of developing and implementing an alternate

approach. The Services and EPA have agreed that a collaborative effort to develop one or more approaches for SAP review is a high priority.

In the meantime, the LOCs used by OPP rely upon the best available data that reflects a fully-reviewed and approved process, including review by EPA's FIFRA SAP. These LOCs reflect an appropriate threshold for determining when the probability of an effect is negligible, and as such, are appropriate thresholds for determining whether pesticide use "may effect" a listed species. Until such time as a new option may be incorporated to allow a different analysis of the available data, OPP will continue to use the existing methods to calculate the levels of concern. In doing so, however, OPP will include in the documentation of its calculations an estimate of the actual probability of mortality from applying the .05 factor to the median lethal concentration for aquatic organisms (or the .10 factor in the case of terrestrial organisms). Consequently, OPP's process will be using the best available information, using it in an approved scientific manner, and fully representing any uncertainties within that process.

5. *Consideration of Pesticide Formulations, Mixtures and Degradates*

Most features of OPP's risk assessment process principally focus upon effects caused by the pesticide product's active ingredient. This emphasis led the Services to examine the extent to which OPP's process addresses other effects potentially associated with use of the pesticide product. In particular, the Services reviewed if and how OPP considered potential effects caused by degradates, metabolites, formulations and mixtures.

In addition to the active ingredients, OPP's risk assessment process adequately considers potential effects caused by significant environmental degradates and metabolites. Environmental fate property testing guidelines require registrants to identify all degradates and metabolites approaching 10% of the dose rate. Additionally, registrants must identify all degradates or metabolites, including those less than 10% of the dose rate, that present known toxicological or ecological concerns. Toxic degradates or metabolites are subject to the same testing requirements used for active ingredients.

Formulations include all components of a pesticide product as sold or distributed, including multiple active ingredients (pre-mixes), inerts and surfactants. Based upon past experience, OPP believes the active ingredient generally constitutes the most toxic component of a pesticide product. Indeed, EPA previously reviewed large categories of inert ingredients commonly used in pesticide formulations to determine whether they are harmful (although the level of data supporting these determinations varies and usually is more limited than the data set available for an active ingredient). While this general assessment may be true, the Services examined OPP's process for identifying product components or formulations that may cause different or more extensive effects than the active ingredient.

OPP conducts a screening level assessment on a formulated product only if data is available indicating the formulation is more toxic than the active ingredient. OPP would expect to receive such information pursuant to section 6(a)(2) of FIFRA, which obligates registrants to submit any

information related to known adverse effects to the environment caused by a pesticide. OPP's approach differs from procedures followed within the European Union (EU), only to the extent that the EU requires registrants to submit acute toxicity data on the product formulation for mammals and aquatic fish and invertebrates if initial tests on the active ingredient suggest concerns. Because OPP would expect data required by the EU to be reported to OPP under section 6(a)(2) if the tests involve a formulation that is approved in the United States and the data indicate greater toxicity than other available studies, OPP's process ultimately would be expected to produce largely comparable data as the data used by the EU. To the extent additional and accessible data exist, however, OPP has agreed to obtain and consider such information in its risk assessment process. Additionally, OPP's review of the open literature as described above, will be expected to identify other available data addressing the effects of pesticide formulations.

Because new environmental fate and toxicity data specific to product formulations will not always be available, OPP's process for examining formulated products is less robust than the process used to assess active ingredients. The Services conclude, however, that OPP's existing process for evaluating formulations makes use of the best scientific and commercial data available. Beyond this, the Services note that EPA is engaged in several efforts designed to improve its assessment of formulated products. Under FIFRA, EPA is engaged in a Congressionally mandated, multiple year review of all food use inert ingredients, to verify safety determinations previously made by the Agency under the Federal Food, Drug and Cosmetic Act. Internally, OPP is actively reviewing in-house ecological effects databases, to summarize information on the distribution of the relationship between the toxicity of active ingredients and formulated products.

Pesticide mixtures, as discussed by the Services and EPA, fall into three separate categories: mixtures created by components added by the user, including surfactants or other additives; separate pesticide products used in combination with one another by the user; and mixtures occurring within the environment as a result of independent application of pesticide products and their interaction with environmental substances. At the present time, OPP's screening level assessment does not consider effects to non-target species caused by such mixtures. Moreover, general agreement was reached between OPP and the Services that it is unlikely OPP can develop specific testing methods to measure the effects of such mixtures in a quantifiable manner. However, OPP will survey the open literature for any data addressing the effects of these types of mixtures, which it will use in its risk assessment process. The Services agree with this approach, and believe it will likely capture the best available scientific and commercial data.

6. *Sublethal Effects*

OPP's risk assessment approach addresses potential sublethal effects through acute and chronic exposure conditions. OPP evaluates multiple sublethal endpoints for aquatic organisms, birds and mammals. For example, sublethal endpoints for aquatic species include embryo hatch rate, time to hatch, growth, exposed egg production, second generation hatch rate, and second generation growth. For screening risk assessments, OPP selects the most sensitive toxicity

endpoints for establishing RQs (e.g., for aquatic species, the chronic RQ is based on the dose level at which none of these sublethal toxicity endpoints is effected, otherwise referred to as the NOEC), that are then compared to LOCs for chronic risk.

The Services have deemed appropriate the existing sublethal endpoints that are included by OPP in its risk assessment process, and the manner in which they are used for purposes of assessing potential sublethal effects. While recognizing that these endpoints may establish the best available data for OPP's use, the Services also note that future consideration will be given to the development of additional sublethal endpoints. OPP has the option of including additional sublethal data in its risk assessment, if sufficient and reliable information establish a scientifically sound relationship between the proposed sublethal effect and the survival or reproductive capacity of an organism. The Services and EPA intend to hold future discussions about including additional sublethal endpoints in OPP's risk assessment process, subsequent to external peer review by the FIFRA SAP.

7. *Indirect Effects*

When considering the effects of an action on listed species and critical habitat, the Services consider a variety of effects, including "indirect effects." Indirect effects are defined as those effects caused by the proposed action that are later in time, but still reasonably certain to occur. See 50 C.F.R. 402.02. Such effects may occur outside of the area where a pesticide is applied. Indirect effects may be difficult to identify and assess, given limited available data and causal relationships that are not always well understood.

During interagency discussions examining this risk assessment process, OPP and the Services discussed methods to ensure OPP's process uses appropriate available information to identify potential indirect effects during the screening level assessment. Through these discussions, the Services and OPP identified ways that existing LOCs established by OPP will inform their consideration of indirect effects on listed species.

* If exposure levels do not trigger established taxonomic LOCs for any listed species, OPP can conclude that pesticide use will not cause indirect effects to listed species that may be dependent (as food, habitat, etc.) upon that taxonomic class of species.

* If exposure levels trigger established taxonomic LOCs for non-listed species, OPP will conduct a more thorough review of possible indirect effects. Exceeding this substantially lower threshold elevates concerns that non-listed species may be directly affected, which in turn raises concerns that listed species dependent upon such non-listed species may indirectly be affected as well. Under this scenario, OPP will proceed to more closely evaluate the nature, likelihood and magnitude of any indirect effects. This evaluation will review whether any listed species may be dependent upon a species within the class whose tests triggered the non-endangered species LOC, will review the nature of the dependent relationship, and will review the likelihood and magnitude of the potential

indirect effects on the listed species due to the direct effects on the non-listed species, using the best scientific and commercial data available.

* If exposure levels trigger established taxonomic LOCs for listed species, but do not exceed established LOCs for non-listed species, OPP will exercise its professional judgment in determining the level of additional inquiry necessary to evaluate the potential for indirect effects. In exercising such judgment, OPP will in part document the actual probability of an effect (using data from its direct effects analysis), the listed species within the action area, and the nature and importance of any interrelationships between listed species and the non-listed species upon which they depend. If in the exercise of its professional judgment OPP determines that pesticide use may pose indirect effects to listed species, it will proceed to more closely evaluate the nature, likelihood and magnitude of any indirect effects using the best scientific and commercial data available.

Where appropriate, OPP will work collaboratively with the Services to identify relevant biological and ecological relationships to ensure that OPP appropriately considers potential indirect effects.

The Services believe this approach makes full use of any available information to examine potential indirect effects. Identifying appropriate triggers within the screening assessment process leverages existing and scientifically defensible processes used by OPP. The approach also facilitates analysis of potential indirect effects earlier in the risk assessment process. Reliance upon established LOCs also provides objective and quantifiable benchmarks signaling potential indirect effects, screening out false positive concerns and allowing OPP to focus upon potential indirect effects of legitimate concern. By using an appropriate screen to identify potential instances of indirect effects, this process also recognizes that indirect effects to listed species may stem from varying dependent relationships including food sources, predator bases, or habitat. Consequently, the process follows this screen with a consideration of the likelihood of indirect effects based on a more specific review of the interrelationship of the species in question.

8. *Cumulative Effects*

During formal consultation, the Services also consider any "cumulative effects," which are defined to include the effects of future State and private activities reasonably certain to occur within the action area of the Federal action subject to consultation. 50 C.F.R. 402.02. A cumulative effects analysis is required for Federal actions likely to adversely effect listed species. See 50 C.F.R. 402.14(c). Within the biological opinion, it commonly is the least documented part of any effects determination, given the lack of definitive information on future State and private activities. See Consultation Handbook, Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act, Page 4-30 (FWS and NMFS, March 1998).

Where OPP has determined that an action is likely to adversely affect listed species or result in destruction or adverse modification to critical habitat, OPP will consider cumulative effects as part of its effects determination. This analysis will be based upon the best scientific and commercial data available. The extent of this analysis will vary depending upon the level of concern initially identified and the geographical reach of the action area. To assist OPP in developing sound cumulative effect analyses, the Services have shared past biological opinions involving action areas of varying size, which include appropriate cumulative effects analyses. The Services are prepared to assist OPP in development of cumulative effects assessments for pesticide registrations that are likely to adversely affect listed species. Through this collaborative process, the Services believe that effects determinations developed by OPP will appropriately assess any cumulative effects and will be based upon the best scientific and commercial data available.

9. *Environmental Baseline*

When initiating formal consultation under the existing ESA consultation regulations, an action agency is required in part to provide the appropriate Service a "description of the manner in which the action may affect any listed species or critical habitat." 50 C.F.R. 402.14(c)(4). In doing so, an action agency must identify all direct and indirect effects of an action, together with the effects of other activities that are interrelated or interdependent with the action, "that will be added to the environmental baseline." 50 C.F.R. 402.02. The "environmental baseline" is defined to include: a) the past and present impacts of all Federal, State or private actions and other human activities in the action area; b) the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation; and c) the impact of State or private actions which are contemporaneous with the consultation in process. The environmental baseline provides a snapshot description of the status of the species in the action area an provides context as to how that condition came to be.

When initiating formal consultation, OPP routinely discusses the environmental baseline associated with the action area. During interagency discussions, OPP and the Services explored ways to improve development of environmental baseline data. All agencies acknowledged that the Services, based upon their responsibilities and technical expertise, possess the vast majority of data relevant to the development of any environmental baseline. For example, through status reviews, the listing process, and the designation of critical habitat, the Services maintain substantial information discussing the status of each species and activities that affect the species' environment. Given their role as consulting agencies, both Services are also aware of anticipated Federal actions that have undergone formal or early section 7 consultation. The Services also are somewhat likely to be aware of State and private actions occurring contemporaneously. Given these information resources, the Services routinely assist action agencies by providing information used to develop an appropriate environmental baseline.

Consequently the Services and OPP have agreed that OPP's risk assessment process will use the following methodology when developing an environmental baseline. Consistent with 50 C.F.R. 402.14, developing an environmental baseline is only necessary where OPP has determined that

a pesticide action likely will adversely affect a listed species, or will destroy or adversely modify critical habitat. In such instances, OPP will ask the Services to provide appropriate information concerning the status of the species and other information necessary to establish an appropriate environmental baseline. Information provided by the Services will be used as the environmental baseline for purposes of satisfying the consultation requirements of 50 C.F.R. 402.14.

The Services have determined this approach will ensure development of a comprehensive environmental baseline which satisfies the requirements of Part 402, and enhances the Services' review of the proposed action during formal consultation. Moreover, this approach will better leverage existing resources by capitalizing on the information possessed by the Services. By establishing a more efficient process for developing baseline information, OPP can more rapidly complete initiation packages, thereby accelerating the formal consultation when necessary.

10. *Critical Habitat*

Section 7(a)(2) requires that all federal agencies ensure that any action authorized, funded or carried out by such agency is not likely to jeopardize the continued existence of any listed species "or result in the destruction or adverse modification of critical habitat." 16 U.S.C. 1536(a)(2). Where a proposed action may affect critical habitat, the Action Agency and the Services: a) identify the primary constituent elements (PCE) for the habitat; and b) examine whether the action will adversely affect the habitat's PCEs or their management in a manner likely to appreciably diminish or preclude the role of that habitat in the survival and recovery of the species. See Consultation Handbook, Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act, Page 4-39 (FWS and NMFS, March 1998).

Through its risk assessment process, OPP considers the effects of pesticide use on designated critical habitat. During interagency discussions, OPP and the Services reviewed how OPP can use the available information to identify effects to critical habitat during the screening level assessment. If initial screening level toxicological tests indicate that the listed species LOC would not be exceeded, then no further analysis would be required, as OPP could reliably determine that no effect on critical habitat would be caused without further specific knowledge about the critical habitat. However, if a listed species LOC is exceeded, OPP would proceed to review the locations and elements of any designated critical habitat, and the potential effects of pesticide use on critical habitat in the following manner:

* OPP will first determine whether any portion of the action area has been designated as critical habitat for any listed species. Through an internal database, OPP will identify all counties in which the pesticide at issue likely will be used, based upon known crop production within that county. OPP and the Services will work on a collaborative basis to identify any relevant counties that also include designated critical habitat.

* Where the pesticide at issue will be used within critical habitat, OPP will determine whether pesticide use "may affect" critical habitat. To do so, OPP will examine relevant

biological information concerning the habitat, including most specifically the critical habitat designation and the identified PCEs. OPP will then use available toxicity data to determine whether the pesticide "may affect" any PCE. For those PCEs that are an organism or can be characterized based on a functional relationship to an organism, this review will include a review of acute and chronic test data, to determine whether the pesticide may affect the class of species by which the PCE would be represented. If the toxicity analysis indicates that the listed species LOC would be exceeded, then OPP would determine that the pesticide may affect the PCE, and therefore may affect the critical habitat. OPP could also determine that the pesticide may affect critical habitat if toxicity data related to exposure indicated a nonbiological PCE (e.g., water temperature as influenced by vegetation cover) would be altered due to the exposure to the pesticide

* If pesticide use "may affect" critical habitat, OPP will then determine whether pesticide use is likely to adversely affect critical habitat. This review will require a more thorough examination of the scope and magnitude of the effects on the relevant PCE, and will require additional review of biological data about the habitat, how it is used by the listed species, and the features that caused the affected portion to be designated a PCE. This review will be similar in analysis and relevant information to the assessment of indirect effects on the listed species, due to the nature of the dependent relationship of a listed species on its designated critical habitat. However, OPP will examine effects on critical habitat distinct from its analysis of effects on listed species, to ensure that pesticide use is not likely to result in destruction or adverse modification of critical habitat. OPP's assessment will be based upon the best scientific and commercial data available, which may include information from the critical habitat designation, listing notice, recovery plan, status reviews, and other relevant information, and include a review of the open literature consistent with the process identified in our earlier discussion of best scientific and commercial data available.

This process recognizes the important features of designated critical habitat, and the distinction that effects on critical habitat must be analyzed separately from the effects on the listed species. Consequently, the Services agree that this process uses best available information in an appropriate manner to determine possible effects to critical habitat.

11. *Addressing Uncertainty in Decision Making*

When exercising its responsibilities under section 7, the Services frequently must make decisions in the absence of complete information. Given their exceedingly limited populations, much remains unknown about the biology, population dynamics and ecology of listed species, to the point that even when using the best scientific and commercial data available, management decisions are made against a backdrop of significant data gaps and information of questionable reliability. In order to ensure prudent and sufficiently protective management decisions, the Services identify and document data gaps and then provide the benefit of the doubt to the species concerned, with respect to such data gaps. See Consultation Handbook, Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species

Act, Page 1-6 (FWS and NMFS, March 1998). Because uncertainty is fundamentally inherent to the ESA decision making process, the Services have carefully examined the manner in which OPP makes decisions in the face of uncertainty, to ensure that decisions it makes under the ESA afford sufficient protection to listed species and the habitat upon which they depend.

To minimize the level of uncertainty associated with pesticide decisions, FIFRA and implementing regulations mandate that registrants submit a broad suite of information supporting the pesticide action at issue. Beyond this extensive information, OPP will conduct an independent and appropriately broad search of additional toxicological and ecological information, to ensure decisions are based upon the best scientific and commercial data available. In the absence of required data necessary to appropriately evaluate risks, EPA will not register or reregister a pesticide. This approach is consistent with FIFRA, which prohibits registration or reregistration of a pesticide product that causes unreasonable adverse effects on the environment either when performing its intended function or when used in accordance with widespread and commonly recognized practices. 7 U.S.C. 136a(c)(5).

Nonetheless, in many instances data may exist to support a registration decision, but the possibility remains that the data retains some level of uncertainty. This reality is inherent in any analysis attempting to prospectively measure potential effects of pesticides in real-world, variable conditions, and for all types of species. Consequently, many steps in OPP's approach are intended to use conservative estimates, as discussed elsewhere in this document. Moreover, OPP will incorporate discussion of these uncertainties in the documentation of its assessment. This practice will ensure that these uncertainties are considered appropriately by OPP decision-makers, and will demonstrate the application of professional scientific judgment in the resolution of the uncertainties. The Services believe this practice will ensure that decisions made in the face of uncertainty will be made in a responsible manner.

IV. Conclusion

Through our review of documentation furnished by OPP and extensive interagency discussions that have taken place over the past year, the Services have analyzed the approach to ecological risk assessment used by OPP to evaluate the effects pesticide use may have on listed species and critical habitat when considering regulatory actions under FIFRA. Based upon this careful review, the Services have concluded that this approach, as understood and reflected in this letter, will produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations. The Services have further concluded that this approach used by OPP should produce effects determinations that appropriately identify actions that are not likely to adversely effect listed species or critical habitat, and that are consistent with those that otherwise would be made by the Services. This approach also will produce all information necessary to initiate formal consultation where appropriate.

DATED: 1/26/04

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DATED: 1-26-04

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