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Pesticide Regulation and the Endangered Species Act

EDITED BY

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James L. Cowles, A. Tilghman Hall, Scott H. Jackson,
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Foreword

The ACS Symposium Series was first published in 1974 to provide a mechanism for publishing symposia quickly in book form. The purpose of the series is to publish timely, comprehensive books developed from the ACS sponsored symposia based on current scientific research. Occasionally, books are developed from symposia sponsored by other organizations when the topic is of keen interest to the chemistry audience.

Before agreeing to publish a book, the proposed table of contents is reviewed for appropriate and comprehensive coverage and for interest to the audience. Some papers may be excluded to better focus the book; others may be added to provide comprehensiveness. When appropriate, overview or introductory chapters are added. Drafts of chapters are peer-reviewed prior to final acceptance or rejection, and manuscripts are prepared in camera-ready format.

As a rule, only original research papers and original review papers are included in the volumes. Verbatim reproductions of previous published papers are not accepted.

ACS Books Department

Preface

This book addresses the confluence of two great streams of environmental protection and regulation, both geographically situated within a continent of abundant natural resources, incredible biodiversity, and advanced agricultural production technologies. One stream concerns the *regulation of pesticides for environmental protection* within a risk-benefit paradigm grounded in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of 1947. Amendments to FIFRA (e.g., 1972, 1988, 1996, 2006) have been achieved through a Congressional process that requires compromise in viewpoints in order for legislation to be passed. Regulatory oversight by the U.S. Environmental Protection Agency (EPA), and a wealth of guideline-compliant studies from industry have yielded arguably the most comprehensive and science-based system for protecting against “unreasonable adverse effects” on the environment and human health as relates to pesticide use. As of 2012, more than 700 pesticide active ingredients and many thousands of end-use products have been evaluated and registered under FIFRA for pest management use in American agriculture, forestry, residential, and public health protection. The other stream concerns the *protection of species that are endangered or threatened* with extinction as well as preservation of the ecosystems on which they depend. This stream springs from provisions of the Endangered Species Act (ESA) of 1973, which requires each federal agency to ensure that any action it takes is not likely to jeopardize the continued existence of any endangered species or threatened species. Oversight is provided by the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS), collectively referred to as the “Services.” As of 2012, nearly 1,400 animal and plant species have been listed under the ESA as being afforded such special protections. Interpretation of the ESA and application of its provisions to species protection have evolved primarily through court decisions rather than amendments to the Act itself. Such circumstances have set a climate of dispute rather than compromise. Because the ESA is very site-specific in its orientation, the vast amount of expertise and data supporting it is scattered across the nation and not readily available for a national-level decision such as is made for the registration of a pesticide.

Achieving a harmonious, practical convergence of these streams of environmental protection and regulation has proven devilishly difficult during the past four decades. Both FIFRA and ESA regulations provide a strong basis for environmental protections based on scientific assessment, but they were not constructed in a complementary manner which would provide for ready interface. Instead, two divergent schools of thought, assessment systems, and regulatory procedures have grown up — one overseen by the EPA and the other by the Services. Despite historical efforts for scientific cooperation and procedural rapprochement between the two streams and their associated agencies, a satisfactory and workable system of regulating pesticides at the federal level to meet both FIFRA and ESA requirements has not emerged. EPA's approaches have frustrated the Services because USFWS and NMFS believe EPA has not thoroughly considered all potential risks to the species. The Services' assigned mission to protect the species at all costs has frustrated growers and registrants alike because agriculturally incompatible restrictions, not always reflective of local conditions and practices, have arisen. Environmental advocates have grown frustrated with the lack of progress by both EPA and the Services in developing a cooperative approach to species assessment and protection, and their impatience has found expression in a series of lawsuits that inhibit the pesticide regulatory and consultation process and consume precious agency resources with court-ordered activities. Does the current state of affairs indicate that currently registered pesticides pose significant, unmitigated risks to the nation's endangered and threatened wildlife and plant communities? Many would say "no"; some would say "yes" or "possibly." But all stakeholders would agree that pesticides should be regulated to meet both FIFRA and ESA obligations and that finding science and policy accommodations to achieve this goal is urgently required to maintain the standards of agricultural productivity, public health protection, and environmental quality that our society collectively expects.

The basis of this book is an emerging spirit of cooperation, increasing commitment to constructive dialogue, and solutions-oriented focus among the key stakeholders. There is a genuine desire on the part of key decision-makers to identify and implement both scientific and process improvements to resolve current areas of impasse. At the 242nd meeting of the American Chemical Society (ACS) held in Denver, Colorado, during August 30 to September 1, 2011, an extraordinarily diverse assemblage of federal and state regulators, scientists, and expert consultants along with agricultural and environmental advocates gathered to advance the dialogue related to pesticide regulation and endangered species protection. During the course of three days of invited lectures, panel discussions, and informal chats during coffee, participants were able to highlight lessons from existing case studies, explore promising scientific advances, and exchange views for process and policy improvements. This book of contributed chapters by symposium participants represents the first comprehensive collection of information and ideas related to pesticide regulation and the Endangered Species Act. As had been the case for the symposium, chapter contributors have gone beyond merely outlining the present difficulties and included specific recommendations for scientific and/or process improvements. Chapters have been organized into sections which are loosely clustered around policy and process considerations, case studies, and advanced scientific assessments. You will find a diversity of approaches and perspectives captured in this book, which in some cases will appear contradictory. Based on the paradigm from which you operate, these chapters or portions thereof may alternately encourage and enlighten you, puzzle or irritate you. In any case, we trust that you will be challenged and stimulated and ultimately driven to constructive action, whether your sphere of influence involves the policy or scientific realms, whether you are regulator or regulated, and whether your primary calling involves production or protection. It is also our sincere desire that this book will contribute in a positive way to fostering additional constructive dialogue among stakeholders and to energizing this generation of policy-makers, advocates, and scientists to collectively merge the 40-year-old streams of pesticide regulation and endangered species protection into a more perfect harmony.

The fountains mingle with the river *And the rivers with the ocean* P.B. Shelley	*Eventually, all things merge into one,* *and a river runs through it.* Norman Fitzroy Maclean

We'd like to thank the AGRO Division of ACS for organizing the symposium on which this book is based, and also thank the invited speakers, expert panelists, and attendees who participated in the lively sessions in Denver. The financial support of Dow AgroSciences, CropLife America, and Intrinsik Environmental Sciences for the symposium is also acknowledged. Special appreciation is offered to Don Brady of EPA's Environmental Fate and Effects Division for his early encouragement in having ACS address this topic and arrangement for federal agency participation. Finally, in producing this book we are indebted to the invited speakers who willingly captured their perspectives and/or scientific results in written form, to the peer reviewers and co-editors who critically examined each chapter, and to those who provided permissions for use of existing tables, figures and artwork. Regarding the book cover montage, we'd like to give credit to those who provided permission to use their images and photos:

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Bernalyn D. McGaughey

Bernalyn D. McGaughey, in addition to providing corporate executive oversight to Compliance Services International (CSI), has an extensive regulatory background involving issues with U.S. Environmental Protection Agency pesticide registration, evolving regulatory environment in the European Union, and challenges related to endangered species regulation. She has over 30 years of experience in data evaluation, chemical research, study monitoring, and project management related to pesticides and other chemicals. She is a recognized scientific expert witness, endangered species task force manager, and a specialist in data compensation. Prior to founding CSI in 1988, she held various regulatory, sales, and technical positions with Pennwalt and Shell Chemical Corporation's agricultural chemical divisions.

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Scott H. Jackson (Ph.D., Union Institute) is a principal scientist for BASF Corporation in Research Triangle Park, North Carolina. He has worked in industry for more than 20 years in various technical capacities. In his current role with BASF's stewardship group, he is focused on exposure questions that involve modeling, environmental fate, and analytical chemistry, and his activities involve frequent interactions with state, local, and federal regulators. Scott is an active ACS AGRO symposium organizer and committee chair, and a frequent speaker at national and international conferences. He is also active with a number of other organizations including the Pesticide Stewardship Alliance and CropLife America. Scott serves as an adjunct professor at Regent University, teaching earth science.

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Jeffrey J. Jenkins (Ph.D., Michigan State University) is professor of Environmental and Molecular Toxicology at Oregon State University, which he joined in 1990. His current research focuses on impacts of pesticide use on air and water quality, and human and wildlife exposures in both agricultural and urban settings. He has been active for many years with ACS AGRO as symposium organizer, committee chair, and Division Chair. Dr. Jenkins serves as Principal Investigator for the National Pesticide Information Center, and is active in outreach and education at both the national and international levels. Prior to joining Oregon State, he served as a Senior Research Chemist at Merck Sharp & Dohme for insecticide development and as Extension Specialist and Associate Director of the Massachusetts Pesticide Analysis Laboratory.

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Chapter 1

Pesticide Regulation and Endangered Species: Moving from Stalemate to Solutions

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Shortly after the U.S. Environmental Protection Agency (EPA) assumed responsibilities for federal pesticide regulation under FIFRA (Federal Insecticide, Fungicide and Rodenticide Act), the Endangered Species Act (ESA) became law. Although FIFRA deals with licensing and registration under the mandate "not to cause unreasonable adverse effects" on the environment, ESA obligations include ensuring that registration actions "are not likely to jeopardize" the continued existence of an endangered species, and require consultation with the U.S. Fish and Wildlife Service (USFWS) or National Marine Fisheries Service (NMFS) if the registration action "may affect" an ESA-listed species. Over the years, EPA has modified data requirements, developed ecological risk assessment methodologies, and proposed several successive field implementation plans, including county bulletins, to ensure protection of endangered species in pesticide regulatory decision-making. Industry has also been active in generating supporting data, and a significant outcome has been development of a task force-sponsored species location system. During the past 35 years, EPA has developed a conservative, screening-level ecological risk assessment approach designed to provide a high degree of protection for ecosystems, including endemic endangered species. However, limited success has been experienced in forging a collaborative process between EPA and the Services (USFWS, NMFS) with respect to ESA

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consultation activities. A variety of operational and technical issues has impeded progress in effectively meshing FIFRA and ESA obligations. At present, efforts to make a fresh start on ESA-related consultations via the EPA Registration Review program are making slow progress, and a spate of ESA-related lawsuits unrelated to Registration Review has clogged the system and exacerbated unresolved issues. This chapter reviews historical developments related to implementation of ESA obligations for pesticide regulation, examines the current state of affairs with respect to Registration Review and litigation, and highlights a movement toward process and science improvements described in succeeding chapters of this book.

Introduction

The North American continent has experienced colossal ecosystem changes and associated floral and faunal fluxes over the eons. Many of these changes were due to natural cycles and global processes including climate changes which led to successive ice ages. Human changes to the landscape began some thousands of years ago with the arrival of Native Americans and later the European migrants. By the late 19th Century there was a growing realization that many precious natural areas and diversity of wildlife and plants were fast disappearing. From a species standpoint, the harvesting of forests and conversion of lands to urban and agricultural uses paralleled the extinction or near-extinction of some creatures which had blanketed the country in seemingly inexhaustible swarms, such as the American bison and passenger pigeon. Increased public awareness awakened a conservation movement which began to promote protections for selected natural areas. By the mid-20th century, some of the potential risks associated with modern technologies led to a realization that chemical use and pollution also required attention. The great advances in synthetic chemistry brought use of new technologies for effective pest management during the 1940's and 1950's. In turn, increased chemical use led to a realization by the late 1950's and early 1960's that in some cases unanticipated environmental and species-level impacts were possible.

It was in the heady days of the environmental movement of the late 1960's and early 1970's that key events took place to lay the foundation of contemporary environmental protections. Landmark environmental legislation was passed, and the EPA was established to oversee implementation of new laws. In 1970, EPA assumed responsibility for pesticide regulation. As public concerns mounted for disappearing and highly visible species such as the whooping crane and blackfooted ferret, in 1967 the USFWS published a first official list of domestic "endangered species," some 78 in all (*1*). In 1973, the Endangered Species Act (ESA) was passed. This act, characterized as the "pit bull" of environmental statutes, mandates strong protections for conservation of endangered and threatened wildlife and plants (*2*). These protections place great emphasis on ensuring that federal agency actions do not jeopardize endangered species or their designated critical habitat and that recovery efforts are promoted. Statutory obligations are placed on "action agencies" and oversight of federal actions is provided by USFWS and NMFS (the "Services").

During the four decades since EPA assumed oversight of pesticide regulation and the Services were empowered for endangered species protection, most stakeholders would agree that significant progress has been made. The suite of pesticide products and use practices in agricultural pest management have grown increasingly environmentally sustainable and safer for humans and wildlife alike. A handful of high-profile species that had tottered on the edge of extirpation have recovered and been removed from the ESA list, including the bald eagle, peregrine falcon, brown pelican and gray wolf. Most other species have active recovery plans in place. With greater realization of the importance of species protection, many efforts are underway to preemptively impose management practices intended to prevent the need for listing under ESA.

Regulatory activities embracing environmental protection for pesticides under FIFRA and protection of endangered species under ESA have not yet been fully integrated, however. Although there has been sporadic cooperation, a significant gap remains between EPA's nationalized and chemical-specific, risk/benefit focus and the Services localized and species-specific, precautionary emphasis. One author has described this as being the difference between application of "the scientific method" (FIFRA requirements) and the "expert opinion method" (ESA requirements) (*3*). This introductory chapter will review historical developments related to pesticide regulation and endangered species protection, examine contemporary challenges for integration of FIFRA and ESA requirements, and introduce some of the promising ideas and developments for resolution detailed in succeeding chapters.

Pesticide Regulation and Endangered Species Protection

FIFRA and ESA Provisions

Pesticides are regulated under FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act. FIFRA was introduced in 1947 and has undergone significant amendments and modifications since that time (e.g., 1972). A key provision of FIFRA is that before EPA's action of "registration," it must be shown that a pesticide "when used in accordance with widespread and commonly recognized practice will not generally cause *unreasonable adverse effects* on the environment." [FIFRA Section 3(c)(5)(D)] Unreasonable adverse effects are defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." [FIFRA Section 3(c)(5)(D)] Since the 1970's, when EPA assumed regulatory oversight for FIFRA from USDA, the Office of Pesticide Programs has applied ecological risk assessments to determine whether a proposed use may present unreasonable risks and, if so, whether its approval may be enabled by adoption of risk-mitigating restrictions. The primary information for EPA's assessments arises from studies generated by registrants to meet environmental fate and effects guidelines as embodied in 40 CFR 158. EPA's approach to ecological risk assessment has evolved over the years, but generally consists of a *hazard characterization* phase to understand potential effects and sensitivity of non-target terrestrial and aquatic wildlife and plants, an *exposure estimation* phase in which predicted or observed data on exposure concentrations, distribution and frequency is developed, and a *risk assessment* which compares exposure and effect levels (*4*). Between the mid-1970's and early 1990's, higher tiered and more detailed studies were used when the first screening level process indicated a potential risk. Elaborate field and simulated field studies, aimed at more precisely quantifying risk, were employed. However, the resources required to conduct and review these studies and their inherent complexity – and thus uncertainty – eventually led EPA to develop what at the time was coined "a new paradigm." Since the early 1990's, EPA has placed a strong emphasis on screening level assessments and rapid identification of appropriate mitigation measures to reduce potential risks, without advancing to heavy reliance on complex field effects testing (*5*).

In addition to an initial registration decision for a new active ingredient or newly proposed uses, EPA also considers ecological risks as part of periodic pesticide reevaluation. This has evolved from a process oriented toward the challenge of a registration when an adverse effect was suspected (a "rebuttable presumption against registration," the method used in the 1970's) to a continually cycling registration review of every registered product, every 15 years (a program initially organized as "Reregistration,' and now in the new millennium, "Registration Review").

The Endangered Species Act (ESA) of 1973 provides for the conservation of species that are endangered or threatened with extinction as well as the preservation of the ecosystems on which they depend. There are currently more than 1,300 endangered and threatened U.S. animal and plant species "listed" for protection under the ESA (Table I). The National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) share responsibilities for implementing key ESA provisions. Generally, USFWS manages terrestrial and freshwater species, while NMFS manages species with complete or partial marine life cycles. Responsibilities of USFWS and NMFS have been well described in Chapters 2 and 19 of this book (*6*, *7*). A listing under ESA provides extensive protections for a species and its designated critical habitat, including making it illegal to "take" (e.g., harm, kill, harass, under Sections 3 and 9 of the ESA) that species by any private or public action. This includes prohibition of significant habitat modifications that may negatively impact the species within areas legally defined as designated critical habitat. Section 7 of the ESA requires that each federal agency take steps to ensure that any action it takes "*…is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species*." Thus, when a federal permit is issued for building a bridge or dam or highway, the action agency is required to make an "effects determination" as to whether approval "may affect" or is "likely to affect" an endangered species or its habitat and, if so, the action agency must "consult" with NMFS or USFWS for a Biological Opinion (BiOP) regarding whether the action poses jeopardy to the species. Depending on the jeopardy finding, the action may be recommended for rejection, for approval with no conditions, or for conditional approval with certain restrictions recommended as "Reasonable and Prudent Alternatives" (RPA's) to avoid jeopardy and "Reasonable and Prudent Measures" (RPM's) to reduce the likelihood of incidental take. It is then up to the action agency to determine appropriate implementation steps to ensure compliance with any "incidental take permit" (ITP) identified by the Service.

Table I. U.S. Endangered and Threatened Species Listed as per ESA*. *Source: USFWS, 2012 (URL: http://ecos.fws.gov/tess_public/pub/boxScore.jsp)

Group	*Number of Endangered Species*	*Number of Threatened Species*	*Total listings*	*Active Recovery Plans*
Mammals	71	14	85	59
Birds	76	16	92	85
Reptiles	13	23	36	36
Amphibians	15	10	25	17
Fishes	78	71	149	102
Clams	68	8	76	70
Snails	25	12	37	29
Insects	52	10	62	40
Arachnids	12	0	12	12
Crustaceans	19	3	22	18
Corals	0	2	2	0
Flowering plants	613	147	760	638
Conifers, cycads	2	1	3	3
Ferns and others	29	2	31	28
Total Species	1073	319	1392	1137

Historic Pesticide Regulatory Decision Making

In making regulatory decisions related to pesticide registration or reevaluation, EPA is obligated to consider the ecological protection goals of both FIFRA and ESA. The ecological risk assessment process utilized by EPA has evolved over the years in terms of scientific methodology and procedural approach. While EPA has long included risks to endangered species as a part of its assessment process, more recent provisions have expanded and described these assessments to more specifically address endangered species protection in terms relevant to the ESA as well as FIFRA (*8*). Historically and currently, in calculating a “level of concern” (LOC) in the screening level assessment (i.e., ratio of “effect-related concentration” to “predicted exposures concentration”), EPA has used a more conservative target ratio for endangered vs. other species. The conventional wisdom associated with EPA’s assessment approach has been that, based on the conservative nature of the assessment design, restrictions identified for protection of species groups in general will also provide significant protections for endemic endangered species, and any edge of doubt (or “uncertainty”) would be further removed by the extra factor applied specifically to the endangered species LOC.

Consultations between EPA and USFWS began on a case-by-case basis in the late 1970’s, generally involving a single pesticide and handful of proposed new uses. A number of BiOps were developed, but realizing the inefficiency of the process and inequities for existing pesticides with the same uses, EPA and USFWS moved forward cooperatively in 1981 with a “cluster analysis” approach (*9*). This involved evaluation of a group of pesticides for a common use (e.g., corn, cotton, forestry, mosquito larviciding) and multiple endangered species. The case-by-case and cluster analyses resulted in production of a series of approximately 106 BiOps, nearly all from USFWS (*10*). As a result of cluster consultations, EPA in 1987 announced initial implementation steps and further codified this as an “Endangered Species Protection Program” (ESPP) in 1988 (*9*). Implementation of the program would have involved label modifications to proactively manage pesticide use in certain counties through reference to a series of voluntary, county-level bulletins. The proposed bulletins included maps indicating ranges of endangered species and product-specific restrictions, but by 1988 the plan was abandoned based on opposition from agricultural and other user groups regarding its feasibility. In 1989, EPA published a revised ESPP which outlined how future consultations would take place (*9*). By the early 1990’s, the cluster analysis initiative was abandoned as infeasible and a species-specific approach was instead adopted. The first species-based consultations occurred in 1991 for the kit fox and spotfin chub, and a total of 31 pesticides were involved in such consultations with USFWS. Ultimately, the species-specific process also proved unwieldy in terms of “process” between the Services and EPA. In parallel with these policy developments, to meet EPA’s growing need for species location data, as well as specific conditions placed on certain registrations, industry discussions on meeting EPA’s endangered species data needs began in 1993 and culminated in formation of the FIFRA Endangered Species Task Force (FESTF) in 1997 (*11*). In 2002, and in conjunction with the adoption of a proposed new rule on FIFRA/ESA consultation, EPA proposed a modified policy for the ESPP, which followed the terms of the proposed new rule as well as a jointly-executed Alternative Consultation Agreement between EPA and the Services. In this policy, field implementation was mandatory but remained based on a county bulletin system outlining geographic- and product-specific restrictions. The program was finalized in 2005 (*12*). In 2004, “Joint Counterpart Endangered Species Act Regulations” were established by the Services and EPA, for a streamlined consultation process for pesticides that would allow more resources to be focused on actions most likely to pose risk to listed species. Although bearing great promise, several key provisions of the Joint Regulations were invalidated by court order in 2006 following litigation by environmental groups (Case No. C04-1998C, US District Court Western District of WA at Seattle). Since the enactment of ESA, cooperation between EPA and the Services on pesticide regulation and endangered species protection has progressed in fits and starts (Table II). Several generations of ESPP initiatives were launched; several approaches to consultations with USFWS were undertaken; and some field-level implementation was ascribed. In a very few instances, labeling restrictions were adopted for a particular pesticide-species combination (e.g., Attwater's prairie chicken relative to the pesticide thiram, Delmarva fox squirrel relative to the pesticide carboxin). By 2005, EPA announced intentions of fully implementing ESA compliance via the Registration, Reregistration, and Registration Review programs (*12*), with the intent of using Registration Review, scheduled to initiate its first 15-year, recurring cycle between 2007 and 2022, as the platform upon which to come into full compliance.

Despite the uncertain and evolving process, how then did routine registration and reevaluation decisions proceed, and how were endangered species considerations incorporated? EPA screening-level ecological risk assessments continued to calculate LOC's for both non-endangered and endangered plants and animals, and regulatory decisions and best management practices reflected a conservative, protective approach for standard species that was believed also to be generally protective of endangered species. Within EPA, a policy for managing risk to listed species was in place, but this policy did not conform to the procedural requirements for routine and productive ESA Section 7 consultations between EPA and the Services. Instead, EPA registration and reevaluation documents have included caveats and commitments related to future implementation of ESA provisions via the ESPP:

- 1988 - "*Therefore, triggers established for endangered and threatened aquatic fauna are exceeded…The registrant will be notified of labeling requirements upon implementation of the cluster opinions." (13).*
- 1996 - *"The endangered species LOCs have been exceeded for birds, mammals, and semi-aquatic plants…The Endangered Species Protection Program will become final in the future…The Agency anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program." (14).*
- 2000 - *"…there is concern over the most vulnerable organisms, i.e., the threatened and endangered species…The Agency is not imposing label modifications at this time through the Section 3 (sic). Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program." (15).*
- 2007 - *"Acute and chronic risks are possible for avian and mammalian endangered species…the RPMs in the 1989 opinion may need to be reassessed…This can occur once the Program is finalized and in place." (16).*

Contemporary Challenges for Integrating FIFRA and ESA

During the past decade, regulatory agency aspirations and environmental advocate frustrations related to successful integration of FIFRA and ESA obligations for pesticides have developed along two primary tracks, one instigated by EPA and the second by the environmental advocates. They each serve to highlight contemporary challenges and opportunities related to procedural and scientific issues.

Table II. Chronology of Key Events for Pesticide Regulation and ESA

Year	*Event*
1947	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) enacted
1967	USFWS published first list of 78 endangered species
1970	EPA Office of Pesticide Programs assumed FIFRA duties from USDA
1973	Endangered Species Act (ESA) enacted
1977	First EPA case-by-case endangered species consultation with USFWS
1978	Supreme Court released Tellico Dam decision, giving ESA authority over other federal actions that could affect listed species
1981	First EPA endangered species cluster analysis
1988	First EPA Endangered Species Protection Program (ESPP) published
1988	FIFRA amendments established Reregistration program
1989	EPA published revised ESPP
1991	EPA report to Congress on ESA implementation efforts
1993	EPA requires endangered species data as condition of registration
1997	FIFRA Endangered Species Task Force (FESTF) founded
1998	USFWS, NMFS publish ESA consultation handbook
2001	Washington Toxics lawsuit against EPA for Pacific salmonids
2002	EPA published proposed new ESPP for implementation methods
2003	Pesticide Regulation Improvement Act (PRIA) enacted
2004	USFWS/NMFS Joint Counterpart Regulations enacted
2004	EPA published endangered species ecorisk process
2005	EPA published finalized new ESPP with mandatory bulletins
2006	Court invalidates key sections of the Joint Counterpart Regulations
2007	EPA Registration Review Program initiated
2007	NCAP lawsuit against NMFS for Pacific salmonid consultation

Continued on next page.

Table II. (Continued). Chronology of Key Events for Pesticide Regulation and ESA

Year	*Event*
2008	First Pacific salmonid BiOp released by NMFS
2009	First active EPA ESPP bulletins for Karner Blue Butterfly
2009	EPA pilot project under Registration Review and ESA for clomazone
2009	USFWS rejects multiple consultation requests from EPA
2009	NMFS rejects requests for Registration Review related consultation pilot projects for clomazone and fomesafen
2010	Center for Biological Diversity filed lawsuit against EPA for ESA consultations for 887 species and 395 pesticides
2011	Interagency FIFRA-Endangered Species Act Work Group formed of EPA, USDA, Dept. of Commerce and Dept. of the Interior
2012	NRC panel on "Ecological risk assessment under FIFRA and ESA"

Registration Review

Under FIFRA (as amended in 1988), EPA is required to periodically reevaluate existing active ingredients for human health and environmental effects as per updated regulatory standards, testing guidelines, and assessment approaches. EPA began a first round of reevaluation under the "Reregistration" program in the mid-1980's and had completed a majority of assessment activities under the program by 2008, with label changes for individual products expected to continue until 2014 (*17*). As noted in the previous section, although EPA risk assessments also considered endangered species, explicit consultation activities and field program implementation of endangered species-specific protections were generally deferred.

With passage of the Pesticide Registration Improvement Act (PRIA) in 2003, the stage was set for a new 15-year reevaluation program called "Registration Review" to occur between 2007 and 2022. PRIA mandated that all pesticides would pass through reevaluation, and EPA established a transparent, science-based series of review and assessment steps expected to take 5-6 years for each active ingredient. These steps included new data generation by the registrant, updated environmental and human health assessments by EPA, and opportunity for public comment at multiple stages, all leading to the final regulatory decision. The magnitude of the job is immense, and by the PRIA effective date of October 2006, there were 722 "cases" comprising some 1135 existing pesticide active ingredients subject to reevaluation (*17*). To take advantage of the scientific assessments that would be conducted under Registration Review, EPA determined it would incorporate endangered species assessments and implement the ESPP as a major emphasis of the program. As envisioned by EPA (*17*), ESA-related aspects of Registration Review would involve these steps:

- EPA issues a data call-in and obtains necessary information for updated assessments
- EPA completes new risk assessments, including national-level endangered species assessments when needed
- EPA publishes a regulatory decision for comment
- EPA consults with USFWS and NMFS if necessary for endangered species considerations
- EPA implements regulatory decisions through label amendments, and with ESA-specific restrictions communicated via the ESPP

Since Registration Review began in 2007, EPA has made significant progress with preliminary phases of reevaluation (i.e., opening initial docket for public comment, publishing a final workplan, issuing a data call-in) for many active ingredients. By May of 2012, the Agency had opened more than 300 dockets and published more than 250 final work plans (*18*). The Agency intends to open 70 new dockets each year to keep the program on track for the 15-year cycle. As each finalized Registration Review workplan is published, EPA clearly states its intentions related to endangered species:

> *"The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine if [chemical's] use has "no effect" or "may affect" federal listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate (19)"*

With hundreds of Reviews already initiated, modest progress has so far been achieved with respect to EPA ecological risk assessments and endangered species effects determinations. As of May 2012, only two preliminary ecological risk assessments under Registration Review have been developed (*10*). In many other cases, data call-ins are pending and must be completed prior to initiating the risk assessment process. Experience from the first two national-level endangered species assessments has provided practical lessons but also a sobering realization that serious procedural and scientific challenges remain unresolved. Thus, it appears increasingly likely that the Registration Review program may take far longer to complete than the originally mandated 15-year period, in particular for ESA considerations.

With cooperation from the registrants and FESTF, EPA chose two herbicides, clomazone and fomesafen, as pilot projects to determine the value of focusing on species biology or species location information to support impact assessments for endangered species. These molecules were chosen as relatively straightforward examples in light of their recent registration approvals and lack of need for a data call-in. A brief synopsis of the clomazone and fomesafen case studies follows; full details may be found in Chapters 9 and 10 of this book (*20*, *21*).

Following registrant submission of detailed species location information and other supporting data, EPA completed the first two comprehensive, national-level risk assessments for fomesafen and clomazone during 2009. The preliminary EPA "ecological risk assessment and effects determination" for each molecule included a significant number of "may affect" and "likely to adversely affect" determinations. The preliminary assessment for clomazone, for example, ran to more than 450 pages and for non-rice uses highlighted endangered species concerns for *"…8 amphibians, 1 freshwater crustacean, 1 arachnid, 1 conifer, 26 ferns, 2 lichens, 2 aquatic plants, 507 flowering plants, 51 birds, 23 terrestrial insects, 20 mammals, 47 land and arboreal snails and 8 land reptiles."* (*22*). Depending on formulation type and application method, EPA's area of concern extended from 1 to 2 miles beyond the border of treated fields. The fomesafen preliminary assessment reached similar conclusions, with many species of concern noted, and the potential mitigation measures flagged included no-spray buffers of up to 1,000 feet (*23*).

EPA's preliminary assessments were simultaneously released for public comment and submitted to USFWS and NMFS for Section 7 consultation during April of 2009. EPA received little satisfaction from the Services; USFWS didn't formally respond to the requests and NMFS rejected EPA's requests for consultation finding the draft assessments "premature" based on the view that consultation should occur based on the final actions an agency proposes to take. In addition, NMFS identified a number of deficiencies in the EPA consultation request including description of the "action" and "action area," description of any listed species or critical habitat that may be affected by the action, cumulative effects analysis, analysis of potential mixtures, information on direct lethal or sublethal responses, information on indirect effects on prey, primary producers, or riparian vegetation (*24*). As of September 2012, finalized assessments for clomazone and fomesafen and initiation of consultation activities are still awaited, some five years after initiation of the Registration Review process.

Litigation

Under ESA, EPA is required to consider endangered species in making its pesticide regulatory decisions, whether related to new registration activities or reevaluation. In the view of some environmental advocates, however, "*The EPA displays a stunning lack of initiative in complying with the Endangered Species Act…EPA has failed to implement an overarching program to address pesticide impacts to endangered species…*" (*25*). The ESA includes a provision that allows a member of the public to bring a "citizen lawsuit" against a federal agency when listed species are believed not to be adequately protected. During the past decade, frustrations on the part of environmental advocates have boiled over into a series of such citizen lawsuits designed to spur action by EPA and the Services for selected species.

Litigation entered the scene by the 1990's, and has accelerated in frequency and publicity since. The herald of a series of suits to come was a lawsuit which arose in 2000 concerning EPA's regulation of pesticides and attention to ESA obligations. Californians for Alternatives to Toxics and other groups sued the Agency for failure to consult with USFWS and NMFS before registering pesticides that "may affect" 6 salmonids and 33 plant species. The plaintiffs settled the lawsuit with a consent decree in 2002 establishing a schedule by which EPA agreed to initiate consultation for 18 pesticides. Since that time, a number of suits have been filed covering many different pesticides and endangered species. In some cases, court-ordered interim restrictions have been mandated until consultation is complete. The lawsuits are at various stages but have generated an enormous amount of work for EPA in development of assessments and initiation of consultations with USFWS and/or NMFS. Subsequent suits demanding the Services' responses to requests for consultation have placed equally burdensome demands on Services staff. As of September 2012, ESA litigation-based settlement agreements had resulted in generation of some 177 detailed effect determinations, a majority of which led to formal requests for consultation with the Services (*10*). Nearly all the consultation requests with USFWS have been rejected as incomplete since USFWS believes "*it has not received all of the information necessary to initiate formal consultation*" (*26*). USFWS cited a number of deficiencies including description of the "action" and "action area", description of any listed species or critical habitat that may be affected by the action, cumulative effects analysis, and analysis of potential mixture and inert ingredients. In addition, USFWS noted that "*the volume and complexity of EPA's section 7 consultation requests on pesticide reregistrations exceed our capability to complete consultations within normal statutory timelines*" (*26*). The litigation-based consultation requests EPA forwarded to NMFS during the early 2000's, most involving Pacific salmonids, were initially ignored. However, subsequent litigation against NMFS and a settlement agreement mandated progress on the consultations. The salmonid-associated litigation has prompted the most action to date concerning the consultation process, and it will be instructive to review briefly this case.

During 2001, the Washington Toxics Coalition sued EPA for failing to consult on 54 pesticides and their effects on 26 threatened and endangered Pacific salmon and steelhead populations occurring in four western US states. EPA entered into a settlement agreement with the plaintiffs in 2002 establishing a schedule by which EPA was to complete consultations with NMFS. During the period 2002 to 2004, EPA dutifully completed effects determinations for the 54 active ingredients and requested consultation with NMFS. Meanwhile, during 2004 the plaintiffs received injunctive relief from the court for imposition of interim measures, including no-spray buffer zones around salmon-bearing waters of 60 and 300 feet for ground and aerial applications, respectively. The request for consultation with NMFS went unanswered, so in 2007 the Northwest Coalition for Alternatives to Pesticides sued NMFS for lack of compliance with ESA obligations. In 2008, the plaintiffs and NMFS reached a settlement agreement whereby NMFS would produce BiOps for 37 of the pesticides according to a set schedule. NMFS developed the first draft BiOp in 2008 and, as for nearly all the subsequent salmon BiOps, the Agency concluded that use of the pesticides jeopardized the continued existence of one or more salmonids and thus recommended RPM's and RPA's. The RPA's for the first draft BiOp included 500 foot ground and 1000 foot aerial buffers from salmon-bearing waters and connected drainages. EPA, state agencies, registrants, and growers responded critically to the draft BiOp, which was finalized in slightly modified form in late 2008. During 2009, EPA proposed a set of modified restrictions, including a sliding scale of buffers based on application rate, water body depth, and spray droplet size. Later that year, the registrants declined to "voluntarily" adopt the restrictions and instead brought suit against NMFS for what they perceived as serious flaws in the BiOp science. During 2010 environmental advocates brought a lawsuit against both EPA and NMFS for failure to implement the restrictions for the pesticides in the first two salmon-related BiOps. As of September of 2012, both cases remain unresolved.

The spate of ESA-related lawsuits against EPA, NMFS and USFWS has forced EPA and the Services to pour massive resources into endangered species assessments to meet court-ordered timelines for ESA consultations, without the benefit of an agreed formal process of interaction. A "litigation cycle" has emerged as outlined below:

- A lawsuit is filed against EPA for failure to fulfill ESA obligations for one or more pesticide/species combinations
- A settlement agreement is reached between EPA and the plaintiff, with a schedule for consultation
- A request for injunctive relief often results in interim protections being mandated by the court
- EPA completes an effects determination and requests consultation with a federal service
- The Service does not respond to the request or rejects it based on incomplete information
- A lawsuit is subsequently filed against the Service for inaction under ESA statutory timelines
- A settlement agreement is reached with a schedule for a BiOp
- The Service prepares a BiOp with RPM's and RPA's

Although ESA-related litigation during the past decade has generated an enormous compliance burden for EPA and the Services, no reasonable, science-based species-protective actions seem to have emerged. In fact, activities around litigation may instead be detracting from previously announced EPA efforts for advancing the ESPP via Registration Review. The primary result of ESA-related pesticide litigation appears to be an escalation of concerns for unresolved process and scientific issues on the part of EPA and the Services, and a growing realization on the part of all parties that the current system is "broken," the consultation burden is overwhelming, and strong agency cooperation and creative approaches to consultation are required.

Process and Science Issues

A number of contemporary process and science issues have been brought to light by attempts at implementation of ESA Section 7 consultations through Registration Review and litigation during the past several years. These are briefly outlined below.

Immense Scale and Complexity of Endangered Species Considerations for Pesticide Regulatory Decisions

the ESA consultation process seems best tailored for rather discrete and localized regulatory actions such as approval of a federal permit for a new dam or a highway bridge. In contrast, pesticide regulatory decisions can involve a bewildering complexity of scenarios, with use allowed across potentially millions of acres and intersecting with the habitat range of dozens or hundreds of endangered plants and animals. A single pesticide active ingredient may be used in hundreds of end-use products, each with its own label and use instructions. It's no wonder that the Services, in responding to both litigation and Registration Review-related requests have had difficulty grasping the nature of the "action" and "action area." Writing a BiOp for a dam or bridge project is complicated enough, but it would seem completely infeasible for a single effects determination or BiOp to encompass potential use of a pesticide across the nation, in many different agricultural ecosystems and by many farmers working under regionally adjusted best management practices.

Lack of Consensus on Endangered Species Assessment Priorities and Insufficient Federal Agency Resources for the Task

Based on modest progress made in the nearly 40 years since enactment of ESA, the unresolved job of integrating endangered species considerations with FIFRA-related pesticide registration and reevaluation decisions is enormous. Despite concerns from the environmental community that "*Diverting scarce resources into unproductive agency process has further handicapped conservation…*" (*27*), the environmental advocacy litigation initiatives of the past decade have done just this. The Registration Review schedule has been proposed as offering a viable option for implementing EPA's ESPP, but it is unclear that either EPA or Services resources are adequate to work within the timeframes mandated for Registration Review. It has been estimated that the intended pace of 70 active ingredients per year for Registration Review would generate more than 70,000 species-specific effects determinations each year (*28*). Even if EPA could maintain this pace for Registration Review, in spite of diverting resources to litigation-based efforts, Services resources for consultation efforts appear hopelessly inadequate. Of the more than 150 consultation packages EPA has submitted to the Services during the past several years, little action has resulted beyond a handful of salmon-related BiOps from NMFS. The USFWS has clearly stated it can't keep up with the workload. NMFS alone, which covers only a portion of listed species, has estimated that approximately 40 additional staff members and $6 million annual budget increase would be needed to handle the volume of requests (*29*).

Lack of a Cooperative Process between Federal Agencies for Implementation of ESA Obligations

Under pressures from unrealistic schedules for litigation-based consultations and with an impending flood of Registration Review consultation requests looming, the lack of seamless integration of cooperative procedures between EPA and the Services has been highlighted. Although the Joint Counterpart Regulations of 2004 offered promise for a smoother path forward, deep-seated disagreements on scientific methodology between EPA and Services staff were cited by Judge Coughenour in his decision to set aside several key provisions. Perhaps nothing better exemplifies this than the rejection by USFWS of the hundred or more consultation requests from EPA based on the perceived insufficiency of the consultation packages. Likewise, the first draft NMFS salmon BiOp, in which EPA's effects determinations were essentially redone by NMFS, but in more conservative fashion, prompted this response from EPA:

> *"The Draft lacks a level of transparency necessary for EPA to understand NMFS' rationale for its opinion that any of these pesticides will jeopardize the continued existence of any of the species at issue. It is generally not transparent as to what methodology NMFS employed to collect information…The Draft seems to draw conclusions based on a body of data that fails to include certain studies and information provided by EPA in its consultation package while including other information. There seems to be no explanation of the criteria that were used to determine what information was included or excluded…we do not believe the available data support NMFS' draft jeopardy conclusion (30)."*

Ineffectual Stakeholder Involvement

The ESA consultation process is focused around activities of the federal agencies with some level of involvement by the "applicant," which for FIFRA-related actions has been recognized by EPA as the registrant. However, there are other stakeholders with a keen interest and who may be directly impacted by the consultation outcome. These include pesticide users, growers and land managers, state regulatory agencies, and environmental advocacy organizations. The frustrations of the environmental advocates have already been described, but pesticide users and growers have generally felt sidelined by the process, with no ready mechanism for introducing information on actual pesticide use practices and ideas regarding feasible risk mitigation options. Chapter 4 describes from the grower's perspectives what improvements could be made to bring their valuable knowledge into the process (*31*). ESA should also promote a well-integrated and cooperative relationship between federal and state agencies, the latter of which operate under delegated authority from EPA for certain FIFRA obligations, but this has not yet been realized.

No Agreed upon Definition of "Best Available Data and Scientific Information"

ESA requires that consultation decisions be made based on the "best scientific and commercial data available" but a consensus as to what constitutes "best" and how to obtain it has not emerged among the federal agencies. Instead, divergent approaches have been employed by EPA and the Services. EPA relies primarily on registrant-submitted studies completed to meet regulatory guideline requirements and conducted under Good Laboratory Practices, whereas the Services employ a "broader set of scientific norms" and seem to place greater weight than EPA also on peer-reviewed scientific publications and "gray literature" (i.e., non-peer reviewed reports and bulletins) (*32*). The Services and EPA approach the identification of "best available scientific information" using a variety of differing protocols pertaining to the type and character of scientific information that may be appropriate for these evaluations.

Failure To Standardize Geospatial Information and Geographically-Specific Assessments

One of the major challenges for an endangered species assessment involving a pesticide regulatory decision is determining overlap of species location and habitat with the area of intended or actual pesticide use. Definition of the "action area" for a consultation has been an area of disagreement between EPA and the Services. There is at present no uniform or centralized database recognized by all federal agencies as containing authoritative location and habitat data for listed species. Compounding this discrepancy is the fact that, while the standardized EPA screening-level ecological risk assessment methodology relies on generic, non-geographically related input parameters, the EPA ESPP program is based on site-specific implementation at the county level.

Unresolved Scientific Assessment Issues

Finally, there are a number of unresolved scientific assessment issues impacting a differential approach to effects characterization, exposure estimation, and risk assessment for pesticide endangered species consultations. At the moment, a lack of consensus within the broader scientific community, discordant methodology, or divergent approaches by EPA and the Services are impeding advancements. These assessment issues include:

- Consideration of sub-lethal, indirect and cumulative effects on endangered species and their critical habitats
- Impact of pesticide co-formulants and inerts on toxicity
- Role of environmental mixtures in modulating species effects
- Expression and interpretation of evaluation uncertainties
- Estimation of pesticide exposures, including use of modeling and monitoring data
- Applicability of data from surrogate test species for endangered species
- Determination of an appropriate environmental baseline for the assessment

Search for Process and Science Improvements

Despite the difficulties of the past decade, there have recently been positive signs and encouraging developments among federal agencies and other stakeholders for possible procedural and scientific improvements. This section briefly summarizes some of these developments, many of which are described in detail in succeeding chapters of this book.

Constructive Dialogue

The past several years have seen an increase in productive dialogue and debate of constructive proposals among the various stakeholders. Several scientific symposia have been organized around advances in pesticide endangered species assessment methodology, including sessions sponsored by the Society of Environmental Toxicology and Chemistry in 2010 and 2011 and the American Chemical Society in 2011. From an ESA-pesticide regulation policy standpoint, there have been Congressional hearings held before the Senate Agriculture Committee in 2010 and the House Committee on Agriculture and Committee on Natural Resources in 2011.

An excellent example of a multi-stakeholder approach is the report commissioned by the non-profit Council for Agricultural Science and Technology, which critically examined the current state of affairs for ESA implementation and impacts on agriculture. Recommendations for process improvements related to the consultation process and pesticide regulation were developed, and these are outlined in Chapter 3 (*33*).

In some cases, organizations representing industry or environmental advocacy organizations have sponsored forums for exchange of proposals on ESA and pesticide regulation or developed comprehensive recommendations for improvements. For example, on the regulated industry side, CropLife America (CLA), an organization representing pesticide registrants, hosted an ESA-pesticide symposium as part of its spring conference in 2010 to provide federal agencies and industry an opportunity to share views. It was also in 2010 that CLA announced its “Ecological Risk and Endangered Species Roadmap”, which outlined a design for better communication and information sharing between government agencies, industry and others in development of environmental policy and regulation. On the environmental advocacy side, Defenders of Wildlife has been active in promoting endangered species protection for some time through various initiatives. A series of policy- and process-related improvements to ESA consultation for pesticides is outlined in Chapter 5 (*34*).

Improved Federal Agency Cooperation

Emblematic of an increased commitment for reconciliation and cooperation among federal agencies have been the efforts of the Interagency FIFRA-Endangered Species Act Work Group, formed in 2009. In addition to a group of senior policy leaders from EPA, NMFS and USFWS, there are teams of operational managers and also technical science staff who are meeting regularly to discuss issues related to ESA consultations for pesticides. During 2010, the group was expanded to include the U.S. Geological Survey and U.S. Department of Agriculture. An excellent description of the early efforts of this group in seeking improvements may be found in Chapter 2, jointly authored by senior staff from NMFS, USFWS and EPA (*6*).

Perhaps the most noteworthy early outcome of this cooperation has been to enlist the assistance of the National Research Council of the National Academy of Sciences (NAS) in convening a panel to provide expert advice for a set of challenging scientific and technical issues which serve as the foundation for assessing risks to listed species associated with EPA's FIFRA-related activities. The scientific issues of emphasis for the NAS panel are well described in Chapters 2 (*6*) and 15 (*35*). The NAS panel began its deliberations in late 2011 and is expected to produce a final report on the topic "Ecological Risk Assessment Under FIFRA and ESA" by 2013.

Increased Stakeholder Engagement

Attempts have been underway for the past several years to increase participation of non-applicants in the ESA consultation process for pesticides. For example, beginning with release of the first salmon-related draft BiOp by NMFS in 2008, EPA has arranged for open public comment periods for these documents. During 2012, EPA also organized a series of regional "listening sessions" which included agricultural interests and state regulatory agencies and sought to identify practical, interim protections for endangered salmon while formal BiOp implementation is delayed.

Agricultural commodity organizations have grown increasingly concerned about potential restrictions that may emerge from EPA's endangered species consultations, primarily questioning the actual need for and practicality of some of the proposed restrictions. This interest is exemplified by an ESA-pesticide regulation workshop organized during 2011 by the Minor Crop Farmer Alliance (MCFA). Representatives of a number of agricultural commodity organizations, state agencies and industry met with federal agency officials to discuss existing processes, case studies, and improvements for incorporation of grower information into the ESA consultation process for pesticide regulatory decisions. Recommendations from the MCFA workshop are outlined in Chapter 4 (*31*).

In light of their role in promoting the interests of agriculture and implementing pesticide regulation at the local level, state agencies have also increased activities around endangered species considerations. During 2010, the National Association of State Departments of Agriculture adopted a policy statement for improvements in ESA consultation activities by EPA and the Services. In several instances (CA, ND, WA), state-initiated endangered species protection programs have been implemented. State-led initiatives for endangered species protections and ways that states can contribute data and insights to the ESA consultation process for pesticides are outlined in Chapters 6, 7, and 21 (*36–38*).

Case Study Lessons

There are now several ESA-pesticide regulation "case studies" available from which to draw lessons and ideas for future improvements. The steps involved in the ESA consultation leading to development during 2009 of the first county bulletins under the 2004 EPA ESPP policy are described in Chapter 8 (*39*). This interesting case, involving use of the insecticide methoxyfenozide on cranberries and protections for the Karner blue butterfly, highlights the importance of having state agencies and growers involved in the consultation process. Case studies related to ESA assessment under EPA's Registration Review program are described in Chapter 9 (*20*) and Chapter 10 (*21*) for the herbicides fomesafen and clomazone, respectively. These case studies, involving first attempts by EPA and registrants at integrating ESA into reevaluation under Registration Review, highlight the importance of reliance on more highly refined pesticide use information, species location data, and advanced exposure assessments.

Finally, the litigation-instigated endangered species consultations between EPA and NMFS concerning endangered Pacific salmonids have spawned a number of innovative approaches to effects characterization, exposure determination, and risk assessment. These case studies are included as chapters in this book (*40–43*).

Scientific Improvements

There have been a number of improvements in scientific approach for endangered species assessments of pesticides proposed or tested during the past several years. These are described in detail in various chapters in this book and are briefly summarized below.

Data Quality

Methods for ensuring that high quality data are selected for an endangered species risk assessment, as well as criteria for deciding whether data are in fact relevant for that assessment, are described in Chapter 16 (*44*).

Best Available Species and Pesticide Use Data

A key input for endangered species assessment is location of the species in relation to intended pesticide use. The most widely available data on endangered species and habitat location has been incorporated into the NatureServe system, which is described in Chapter 20 (*45*). This data is available for use through the FIFRA Endangered Species Task Force (FESTF), and, along with land use details, has been incorporated into the FESTF Information Management System (IMS). The Registration Review case study for the herbicide clomazone, described in Chapter 10 (*21*), documents use of NatureServe data and the FESTF IMS for an endangered species assessment.

Information on agricultural land and pesticide use information is another critical component for ESA assessments, and in some cases detailed information has been accumulated at the state agency level. California's Pesticide Use Report (PUR) is the largest and most complete database on actual pesticide use in the world, and Chapter 7 describes its utility for ESA assessments (*37*). Washington's approach to incorporating estimates of pesticide use and actual land use in a spatially accurate geographic information system (GIS) is described in Chapter 21 (*38*). Linking pesticide use and land information is also described in Chapter 6, using Florida and North Dakota as examples (*36*).

More Comprehensive Characterization of Effects

Screening-level ecological risk assessments for endangered species have typically relied upon single point estimates of effect (e.g., lethality or no effect) under standard test conditions (e.g., uniform exposure for 48 or 96 hours) to representative test species. Often, the test result from only the most sensitive species is selected for use in assessment of direct and indirect (e.g., prey, habitat) effects on an endangered species. An improved approach using Haber's Law to model specific toxicity for different concentration-time profiles is described in Chapter 11, and it may better account for the short, pulsed nature of exposures which often characterize field behavior (*41*). Use of the joint probability distribution of toxic effects and exposure concentrations offers a way of more fully utilizing data across a variety of test species. This approach is demonstrated in Chapter 12 for characterizing risks for salmonid prey (*43*).

Advances are also being pursued with respect to moving from a single-species, lethality approach to organismal and population-based approaches. Consideration of sub-lethal effects via use of the "adverse outcome pathway" framework has been explored, as described in Chapter 19 (*7*). Use of demography and population modeling to incorporate differential susceptibility of a population's pesticide exposure as influenced by life history traits is described in Chapter 18 (*46*).

Geographically-Specific Assessments

Incorporation of geospatial information concerning species location and pesticide exposures requires movement beyond screening-level assessments. Use of proximity analyses to help define potential spatial overlap of a species and agricultural activities such as pesticide use is described in Chapter 10 (*21*) and Chapter 13 (*42*). Such approaches rely on Geographical Information Systems (GIS) and evaluation of "layers" of data including species location, land classification, soil type, and hydrology.

Advances in incorporating spatial variability in estimated pesticide exposures and spatial species behaviors into assessments have also been made. An index method developed to evaluate the spatial and temporal co-occurrence of pesticides and species at an ecosystem scale is described in Chapter 22 (*47*). This case involved modeling estimates of exposure of 40 widely used pesticides to 12 aquatic and semi-aquatic threatened or endangered species. In another case, described in Chapter 14, pesticide exposure monitoring data and information on temporal distribution of endangered salmon lifestages was evaluated in agricultural watersheds (*40*).

Science-Based Risk Mitigation

Where assessments may flag potential concerns for pesticide exposures and endangered species impacts, development of risk mitigation recommendations may be opinion based or qualitative in nature. With respect to development of recommended "no spray" buffers, Chapter 23 outlines an approach for using best available effects and exposure modeling for determining protective but scientifically based realistic setbacks (*48*).

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Chapter 2

Federal Agency Perspectives on ESA Process, Issues, and Potential Improvements

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Endangered Species Act (ESA) consultations on effects of pesticide registration activities pursuant to the Federal Insecticide, Rodenticide, and Fungicide Act are challenging, complicated and contentious. This paper outlines the ESA consultation process, the challenges in conducting consultations on pesticide registration activities, and some potential improvements to the process.

Introduction

The Endangered Species Act (ESA) provides for the conservation of species that are endangered or threatened with extinction throughout all or a significant portion of their range, and the ecosystems on which they depend. There are currently 2,000 listings for endangered and threatened species under the ESA, with 1,394 of those species found in the United States or its waters. The National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) [the Services] share responsibility for implementing the ESA. Generally, USFWS manages terrestrial and freshwater species, while NMFS manages marine and anadromous species (ocean species that return to rivers to spawn).

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

The listing of an endangered species of fish or wildlife provides strong protections for the species, making it illegal to "take" (harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect) a listed species. The take prohibition may also be extended to threatened species. The Services have defined "harm" through regulation as "any significant habitat modification or degradation that results in death or injury by significantly impairing behavioral patterns such as breeding, feeding, or sheltering" (50 CFR §222.102 and 50 CFR §17.3). The USFWS has also defined "harass" as actions "that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavior patterns which include but are not limited to, breeding, feeding or sheltering" (50 CFR §17.3). Although NMFS has not defined "harass" in regulation, it uses a very similar definition in its consultations.

ESA Interagency Cooperation

Section 7 Consultations

Section 7 of the ESA requires all Federal agencies to utilize their authorities to further the purposes of the ESA by conducting programs to conserve endangered species and threatened species. It also requires all Federal agencies to ensure, in consultation with the Services, that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or destroy or adversely modify its critical habitat. While Federal agencies are in consultation with the Services, they are prohibited from making an irreversible or irretrievable commitment of resources which have the effect of foreclosing the formulation or implementation of any reasonable and prudent alternatives measures. If any action a Federal agency proposes to authorize, fund or carry out may affect a listed species or critical habitat, the agency must initiate consultation with either the USFWS or NMFS depending upon which Service has jurisdiction over the affected species.

Actions undertaken by the U.S. Environmental Protection Agency (EPA) pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) are subject to Section 7 consultations. Specifically:

- Section 3 – New pesticide products or new uses of registered products
- Section 4 – Reregistration of pesticides
- Section 18 – Emergency exemption requests
- Section 24(c) – Special Local Need registrations.

Types of Consultations

By regulation, there are two types of Section 7 consultations: informal and formal consultations. Informal consultation is a process to assist agencies in evaluating potential effects on listed species and their critical habitat. It consists of discussions between the Federal agency proposing the action and the Service to determine if there are ways to avoid adverse effects to the listed species or critical habitat. If the proposed action avoids adverse effects to listed species or critical habitat due to the nature of the action or through modifications made to the proposed action, and the Service concurs that the action is not likely to adversely affect listed species or critical habitat, consultation is concluded. If however, a proposed action is likely to adversely affect listed species or critical habitat, formal consultation is required.

"Not likely to adversely affect" a listed species is defined in the joint Services ESA Section 7 Handbook as effects on listed species that are expected to be discountable, insignificant, or completely beneficial. A discountable effect is one that is extremely unlikely to occur and which can't be measured or detected. Insignificant effects should never reach the scale where take occurs (*1*).

"Likely to adversely affect" a listed species is defined as any effect to a listed species that may occur as a direct or indirect result of the proposed action and is not expected to be discountable, or insignificant, or completely beneficial (*1*).

If adverse effects of a proposed action are unavoidable, formal consultation is conducted. The Federal agency initiates formal consultation by submitting the necessary information regarding the action, listed species and/or critical habitat to the Service. That information includes:

- A description of the action;
- A description of the specific area affected by the action;
- A description of the manner in which they may be affected;
- Any relevant reports prepared on the proposal and;
- Other relevant studies or available information.

Once initiated, the formal consultation process concludes within 90 days. Within 45 days of the conclusion of formal consultation, the Service will issue a document called the Biological Opinion. There are opportunities to extend the consultation process, if necessary. There are two possible outcomes of formal consultation. The first is a determination by the Service that the proposed action is not likely to jeopardize species or destroy or adversely modify critical habitat. The other is a determination by the Service that the proposed action is likely to jeopardize a listed species and/or destroy or adversely modify critical habitat.

If a proposed action is not likely to jeopardize a listed species, the biological opinion includes an "incidental take" statement estimating the amount or extent of take that may occur incidentally to the action and exempts the Federal agency from the take prohibitions on listed species. The incidental take statement identifies reasonable and prudent measures the Federal agency must take to minimize the impact of take in order to be exempted from the prohibition on take.

If an action is likely to jeopardize a listed species, or result in the destruction or adverse modification of critical habitat, the biological opinion includes reasonable and prudent alternatives to avoid jeopardy or destruction or adverse modification of critical habitat. Compliance with reasonable and prudent alternatives allows the proposed action to continue. Because federal agencies are prohibited from jeopardizing listed species or destroying or adversely modifying critical habitat, they cannot proceed with a proposed action that is likely to jeopardize a listed species or destroy or adversely modify its critical habitat unless an exemption is received pursuant to Section 7(h) of ESA.

Entities Involved in Consultation

Section 7 consultation is a process between Federal agencies. It is not a rulemaking process and is not subject to notice and comment. However, the ESA does provide certain rights in the consultation process to entities that rely upon a Federal agency for authorizations or permits. In FIFRA-related consultations, pesticide registrants have been designated as applicants in the consultation process. An applicant is any person who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action being consulted on under Section 7 of the ESA.

If the Federal agency identifies an applicant, the Services and the action agency meet their obligations to that party through the following:

- The action agency provides the applicant an opportunity to submit information for consideration during the consultation;
- The applicant is entitled to review draft biological opinions obtained through the action agency, and to provide comments through the action agency;
- The Service will discuss the basis of its biological determination with the applicant and seek the applicant's expertise in identifying reasonable and prudent alternatives to the action if jeopardy or adverse modification of critical habitat is determined; and
- The Service will provide the applicant with a copy of the final biological opinion.

The Services do not work directly with or take comments directly from the applicant without the knowledge or consent of the action agency.

Consultation Process

The consultation process is outlined in the Joint NMFS/USFWS Section Consultation Handbook (*1*). A major outcome of the process is a "Biological Opinion". The major sections of a Biological Opinion include:

- The Proposed Action
- Status of the Species
- Environmental Baseline
- Effects of the Action
- Cumulative Effects
- Integration and Synthesis

Proposed Action

The first step in conducting an ESA consultation is to define the federal action subject to consultation. The ESA defines the Federal action as "any action authorized, carried out or funded" by the Federal agency. Defining the federal action is an important step during the risk assessment planning phase of the consultation. NMFS, USFWS and EPA have defined the federal action in FIFRA related consultations as "authorization for use or uses described in labeling of a pesticide product containing a particular pesticide active ingredient." This definition was agreed at a NMFS-USFWS-EPA meeting in Shepherdstown, West Virginia, during December of 2007.

In consultation, the effects of the proposed action must be analyzed comprehensively. Once the proposed action is identified, it is deconstructed. In FIFRA consultations, the proposed action is deconstructed to identify all of the stressors associated with the action based on a review of EPA authorized labels. Those stressors are:

- The active ingredient as well as any metabolites and degradates
- Other ingredients
- Recommended tank mixtures
- Adjuvants
- Application restrictions and methods

To identify that information, the Services review the EPA-approved product labels to determine where that pesticide can be applied (agricultural use, residential use, etc), the methods of application and rates that are authorized, ingredients, and tank mixtures, and any restrictions on use that may reduce risk to listed species.

Approach to the Assessment

The Services approach Section 7 analyses through a series of steps. The first step identifies those aspects of proposed actions that are likely to have direct and indirect effect on the physical, chemical, and biotic environment of an action area. As part of this step, they identify the spatial extent of these direct and indirect effects, including changes in that spatial extent over time. The result of this step represents the action area for the consultation. The second step of their analyses identifies the listed resources that are likely to co-occur with these effects in space and time and the nature of that co-occurrence (these represent their exposure analyses). In this step of their analyses, they try to identify the number, age (or life stage), gender, and life-histories of the individuals that are likely to be exposed to an action's effects and the populations or subpopulations those individuals represent. Once they identify which listed resources are likely to be exposed to an action's effects and the nature of that exposure, they examine the scientific and commercial data available to determine whether and how those listed resources are likely to respond given their exposure (these represent their response analyses).

In the final steps of their analyses they establish the risks posed to listed species and to designated critical habitat. Jeopardy determinations for listed species must be based on an action's effects on the continued existence of threatened or endangered species as those "species" have been listed, which can include true biological species, subspecies, or distinct population segments of vertebrate species. Because the continued existence of listed species depends on the fate of the populations that comprise them, the viability (probability of extinction or probability of persistence) of listed species depends on the viability of the populations that comprise the species. Similarly, the continued existence of populations are determined by the fate of the individuals that comprise them; populations grow or decline as the individuals that comprise the populations live, die, grow, mature, migrate, and reproduce (or fail to do so). Determination of adverse modification or destruction of designated critical habitat is based on an action's effects on reductions in the conservation value of critical habitat. These reductions in the conservation value of critical habitat can be in the quantity, quality, or availability of physical, chemical, or biotic resources in the habitat (i.e., primary constituent elements).

Risks to listed individuals are measured using the individual's "fitness" which is measured using an individual's growth, survival, annual reproductive success, or lifetime reproductive success. In particular, the Services examine the scientific and commercial data available to determine if an individual's probable responses to an action's effects on the environment (which we identify during our response analyses) are likely to have consequences to an individual's fitness.

Reductions in abundance, reproduction rates, or growth rates (or increase variance in one or more of these rates) of individuals is a necessary condition for reductions in a population's viability, which is itself a necessary condition for reductions in a species' viability. On the other hand, when listed plants or animals exposed to an action's effects are not expected to experience reduction in fitness, the action would not be expected to have adverse consequences on the viability of the populations those individuals represent or the species those populations comprise (*2–4*). If the Services conclude that listed plants or animals are not likely to experience reduction in their fitness, they would conclude their assessment.

If, however, the Services conclude that listed plants or animals are likely to experience reductions in their fitness, the assessment determines if those fitness reductions are likely to be sufficient to reduce the viability of the populations those individuals represent (measured using changes in the populations' abundance, reproduction, spatial structure and connectivity, growth rates, or variance in these measures to make inferences about the population's extinction risks). In this step of the analyses, the population's base condition (established in the Environmental Baseline and Status of the Species sections of this opinion) is used as the point of reference. Finally, the assessment determines if changes in population viability are likely to be sufficient to reduce the viability of the species those populations comprise. In this step of the analyses, the species' status (established in the Status of the Species section of this opinion) is used as the point of reference.

Exposure Profile

In examining the potential exposure of listed species and their habitats the Services identify the co-occurrence of the action stressors and listed species. That co-occurrence is compared with the distribution of individuals and their habitat to develop the exposure profile. To develop that profile, the Services examine all product uses of pesticides including agricultural crops, residential uses such as turf, industrial uses, rights-of-way, golf courses, aquatic weed management and forestry uses.

In developing the exposure profiles, there are a number of uncertainties that must be accounted for including any inert ingredients whose toxicity may not have been studied or identified, formulations and tank mixtures used when pesticides products are applied, and uncertainty regarding actual use of pesticides (rates, locations) versus what is authorized on the label. These uncertainties are very difficult to incorporate into the analysis. Nevertheless, the Services must incorporate such uncertainty even in a qualitative way into the analysis of the effects of the action.

The ESA requires consultation to be based on the best scientific and commercial data available. In conducting consultation, the Services must rely upon whatever data is available. The Services' obligation to base their inquiries and biological opinions on reliable, explicit, rational, objective evidence however, does not limit the evidence to published, peer-reviewed literature. Suitable data may come from a wide variety of sources ranging from peer-reviewed literature to unpublished empirical information commonly shared by the relevant scientific community.

In conducting a Section 7 consultation, the Services determine which of the data are 'best' by (1) critically appraising the methods that generated the data (the rigor and power of the study design, the execution of the study design, the size of the samples produced by the study, the reliability of the measurements taken in the study) and (2) identifying the data that are most relevant for assessing potential effects to listed species and designated critical habitat.

Scientists have two general points of reference available when they consider data, information or other evidence to support their analyses. They can analyze the information available to avoid concluding that an action: (1) had an effect on listed species or critical habitat, when, in fact, it did not, or (2) had no effect on listed species or critical habitat when, in fact, the action had an effect. The former is an example of a "Type I" error, while the latter is an example of a "Type II" error. Although analyses that avoid either type of error are statistically valid, most scientific investigations tend to focus on minimizing the risk of concluding that there was an effect when in fact, there was no effect (Type I error) and tend to ignore Type II error.

To comply with the direction from Congress to provide the "benefit of the doubt" to threatened and endangered species, the Services design their analyses to avoid concluding that actions had no effect on listed species or critical habitat when, in fact, there was an effect (Type II error). This approach to error may lead to a different conclusion than scientists who take a more traditional approach to avoiding error, but is more consistent with the purposes of the ESA and direction from Congress.

Recent FIFRA Consultations

Between 2008 and 2011, NMFS issued four biological opinions covering the effects of 24 pesticide active ingredients on listed Pacific salmonids in California, Oregon, Washington, and Idaho. Those consultations followed the process described earlier. In those consultations NMFS examined a number of salmonid health and habitat assessment endpoints. Those assessment endpoints are identified in Table I and Table II.

Table I. Salmonid Health Assessment Endpoints

Assessment Endpoints	*Assessment Measures*
Juvenile Growth	Foraging behavior Growth rate Condition index
Reproduction	Courtship behavior Number of eggs produced Fertilization success
Early Development	Gastrulation Organogenesis Hatching success
Smoltification	Ion exchange Blood hormone Salinity tolerance
Disease-induced mortality	Immuno-competence Pathogen prevalence in tissues Histopathology
Migration or distribution	Use of juvenile rearing habitats Adult homing behavior Selection of spawning sites

Table II. Salmonid Habitat Assessment Endpoints

Assessment Endpoints	*Assessment Measures*
Prey availability	Acute and chronic toxicity
Primary productivity	Macro-algal cover Chlorophyll concentration Dissolved oxygen production
Habitat structure	Sediment grain size (embeddedness) Shelter availability Large woody debris
Riparian function	Plant community composition Allochthonous inputs of organic matter Riparian buffer width
Water quality	Temperature Dissolved oxygen concentration

NMFS is particularly concerned about potential impacts of pesticides to listed salmonids in floodplains and small streams. Such areas provide essential habitat for small fry/juveniles to rear and seek protection from high velocity flows. Those habitats are spatially and temporally variable in occurrence, flow and size.

The biological opinions issued by NMFS between 2008 and 2011 concluded that several of the pesticides active ingredients were likely to jeopardize listed salmonids or destroy or adversely modify their critical habitat. Reasonable and prudent alternatives were developed as a result. Those reasonable and prudent alternatives have included chemical-specific risk reduction measures and conventional risk reduction measures for pesticides.

Challenges in FIFRA Consultations

There are a number of challenges that make consulting on pesticide registration activities difficult. These include:

- Consideration of all effects including sublethal effects
- Consideration of interactions with other chemicals or pollutants in the water column (i.e., additive or synergistic effects)
- Effects of ingredients besides the active ingredient (inerts, surfactants, degradates)
- Estimates of exposure and potential future use
- Assumptions about the use of data from surrogate test species
- The number of pesticide registration activities conducted by EPA and the Services limited consultation resources

The Services and EPA have for many years discussed and worked to develop methods to address these multiple challenges.

Addressing Scientific Uncertainty

In 2011, EPA and the Departments of Commerce, Interior and Agriculture requested the National Academy of Sciences convene a panel to provide its expert advice on certain core scientific and technical issues which serve as the foundation for assessing risks to listed species associated with EPA's FIFRA-related activities. To that end, the National Research Council (NRC) of the National Academy of Sciences was asked to provide the agencies with its independent advice on the following six specific topics: (1) best available scientific data and information; (2) sub-lethal, indirect and cumulative effects; (3) mixtures and inert ingredients; (4) modeling; (5) interpretation of uncertainty; and (6) geospatial information and datasets. That review is ongoing and should provide useful guidance to address these difficult and challenging areas.

Consultation Process Improvement

The agencies and affected stakeholders have also been discussing process improvements to the consultation process. EPA solicited input from its Federal advisory committee, the Pesticide Program Dialogue Committee (PPDC), regarding potential process changes that would facilitate greater opportunities for public participation and transparency in the registration review process that would have the additional benefit of streamlining any needed ESA consultation with the Services.

After considering this public feedback and advice from the PPDC, EPA has determined that it could implement several changes to the Registration Review process, further augmenting opportunities for public involvement in the process. These changes are described below.

Earlier Involvement of Stakeholders in the Registration Review Process

As part of the Registration Review process, EPA annually publishes a 4-year outlook schedule for when individual pesticides will enter the Registration Review program. To enhance transparency in the process, EPA could begin including information on the specific timeframe within any fiscal year when the pesticide will begin its review. Having this information available many years in advance would provide early notice for interested stakeholders to provide information to EPA in advance of the pesticide beginning its re-evaluation.

In addition, EPA could begin to hold "focus" meetings during the early stage of Registration Review. These focus meetings would provide interested stakeholders with opportunities to: 1) identify the uses that the registrant intends to support for Registration Review, 2) provide an opportunity to address label clarity issues at an early stage of the review process, and 3) based upon previous assessments, provide for early adoption of risk mitigation before the Registration Review begins.

By working with growers and registrants, any confusion regarding label directions could be addressed at an earlier stage in the process so that a risk assessment that more accurately reflects the intended use of the pesticide can be conducted. Such clarification might include greater specificity on the maximum number and frequency of applications.

Previous assessments, conducted either to support reregistration decisions or litigation, may have indicated the potential ecological risks. Alternatives may have been developed since those initial evaluations which may indicate that the benefits of the pesticide beginning Registration Review have changed. There may also be the potential, based upon further field experience with the pesticide, to identify the key efficacious rates critical for crop protection and/or existing conservation practices being employed that could be incorporated into labels as part of "early mitigation".

It would be EPA's goal to have any early mitigation incorporated onto product labels before the pesticide reaches the preliminary risk assessment stage.

Consideration of Pesticide Use and Usage Data

During the intervening 2-3 years after completion of the final workplan, the registrant is often developing toxicity and exposure data to support the preliminary risk assessment for the pesticide's Registration Review. As this information is being submitted to EPA, EPA could also solicit updated use and usage information from a variety of reliable sources, including the U.S. Department of Agriculture and grower organizations, to help frame the environmental risk assessment. These data, such as application methods, application rates, frequency of application, and application timing are critical pieces of information in developing the ecological risk assessment and effects determination. For example, having more complete information on the times of the year when a pesticide is used may enable EPA to more accurately predict the opportunities (or lack thereof) for exposure to listed species.

As a result, these data can be used to help refine the biological evaluation and, perhaps, the pesticide label, taking into account use patterns on a more local or regional basis. Consideration of typical use rates and prescriptive specification on product labels of the conditions under which higher rates may be utilized would further help in clarifying potential ecological exposure scenarios. Utilizing this information, EPA believes that it could develop additional risk mitigation (as necessary) to further reduce concerns for listed species, having the direct result of fewer "may affect" determinations, which could potentially preclude or minimize the need for consultation with the Services

Increased Use of the Informal Consultation Process

A critical step in developing the biological evaluation is having reliable data on species habitat, range, and behavior. Where necessary, EPA could utilize the informal consultation process to work with the appropriate Service to gather that information for inclusion in a more refined biological evaluation prior to the initiation of any needed formal consultation. Reaching out to the Services for this information at an earlier stage in the process has a number of potential benefits, including 1) incorporation of more refined species biology and habitat information into EPA effects determinations prior to formal consultation, 2) a further reduction in the number of "may affect" determinations, and 3) fewer resources (for both EPA and the Services) needed to complete any required consultation because the best available information has been incorporated into EPA's biological evaluation. As a result, this assistance would allow EPA to verify any draft conclusions regarding the potential risk to listed species and their habitats and would position EPA to begin discussing potential mitigation measures with the pesticide registrant. Additionally, this consultation should position the Services well to undertake any formal consultation that may be necessary later in the process since they will previously have been advised of the assessment, supporting data, species potentially at risk, and other aspects of the consultation.

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As a result of incorporating these changes into its Registration Review process, EPA would initiate any needed formal consultations at a later stage in the review process. Therefore, rather than initiate formal consultation during the preliminary risk assessment stage, EPA envisions that it may instead initiate informal consultation at the preliminary risk assessment stage to help in the identification of species-specific information to further refine the biological evaluation. If necessary, EPA would initiate formal consultation at a latter point in the Registration Review process, perhaps at the proposed decision phase. Figure 1 shows what such a revised Registration Review process would look like.

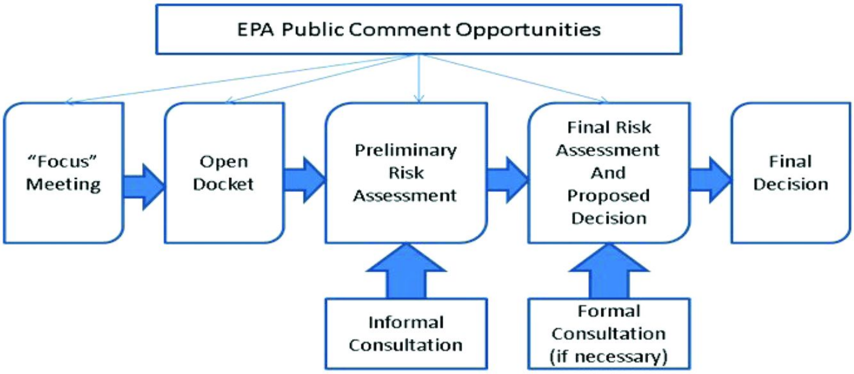

Figure 1. Revised Design for the Registration Review Process.

One major end result of these process changes is that, through public involvement, particularly with growers who are responsible for "on the ground" implementation of labels, mitigation measures that achieve the protection goals established by the Services and that are technically and economically feasible can be achieved. The involvement of growers will insure that the protection measures are workable.

Conclusion

ESA consultations on pesticides registrations are among the most challenging of all consultations the Services conduct. The Services are working with EPA to facilitate this process and are seeking the scientific advice of the National Academy of Sciences to address many of the challenging scientific issues. Process improvements, along with implementation of the Academy's scientific recommendations, should substantially improve the process and outcome of consultation.

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Chapter 3

The Endangered Species Act: Interfacing with Agricultural and Natural Ecosystems

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This chapter is based on a publication originally sponsored by the Council for Agricultural Science and Technology (CAST). In that issue paper, CAST explored why the Endangered Species Act consultation process is not functioning efficiently or effectively. In part, this dysfunctionality is because important stakeholders are disenfranchised. The lack of an established, transparent process impedes decisions and undermines trust amongst the affected stakeholders, resulting in necessary interagency communications being inhibited. And as a further result, litigation, which is not the most effective way to recover listed species, proliferates. In this chapter, we restate and expand upon the intersections between agriculture and the Endangered Species Act as explored in the CAST issue paper. We examine the polarity that can occur and endure in endangered species matters. We then discuss how the process should be improved, with an emphasis on the consultation process and pesticide regulation.

Introduction

The Endangered Species Act (ESA) was enacted by the U.S. Congress in 1973 for the purpose of protecting and recovering imperiled species and the ecosystems on which they depend. The Act is administered by the Department of Interior's U.S. Fish and Wildlife Service (FWS) and the Department of Commerce-National Oceanic and Atmospheric Administration's National Marine Fisheries Service (NMFS) (collectively, "the Services"). The FWS has primary responsibility for terrestrial and freshwater organisms, whereas the NMFS principally is responsible for marine species and anadromous fish (those that return from the sea to breed in the rivers where they were born) such as salmon (*1*).

Legal and administrative modifications to the ESA have failed to remove the polarity this law seems to evoke. Scott (*2*), an independent science writer based in Albuquerque, New Mexico, notes:

> What all of this fails to achieve is . . . a restored sense of trust and cooperation between agencies, regulated groups, and environmental interests. One prerequisite for restoring trust is clarity. . . . The challenge is in striking an appropriate balance between the need for procedural clarity, agency flexibility, and positive incentives on the one hand, and the need for regulatory authority and recognition of the inherently uncertain nature of conservation science on the other. . . . Programs need to be coordinated, simplified, and streamlined. Stakeholder participation in ESA decision-making should be increased, and the science underlying decisions should be more transparent.

Progress toward achieving the goals of the ESA has been slowed by litigation from all sides, consuming agency resources in response to legal actions rather than meaningful protection of species. Using pertinent examples of conflicts, litigation, and delays resulting from lack of procedural clarity and coordination, this Chapter (i) introduces the intersections between the ESA and management of agricultural and natural ecosystems within the United States and (ii) explores ways those intersections might be addressed not only to restore a process to protect critically imperiled species but also to establish process and rebuild lost trust among all affected parties.

The Regulation

Requirements for compliance with the ESA impact agricultural and natural ecosystems by placing burdens on:

- Lands in agricultural use, access to registered pesticides, permits for construction, and irrigation;
- Construction and maintenance of rights-of-way where power lines, railroad tracks, roadways, or pipelines pass through public and private lands;

- Grazing permits and invasive weed control on public grazing lands;
- Forest harvest and reforestation on private and public lands; and
- Water use and quality, exercise of water rights, and invasive aquatic pest control.

Section 7 of the Act governs most interactions between the Services and an applicant for a federal action (an applicant is either the agency granting a permit or the entity seeking a permit from the "action agency"). Section 7 directs all federal agencies to use their existing authorities to conserve threatened and endangered species ("listed species") and, in consultation with the Services, to ensure actions do not jeopardize the continued existence of listed species or destroy or adversely modify critical habitat. This section applies to management of federal lands as well as any other federal actions that may affect listed species, including private activities through the issuance of federal permits, licenses, or other actions (*3*). Permitted actions in some circumstances may result in an acceptable and permitted loss of the protected species.

Section 9 of the ESA prohibits any person or entity from engaging in "take" of a listed species (a term defined by the ESA as "means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct"). It also includes prohibition of other actions such as possession, transportation, and selling of listed species. It applies both to applicants for federal actions and actions by nonfederal entities. "Harm" is defined by FWS regulation as "an act which actually kills or injures wildlife." The regulation notes that "Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impacting essential behavioral patterns, including breeding, feeding, or sheltering."

What the Act does not provide is (i) clear guidance on assessment, consultation, and enforcement processes; (ii) consideration of the complexities of ecosystems; (iii) implications of proposed actions on affected stakeholders; and (iv) a mechanism for embracing sound science from nonfederal agencies or between agencies having differing regulatory drivers. Once enacted, the ESA was quickly tested in court by the Tellico Dam/Snail Darter conflict (*4*), establishing early in the maturity of the law a pattern of action– litigation–action–litigation that dominates it today. Congress ultimately exempted the Tellico Dam Project from the ESA and allowed its completion, and other populations of the snail darter were discovered (*5*), but many of the financial resources that might have gone into restoring those populations were expended in dispute. This initial litigation decision was the first of many that have shaped how the ESA is now interpreted and enforced. The Tellico Dam is the first example of the polarity that can occur in, and endure after, resolution of ESA-related disputes. Although many potential conflicts between human activities and the protection of endangered species are resolved through Section 7 consultation and Section 10 permits, they often are not resolved as efficiently as might be wished.

Harmonizing Agricultural Practices and Species Protection

The objective of the ESA is to prevent loss of rare or imperiled species so that ecosystems remain sustainable. Management goals are aimed at species recovery, and recovery goals are unique for each species. In some habitats, listed species and their critical habitats may benefit from removal of invasive species through use of herbicides. In other habitats, use of herbicides may pose potential risk to listed or nontarget species. Inaction may pose even greater risk to listed species, further complicating the issue. There is no requirement for benefit analysis per se in the ESA, a circumstance that can present challenges for stakeholders when alternatives for species management and action mitigation are evaluated.

Additionally, in many cases, the Services must weigh actions that avoid or mitigate for short-term (acute) risks to listed species against actions that might benefit a species for the long term (e.g., multiyear or multidecade). Irwin and Wigley (*6*) note that "In this 'relative risk' assessment process, thresholds for unacceptable short-term risks are not commonly defined or understood, whereas tools and procedures for assessing long-term effects of no restoration management are generally lacking. As a result, decisions are frequently based on the precautionary principle, in which short-term, risk-averse positions prevail." Thus, long-term benefits that may require higher short-term risks (including "take") may not be understood in the context of alternative actions having lower short-term risk but fewer long-term, sustainable benefits.

Management practices such as crop production and silviculture (the study, cultivation, and management of forest trees) can have variable and often complex impacts on species diversity—including benefits and risks to listed species. For example, in permanent-plot studies conducted within managed and unmanaged forests of the Pacific Northwest, Halpern and Spies (*7*) found that changes in understory diversity were short-lived after clear-cut logging and slash burning, with populations of most vascular plant species recovering to original levels before canopy closure. But these authors reported that diversity may remain depressed for more than two decades on severely burned sites, and some species may experience local extinction. Likewise, development of irrigated agricultural areas may attract new species (e.g., endangered song birds) while displacing other species that depend on desert habitat or aquatic ecosystems that supply water to arid areas.

As Scott (*2*) noted, unclear policy and uncertainties about outcome promote divergent agendas and can inhibit trust and derail process when listed species are the subject of ESA evaluation and consultation, hindering cooperation among stakeholders and prolonging final decisions. Consistent and rigorous science-based characterization of potential impacts to listed species ultimately will support a predictable and reliable consultation process between a federal action agency and the Services. A predictable process would move smoothly and include (1) a clearly defined proposed action; (2) informal consultation to familiarize all participants with the action and its specific provisions; and (3) agreement on "no effect" or "not likely to adversely affect" or, in absence of this, initiation of formal consultation. To increase the quality and timeliness of endangered species assessments and biological opinions, all stakeholders must have a mutual understanding of the proposed action and the risks and benefits of all alternative actions to focus consultations on appropriate endpoints and issues.

In the absence of a transparent and predictable process, stumbling blocks inevitably emerge and can include (i) no common understanding of the "action," (ii) conflicts related to short-term versus long-term view, (iii) disagreement on risk evaluation methods, (iv) no consideration of benefits, (v) failure to engage all stakeholders early in the process, (vi) lack of adequate resources, or (vii) a poorly understood baseline.

As an example of lack of transparency to stakeholders, in 1995 the Bureau of Indian Affairs (BIA), responsible for ESA Section 7 compliance on behalf of the various tribes, completed an Environmental Impact Statement and Section 7 consultation for livestock grazing and prairie dog management for two tribal reservations in South Dakota. The two tribes proposed diametrically opposed solutions to prairie dog population management. Following Section 7 consultation on prairie dog management proposals, a procedural requirement for the BIA, the FWS found "jeopardy" regarding impacts to black-footed ferrets for one reservation and "no jeopardy" for the other. The tribes—the most directly affected interests in the proposed actions—had no defined role or clear voice in the process (*8*).

When the utility and positive impacts of a given action are poorly understood, subsequent benefits to listed species may be lost or diminished, thereby impeding recovery. For example, good agricultural management practices can create habitat or control invasive species, but when considered in isolation may be viewed as threats to species recovery. Prairie dog management, for example, may be necessary to preserve permanent vegetation in Conservation Reserve Program (CRP) fields, but control of prairie dogs is restricted when the prairie dogs are a listed species or when listed species such as black-footed ferrets are associated with prairie dog towns. Under the ESA, endangered species management lacks flexibility to support implementation of a time-honored medical prescription: Immediate intervention that adversely affects mobility or general well-being can result in curative action that prolongs vibrant life or increases reproductive capacity.

The largely court-determined primacy of the ESA presents challenges for other federal, state, and local programs meant to benefit the environment, some of which programmatically, if not procedurally, already address ESA goals. For example, the Oregon Invasive Species Action Plan acknowledges that "in light of climate change, invasive species management allows for native species to be reestablished and ecosystems to be restored. Preventing the introduction of invasive species requires proactive planning and strengthening of rules and regulations" (*9*). Yet the Oregon plan contains many actions that require an advanced evaluation under the ESA, slowing its ability to cope effectively with its mission.

The *Egeria densa* Control Program (EDCP) in the Sacramento–San Joaquin (California) Delta provides a good example of both how programmatic adaptive management and flexibility in implementation of the ESA can foster success and how success often "takes too long." With the U.S. Department of Agriculture's (USDA) Agricultural Research Service acting as the federal liaison to the

California Department of Boating and Waterways for Section 7 compliance, a multiyear project was developed to decrease the economic and ecological impact of the aquatic weed *E. densa* (Brazilian waterweed) on this critically important water resource. In this instance, Brazilian waterweed control requires early spring application of the most efficacious systemic herbicide, fluridone. Yet the presence, movement, and potential exposure of salmon (and other listed fish species) to fluridone during spring raised concerns by the Services. Applications specified under the initial Biological Opinion (BiOp) were allowed only after July 1, well past the season to control the invasive weed species effectively.

Through a series of technical discussions, jointly planned research, data review, and refinements of application methodologies, however, the desired early April start date subsequently was approved in a modified BiOp. The change in start date resulted in an 80% reduction in target weed cover and biomass with a concomitant resurgence of some native aquatic plants such as *Stuckenia pectinata* (sago pondweed). The key to this success was an exchange of concerns and ideas that resulted in concrete, testable questions raised by NMFS staff regarding the toxicity of fluridone to listed fish. Open dialog resulting in mutual understanding of the limitations of surrogate testing, demonstrable exposure risks, and extensive monitoring data—together woven into a cohesive regulatory position—achieved both management of a highly invasive aquatic weed and protection of a listed species (*10*, *11*).

Common Points of Controversy and Contributing Causes

Many natural resource uses and typical agricultural practices are questioned by the public and regulatory agencies because of the potential impact on endangered species. In some instances, these concerns arise because the public may not understand fully or appreciate relationships between land uses and listed species, the rigor of regulatory programs such as the registration process for pesticides, or the implications of no management (e.g., proliferation of an invasive species if herbicides are not used).

Oversimplistic Evaluations of Management Impacts

Public Land Use Programs, such as those that issue grazing permits in the western United States, often face opposing views on whether grazing on open lands is beneficial or detrimental to listed species. Broad or simplistic evaluations might conclude that decisions are “good” or “bad” for endangered species protection or land use, when in reality the subject is often much more complex and variable. For example, Middleton *et al.* (*12*) found that grazing can be beneficial to fens in some circumstances and detrimental in others; there was not a “one-size-fits-all” conclusion. The benefits of cattle grazing to fen biodiversity are highly dependent on the amount of grazing, a complicated factor alone. As Bergamini *et al.* and colleagues (*13*) note, the amount of cattle grazing is dependent on productivity and food requirements of the cattle breed, number of cattle, life stage of the animal, duration of the grazing period, and productivity and energy content of the vegetation. Overgrazing can induce soil erosion or other adverse changes. Given these variables and the expectation that the owner of a grazing permit is seeking to maintain a sustainable grazing situation, the goals of the permit holder and ESA-listed species recovery indeed may be identical when (i) best management practices (BMPs) are applied and (ii) complexities are understood relative to long-term impact and benefits.

Failure To Consider Actions that Lessen Impacts on Listed Species

The benefits of landowner and agency actions to lessen impacts on listed species sometimes are not fully recognized by the public or the Services. For example, in its pamphlet titled, "Protecting Water Quality from Agricultural Runoff," the Environmental Protection Agency (EPA) notes that the 2000 National Water Quality Inventory identified agricultural nonpoint source pollution as a leading source of water quality impacts on surveyed sites, and further recommends management practices that can decrease pollution (*14*). Whereas grower education and incentive programs have resulted in implementation of agricultural BMPs that decrease impact on water quality, ESA evaluations of permitted actions such as pesticide registration have no access to data from those programs even though such data would be helpful in quantifying the decreased potential impact of agricultural practices on listed species.

Similarly, even though national water monitoring programs such as the National Water Quality Assessment Program (*15*) in most instances demonstrate a trend of decreased concentrations of pesticides, there currently is no mechanism for incorporating these findings into endangered species assessments. This is partly because the environmental baseline—on a national level—is impossible to define, and sometimes BMPs are not recognized by agencies as effective strategies for water quality protection. Lack of a central data source on the specific benefit brought by these practices also inhibits interagency understanding of their benefits. Likewise, even USDA programs such as CRP lands, the Wildlife Habitat Improvement Program, or the Environmental Quality Improvement Program are not given proper recognition as benefiting listed species. Consequently, a grower who implements BMPs is not credited by a Services assessor who may not be aware or understand how these practices may mitigate species exposure.

Impact on Agriculture by Listed Species

An additional challenge is that the recovery of species sometimes may have unintended impacts on agriculture, thereby resulting in controversy. The return of endangered predators— both naturally and through human reintroduction—can have measurable impacts on livestock grazing. For example, grizzly bear (*Ursus arctos horribilis*) recovery in the Yellowstone ecosystem has resulted in direct livestock mortality in Wyoming and Montana. Similarly, as gray wolf (*Canis lupus*) populations have grown in Minnesota, Wisconsin, and Michigan as a result of ESA protection, livestock losses also have increased. Reintroduced wolf populations in Wyoming, Montana, Idaho, New Mexico, and Arizona have caused conflicts, with livestock destruction the primary reason wolves in New Mexico and Arizona have not recovered further. Additionally, restrictions on traditional predation management techniques were implemented as a result of “reasonable and prudent alternatives” required by Section 7. Although these alternatives serve to protect endangered predators from incidental “take,” they also restrict methods aimed at more common—and more costly—nonlisted predators (e.g., coyotes [*Canis latrans*]), and in essence make predation management difficult to implement and more expensive. Means for offsetting the cost of documenting livestock losses caused by listed species are available in some instances, but options to handle other costs are not. For example, losses caused by listed wolves or bears are compensated with livestock compensation funds operated by Defenders of Wildlife or the states of Wyoming and Montana.

Lack of Data Specific to Listed Species

Management of invasive species is critical to the protection of habitat for certain listed species, and management in many instances requires the use of certain EPA-registered products (e.g., herbicides). But EPA and Services biologists responsible for ESA implementation and assessments have difficulty reaching conclusions in the absence of toxicity data on listed species because there are no standards for bridging data from surrogate species to listed species. This dichotomy has resulted in a 2- to 3-year delay in implementing programs designed to benefit listed species and recover their habitat. These delays—while the invasive species is proliferating—highlight the need for a streamlined ESA approval process allowing rapid response to thwart newly introduced invasive species. Moreover, delays also underscore a need for quick evaluations and a reasonable acceptance level of short-term risks to facilitate early eradication and avoid larger impacts later.

Successfully dealing with lack of specific toxicity data on listed species is exemplified in the Bureau of Land Management (BLM) programmatic environmental impact statement for herbicide use in 17 western States (*16*). This comprehensive environmental impact statement includes detailed biological, human health, and environmental assessments for a range of weed control options and applies “Toxicity Reference Values” by taxa. Under Section 7 of the ESA, the BLM entered into a consultation agreement with the NMFS and the FWS, who concurred with the BLM’s findings of “may affect, but not likely to adversely affect,” through specified standard procedures and protective measures. Although the BLM has local vegetation control consultation streamlining agreements in place to conclude consultations rapidly, the process still is hindered by disputes. For example, one local program was withdrawn after it was appealed by the Center for Biological Diversity and WildEarth Guardians because the “BLM decided that the best way to clarify the intent and scope of our EA [Environmental Assessment] would be to withdraw and revise the current document” (*17*).

Potential Remedies

Better Communication

The Section 7 process would benefit from specific instruction on engaging broader participation by affected stakeholders early in the assessment and consultation process. For example, as described previously, tribal lands and economies were important to the multi-tribe Section 7 consultation regarding livestock grazing and prairie dog control. The tribal community had no defined avenue for contributing meaningful data to the consultation process, but was affected directly by resulting consultation action. Similarly, in the EDCP involving invasive weed species, lack of knowledge of practices and needs, accompanied by the fact there was no process to allow input and review of these details, delayed a program important to the protection of listed species and critical habitat.

Clear Policy and Agency Coordination

In the absence of scientific process, it sometimes is difficult to differentiate between requirements of the Act and procedures implemented based on the outcome of litigation. Clear agency guidance is simply not available, so litigation—even single decisions—sometimes drives implementation and the Service's policies. Court decisions may be problematic because they focus on procedures rather than on sound science in many instances. The court shapes policy because thorough scientific definition and boundaries are missing for many components of the Act (such as "reasonably expected to occur," specific standards defining "best available data," etc.). For example, an initial court decision expanded the definition of "take" to include "take of habitat" for the Palila bird in Hawaii (*18*) and directed the Services to find jeopardy in actions that cause the loss of a habitat component, regardless of the improvement that might ultimately occur as a result of the overall action.

A subsequent Supreme Court decision (*19*) upheld the FWS definition of "harm," including 1981 amendments emphasizing that actual death or injury of a protected animal is necessary for a violation to occur. In such cases, the courts are construing the statute and congressional intent, not creating the standard on their own, but the court decision often serves as a standard that was not reached through scientific definition.

Recognition and Consideration of Long-Term Impacts

Currently there seems to be no separation between short- and long-term impacts, and the ESA does not provide flexibility to apply such consideration easily. This situation results in biological opinions based largely on avoiding or minimizing short-term risks, whereas temporary impacts to habitat ultimately might benefit the long-term recovery of the species. Assessment needs to focus on

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the analytical tools and decision-making procedures that help managers assess and display the short- and long-term risks and benefits of actions that might benefit listed species. For example, controlling invasive species can have long-term benefits even though there is a risk that some individual listed species may be affected in the short term. Many states have implemented “Aquatic Nuisance Species Plans,” and each plan has an early detection/rapid response component (*20*). For these rapid response actions to be effective, a clearly defined “fast-track” procedure needs to be available through the ESA so that weeks—not months or years—are required for approval of very specific, highly focused containment and eradication actions. Given the requirements of the ESA, guidance published in peer-reviewed journals (e.g., *Forest Ecology and Management* (*21*)) could be adopted formally for use in consultation procedures.

Balanced and Consistent Implementation

There are many instances in which long and difficult processes resulted in enlightenment that made later decisions more realistic and informed. Delays often come from the entrenchment of polarized “sides” that address any ESA matter with a predisposed argument, a practice encouraged by some processes that surround ESA implementation. To move from polarized, nonscientifically based arguments, the interface between agricultural practices or natural resource use and the ESA needs to involve a simplified, coordinated, fully defined process that leads to implementation of transparent and sound science supported by strong stakeholder involvement.

Conclusions and Recommendations

It is well known that the endangered species consultation process for pesticides and agriculture is not working to the satisfaction of most stakeholders. This circumstance adversely affects both the recovery of species and the ability to efficiently raise food and fiber. In this paper we present several potential remedies, which, if implemented, can greatly improve matters. These potential remedies fall into the broad categories of: better communication, clear policy and agency coordination, recognition and consideration of long-term impacts, and consistent implementation.

In our opinion, the most important remedies that need immediate implementation are those associated with clear policy and agency coordination. By clarifying how the agencies interact and upon what standards their evaluations are based, the resulting regulatory process would be more transparent, with a consistent agency and stakeholder interaction process. Interagency and stakeholder trust would be built which in turn will allow more meaningful and effective access to and utilization of resources available from the registrant, each involved agency and local entities such as states or regional federal offices of EPA, the Services, and USDA.

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Chapter 4

Growers, Pesticides, and Endangered Species: Outcomes of a Stakeholder Workshop

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As part of the Endangered Species Act Section 7 consultation process for a U.S. Environmental Protection Agency (EPA) pesticide regulatory action, the pesticide's registrant may be involved but growers typically have no inputs. To assist EPA and growers in developing closer cooperation during the ongoing Registration Review program, through which EPA intends to implement endangered species assessments, a stakeholder workshop was convened. The workshop was sponsored by the Minor Crop Farmer Alliance and included representatives of EPA as well as the U.S. Fish and Wildlife Service, National Marine Fisheries Service, and the agrochemical industry. Discussions concerning both the overall ESA process and specific case studies were designed to answer a number of questions related to better incorporation of growers and grower information into the ESA consultation process for pesticide regulatory decisions.

Introduction

In the regulatory decision-making process, when the U.S. Environmental Protection Agency (EPA) completes an endangered species assessment and consults with one of the federal services, pesticide registrants may be invited to be involved and provide information in recognition of their role as "applicants" under the Endangered Species Act (ESA). However, growers and other agricultural stakeholders have no formal role in the ESA Section 7 consultation process and typically have no inputs.

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

The initial outcomes of recent ESA Section 7 consultations between EPA and the National Marine Fisheries Service (NMFS) have raised concerns among growers that decisions impacting use of pesticides may be made without adequate inputs from growers or consideration of grower needs. EPA and NMFS have proceeded with the consultation process for a number of pesticides with major agricultural uses following lawsuits from environmental groups alleging the threatened and endangered salmon in four Western U.S. states were not being adequately protected. The initial Biological Opinion (BiOp) from NMFS for several insecticides based in part on information from an earlier EPA assessment, included recommendations for significant product use restrictions including lengthy no-spray buffers between treated fields and waterways (*1*). The recommended no-spray buffers of 500 to 1000 feet had the potential to significantly impact use of the products across vast areas of productive farmland. Based on the BiOp, EPA later proposed a series of modified product use restrictions (*2*). Unfortunately, the processes used by NMFS and EPA for their assessments and development of proposed restrictions were included little or no input from growers and other stakeholders. Grower information about agriculture production systems, pesticide use practices, and ideas for practical good management compatible with the needs of growers might have better informed the process. Although some information on grower practices was made available by registrants, impact on the BiOp process was limited in part since such practices may be viewed as discretionary rather than mandatory in nature. Although subsequent salmon-related consultations occurred with more opportunities for public and grower comments, growers are concerned that they are not being fully involved in the process. This is especially concerning as EPA moves forward with endangered species assessments and ESA consultations as a major priority during the Registration Review program, under which all pesticide products will be reevaluated during the period 2007 to 2022.

To assist EPA and growers in developing closer cooperation regarding endangered species assessments during the ongoing Registration Review program, a stakeholder workshop was convened. The workshop was sponsored by the Minor Crop Farmer Alliance (MCFA) and included representatives of EPA as well as the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS). Discussions concerning both the overall ESA process and specific case studies were designed to answer the following questions concerning pesticide use and potential pesticide exposure. 1) Is there grower information that may be valuable in the ESA Section 7 consultation process, including risk assessment and risk mitigation development, among the Agencies? 2) If grower information is useful, what information is most valuable, and how should it be collected and entered into the process? 3) What is the appropriate entry point for growers in the evaluation process?

The Workshop

The Minor Crop Farmer Alliance ESA Workshop was held at the Denver Tech Center Marriott, Denver, Colorado, over the two day period of May 24 to 25, 2011. More than 75 people participated, including representatives from

EPA, NMFS, USFWS, US Department of Agriculture (USDA), State Agencies, grower groups, the crop protection industry and consultants involved in pesticide regulatory actions.

The primary purpose of the workshop was to discuss grower involvement in the endangered species review and regulatory activities surrounding the pesticide Registration Review process. The first day of the workshop involved technical presentations designed to provide a better understanding of each government agency's role in the review process and the information needed to enhance the endangered species risk assessment process and development of possible mitigation measures. Copies of the workshop summary and individual presentations are available (*3*).

The workshop included two case studies, one involving an insecticide and the other an herbicide. These were selected based on registrant cooperation and commitment to preparing a case study and broad geographic distribution and use patterns that included specialty crops. These chemicals were used to illustrate the diversity and types of information that may be needed at the grower level to adequately address the risk assessment issues described by the governmental entities. The focus of the workshop was on the Registration Review process at EPA, including information needs and potential sources for that information. A short synopsis of each of the presentations follows.

ESA Policy and Processes

MCFA provided a short summary of the genesis of the workshop, and identified the planning committee and sponsors. The presentation also detailed the goals and objectives and process to be followed during the workshop.

EPA – Overview of Nontarget Risk Assessment Process and Endangered Species Risk Determination

This was a three-phase presentation given by Kevin Costello, Pesticide Reevaluation Division, Office of Pesticides Programs (OPP); Diann Sims, Biological and Economic Analysis Division, OPP; and William Eckel, Environmental Fate and Effects Division, OPP. Each of the presentations focused on part of EPA's process to reassess, define and mitigate non-target impacts of pesticide use. The first presentation was a comprehensive look at the pesticide Registration Review process currently underway at EPA. It described the process and proposed several points in the timeline during which the Agency hoped to collect and review information necessary to provide a robust and meaningful endangered species assessment. It identified the tiered information needs which can trigger the need for more refined geospatial information about pesticide use. The presentation also proposed several points for informal consultations with both the stakeholder community and the "Services" (NMFS and USFWS) to facilitate the endangered species risk assessment process. The second phase of the presentation described the scope and limitations of use and usage information as currently collected by the Agency. The sources for existing information were characterized and potential additional sources of information were identified. This presentation also detailed the critical importance of the label in the assessment process, particularly the need to confirm the accuracy of use sites and clearly defined label use directions. The third phase of the presentation focused on EPA's ecological risk assessment process with emphasis on the endangered species component. The presentation centered on the stages of the Registration Review process and how input from growers and registrants could make it more efficient and meaningful. It described a tiered process with broadly defined risk triggers at the initial stage of review keyed off label language, through the more refined and very local specific assessment at the individual species stage when a "may affect" trigger is exceeded. The presenter highlighted the importance of the initial "problem formulation" stage in helping ensure an efficient review and that appropriate information was identified and could be collected for the more refined risk assessment. The potential benefits from informal consultations during the assessment process were also highlighted. The importance of grower involvement during development of risk mitigation steps in the endangered species consultation process was noted.

NMFS – Threatened and Endangered Species: An Overview of NMFS' Process for Assessing EPA Pesticide Registration Actions Pursuant to the ESA

The NMFS presentation was made by Tony Hawkes, Endangered Species Division, Office of Protected Resources. This very comprehensive presentation provided a general overview of the consultation process between the action agency – EPA and NMFS. The consultation process is triggered by a decision document (proposed label) at EPA that defines the Agency action that requires consultation. Mr. Hawkes described NMFS's review process as dictated by regulations developed to implement the ESA. This requires an assessment of impacts beyond the individual organism, to include habitat and population level impacts on species survivability. His presentation characterized the types of data to be considered and the complexities involved in the analysis process. The broad scope of the definition of "take" under the ESA also increases the complexities of the process. The avoidance of "type 2" errors in the risk assessment leads to the addition of safety factors into the trigger levels to assure safety for threatened and endangered species. NMFS also described the process they utilize to develop reasonable and prudent alternatives, which are required if the risk assessment identifies a potential to either jeopardize the continued existence of the species or adversely modify or destroy critical habitat.

USFWS – FIFRA and the ESA: U.S. Fish and Wildlife Service Perspective

Rick Sayers, Chief, Division of Consultations, HCP's, Recovery and State Grants, made the presentation for the USFWS. In his presentation the scope and magnitude of the potential consultation process became apparent. USFWS manages thirteen hundred listed species over a multitude of plant and animal taxa.

The process of risk assessment and risk mitigation definition follows the process and complexity of the NMFS. USFWS detailed their use of surrogates to represent toxicity potentials for listed species which adds a level of uncertainty into the process. USFWS's analysis is more complicated in that several listed species share direct characteristics with organisms that are specifically being controlled by pesticidal products in question. Habitat impacts are also an important component of the USFWS's assessment.

USDA – Role in Endangered Species Risk Assessment and Mitigation

USDA provided an overview of information sources and programs that may be available to the specialty crop production segment to both help define potential impacts and to provide options for mitigation if needed. The USDA presentation was split into three components with Sheryl Kunickis, Director, Office of Pest Management Policy providing a general description across the spectrum of USDA activities that may impact this process. Shaun McKinney, Natural Resources Conservation Service, followed with an overview of programs that can be used to help determine and model specific impact areas in addition to farm-level planning services that can be directed at mitigation efforts. The third component was provided by Howard Hankin, also with the Natural Resources Conservation Service. He provided an overview of the targeted effort being conducted on a pilot basis in specific regions of the country to tailor conservation practices to address species conservation. This is a "best practices" process that can be partially supported through matching funds at the state conservation program level. This effort has been underway for over three years and has resulted in defined programs in several regions.

Conclusions: ESA Policy and Process

In the discussion session after these four presentations there was a general agreement of the need for a better understanding of not only how FIFRA labeling is implemented across diverse cropping systems and regional pest complex differences, but also the need for better pesticide usage information at the species interface level. Grower groups were concerned over when to engage in data collection and the best means to assure that such collection effort was appropriately targeted resulting in quality information that would be used by EPA and the Services. EPA expressed concerns about timing of any efforts to assure the efficiency of the review process. They viewed the process along a continuum that would go from the broadest national consideration (i.e., label- based) to locality specific temporal and culturally specific use patterns (crop- specific farm level). Everyone was in agreement that a robust pesticide Registration Review process was preferable to the current litigation-driven process.

ESA Case Studies

To facilitate a more targeted discussion at the grower level, two pesticides were selected for discussion as ESA case studies. The first of these, Phosmet (Imidan®), is a broad spectrum insecticide registered mostly for fruit and nut crops, and a few vegetables. The registrant for this product is the Gowan Company. It has been the subject of a Biological Opinion (BiOp) from NMFS in the current salmonid litigation on the West Coast and is also currently in Registration Review. The second product, Prometryn (Caparol®), is a broad spectrum, pre- and post-emergent herbicide registered for use on several specialty crops and cotton. The registrant of this product is Syngenta Crop Protection, LLC. It will be the subject of a BiOp in the same litigation but has not yet started the ESA review process; it is also scheduled to start Registration Review in the near future.

Each of the registrants was asked to prepare a summary of the information available for consideration during the endangered species risk assessment and mitigation development process. The information included characterization of existing labels, general overview of relative toxicity, marketing and use information and any labeling language currently in place to limit offsite impacts.

Phosmet

The case study presentation for phosmet (Imidan®) made by Cindy Smith, Gowan Company, included basic information about the chemical and its non-target levels of concern, description of the labels and market information, relative importance in agricultural production, regulatory history, and the current BiOp concerning salmonids in the Northwest. Phosmet was first registered in 1966 and is one of the few broad spectrum organophosphate insecticides still registered for many fruits and nut crops. In her presentation, Ms. Smith identified information used both by EPA and the Services in their analysis of the risk associated with the use of phosmet which could substantially impact the assessment process. This included, in particular, the actual labels currently being marketed in the United States; the relative levels of use in key markets where concern for salmonids exist; and, trend analysis of future use of products. The last point triggered a lengthy discussion of the various use and usage databases and non-reported data retention requirements at the farm level. The use of monitoring data for risk assessments was also highlighted with the actual data suggesting a much reduced potential exposure than indicated in the models based on maximum use rates.

Prometryn

The case study materials for prometryn (Caparol®) were presented by Dan Campbell, Syngenta Crop Protection, LLC. This triazine herbicide was first registered in 1964. Much of the same type of basic information that was provided for Imidan® was included in Mr. Campbell's presentation. Because of its registration on cotton, there appears to be much more information in the publically available databases across a more diverse geographical area. The presentation also highlighted the ability to use a Geographic Information System (GIS)-based tool to determine co-location of pesticide use and counties that have been identified as containing habitat for endangered species. The ability to obtain more refined geospatial analysis was demonstrated in the presentation. Much interest was expressed in the use of these tools and the need to develop a verifiable database on cropping locations and usage information.

Conclusions: Case Studies

Several basic themes and questions emerged from the discussions around the information presented in the case studies:

- What are the appropriate points in the Registration Review process to initiate discussions with both the registrant and the user community to identify, describe and verify crop-specific use and usage information?
- What data sources are most complete and relevant to the risk assessment process?
- How will commodity groups know when to engage in the process and how to ensure that information collected and submitted is considered?
- How would the need for informal dialogue and discussions take place prior to formal consultations between EPA and the Services?

The grower representatives indicated a need for additional information on EPA's risk assessment process and the Services biological opinion development process and resulting triggers used by the Services to drive development of reasonable and prudent alternatives.

The consensus among all participants is that it would be in everyone's best interest to develop a comprehensive and transparent process during Registration Review rather than having the consultation process continue to be litigation-driven.

To facilitate those discussions a matrix was developed to describe points in the process where specific information would be valuable and points where the process would most efficiently utilize the information (Table I). It was clear after the discussions that additional meetings to clarify the process would be necessary.

Table I. Draft Registration Review Information Matrix

Information Needs	*Potential Providers*	*Comments*
Pre-Docket (Problem Formulation)		
Clarification and confirmation of Use/usage (characterized) data and label statements Characterization of tank mixes for environmental risk assessments Crop distribution Information (where grown today and where could be or couldn't be)	Registrant Growers States USDA	**Grower Action**: Know the schedule **EPA action**: identify schedule to let people know critical timing for receiving information **EPA and Services Action**: Definition of data needs
Docket Opens – 1st Public Comment Period		
Preliminary work plan issued Comments sought on scope of registration review and data needs Opportunity to address or refine data needs identified above or created by synthesis done by EPA	Registrant Growers States USDA	**Grower action**: Review preliminary work plan and problem formulation to provide comments to correct or inform Possible information Needs: • Tank mixtures • Environmental mixtures **Registrant Action:** Possible mechanisms for reviewing information to develop a final work plan: • Label review
Final Work Plan Published and Data Call-In Issued		
Comments received and addressed Revised scoping document No comment period	Registrant Growers USDA	**EPA Action**: Identify a process step (draft risk assessment) where they have enough information to identify species of concern and where more information could be provided to refine. Place for informal consultation –technical input from the Services
Preliminary Risk Assessment - Second Public Comment Period		
Integrating data received into risk assessments Human health and eco risk assessments released for comment. Species of concern identified at this phase. Discussion of possible mitigation based risk assessment	Registrant Growers States USDA	**EPA Action**: Potential informal Consultation with Services

Continued on next page.

Table I. (Continued). Draft Registration Review Information Matrix

Information Needs	*Potential Providers*	*Comments*
Proposed Registration Review Decision – Third Public Comment Period		
Finalization of proposed mitigation Revised labels submitted	Registrant Growers USDA	**Grower Action:** Response to proposed mitigation
Final Decision Issued (if no need for consultation)		
EPA Request Initiation of Consultation ***Services Request for Clarification***		
Identify applicants	Registrant Growers USDA	
Final Biological Opinion		
Reasonable Prudent Measures and Alternatives		
Implement Reasonable Prudent Alternatives		

Workshop Outcomes

As a result of the workshop, a number of follow-up action items were identified to advance greater involvement of growers in Registration Review processes involving endangered species assessments:

- Workshop Planning Committee and MCFA Technical Committee Meetings in June to explore specific meeting outcomes and next steps.
- Coordinate website to post all presentations and workshop summary.
- Develop written workshop summary of major topics.
- Post proposed draft matrix/discussion document developed at the workshop that could be used in the pesticide re-evaluation process.
- A review of USDA databases that EPA and the Services could potentially utilize in their review processes.
- Explore ways to maintain the dialogue, including coordinating with other commodity groups and registrants.
- Determine the best route to communicate with MCFA members and others to follow up with recommendations of specific actions for growers during the ESA review process.
- Discuss ways to collect typical use data, typical tank mixes, etc., the data needs identified by the Agency and the Services during the workshop.
- Commitment by MCFA members to review existing BiOps and to thereafter appropriately follow up with the EPA and the Services on specific process issues, with a goal of developing a transparent, simple and common understanding of the process.
- Discuss the process defined in the Section 7 Consultation Handbook. Determine if the registration revaluation matrix can be accommodated.

- Find ways to gather and provide data in a consolidated way that can be used across multiple pesticide Registration Review dockets.
- Explore the use of webinars rather than face to face meetings for future discussions.

Acknowledgments

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Chapter 5

Improving the Endangered Species Act Pesticide Consultation Process

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To improve pesticide consultations under the Endangered Species Act (ESA), at least three key questions should be answered. First, under the ESA, what level of risk to ESA-listed species is acceptable from the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act? Second, how will the federal agencies that implement and comply with the ESA receive enough funding to meet their current and future pesticide consultation workload? Third, how can these agencies improve the process of consultation, so that it is more effective, efficient, transparent, and predictable? This chapter explains the importance of each question and provides a starting point for answers.

Introduction

When Rachel Carson published Silent Spring in 1962, she awakened Americans to the environmental costs of indiscriminate pesticide use. She contended that pesticides had been approved for use "with little or no advance investigation of their effect on soil, water, wildlife, and man himself." Fifty years later, what progress have we made in ensuring that pesticides are applied only after we adequately investigate their effects on wildlife?

Let us assess the numbers. Currently, the U.S. Environmental Protection Agency (EPA) has over 1,100 pesticide active ingredients registered for use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (*1*). How many of these ingredients have been adequately evaluated under the Endangered Species Act (ESA) for their potential impacts to imperiled wildlife? Under three dozen, or less than four percent (*2*). Combine these active ingredients with non-active

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ingredients and we have over 20,000 distinct pesticide formulations approved for use under FIFRA (*3*). FIFRA, as implemented over the past 65 years, does not safeguard ESA-listed species, because EPA has not properly considered impacts to these species.

Under FIFRA, EPA may register a pesticide if it does not cause "unreasonable adverse effects" on the environment (*4*). To determine whether this requirement is met, EPA conducts a cost-benefit analysis (*5*). Pesticides may be registered as long as their purported benefits outweigh their potential harms. In practice, a FIFRA registration often says little about a pesticide's effects on listed species, and even when it does, FIFRA does not give greater weight to ESA concerns. By contrast, the ESA establishes a far more protective standard: a pesticide must not likely "jeopardize" a listed species or "destroy or adversely modify" critical habitat for the species (*6*). Under this standard, the economic benefits of a pesticide cannot override its adverse impacts. Because most pesticides on the market today have not been evaluated under the ESA, presumably dozens, if not hundreds, of pesticides are applied daily without satisfactory measures to protect listed species. From this viewpoint, little has changed since 1962 to adequately protect listed species.

Meanwhile, the few attempts to regulate pesticides under the ESA have been mired in controversy. EPA disagrees with the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) on basic questions, such as the methods and assumptions for evaluating the risks to imperiled species from pesticide exposure. Sharp criticism from the pesticide industry has saddled every recent pesticide biological opinion issued by NMFS. And last year, U.S. Representative Ken Calvert introduced an amendment to the Interior and Environment Appropriations Act (H.R. 2584) that would prohibit EPA from implementing any recommendations in any pesticide biological opinion.

The current situation is nothing short of a crisis, but in every crisis is an opportunity to improve. This chapter focuses on three key challenges to improving pesticide consultations. By tackling these challenges, federal agencies can chart a path to a consultation process that is more effective at protecting wildlife, more efficient to implement, more transparent to the public, and more predictable to regulated entities. Without these fundamental reforms, a voluminous backlog of pesticide consultations will remain the norm.

The Current Pesticide Consultation Backlog

To improve the pesticide consultation process, we first need to understand the origins of the current backlog. For many years, EPA neglected its obligation to consult with USFWS and NMFS (collectively, the Services) when approving pesticides for registration under FIFRA. Once EPA began consulting, it and the Services disagreed on how to properly assess the risk to listed species from pesticide use. EPA's approach to risk assessment requires limited or no consideration of sublethal, cumulative, and synergistic effects of pesticides on listed species or ecosystem impacts (*7*, *8*). The Services, however, believe these effects must be adequately considered under the ESA. As a result of these disagreements and the backlog of pesticides that have never undergone consultation, most of the pesticides on the market today have not been properly evaluated to ensure that their use is not “likely to jeopardize” a listed species or “adversely modify” critical habitat under the ESA.

USFWS currently has over 170 pending requests for pesticide consultations. EPA, for its part, has identified over 1,100 pesticide active ingredients scheduled for Registration Review under FIFRA by October 2022, and plans to complete an endangered species risk assessment for each of these ingredients. Under the current pesticide consultation framework, USFWS will likely need over 30 additional biologists to handle these consultations. Assuming FWS allocates $125,000 annually for each biologist, it alone will need an additional $3.75 million annually for pesticide consultations. NMFS will also need additional funds. Where will these resources come from, especially when the Services have never received enough funding to keep pace with their pesticide consultation workload? As discussed in the next section, inadequate funding is one key challenge to improving the pesticide consultation process.

Key Challenges To Improving Pesticide Consultations

Many of the controversies surrounding pesticide consultations can be framed as challenges to improving the consultation process. To bring effective and lasting improvements, below are four key challenges posed as questions that the Services and EPA should address or seek answers to.

- Policy question – Under the ESA, what level of risk to listed species is acceptable from the registration of a pesticide under FIFRA?
- Science question – What is the proper method of assessing those risks?
- Funding question – How will the Services and EPA receive enough funding to meet their current and future pesticide consultation workload?
- Process question – How can the Services and EPA improve the process of consultation, so that it is more effective, efficient, transparent, and predictable?

EPA and the Services clearly understand the importance of the second question, as evident from the current National Research Council (NRC) study they have funded to address this issue (*9*). But far less attention has been given to the three other questions. The rest of this chapter articulates the importance of these other questions and provides general guideposts for answering them.

Policy Question: Scientific Uncertainty and Risk Tolerance

Scientific uncertainty is present in varying degrees in every ESA consultation, just as it is in almost all government decisions involving natural resources. Federal agencies and the Services never have complete and perfect information about how an activity will affect a listed species. As a result, the biological effects determinations in all section 7 consultations implicitly assume some likelihood of being wrong or inaccurate. How much risk of making a mistake is acceptable under the ESA, and who bears that risk? The answers to these questions are particularly important in pesticide consultations, because pesticide effects determinations involve exceptionally high levels of scientific uncertainty.

At first glance, the answers to these risk-tolerance questions may appear to lie entirely in the realm of science. After all, the root problem is *scientific* uncertainty. But closer scrutiny reveals that these questions hinge on non-scientific, policy judgments. Science can tell us *how* to calculate an acceptable level of risk, but it alone cannot tell us *what* that level should be. In our daily lives, for example, science can help us calculate the probability of developing cancer from smoking, but whether that level of risk is acceptable is based on our personal values. There is no empirically verifiable, objectively correct answer. The same is true of pesticide consultation questions that involve scientific uncertainty. For example, when evaluating the effects of chemicals on listed species, EPA relies on a combination of open literature data and test results on surrogate species (*10*). But no reliable data exists on whether these surrogate species are the most sensitive organisms to any particular pesticide, as sensitivity varies by pesticide. Given this irreducible uncertainty, should the Services and EPA assume a "safety factor" of zero-fold, ten-fold, or perhaps a hundred-fold when extrapolating results from a surrogate species to a listed species? The answer depends largely on how EPA interprets its responsibilities under section 7(a)(2) of the ESA and how much the Services and EPA seek to minimize the risk of harming the listed species by not regulating pesticide use enough (or, conversely, harming crop growers by over-regulating pesticide use beyond the levels needed to protect the species). Science alone cannot answer this question.

In its 1995 study titled "Science and Endangered Species Act," the National Academy of Sciences described this distinction between a science question and a non-science question when agencies confront scientific uncertainty (*11*). The NRC observed that "[e]ven though estimates of risk are grounded in scientific information, those implementing the [ESA] often make value judgments when making decisions about listing, jeopardy, etc" (*12*). Thus, the NRC explained, "science by itself is not sufficient input to policy decisions, apart from the objectives and values it serves" (*12*). Because the ESA's objective—its underlying value—is to protect and recover imperiled species, some courts have rightfully required the Services to resolve scientific uncertainty in favor of giving species the benefit of the doubt.

Aside from this general instruction to act cautiously, however, the Services have tremendous flexibility in deciding precisely how to resolve scientific uncertainty in ESA consultations. The ESA requires federal agencies to use only the "best scientific and commercial data available," not the best data possible (*6*). Because the best available science rarely plugs all knowledge gaps, the Services' Section 7 Consultation Handbook offers two options for addressing substantial scientific uncertainties: delay issuing a biological opinion until more information is gathered, or issue the biological opinion with the available information but give "the benefit of the doubt" to the species (*13*). Under this framework, Services biologists rely on their best professional judgment to resolve scientific uncertainty on a case-by-case basis. If the decision is challenged in court, the standard of review is whether the decision was “arbitrary and capricious” under the Administrative Procedure Act (*14*), a test that is highly deferential to the agency. The Services’ decisions are further buttressed by the fact that under section 7(a)(2) of the ESA, the burden of proof is on the EPA, not the Services, to “insure” that its actions will not likely jeopardize listed species or destroy or adversely modify their critical habitat. Thus, the burden of insufficient knowledge must be carried by EPA, not the Services, in satisfying the requirements of section 7(a)(2).

The Services’ considerable discretion and flexibility in making section 7 effects determinations is a double-edge sword. Discretion and flexibility—exercised in the absence of a transparent framework—often lead to regulatory uncertainty and inconsistent application. In particular, exactly when do the Services give species the benefit of the doubt? And how much benefit is given to any particular species? Because there are no clear answers to these questions as applied to pesticide consultations, frustration and disagreement can ensue.

By creating a general risk-tolerance framework that the Services and EPA can use to address these questions, the Services may relinquish some flexibility in decision-making but realize several compensatory benefits. One is to provide the public with greater predictability and transparency about how the Services will address scientific uncertainty in pesticide consultations. Indeed, the NRC made a similar recommendation in its 1995 study, stating that “[a]rticulating an explicit framework [for making the connection between values, objectives, and scientific evidence] can help link science and values and lead to better and more defensible decisions” and “disarm criticisms that the government is capricious or partisan in implementing the act” (*15*). A related benefit is that the Services will reduce their litigation risk by ensuring that all pesticide risk-tolerance decisions follow a consistent framework, one that should undergo public notice and comment. Another benefit is to ensure that the Services conduct pesticide consultations in a manner sufficiently protective of listed species by establishing a minimum level of precaution that every Service biologist must apply. Even with the best of intentions, decisions on setting acceptable error rates when resolving scientific uncertainty “are complicated and consequential enough that unaided intuition cannot always be trusted to do a good job” (*16*).

Some people assume that the current NRC study can answer these risk-tolerance questions and that it is premature for the Services to begin developing a risk-tolerance framework. The NRC, however, has been charged with answering science and technical questions relating to pesticides, including how to interpret scientific uncertainty. It has not been asked to opine on policy questions about what level of risk is acceptable under the ESA. Thus, the NRC study is necessary but not sufficient to determining how the Services and EPA should address scientific uncertainty in pesticide consultations.

Some people might also assume that risk-tolerance issues will be solved on their own, perhaps through the Services issuing additional biological opinions that help define the “benefit of the doubt” standard or through future court decisions that address the issue. But there are several reasons why this reliance is misplaced. First, it hardly provides the level of regulatory certainty needed to avoid litigation on future biological opinions. Future consultations must evaluate the effects of hundreds of pesticides on perhaps hundreds of species, resulting in thousands of pesticide-species combinations. Each combination will raise substantial issues of scientific uncertainty. Second, many of the current NMFS pesticide biological opinions have focused on salmonids, which have been well-studied relative to many other imperiled species. Future consultations must address effects on species, such as the Salt Creek tiger beetle (*Cicindela nevadica lincolniana*), for which scientists have far less information. Scientific uncertainty may become an even more vexing issue in those consultations. Third, ongoing controversy and litigation on pesticide consultations increase the ESA's political baggage and provide fodder for a wholesale legislative "fix" to the current debacle. The problem, however, is not the ESA itself but the differing perspectives and values of the Services and EPA. If the Services and EPA can resolve their differences through administrative action, they are more likely to retain control over the fate of the pesticide consultation program and defuse volatile controversies.

The Services and EPA should begin constructing a general framework for evaluating, under the ESA, what level of biological risk to listed species is unacceptable from the registration of pesticides. An initial step to creating this framework is to clearly articulate the distinction between a science question and a non-science question in the context of scientific uncertainty in pesticide consultations. To date, there has been a disproportionate emphasis on addressing the former and far less attention paid to the latter.

Any risk-tolerance framework under the ESA should be based on the precautionary principle and the concept of giving species the "benefit of the doubt." The ESA is not a value-neutral statute. It is animated by the idea that preventing extinction and recovering imperiled species is a good thing. As the Supreme Court held, "Congress has spoken in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as 'institutionalized caution'" (*17*). A clear and robust "benefit of the doubt" standard would align squarely with the ESA's normative leanings. On this issue, the NRC has observed that for "a variety of statistical reasons, including those pertaining to availability of data, protection would be more likely if the burden of proof were to show that a proposed action would not harm a listed species rather than to show that it would" (*18*).

To begin developing a risk-tolerance framework, the Services should consider evaluating how scientific uncertainty is addressed under other environmental laws, especially those protecting human health. Ultimately, the Services should begin developing sidebars on how they will address major pesticide risk-tolerance issues, such as the use of safety factors when extrapolating from surrogate to listed species, the treatment of synergistic and additive effects, the effects of pesticides on the ecosystem of listed species, and the assumptions about the timing and extent of pesticide application. The Services should also consider how the level of precaution exercised might vary based on the expected consequences of making an erroneous decision. The 1995 NRC study explains this issue extensively and provides an excellent springboard for developing a risk-tolerance framework.

Funding Challenge: Eliminating the Backlog

Even if all science, policy, and legal issues relating to pesticide consultations are addressed, the consultation backlog remains because the Services lack the resources to address more than a fraction of all pesticide consultation requests. As noted earlier, EPA plans to complete an endangered species risk assessment for each of the over 1,110 active ingredients scheduled for FIFRA registration review by October 2022. It seems unlikely that the Services can keep pace with this schedule by relying on Congressional appropriations alone. After all, EPA can assume this ambitious pace largely because of user fees it receives through the Pesticide Registration Improvement Renewal Act. If the Services do not receive comparable funding, how can they possibly track EPA's progress?

As a path forward, the U.S. Government Accountability Office or another institution should determine the amount of resources required for the Services to complete its current and projected future pesticide consultation workload. Because there has been no clear figure to date, it has been difficult to make a compelling case for support for increased funding to the Services. Next, the Services, EPA, and pesticide stakeholders should start a dialogue on solutions to help fund pesticide consultations for both the Services and EPA. One option is a pesticide user fee devoted specifically to funding consultations. It may currently be difficult for registrants to support this option, particularly because there is profound disagreement about how to conduct pesticide consultations. But if these disagreements can be resolved in a manner that is acceptable to reasonable stakeholders who are truly interested in solutions, then registrants and Congress should seriously consider how they can help fund pesticide consultations, so that pesticides currently on the market are brought into compliance with the ESA.

Process Challenge: Improving the Process of Consultation

The process question is about how the Services and EPA can design and implement a workable pesticide consultation program, one that addresses scientific disagreements, risk-tolerance issues, and funding constraints. As a result, it is perhaps the last question to answer in efforts to improve consultations, although it should always inform attempts to answer the science, risk-tolerance, and funding questions.

In the past decade, the only serious attempt to address the regulatory process question was through a 2004 ESA-FIFRA counterpart rule that created an alternative pesticide consultation process. There were several legal and policy flaws with that rule, including EPA's lack of accountability to the Services for making "not likely to adversely affect" determinations under section 7 of the ESA. Policymakers can learn from those mistakes if they were to design a new collaborative process, which should achieve the general goals of greater effectiveness, efficiency, transparency, and predictability discussed earlier, as well as the following specific goals:

- Improve the Services' ability to help EPA satisfy its duty under the ESA to ensure that the registration and re-registration of pesticides under FIFRA is not likely to jeopardize any listed species or destroy or adversely modify critical habitat.
- Focus on creating enough inter-agency accountability, reliability, and trust within the consultation process, so that the workload between EPA and the Services can be distributed in a way that provides the required level of protection for wildlife, yet enables the agencies to efficiently process hundreds, if not thousands, of pesticide consultations within the next decade. A truly effective framework will allow the agencies to focus less on who completes the first draft of a biological analysis that underlies a section 7 effects determination, provided that the Services' final review and approval authority is clearly maintained (*19*). A key component to realizing this vision is to craft a risk-tolerance framework with a clearly articulated and constrained decision-making process, such that capable agency biologists—whether sitting at EPA or the Services—can easily agree on and draft a biological effects determination that is transparent and defensible.

The Need for Transformation and Bold Leadership

In every crisis is an opportunity to improve. We should all commend the Services and EPA for taking an important step to improving the pesticide consultation process by seeking recommendations from the NRC on key science questions. As argued in this chapter, however, science plays an important but limited role in resolving the pesticide crisis. Other pieces of the solution include articulating a framework for addressing scientific uncertainty in pesticide consultations, securing enough funding to complete current and future consultation requests, and designing an improved consultation process that is more effective at conserving wildlife, more efficient to implement, more transparent to the public, and more predictable for stakeholders. The Services and EPA should lead this transformation by crafting a multifaceted plan that addresses all the key challenges to improving pesticide consultations. Without this comprehensive vision for a better future, the current conflicts between pesticide use and wildlife conservation will languish unresolved.

Acknowledgments

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Chapter 6

State Pesticide Regulatory Agency Role in Effective ESA Implementation

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As “co-regulators” with the U.S. Environmental Protection Agency (EPA) under FIFRA, state pesticide regulatory agencies (SPRAs) have primary responsibility to enforce both federal and state pesticide laws. SPRAs and the pesticide stakeholders they regulate are particularly concerned about uncertainties in the implementation process of the Endangered Species Act (ESA) at the national level and potential obstacles for stakeholders to participate in the development of mitigation measures that are reasonable and enforceable. This paper identifies areas where SPRAs can assist EPA to be in compliance with the ESA. Examples are given on data the SPRAs can provide to assist EPA in determining risk and developing endangered species effects determinations.

Introduction

Pesticides are federally registered by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3). Pesticides also must be registered in each state where they are offered for sale and distribution, and must be used lawfully according to FIFRA requirements and consistent with state laws and regulations. Although state agricultural agencies are typically responsible for the regulation of pesticides, a few states ascribe that responsibility to either their state department of environmental protection (or equivalent) or the state land grant university. As

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

"co-regulators" under FIFRA, state pesticide regulatory agencies (SPRAs) have the primary responsibility to enforce both federal and state pesticide laws. States are also authorized to approve a new use or an additional use of a federally registered pesticide under a special local need (FIFRA Section 24c) or emergency exemption (FIFRA Section 18). Other state responsibilities include pesticide use/safety training and certification, pesticide disposal, worker protection, environmental monitoring and stewardship programs.

The primary role of SPRAs in the Endangered Species Act (ESA) implementation is to assist federal agencies, including EPA, in being in compliance with the ESA requirements including consulting with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service ("the Services") for any pesticide that may potentially impact (i.e., "take") a federally listed species. Section 7 of the ESA requires all federal agencies to "consult" with the Services for any "action" that may adversely impact a listed species. For pesticides, the federal action is the registration of the pesticide by EPA or the use of a pesticide by a federal agency that may impact a listed species (e.g., USDA invasive insect eradication programs). ESA compliance has been challenged with recent lawsuits successfully arguing that EPA failed to consult with the Services for federal pesticide registration decisions that may affect listed species. While states have assisted in the consultation process for federal agencies that use pesticides in their state, involvement is generally limited to consideration of the use of only one or a few pesticides in a specific geographical area. The role of SPRAs in ESA implementation for federal pesticide registration is particularly challenging given the complexity in assessing the constellation of potential risks to endangered species posed by numerous products and uses for any particular pesticide active ingredient.

EPA has signaled its intention to provide a transparent and collaborative consultation process for pesticides which will be coordinated through the Registration Review program (*1–3*). However, SPRAs and the industries they regulate have voiced concerns about their ability to play a meaningful role in the implementation of the ESA for pesticides, particularly in view of the many conflicts and obstacles they have witnessed as a result of litigation-driven consultations for Pacific salmonids (*3*). The primary concerns are uncertainty about how the process will be implemented at the national level and how stakeholders like SPRAs will be able to provide meaningful local input towards developing reasonable mitigation measures. In addition, SPRAs want to ensure that EPA is operating with the most accurate data available and has the flexibility to utilize non-regulatory approaches when they are shown to be effective. This paper indentifies areas where SPRAs can assist EPA to comply with the ESA, including examples of data that the SPRAs can provide to refine biological assessments and recommendations on the ways this data can be used in the implementation of the ESA for pesticide registration.

EPA's Office of Pesticide Programs (OPP) published a notice in 2005 describing how they intend to implement their Endangered Species Protection Program (ESPP) (*4*). The primary approach of the implementation relies on the use of Endangered Species Protection Bulletins that will contain "enforceable use limitations" to ensure that the pesticides "will not jeopardize the continued existence of a listed species." The "Bulletins" are geographically (i.e., county) specific and are considered extensions of the pesticide label and enforceable under FIFRA, as long as the label refers the pesticide user to the bulletin. This approach has many benefits, including providing: 1) maps and information describing the species being protected; 2) pesticide use limitations and other pertinent information that would not be practical to put on a pesticide label; and 3) the ability to update this information relatively quickly. The Bulletins will also serve as a means for EPA to implement reasonable prudent alternatives or measures (e.g., buffers for specific geographical areas) required by the Services in their Biological Opinions (BiOps) (*5*, *6*). EPA has indicated that SPRAs should be afforded specific opportunities for Bulletin review, including review of maps and proposed mitigation, and at their discretion, should be able to initiate alternative approaches for protecting listed species (*4*).

State-Initiated Endangered Species Protection Plans

The 2005 field implementation notice briefly described specific roles for SPRAs in the federal Endangered Species Protection Program (ESPP). One approach is for SPRAs to propose plans for their specific involvement beyond what was outlined in the field implementation notice (*4*). Although state-initiated plans are not a requirement for SPRAs to be directly involved in the partnership with EPA in protecting listed species, they do provide a formal request from SPRAs to EPA to either develop their own state-specific Endangered Species Protection Bulletins or provide substantial input into developing the Bulletins. Currently, only three states have approved state-initiated plans: California (*7*), Washington (*8*), and North Dakota (*9*).

Washington's and North Dakota's state-initiated plans are the most recent to be accepted by EPA and can serve as a template for other SPRAs. The stated goals of the two plans differ somewhat based on the states' experience in dealing with pesticide decisions related to endangered species. For example, Washington (along with Oregon and California) has been affected by several pesticide endangered species lawsuits, including a well publicized lawsuit dealing with potential impacts of pesticides on federally listed salmonids (*10*). Pesticide protective measures arising from these lawsuits have the potential to severely impact agricultural production within these states. Understandably, Washington's primary goals for their endangered species protection plan (*8*) are to reduce uncertainty for pesticide registration decisions. They seek to achieve this by having the opportunity to interact with the Services and EPA in providing the best available data regarding pesticide use and exposure, and by providing a process for Washington stakeholders to have input into the development of mitigation measures, if needed. North Dakota has been less affected by litigation. Their goals focus on three areas: providing state-specific information to EPA to inform their risk assessments during Registration Review (*9*); providing a platform for stakeholder input; and assisting in the development of mitigation and management plans including the creation of Bulletins.

Both the Washington and North Dakota state-initiated plans are similar in their approach to implementation. The North Dakota plan (*9*), summarized below, proposes a process for the North Dakota Department of Agriculture (NDDA) to provide state-specific data and recommendations for consideration in EPA's risk assessment processes, with emphasis on local data that will bolster the accuracy of EPA's risk assessments. The plan helps ensure that EPA has access to accurate and relevant pesticide use data, cropping information, and accurate information on the occurrence and distribution of listed species in their state. Input from the state may also include state-specific risk assessments based on local soil types, weather conditions, or pesticide use patterns. This refined information would allow risk assessments that would afford species protection while avoiding the imposition of unnecessary burdens on pesticide users. NDDA also believes that a state-initiated plan will improve stakeholder buy-in and compliance by helping to ensure that any use restrictions are protective and reasonable.

The North Dakota Plan for Endangered Species Protection includes three developmental phases:

Phase 1 – Submission of state data to EPA
Phase 2 – Development of risk mitigation measures
Phase 3 – Bulletin development and outreach

Phase 1

In this phase, NDDA would supply EPA with relevant data for consideration as the Agency assesses the risk of certain uses to listed species. Some examples of relevant data include pesticide use data, distribution and biology information on listed species, identification of geographic areas where pesticide use and listed species may or may not co-occur, cropping information, environmental monitoring data and soil type information. Much of this data is available or can be compiled into a layered GIS format.

Phase 2

NDDA can follow Phase 1 by supplying EPA with recommendations on potential pesticide use limitations to better protect endangered and threatened species while minimizing the burden to pesticide users. Specifically, NDDA can provide insights on the technological, social and economic feasibility of implementing any proposed pesticide use limitations. Such input is essential since states often have a better understanding of the socioeconomic and political intricacies that exist at the local level. NDDA, like other SPRAs, is responsible for enforcing any pesticide use restrictions and, therefore, is in a good position to provide recommendations on restrictions that are enforceable and practical.

Phase 3

The Endangered Species Protection Bulletins are the cornerstone of the ESPP in that they provide geographic-specific use restrictions beyond those on the product label whenever greater protection is needed (*4*). Bulletins allow pesticide regulators to easily identify those areas where use restrictions are required. If Bulletins are necessary to improve risk mitigation, NDDA will review them for accuracy and determine whether there are better means to identify areas where the use restrictions are in effect and offer recommendations for the proposed mitigation language. Once Bulletins are published, NDDA will provide area-targeted and/or group-targeted outreach to pesticide dealers and applicators to better communicate how to find and comply with Bulletins and the rationale used to develop the risk mitigation measures. Finally, NDDA staff can provide additional outreach through pesticide certification and training sessions, as well as during other education opportunities.

State-Specific Data for Pesticide Registration and ESA Consultation

The previous section provided an overview of the process for SPRA involvement in the ESA implementation. This section provides some examples of the type of data and input that the SPRAs can provide to EPA to assist in their compliance with the ESA. The primary goals for allowing input by the SPRAs in the ESA process is to reduce the uncertainty of the effects determination (by providing EPA with the most accurate data available), and to advance the development of mitigation measures that are reasonable and enforceable.

Crop/Land Use Data

Every state has access to "Census of Agriculture" data published every five years by the U.S. Department of Agriculture (USDA). The latest update was in 2007. The census provides comprehensive agricultural data for every state and county in the U.S. (*11*). For those states that do not have their own agricultural surveys, this is the best source for county acreage totals for most major crops and many minor crops. This data can be used to derive a list of counties where a pesticide may be used for a particular crop.

USDA National Agricultural Statistics Service (NASS) also maintains GIS data of land use based on landsat satellite imagery. The Cropland Data Layer provides a crop-specific land cover classification for the entire contiguous United States (*12*). The national coverage is now available via the CropScape portal (*13*) providing coverage for four consecutive years from 2008-2011. The 2009 coverage for Florida is shown in Figure 1. The benefit of this data layer is that it has national coverage and it can provide spatial data at a subcounty level. However, given that the data represents satellite imagery, the pixel level (raster) accuracy for the agricultural cover types vary by crop and region (*12*). Accuracy of the data is much greater for large scale field crops (e.g., corn, soybean, wheat) grown in intensive agricultural areas than for crops grown in a smaller, more sporadic distribution (e.g., vegetables). Also, given the overall regional scale of the data set, caution is appropriate when using the data at a subcounty level.

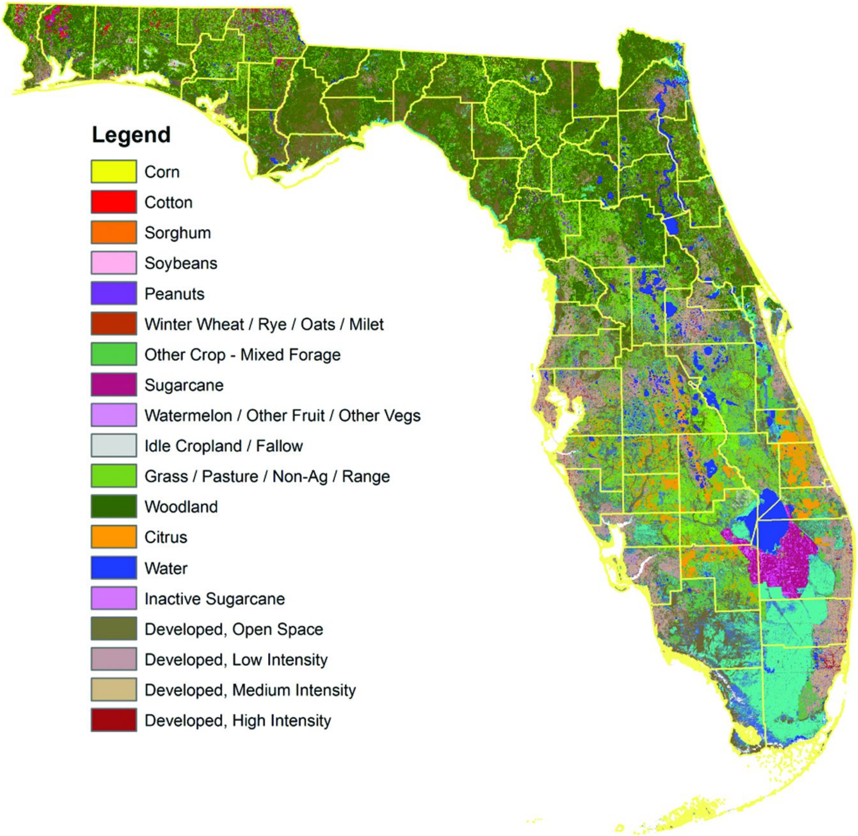

Figure 1. USDA NASS – 2009 Florida Cropland Data Layer.

Some states may have access to additional crop or land use data that can be used in an ecological risk assessment or endangered species effects determination. This data may be unique to their state and unknown to EPA. In Florida, for example, Water Management Districts (WMDs) maintain land use data that utilize aerial photo imagery. Aerial photos can allow for higher resolution data compared to satellite imagery. An example of the increased resolution is shown in Figure 2. The example also demonstrates some of the limitations associated with the USDA Cropland raster data. For instance, some agricultural fields contain both red and purple pixels representing cotton and peanuts, respectively, while it is likely only one of those crops are present. The WMD data is not without issues either. The crop designation of the Florida WMD data is limited to only major crops found in Florida or may only be designated as either a field crop or a row crop. The best approach may be to use a combination of the two data sets to determine both crop type and field boundaries. The GIS WMD land use data and metadata is available at the Florida Geographic Data Library (*14*).

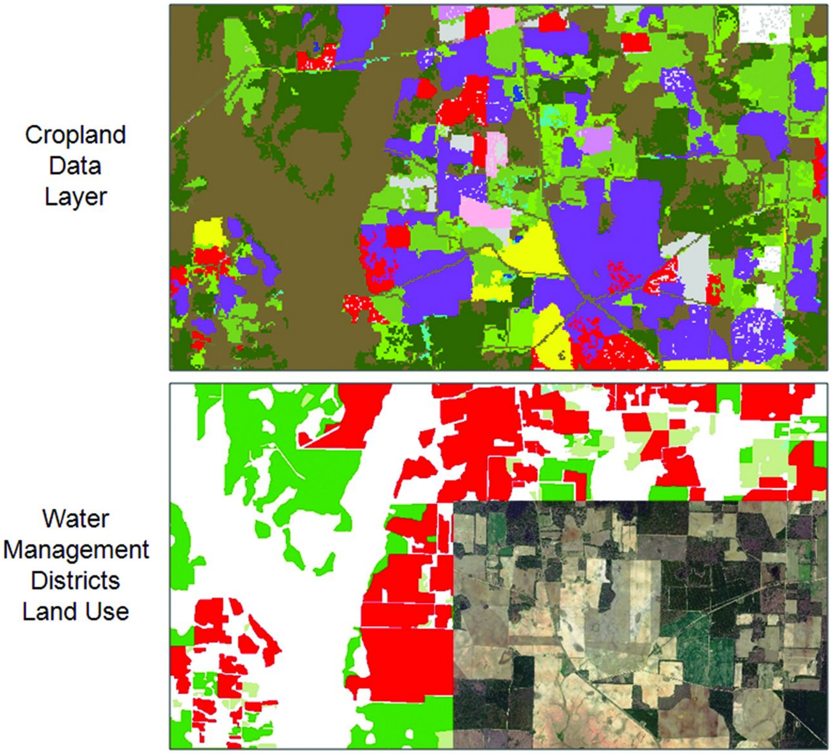

Figure 2. Comparison of the resolution of the Cropland Data Layer (raster data) versus the Florida Water Management District Land Use Data (vector data with an aerial photo overlay) for the same location in Florida.

The Washington State Department of Agriculture (WSDA) has taken crop use data to an even more refined level by actually visiting each agricultural field, mapping the boundary, and listing the crop grown (*15*). They have compiled a very accurate inventory of not only crop production acreage, including an extensive list of commodities grown, but also land that has been taken out of agricultural production. WSDA intends to use their GIS dataset to refine the pesticide exposure assessment for listed salmon species (*15*).

Pesticide Use Data

For many states, data on pesticide use is greatly lacking and perhaps constitutes the greatest level of uncertainty in higher tiered risk assessments. USDA NASS Agricultural Chemical Usage Reports (*16*) represent the best source of pesticide use for those states that do not have the authority or resources to maintain pesticide sale or use information. The NASS chemical usage reports are summaries of pesticide use surveys collected from thousands of interviews with pesticide users (primarily growers). Since these are surveys that represent a sample of growers for a particular crop, estimates are subject to sampling variability. For Florida, recent survey data for citrus (2009) and many vegetable crops (2010) are available for download from the NASS website (*16*). However, many major crops in Florida (e.g., pastures, sugarcane, hay, sod, soybeans, rice, alfalfa and blueberries) have never been surveyed for pesticide use by NASS and others have not been surveyed for several years (e.g., corn, peanuts and cereal grains). Given the resources required to do these surveys and the budgetary constraints placed on both federal and state agencies, SPRAs are very grateful to have access to this data despite the limitations.

Pesticides are not only used on agricultural crops but a significant proportion are used for forestry, golf courses, mosquito control, exotic weed control, structural pest control, residential use, ornamentals, lawns, and many others. Unfortunately, a national pesticide use database does not exist for these particular uses. Pesticide registrants may have access to distribution and sales data, but this data is proprietary and typically not available to the SPRAs. However, some states maintain pesticide use data for some of these uses as part of their statutory authority. For example, Florida requires Mosquito Control Districts to report pesticide use data to the Florida Department of Agriculture and Consumer Services on a yearly basis. This data is available to the public from the Department's website (*17*). Other states may have additional pesticide use data that could be used by EPA if needed.

The current "gold standard" for acquiring and maintaining pesticide use data comes from California's Pesticide Use Reporting program (*18*, *19*). The California program requires full reporting of all agricultural pesticide use on a monthly basis, and their use of the term "agricultural" includes pesticide applications to parks, golf courses, rangeland, pastures and right-of-ways. This data set has been used by EPA for endangered species effects determinations in litigation involving listed species located in California (*19*). Other states (e.g., Oregon) have attempted similar programs but these have been scaled back due to budget constraints.

Endangered Species Data

The U.S. Fish and Wildlife Service's (USFWS) ecological field offices maintain county lists for federally listed threatened and endangered species. These county lists can be obtained directly from the USFWS main website on endangered species (*20*). GIS data for critical habitat boundaries is also available from the USFWS field office websites and from the National Marine Fisheries Service (NMFS). Many states have additional endangered species data including county lists, species occurrence data, and habitat mapping that may be housed at other agencies. For example, the Florida Natural Areas Inventory (FNAI) is a non-profit organization that maintains a database of element occurrence of rare plants, animals and natural communities in Florida and works to gather, interpret and disseminate this information to other agencies and private parties (*21*). FNAI is a member of NatureServe which is the international network of natural heritage programs initially established by The Nature Conservancy (*22*). Other states also have natural heritage programs which are collectively part of the NatureServe network (*22*, *23*).

What can SPRAs do with endangered species data to assist in the ESA process for pesticide registration? The simplest approach, initially, would be to link the crop data by county to the endangered species data by county to determine what species may be exposed to a pesticide used on a specific crop. A simple relational database can be set up using linked tables containing endangered species by county, crops by county and pesticide by crop data (Figure 3). A database set up in this manner can quickly produce a list of species potentially exposed to pesticides used on a specific crop. This list can then be further reduced through a more refined endangered species assessment.

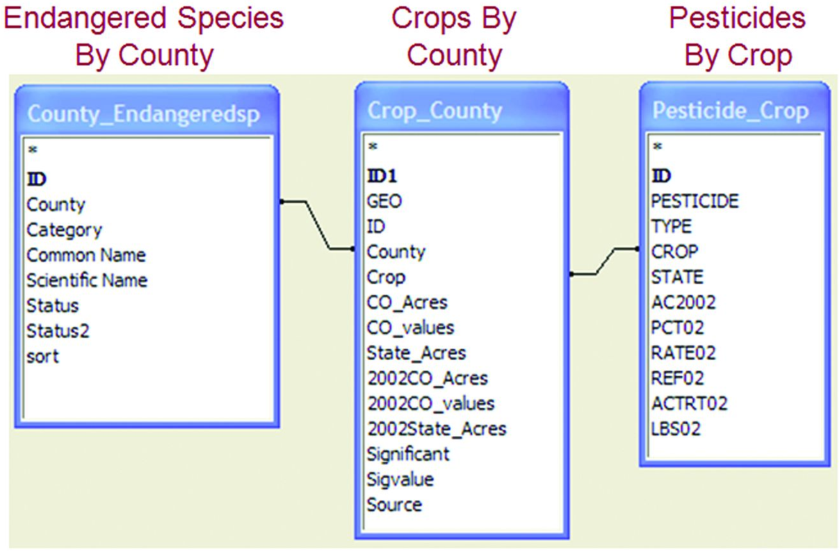

Figure 3. Relational Database using Endangered Species, Crops, and Pesticides by County Data Tables.

Additional refinement of the endangered species assessment can be achieved through the use of subcounty crop (or other pesticide use) and subcounty endangered species data. At this stage, the best tool to analyze geographically specific data is the use of GIS mapping. Figure 4 is an example of mapping the co-occurrence of a particular crop, in this case dry beans, with an endangered species, the Western prairie fringed orchid. Without subcounty level data, one would have to assume that herbicides applied to dry beans in Ransom and Richland County, North Dakota would have the potential to drift and impact the Western prairie fringe orchid. Using the 2009 cropland data layer combined with element occurrence data for the orchid, you can see that the orchid is located at least 2-3 miles from the nearest dry bean field. Even assuming inaccuracies in the cropland data layer, the orchid locations are at least one mile from any center pivot irrigated (circular) agricultural field. Based on geographical distribution of bean fields in relation to the locations of the Western prairie orchid, herbicide applications on dry beans would result in “no effect” (i.e., no exposure) on the orchid.

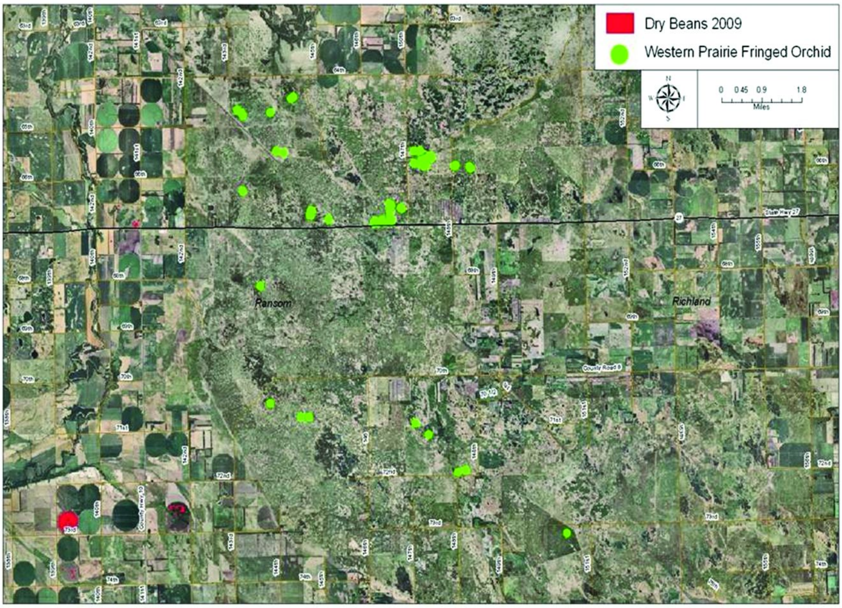

Figure 4. Map showing locations of Dry Beans (USDA NASS - 2009 Cropland Data Layer) and the Western Fringed Orchid in Ransom and Richland Counties, North Dakota.

Environmental Monitoring

EPA has stated their commitment to improve the use of existing monitoring data in their risk assessments (*4*). There are opportunities for EPA to acquire monitoring data to make their pesticide risk assessments more robust. The U.S. Geological Survey conducts the largest nationwide monitoring of pesticides in ground water and surface water as part of the National Water-Quality Assessment (NAWQA) Program (*24*). NAWQA pesticide data is routinely used, at least qualitatively, by EPA in their current risk assessments. Pesticide monitoring data (ground and surface water data) is also collected in many states through requirements under the Clean Water and Safe Drinking Water Acts or by SPRAs as part of their pesticide program.

The quality and quantity of surface water monitoring varies greatly by state. Some states do not conduct any sampling while others have intensive, weekly, state-wide monitoring. For many states, the purpose of surface water monitoring for pesticides is to indicate potential risk to aquatic organisms and/or determine trends in pesticide detections. These programs tend to expand or contract based on findings of the monitoring (e.g., lack of detections) and/or budgetary constraints. For example, in North Dakota pesticide sampling was started in 2008 with only nine sampling locations, but has since been expanded to 33 sites spread throughout the entire state. In Florida, surface water monitoring for pesticides is primarily conducted by the South Florida Water Management District and covered much of South Florida (*25*). Unfortunately, recent budget cuts have reduced the sampling locations in South Florida to only those areas associated with the Comprehensive Everglades Restoration Program.

Some pesticide monitoring is designed to specifically address endangered species concerns as opposed to demonstrating general trends. In North Dakota, for example, proximity to listed species was one of the factors used in selecting wetlands for sampling. One of the most well known examples of pesticide monitoring specifically designed for determining exposure to listed species comes from efforts by the Washington State Department of Agriculture (WSDA) in cooperation with the Washington State Department of Ecology. WSDA began its surface water monitoring program in 2003 to determine the extent of pesticide concentrations in salmonid-bearing streams during typical pesticide use periods (*26*). WSDA sampled approximately fifteen sites weekly and analyzed over 150 registered and historically-use pesticides. Unfortunately, despite all of the data generated from this program, the information was not adequately considered in the initial BiOps issued by NMFS (*27*). Given the costs associated with pesticide monitoring, it is discouraging for SPRAs and other stakeholders to see EPA and the Services disregard monitoring data in their assessments particularly for monitoring programs that were developed specifically to address endangered species concerns. It is important that all quality controlled and assured monitoring data is used in a risk assessment, including data showing lack of detections. EPA and the Services often rely exclusively on pesticide fate modeling representing worst-case scenarios while monitoring data is overlooked in the risk assessment. Monitoring data often demonstrate more typical exposures which can be as important in a risk assessment as estimating a worst-case, edge of field type scenario with concentrations that would only be expected to occur once every 10 years. Spatial and temporal variability in exposure to all life stages of an endangered species, like salmonids, are important factors for determining risk or jeopardy to a population (*28*).

Stakeholder Input

One of the SPRA's greatest concerns is the lack of adequate input in the endangered species consultation process and for subsequent development of mitigation measures for protection of listed species. EPA has built into the Registration Review process steps for public input into the Federal docket concerning the ecological risk assessment, but very little is mentioned concerning input into the actual consultations with the Services (*1*). The SPRAs can facilitate exchange with pesticide stakeholders in their state or suggest directly to EPA recommendations on the technological, social and economic feasibility of implementing any proposed pesticide use limitations. Such input is essential since states and concerned stakeholders often have a better understanding of the socioeconomic and political intricacies that exist at the local level. In addition, SPRAs are responsible for enforcing any pesticide use restrictions and, therefore, should be directly involved in developing pesticide use restrictions that are enforceable and practical.

The only examples for stakeholder input into the consultation process for pesticides, to date, have occurred as part of litigation between EPA and various environmental groups. The most publicized is the lawsuit on pesticide impacts on listed Pacific salmonids (*10*), a case demonstrating that state agencies and stakeholders currently have very little opportunity for input in the consultation process between EPA and NMFS. WSDA developed a white paper to express their concerns over the lack of state and stakeholder input into the process and potential impacts the mitigation measures may have on pesticide users in their state (*27*). Based on their assessment, mitigation measures proposed by NMFS in their first BiOp could prevent the use of affected pesticides on up to 75 percent of farmland in the State of Washington, which may result in unreasonable economic burden to growers. To further characterize the need to establish a collaborative and transparent consultation process for both pesticide litigation and consultation, WSDA posted a one page list of recommendations for improving the process (*28*) which was further reiterated by the State-FIFRA Issues Research & Evaluation Group (*29*).

While the salmon case involved consultation with NMFS, until recently, no formal consultations with USFWS on pesticide use has occurred for at least two decades. In February 2012, USFWS sent out for public comment a draft BiOp for Rozol use on black-tailed prairie dogs (*30*). Several states including Colorado, Kansas, Nebraska, New Mexico, North Dakota and Montana took the opportunity to review the draft BiOp and made comments in the Federal Register (*30*). The draft BiOp indicated risk for secondary poisoning of endangered species whose habitats overlap with black-tailed prairie dogs and included reasonable and prudent measures (RPMs) "necessary and appropriate" to minimize the impact of incidental take of the species in question. The majority of concerns of the SPRAs focused on the RPMs, particularly the RPMs that required label restrictions and establishing a system required to track Rozol use on a county and state level. However, the draft BiOp was void of specific information on who would be responsible for tracking Rozol use; the SPRAs were concerned that ultimately, they would be held responsible for maintaining this tracking system. In their comments, Nebraska, Colorado, New Mexico, North Dakota and Montana SPRAs all described the types of data they could collect and give to EPA following their current state laws (*30*). SPRAs also voiced concerns about proposed label language which, if not worded precisely on the label, could result in enforcement that is extremely difficult if not impossible to achieve. Some states expressed concerns about the enforceability of certain label language and recommended alternative approaches, such as more IPM education and outreach (*30*). The final BiOp was released on April 10, 2012 and appears to have addressed some of the states' concerns. For example, the implementation of the RPM for tracking use will be provided by the registrant and EPA through gross distribution data per state for a period of 5 years. New restrictions on Rozol use in six states are now published on EPA's Bulletins Live! Website (*31*) and will become enforceable on October 1, 2012, which is the start of the Rozol Prairie Dog Bait use season. This latest BiOp is encouraging and appears to be a step in the right direction in that EPA and the USFWS are willing to work with SPRAs and stakeholders in developing RPMs which are reasonable and enforceable.

Conclusions and Recommendations

The litigation-driven ESA process has not been a positive experience from the state perspective particularly concerning the lack of input provided by the SPRAs and other stakeholders during the consultation process with NMFS (*27–29*). However, the latest BiOp released by the USFWS is encouraging in that it shows that USFWS and EPA can work with SPRAs in developing RPMs which are reasonable and enforceable. Overall, we strongly support a non-litigation driven ESA process that is incorporated into Registration Review of pesticides. While stakeholder input appears to play a central role in the risk assessment development and endangered species effects determinations during Registration Review, it is up to EPA and the Services to demonstrate that they are willing to not only allow for state input into the process but actually use the data and information provided to them. We also encourage EPA and the Services to move from worst-case, screening level assessments that only considered edge of field modeling results (e.g., from a farm pond scenario) to more refined level assessments that utilize all of the best available data and information including spatially and temporally specific modeling (*32*) and the use of appropriate geographically specific pesticide use and surface water monitoring data (*15*).

In line with what has already been proposed by the WSDA (*28*) and the State-FIFRA Issues Research and Evaluation Group (*29*), our main goal is that SPRAs have the opportunity to have input into the entire ESA process, from framing the federal action (i.e., pesticide use scenarios), refining the effects determination, determining the best options to comply with RPMs and RPAs while addressing the costs associated with mitigation, to finally communicating risk/mitigation to pesticide users in our states. We hope that this paper has given EPA and the Services a better understanding of the importance of SPRA contribution to the ESA process for registered pesticides.

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Chapter 7

California Pesticide Use Data and Endangered Species

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Most biological opinions related to pesticides and endangered species assume worst-case scenarios for pesticide use, largely due to a lack of reliable pesticide use data. California maintains a large database of pesticide use data with 38 years of detailed and accurate data on each production agricultural pesticide application and summary information on other, mostly non-agricultural applications. These data can be used to develop more realistic assessments of the effects of pesticides on endangered species.

Introduction

Section 7 of the Endangered Species Act requires all federal agencies to consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service when any action the agency plans to take may affect a listed endangered or threatened species or their designated habitat. If the initial consultation indicates that the proposed action is likely to adversely affect a listed species, the appropriate Service will prepare a biological opinion to determine if the action will jeopardize the continued existence of a listed species. Several biological opinions have been developed by the U.S. Environmental Protection Agency (EPA) to evaluate the potential effect of pesticide registrations on listed species. In these biological opinions, several assumptions were made about pesticide use: pesticides are applied at maximum label rates, all agricultural areas are treated, and treatments can occur at any time of the year. These assumptions are generally

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quite unrealistic but are made because most states do not have adequate data on actual pesticide use. In the absence of data, these worst-case scenarios are made to ensure adequate protection of endangered species.

However, California has detailed and accurate pesticide use data, which can be used to make more realistic assessments (*1*). With these data one can determine which pesticides were applied, their actual rates, the specific geographical areas where the pesticides were used, the dates the pesticides were used, and the methods of applications. Also, data exist for more than 20 years for all agricultural pesticide use and 38 years for federal and California restricted use pesticides.

Description of the California Pesticide Use Reporting System

The California Department of Pesticide Regulation's (DPR) Pesticide Use Report (PUR) is probably the largest and most complete database on pesticide use in the world. The system to collect data on pesticide use in California started in the 1950s, although only data since 1974 are stored in DPR's database. Also, before 1990, only use data of restricted use pesticides was collected. Starting in 1990, all pesticide applications in production agriculture and all applications made by businesses that sell or apply pesticides were required to be reported.

In 1990, DPR expanded pesticide use reporting primarily to assess more accurately dietary risks from pesticide exposure. However the data are now used for a wide variety of environmental and public health purposes, including refining risk assessments, promoting farm worker health and safety, analyzing human exposure patterns, protecting threatened and endangered species, monitoring and investigating environmental issues, and improving pest management. State and federal agencies, universities, farmer organizations, the pesticide industry, and public interest groups use the PUR extensively.

The data collected on production agricultural pesticide use differ somewhat from data collected on other kinds of applications. Production agricultural use data include applications of pesticide products to growing crops, agricultural fields, most forest trees, and ornamental turf. For brevity, these uses will be referred to as "agricultural uses." The other kinds of use include post-harvest commodity treatments and non-agricultural uses by commercial applicators, such as applications to rights of way, landscapes, and structures. These heterogeneous applications will be referred to as "non-agricultural use." The agricultural data collected includes the pesticide product's name and EPA registration number, the amount of pesticide applied, the method of application, the crop treated, the application date, a grower identification code, a code for the field treated, the area of the field treated and planted, and the field location within a square-mile section. Less information is collected for non-agricultural use: rather than the specific geographical location and day of application, only the county where the application was made and the month of application are reported. The total amount of pesticide applied is still reported. After the data are entered into DPR's database, a procedure is run to determine the active ingredients in each

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ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

reported pesticide product and the pounds of each active ingredient applied. This information is provided by another DPR database containing the properties of all pesticide products registered in California.

Data collection starts when pesticide users fill out a form to report each pesticide application. Most of these forms are paper, but web-based reporting is becoming more prevalent. These reports are sent to the appropriate county agricultural commissioner's (CAC) office where the data are stored in a county database. Data are periodically sent to the state headquarters at DPR. Each day a DPR program loads all new data from the counties and checks the data for errors. Errors are sent back to the originating county, where staff members are requested to correct them. By April, DPR should have received nearly all the county data from the previous year. However, the error corrections may take a few more months. The final versions of the PUR annual reports are typically available in December and contain the prior year's data.

Data Quality

Because of the importance of the PUR for many groups and individuals, it is critical that the database be as accurate and complete as possible. Any complex database with over 45 million records and 30 data fields, as is the case with the PUR, will almost certainly contain errors. Errors are especially likely to appear in the PUR because of the nature of the data, the diversity of people submitting the data, and the diversity of people entering the data. PUR data are complex and many of the people who submit data may not have an incentive to take the time to insure their accuracy. There are many possible explanations for errors. For example, there are many pesticide products with similar names and registration numbers and product-specific label information is often incorrectly recorded. It is easy to report the wrong units of weight or volume for an application since reporting forms offer several choices of units and type size is undeniably small. When only part of a field is treated, it may not be clear how many acres to report as treated. The crop actually planted may differ from that originally anticipated when growers get a permit to apply restricted use pesticides, and growers may not inform the CAC about this change.

The PUR is extensively checked for errors both at the CAC office and at DPR headquarters, so despite all the potential problems, the data are quite accurate. When the data are checked at DPR, about 2% of records are found to have some kind of error. Most of these detected errors are corrected before the final versions of PUR annual reports are available. However, not all errors can be identified and so the true error rate is unknown. Also, even a 0.1% error rate in amount applied, if the magnitude of an error is large, could seriously affect an analysis. For example, an error was discovered in a record of an application of a product containing the active ingredient orthosulfuron in 2010 that would have changed the statewide total pounds of orthosulfuron applied from 665 to 5,700.

Uses of the PUR

Pesticides can have detrimental effects on wildlife species, affecting health and reproduction and in some cases causing mortality. Data available from the PUR, such as the pesticide product, use rate, timing, and geographical location of applications, can be useful information for identifying and regulating pesticides potentially harmful to species of concern. DPR works with the CACs to merge PUR data with geographic information on locations of endangered species habitats provided by the California Department of Fish and Game, the U.S. Fish and Wildlife Service, and the National Marine Fisheries Service. The resulting database helps CACs resolve potential conflicts when pesticide applications occur in or near endangered species habitats. DPR and the CACs can also examine patterns of pesticide use near habitats to determine the potential effects of prospective measures aimed at protecting vulnerable species. This location- and pesticide-specific information can be accessed using DPR's Endangered Species Custom Realtime Internet Bulletin Engine (PRESCRIBE) (URL http://www.cdpr.ca.gov/docs/endspec/prescint.htm).

Studies incorporating PUR data into analyses of pesticide impacts on wildlife have appeared in the scientific literature (*2–4*). For example, Davidson (*2*) analyzed the association between declining populations of amphibians in California and pesticide use. Many granting agencies have taken on the challenges of risk analysis to wildlife in association with pesticide use, such as the project funded by the CALFED Bay-Delta Program (*5*), and PUR data played an important role in the analyses.

Suggestions on Using the PUR To Evaluate Pesticide Exposures to Endangered Species

Data from the PUR could be used in a number of ways to improve the estimates of exposure of endangered species to pesticides described in biological opinions prepared by the National Marine Fisheries Service (NMFS) (*6*). Currently, NMFS scientists make a number of assumptions related to pesticide use in salmonid-supporting watersheds that in aggregate result in overestimates of pesticide applications and subsequent salmonid exposure in those watersheds. For example, potential exposure scenarios are based on the assumption that pesticide products are applied at maximum labeled rates. Another assumption is that if an agricultural crop is listed on a product label, all agricultural land in specified watersheds delineated in the National Land Cover Database (*7*) will be treated with that product, whether or not that crop was grown in the watershed.

Using the PUR data, one does not need to assume that maximum label rates were used or that any crop would be grown in any agricultural area. Rather, one can sort the PUR database to determine the amount of each pesticide active ingredient used in each square mile section in all areas of concern. PUR data exist for all years from 1990 to the present, so one can determine use over a wide range of realistic environmental and economic conditions. Also, since the PUR data include the date of application, exposure assessments could examine use during times of the year when salmonids are vulnerable. Finally, the PUR data include the application method (air, ground, or other method), and this information could be important in determining, for example, the potential for drift into salmonid habitats.

A PUR analysis would also help define the expected range of uses of each active ingredient in each area. NMFS is often most interested in worst-case exposure scenarios, and there are many ways PUR data could be analyzed so that such scenarios can be realistically described. First, statistical forecasting methods can be used to determine expected use in the future at the 95th or 99th (or other percentage) confidence interval of use based on historical use in watersheds of interest. Alternatively, one could determine the probability distribution of each active ingredient's use rates for a watershed. The 95th or 99th percentile use rate values could represent, at least, very high use rate scenarios. A high estimate of total pounds applied could then be calculated by multiplying the high percentile rate of use by total area of the crops on which the product may be used. Unless PUR-based methods are available and can support alternative methodologies for determining pesticide use in salmonid-bearing watersheds, one might still want to use NMFS's current method to set a maximum use rate.

The PUR data are less useful for pesticides applied in urban settings, since not all such use is required to be reported. However, one could use the pesticide sales database, another database administered by DPR (*8*) to estimate urban pesticide use. Sales of all pesticides, urban and agricultural, are reported to DPR. Thus, dividing the total agricultural pounds reported in the PUR by the total pounds sold of a pesticide product gives the proportion representing agricultural use; one minus that proportion is the proportion used in urban areas. This, of course, is just an estimate since the sale of a pesticide does not necessarily mean it was actually used. Another limitation of the sales database is that sales are only reported for the entire state. To get urban use in some area, one could make an assumption that urban use is proportional to the population in that area.

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Chapter 8

Cranberry Pest Management and Karner Blue Butterfly Protection: A Wisconsin Case Study

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Wisconsin cranberry production occurs in counties that may support wild lupine, host for the endangered Karner blue butterfly (KBB). Growers manage several Lepidoptera pests, and tools include insecticide sprays. During 2003, the insecticide methoxyfenozide was approved by the US Environmental Protection Agency (EPA) for use in cranberries. EPA's assessment concerns for potential spray drift impacts on KBB populations resulted in labeling restrictions for a 1-mile buffer around sandy habitat supporting wild lupine. This buffer rendered the product unusable by cranberry growers. At their request, during 2007 a formal ESA consultation process was initiated by EPA with the US Fish and Wildlife Service (USFWS). The outcome of cooperation involving federal and state agencies, growers and the registrant was an alternate set of drift management measures compatible with agriculture. By 2009, the measures were included in the first EPA endangered species bulletins. This case highlights key lessons for pesticide regulation within the context of both ESA and agricultural interests.

Introduction

Since its formation in 1972, EPA has had oversight of national registration of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and obligations related to the Endangered Species Act (ESA) have been in place since 1973. EPA introduced its Endangered Species Protection Program

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(ESPP) in 2005 and has committed to incorporate ESA assessment obligations for existing products into the Registration Review program during 2007 to 2022. Meanwhile, most ESA-related pesticide regulatory activities have been driven by litigation actions and, while stimulating attempts for resolution of a number of scientific- and process-related issues, little progress has so far been achieved with completion of effects determinations, initiation of ESA Section 7 consultations, and introduction of ESPP county bulletins. An exception involves the case of the insecticide methoxyfenozide and its use on cranberries, for which a series of WI and MI county bulletins were introduced by EPA in 2009 to help protect the Karner blue butterfly (KBB). What is the story behind these first ESPP county bulletins and are there implications for effective future ESA implementation for pesticide regulation? To highlight relevant lessons, this paper will examine cranberry pest management practices in Wisconsin, protection efforts for the KBB, and EPA registration and consultation efforts for the insecticide methoxyfenozide.

Cranberry Agriculture and the Karner Blue Butterfly

Cranberry Agriculture and Pest Management

The cranberry (*Vaccinium macrocarpon* Ait) is a perennial, low-growing, woody broadleaf vine which favors moist but well-drained, acidic, peat-bog or sandy soils. Commercially managed cranberry beds have been drained, cleared, and leveled and are surrounded by dikes, flumes, ditches and marshes to allow management of the water required at various points in the annual crop cycle. It may take 2 to 3 years for a first crop to be harvested from a new bed, which will then produce for decades. Pollination is by domesticated honeybees as well as wild bees, and a single crop of berries is produced each year (*1*).

Commercial cranberry production in Wisconsin began about 1860, and harvested acres have steadily risen from less than 8,000 acres in 1982 to 12,000 acres in 1996 to around 18,000 by 2007 (*2*). As of 2012, Wisconsin cranberry marshes occupy more than 180,000 acres, with cranberries harvested on about 18,000 acres by more than 250 growers (*2*). Cranberry agriculture in Wisconsin occurs in 18 different counties in central and northern parts of the state, and some of the counties with greatest production are Wood, Jackson, and Monroe (Figure 1). Cranberries are Wisconsin’s most important fruit crop, and the state produces nearly 60% of the US cranberry crop. In 2011, the Wisconsin cranberry crop was valued at some 193 million dollars (*3*).

Cranberries are subject to damage by a number of insect pests, and virtually every marsh is susceptible to annual attack. The most important pests in Wisconsin are the Blackheaded fireworm (*Rhopobota naevana* Hubner) (BF), cranberry fruitworm (*Acrobasis vaccinii* Riley) (CF) and sparganothis fruitworm (*Sparganothis sulfureana* Clemens) (SF) (*4*). These Lepidoptera pests cause damage to vegetation as well as developing berries via either a single (BF, SF) or double (CF) annual generation of larvae (*5*) active during the period May to August. Significant economic crop damage can occur if controls are not adequate, and yield losses of between 15 and 50% may occur in the absence of pest management practices (*1*, *5*, *6*).

A variety of measures are employed to manage insect pests of cranberries, including the use of chemical insecticides. Integrated Pest Management Programs (IPM) have been widely adopted, and by 1998 more than 80% of the acreage in Wisconsin was scouted on an annual basis (*6*). Although insecticide use fluctuates each year depending on observed pest pressures, insecticide use in the state is relatively high because of high insect pest pressures (*6*). Several applications may be required per season based on pest population dynamics, and while most pesticides are applied by ground booms, applications by chemigation or via aircraft may also be utilized (*6*). Traditionally, many insect pests have been controlled by use of broad-spectrum insecticides. By 1998, 79% of all acres in Wisconsin were treated with either organophosphosphorus (OP) or carbamate (CB) insecticides, with the major products including azinphos-methyl, carbaryl, chlorpyrifos, diazinon, and acephate (*6*, *7*).

Karner Blue Butterfly Protection

The Karner blue butterfly, or KBB (*Lycaeides melissa samuelis*), is a Lepidoptera in the family Lycaenidae. Adult butterflies are small (2.5 cm wingspan). The upper (dorsal) side of the male wings are violet blue with a black margin and white fringed edge; the upper side of the female wings range from dull violet to bright purplish blue near the body and the hind wings have marginal orange crescents (*8*). Larvae are pale green and about one-half inch long at maturity, and feed exclusively on foliage of wild lupine (*Lupinus perennis*). The KBB is bivoltine, with two generations per year, and larvae are present and actively feeding on lupine during the period April to mid-July (*8*). Larvae have a mutualistic relationship with many species of ants, with the ants harvesting a nutritious secretion from the larvae and in return providing some degree of protection from predators. First-flight adults emerge in late May and the flight extends through June. Second brood adults emerge in July and August. KBB adults are weak flyers and typically do not travel far, often only venturing several hundred feet from where they emerge (*9*). Adult KBB obtain nectar from both native and non-native flowering plants, and have been found feeding on 41 different species in WI (*8*).

The existence of the KBB is inextricably linked with the wild lupine. Wild lupine is a perennial plant characteristic of oak-pine barrens, oak savannas and dune/sandplain communities. It occurs primarily on dry, sandy soils in open to partially shaded habitats (*8*). Lupine is a pioneer species which favors recently disturbed (e.g., burned) habitat (*9*). If natural forces such as wildfire or management practices that create the open areas it prefers are suppressed, the ecological succession of savanna and barrens communities to shrubs or forests essentially shades the lupines out (*10*).

Historically, KBB range extended across a dozen states in the upper Midwest and the Northeast, and populations currently exist in 7 states (NH, NY, OH, IN, MI, WI, MN), with the greatest number of occurrences in the western part of the range in WI and MI (*8*). Historic habitat of the KBB and wild lupine was the savanna/barrens ecosystem, much of which has been destroyed by development, fragmented, or degraded by unsuppressed ecological succession. Loss of habitat resulted in a decline of KBB locations and numbers. Fire suppression has been consistently identified as the primary factor affecting the butterfly's population decline and reduction in range (*10*). The KBB was formally listed as a federally endangered species in 1992, and in 2003 a species recovery plan (SRP), the KBB recovery plan, had been completed (*8*). Presently, the KBB occupies remnant savanna/barrens habitat and other sites that have historically supported this habitat, such as young pine stands, rights-of-way, airports, military bases, and utility corridors (*8*). Where the KBB persists, land management activities that may be harmful include lack of fire or other successional disturbances, close-cropped grazing, frequent or poorly timed mowing, use of herbicides that kill lupine or nectar plants, and use of pesticides detrimental to KBB or ants they associate with (*8*, *9*). Based on the potential for negative impacts from area-wide gypsy moth control programs relying on aerial spraying of *Bacillus thuringienseis* (Bt) insecticide, USFWS recommends that no aerial applications of Bt occur within one-half mile of any KBB sites (*8*).

Karner Blue Butterfly in Wisconsin

Wisconsin supports the largest and most widespread KBB populations, which occur where wild lupine grow in the central and northwest sands regions of the state (*11*). The most reliable location records for KBB document its existence in 15 counties, with some of the largest populations observed in portions of Juneau, Monroe, Burnett, Eau Claire, and Jackson counties (*8*). There are several counties populated by KBB in Wisconsin in which cranberry agriculture may occur (Figure 1).

Within 14 months of the KBB federal listing, discussions began in Wisconsin around development of a statewide Habitat Conservation Plan (HCP). The plans are envisioned under the ESA as partnerships with non-federal parties for habitat conservation efforts. An HCP is a planning document required for obtaining an Incidental Take Permit (ITP) from the USFWS, and includes a description of the anticipated effects of the proposed taking and how those impacts will be mitigated. After several years of discussion among both federal and state agencies as well as private organizations, under the leadership of the Wisconsin Department of Natural Resources (DNR) a "Karner Blue Butterfly Habitat Conservation" plan was completed and implemented in 1999, and it initially included 26 major land management organizations as partners (*11*).

An innovative aspect of the HCP is the voluntary participation (and automatic inclusion) of private landowners and land users, including the agricultural community, in the KBB conservation program (and ITP). Although the HCP recognized that "*Most agricultural operations do not appear to support habitat for the Karner blue butterfly or present a threat to the continued existence or recovery of the Karner blue butterfly in Wisconsin*", the take (per the ESA) of the KBB from agricultural activities, including agricultural use of pesticides, is covered by the ITP issued for the HCP, and supported by the membership of the state pesticide regulatory lead agency, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) (*8*, *11*). The DATCP, with inputs from agriculture, has developed pesticide guidelines for use by HCP partners and is engaged in educational activities with growers (*11*). The ITP also covers any incidental take that may occur from pesticide use on agricultural lands in Wisconsin (*12*).

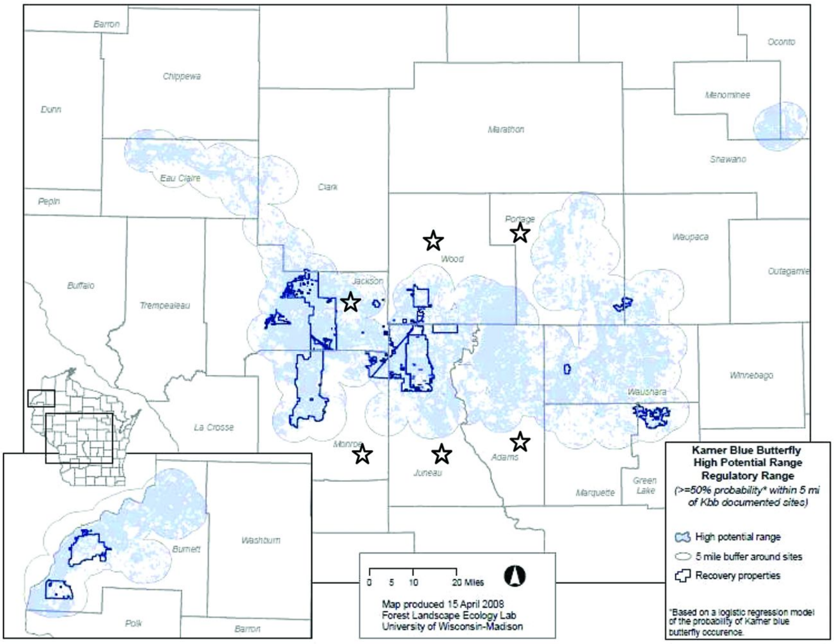


Figure 1. Map of WI KBB Habitat, Including Counties (☆) with Significant Cranberry Cultivation (>500 acres) (2, 11).

Registration and Introduction of Methoxyfenozide

Methoxyfenozide Development and Registration

Methoxyfenozide (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide) (CAS No. 161050-58-4) is an insecticidal member of the bisacylhydrazine class (BAH). The BAH's manifest their toxicity to target insect pests by mimicking the action of 20-hydroxyecdysone, the steroidal molting hormone, and causing a premature and/or incomplete molt in exposed individuals. The ecdysone receptor in larval Lepidoptera has a very high affinity for binding with methoxyfenozide, so the product is particularly effective in killing caterpillars following ingestion, and at the field level may control pests at application rates of 0.06 to 0.25 lb ai/acre (*13*). Methoxyfenozide is a highly selective product and has virtually no effect on other orders of insects or arthropods. This is in contrast to classical broad-spectrum insecticides, which typically exhibit insecticidal activity across many orders of insects but are generally less active than methoxyfenozide and must be applied at rates of 0.5 to 3 or more lb ai/acre.

Based on its selective mode of insecticidal action, methoxyfenozide exhibits low or no toxicity towards most non-target wildlife including mammals, birds, fish, honeybees and beneficial insects (Table I). Safety to insect predators and parasites makes it a good fit with IPM programs (*4*, *13*). From an environmental fate standpoint, methoxyfenozide is stable to hydrolysis and photolysis in water and laboratory studies suggest it may be moderately persistent in soil but more rapidly degraded under field conditions (mean half-life in U.S. soils of 177 days) (*13*).

Intrepid* 2F (*Trademark of Dow AgroSciences LLC), a flowable, suspension concentrate formulation of methoxyfenozide containing 2 lbs ai/gallon, was initially developed by Rohm and Haas in the 1990's (acquired by Dow AgroSciences in 2001) as a selective insecticidal product for control of Lepidoptera pests. EPA first registered Intrepid* 2F in 2000 for use on cotton and pome fruits, and approvals on a variety of fruit, nut and vegetable crops followed in subsequent years. EPA approval of Intrepid* 2F was preceded with classification of the product as both a "reduced risk" alternative for available insecticides and an "OP replacement" priority. EPA's classification was based on favorable properties of methoxyfenozide including low mammalian toxicity, low toxicity to non-target wildlife, safety to beneficial insects and compatibility with IPM (Table I).

EPA Environmental Risk Assessments and Labeling

Intrepid* 2F labeling for cotton and pome fruit approved by EPA in 2000 reflected many of the highly favorable properties for which it had received "reduced risk" classification. The signal word for the label is "Caution", protective clothing requirements for handlers and applicators are minimal, and the restricted entry interval for agricultural workers following application is very short. Based on EPA's screening-level ecological risk assessments, however, labeling did include precautions for minimizing environmental exposures. These precautions included spray drift setbacks of 25 feet for ground and 150 feet for aerial application for protection of aquatic habitats. The Intrepid* 2F label also included restrictions related to protection of endangered species. Product applications were not allowed within one mile of sandy habitats that supported wild lupine plants in 22 counties in WI and 6 counties in MI. How were these environmental precautions, and in particular the restrictions related to endangered species, derived for a "reduced risk" product with a highly specific mode of insecticidal action? The answers lie in EPA's historical approaches to ecological risk assessment and endangered species assessment.

The Environmental Fate and Effects Division (EFED) within EPA's Office of Pesticide Programs relies on conservative, screening-level ecological risk assessments that utilize worst-case inputs regarding potential exposures (e.g., highest application rate, longest persistence under lab conditions, greatest drift) and effects (e.g., most sensitive non-target organism with added safety factor). Use of such screening-level assessments allows the Agency to quickly complete a large number of assessments and fits well with EPA's paradigm for rapid identification of precautionary use restrictions. The downside of using screening-level results is that they often significantly overestimate potential exposure and effects. At the time of Intrepid* 2F's first registration by EPA, EFED's assessment assumed a standard offsite spray drift deposition of 5% on nearby water bodies and runoff entry predicted by PRZM/EXAMS modeling based on 10 acres of land draining into a theoretical 1 acre farm pond. Using these approaches for Intrepid* 2F, the Agency flagged a "level of concern" for aquatic non-target organisms for the proposed uses on cotton and apples and recommended restrictions which included the spray buffers (*14*).

Endangered Species Assessment

With respect to assessment of potential risks of Intrepid* 2F use in cotton and apples to endangered species, EPA's assessment calculated acute or chronic "levels of concern" for freshwater and estuarine invertebrates and for birds (*14*). However, in its assessment EPA noted that it was deferring most considerations related to endangered species to future implementation of the Agency's ESPP. The exceptions related to EPA's consideration of endangered insects. Although EFED "*does not quantify the risks to terrestrials insects*" (*14*), the agency qualitatively believed that proposed use of Intrepid* 2F on apples would be "*likely to impact*" three endangered insects occurring in apple-growing regions and that restrictions were warranted. EPA deferred consideration of any necessary protections of the valley elderberry longhorn beetle to California's Department of Pesticide Regulation. The Agency also determined that the primary target pests for Intrepid* 2F did not occur frequently in the single WI county (Door) in which the Hine's emerald dragonfly occurred, so the label prohibited use in this county (*14*).

With respect to protection of the KBB, EPA completed a very brief, qualitative endangered species assessment (*15*). The Agency noted that the KBB occurred in 24 counties in NH, NY, MN, WI, IL, and IN where apples were grown, but understood that apples were not grown anywhere in the vicinity of KBB in NH and NY. EPA also noted that, due to small acreages of apples in IN and IL, further assessment was not required. Therefore, the Agency's concerns for Intrepid* 2F and KBB focused on WI and MI. In WI, a one-half mile buffer around sandy lupine habitats is recommended by USFWS for area-wide aerial applications of Bt insecticide. EPA deduced that doubling this to a 1-mile buffer zone would provide protection for the KBB for use of Intrepid* 2F. Therefore, for 6 counties in MI and 22 counties in WI the following label restriction was required to assure a "no effect" determination for use of Intrepid* 2F and the KBB:

> *"To protect the Karner blue butterfly, do not apply within one mile of sandy habitats that support wild lupine plants."*

Table I. Characteristics of Commonly Used Cranberry Insecticides (*18*, *19*)

	Azinphos-Methyl	*Carbaryl*	*Chlorpyrifos*	*Spinosad*	*Methoxyfenozide*
Insecticidal Activity Type	Broad-spectrum	Broad-spectrum	Broad-spectrum	Selective	Selective
Cranberry pests controlled	Fireworms Fruitworm Sparganothis Cran. Weevil	Fireworms Fruitworm Sparganothis Flea beetle	Fireworms Fruitworm Sparganothis Cran. Weevil	Fireworms Sparganothis Thrips	Fireworms Fruitworm Sparganothis
Typical application rate (lb ai/A)	0.5-1.0	2.0-3.0	1.5	0.06-0.16	0.16-0.25
Year of Introduction	1975	1962	1985	1999	2004
Toxicity to Mammals	highly toxic	moderately toxic	moderately toxic	Slightly toxic	non-toxic
Toxicity to Birds	moderately toxic	non-toxic	moderately to highly toxic	Non-toxic	non-toxic
Toxicity to Fish	very highly toxic	moderately toxic	very highly toxic	slightly to moderately toxic	non-toxic
Toxicity to Aquatic Invertebrates	very highly toxic	very highly toxic	very highly toxic	slightly to highly toxic	mod. Toxic
Toxicity to Honey Bees	highly toxic	highly toxic	highly toxic	moderately toxic	relatively non-toxic
EPA Reduced Risk?	No	No	No	Yes	Yes

Intrepid* 2F is highly effective at low application rates against several key Lepidoptera pests of cranberries including blackheaded fireworm, cranberry fruitworm, and sparganothis fruitworm (*16*). The product was rated as “excellent” for insecticidal efficacy against these major pests and secondary pests such as spanworms, gypsy moths, and spotted fireworm (*7*). Intrepid* 2F demonstrated very good control under field conditions in University of Wisconsin trials at application rates of 10 to 16 fl oz/acre (0.16 to 0.25 lb ai/acre) (*17*). As for nearly all new insecticide products, however, initial field research efforts and regulatory approvals for methoxyfenozide were focused on major agronomic crops. Development efforts for a large number of minor crop uses were instead dependent on cooperation with growers and federal minor use programs.

By the mid-to-late 1990's, cranberry growers eagerly sought new, more selective insecticide products to effectively manage the suite of insect pests they faced in a more sustainable fashion (*1*, *7*). Issues of potential concern for use of insecticides in cranberries included pest resistance, safety to pollinators, and surface and ground water quality protection. Environmental and human health concerns had already led to the loss of the major broad-spectrum insecticide parathion in the early 1990's (*1*). By the mid-1990's, cranberry growers were heavily reliant on OP and CB insecticides (pyrethroids were not widely adopted due to aquatic sensitivity and proximity to water). Of particular concern to growers from an operational standpoint was safety to pollinators, since this affected materials that could be safely sprayed around the time of crop blooming. Methoxyfenozide is one of the very few products classified as "relatively non-toxic" to bees (i.e., "a product that will cause a minimum amount of injury to bees") whereas most current products were classified as "highly toxic" (i.e., "use at any time of day or night during blossom may result in severe bee losses") and use was restricted within 7 days of blossom (*4*). Growers were also very concerned about the potential loss or restriction of currently used OP and CB insecticides following passage of the Food Quality Protection Act of 1996 (*6*, *7*).

By 1998, the Cranberry Institute (CI) was investing heavily in the discovery, testing, and registration of OP and CB alternatives (*6*). Priority products of interest included both methoxyfenozide and spinosad (*7*, *20*). Based on this interest, the CI formally requested inclusion of methoxyfenozide in the U.S. Department of Agriculture's (USDA) IR-4 Minor Crop Program for use on cranberries (*21*). By 1999, both USDA IR-4 and its Canadian minor crop counterpart were pursuing field testing and data development for several new, reduced risk insecticides for cranberries including methoxyfenozide. A series of six field residue trials was initiated during 1999 in MA, NJ, OR, WI and British Colombia. Rohm and Haas (and later Dow AgroSciences) supported the program with product, draft labeling and a dietary risk assessment. By April of 2002, residue studies were completed and a draft label and tolerance petition were submitted to EPA (*21*). During early 2003, EPA declared the action a "reduced risk/OP replacement" priority and by mid-year registration for use of Intrepid* 2F on cranberries was approved. As had been EPA's practice for adding new crop approvals for Intrepid* 2F, the Agency included the same environmental and endangered species-related restrictions on the cranberry use label that had been developed initially for apples and cotton. This included the 1-mile setback from sandy areas supporting wild lupine in parts of WI and MI.

EPA's action in registering Intrepid* 2F in 2003 with the support of the CI and the USDA IR-4 program would seem to have cleared the way for introduction of this reduced risk product for the 2004 season. In fact, for some regions this goal was realized. For example, in New Jersey, where the product's safety to beneficial arthropods including bees made it an excellent fit with ongoing IPM programs, Intrepid* was used on more than one-third of all insecticide-treated cranberry acres within two years of its introduction (*16*). For growers in Wisconsin, however, there were Karner blue butterfly "complications".

Consultation Process and County Bulletins

Karner Blue Complications

Although by the spring of 2004 both EPA and state regulatory agency approval (DATCP) of Intrepid* 2F for use on cranberries had been received, Wisconsin growers were largely unable to use the product. According to the Wisconsin State Cranberry Growers Association (WSCGA), cranberry growers had no reliable way of knowing whether sandy habitats that supported wild lupine occurred within one mile of their fields (*12*). By placing the burden on growers to assure there was no wild lupine growing within a mile of the target application site, the label approved by EPA and DATCP essentially precluded its use by the cranberry growers in Wisconsin, even in counties where the Karner blue protection zone occurs in a relatively small area (*7*, *12*). So instead of adopting use of the product on cranberries that EPA had declared as "reduced risk" compared to current alternatives, growers instead continued to rely upon use of non-selective, broad-spectrum insecticides. This situation was not only ironic from standpoint of the "reduced risk" designation, but also by the fact that no KBB-specific risk assessments had been completed or protections implemented for any of these broad-spectrum insecticide products.

The cranberry growers, however, were persistent in their efforts to secure long-awaited access to a serviceable Intrepid* 2F label. During 2005, the WSGCA first approached the regional USFWS office in Wisconsin for assistance in seeking modification of the labeling restrictions for Intrepid* 2F (*12*). A shared interest for the effort developed among cranberry growers, the DNR, the statewide KBB HCP Coordinator, DATCP and USFWS. Based on this statewide consensus, USFWS submitted a proposal to EPA in March of 2007 (*12*). The USFWS noted that use of Intrepid* 2F by growers included in the HCP was not expected to result in jeopardy to the KBB and any incidental take was already covered by the ITP associated with the HCP. The USFWS recognized that, although the 1-mile buffer established by EPA would certainly offer protection, "*it unnecessarily, in our opinion, restricts the pesticide's use and forces operators to use more broad spectrum insecticides*" (*12*). The USFWS proposed that EPA modify the labeling restriction regarding the 1-mile buffer so that it would not apply to lands of the KBB covered by the HCP. USFWS also pointed out that the label restrictions had been developed in the absence of ESA Section 7 consultation, and USFWS believed that the process would have allowed the Service to work with EPA and the registrant to identify label restrictions that would allow greater use of Intrepid* 2F by cranberry growers while ensuring use did not jeopardize the KBB.

Karner Blue Consultation

In response to requests from the cranberry growers, USFWS, and DATCP, during June of 2007 EPA formally requested ESA Section 7 consultation with USFWS regarding use of methoxyfenozide on cranberries in Wisconsin (*22*). The consultation was based on an interim risk assessment for the KBB that EPA had prepared (*23*). This risk assessment concluded that "*with no application restriction, methoxyfenozide is likely to adversely affect Karner blue* *butterfly larvae found within 5.4 miles of cranberry production sites on which methoxyfenozide is applied*." EPA's conservative assessment of methoxyfenozide was based on comparison of worst-case wild lupine residues that might result from offsite drift of very fine to fine spray (constant wind, no barriers) compared with an LC_{50} value for the most sensitive Lepidoptera larvae tested (*Ostrinia nublilalis* as surrogate for KBB) modified by a standard, 20-fold endangered species safety factor. The EPA assessment noted a number of uncertainties that could have resulted in under- or over-estimation of risks, but most importantly it determined that the risks could be significantly reduced by several drift management practices. These included reducing the number of seasonal applications, restricting spray boom height and using spray nozzles producing coarser droplets and drift retardant additives.

In responding to EPA's request for Section 7 consultation, the USFWS referred EPA to their 1999 Biological Opinion associated with the statewide KBB HCP in which it had been determined that pesticide use by cranberry growers was covered by the existing ITP as cranberry growers were part of the "Voluntary" land owner group. The strategy to allow the "Voluntary" group to incidentally take KBBs was analyzed in the 1999 Biological Opinion (BiOp) which determined that activities conducted per the HCP (including those by the "Voluntary" group) would not jeopardize the KBB. The 1999 BiOp also provided a streamlined ESA Section 7 consultation process for federal agencies (such as EPA) for federal programs that affect landowners in the "Voluntary" group (*22*). The streamlined consultation procedures required EPA to "provide advice and encouragement as well as information materials to the landowner to design the project to conserve the KBB." The USFWS provided comments to EPA on its risk assessment and identified measures to minimize pesticide drift, based in part on inputs they had received from the WSCGA regarding agronomic practices that were already in place or could be put in place for drift management. The USFWS subsequently endorsed EPA's proposals regarding adoption of measures to minimize pesticide spray drift and suggested limiting use to ground spray application, use of coarse droplet sizes and drift retardant, and application when wind was blowing away from known KBB populations. Based on the risk mitigation proposals in its own assessment and the consultation feedback received from USFWS, during 2008 EPA began moving forward with practical steps for implementing revised use restrictions for Intrepid* via the Agency's dormant "Bulletins Live!" system.

First EPA ESPP County Bulletins

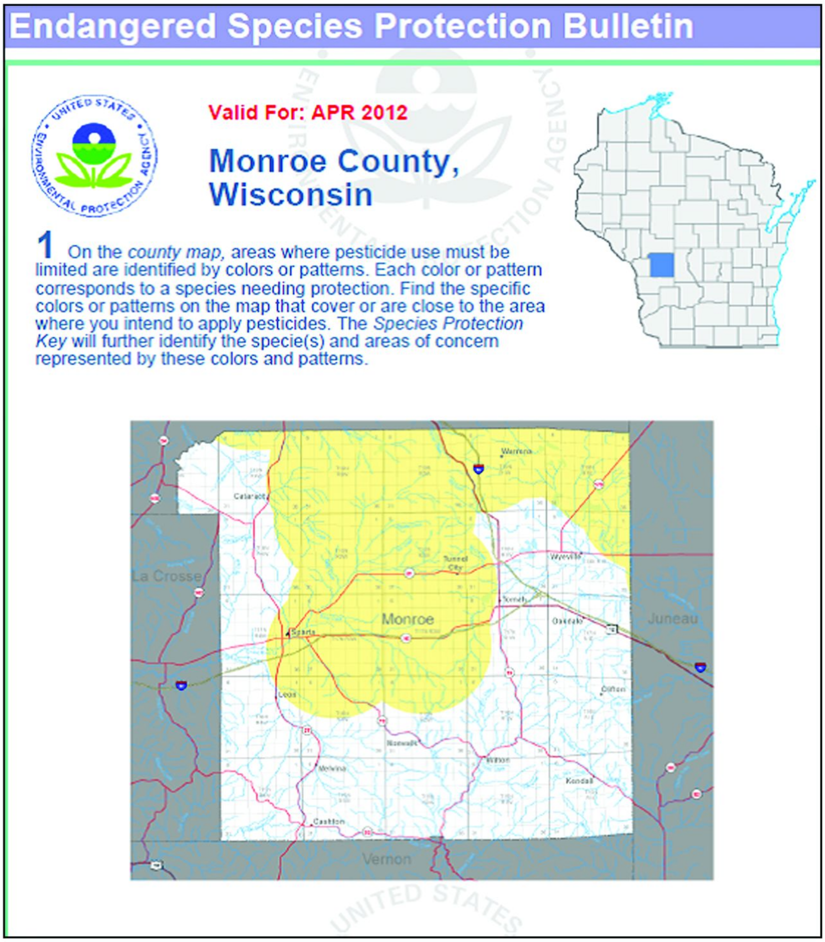
The idea of using county-level bulletins, including maps showing specific endangered species distributions, to assist pesticide-users in protection of endangered species originated nearly 25 years ago. During 1988, EPA first proposed a "voluntary" program of county bulletins that provided geographically-specific pesticide use limitations in areas of concern based on historic Biological Opinions issued by the Services. This voluntary program was not implemented, and instead in 2002 EPA proposed elements of an ESPP that would include a system of *mandatory* county bulletins to support implementation of geographically-specific use limitations it had determined were necessary to ensure a pesticide registration complies with ESA. The system finalized in 2005 and known as "Bulletins Live!", involves bulletins containing county-level maps of endangered species distributions and listing of any geographic and product-specific restrictions (*24*). The bulletins are posted on the EPA website www.epa.gov/espp/bulletins.htm, and a statement on the pesticide label requires users in affected geographies to refer to the bulletins. Since the bulletins are cited as required on the approved product label, they are legally considered an enforceable part of labeling (*24*).

By mid-2008, U.S. EPA had begun to develop draft county bulletins to document a revised set of use restrictions for use of Intrepid* 2F on cranberries in WI and MI to replace the currently approved default 1-mile buffer from sandy habitats supporting wild lupine. Parties involved in the county bulletin discussion included DATCP, WSCGA, and USFWS. Detailed Wisconsin county maps showing regional distribution of the KBB were already available in connection with efforts to manage gypsy moth pests in the state. By January of 2009, EPA developed a draft set of 15 county bulletins for WI and 6 bulletins for MI that were subject to state agency and registrant review. The MI bulletins merely documented the existing 1-mile buffer (there is no HCP in the state), but in WI counties where the statewide KBB HCP was implemented, a set of relaxed restrictions (to replace the 1-mile buffer) for use of Intrepid* 2F in affected areas was proposed:

- Application limited to ground application or chemigation (no aerial application allowed)
- Ground applications to be made using a drift retardant and nozzles producing a coarse (ASAE) droplet size
- Chemigation applications to be made with drop size of 500 microns or larger
- Spray applications limited to when windspeed is 2 to 10 mph

One additional bulletin for Door County, WI, was also proposed to capture the earlier prohibition of use for protection of the Hines emerald dragonfly.

With the support of the registrant, Dow AgroSciences, this first-ever set of ESPP county bulletins was implemented by EPA during the spring of 2009 through two actions. First, during April EPA approved an amended product label for Intrepid* 2F that replaced the previous 1-mile buffer to sandy habitats with a statement requiring users in the affected counties to refer to the ESPP bulletin for geographically-specific restrictions. Second, during May the 22 county bulletins listing the geographic-specific limitations for use of Intrepid* 2F related to KBB (or HED) protection were posted to the EPA ESPP "Bulletins Live!" website (Figure 2).



Endangered Species Protection Bulletin

Valid For: APR 2012

Monroe County, Wisconsin

1 On the *county map*, areas where pesticide use must be limited are identified by colors or patterns. Each color or pattern corresponds to a species needing protection. Find the specific colors or patterns on the map that cover or are close to the area where you intend to apply pesticides. The *Species Protection Key* will further identify the specie(s) and areas of concern represented by these colors and patterns.

Figure 2. Example of ESPP County Bulletin for KBB Protection in WI.

Lessons and Implications

Beginning in 2009, Intrepid* 2F became an integral part of cranberry insect pest management practices in Wisconsin, and estimates are that it is currently used on more than half the treated acres and often two sprays per season are utilized (*25*). All applications of Intrepid* 2F are made via ground boom or chemigation. Use of the product is particularly popular due to its safety for honeybees during the period of pollination. Intrepid* 2F has joined a number of newer, more selective products available to growers (e.g., spinetoram, novaluron, indoxacarb, clothianidin) as they continue to decrease reliance on older, less selective, broad-spectrum products (*4*). For one long-used product, azinphos-methyl, use will no longer be allowed after the 2012 season. Where aerial applications are required, other products such as the BAH analogue tebufenozide (Confirm* - *Trademark of Dow AgroSciences LLC) are utilized. Although none of the other insecticide products used in Wisconsin cranberries has yet been evaluated by EPA for safety to the KBB, the Agency has announced intentions of conducting comprehensive endangered species assessments as products move through reevaluation under the Registration Review program during 2007 to 2022.

The case of Intrepid* 2F for use on cranberries in Wisconsin presents noteworthy ESA-related developments. First, it represents a rare instance of an effective Section 7 consultation for a pesticide between EPA and one of the federal services. In general, recent attempts at ESA consultations by EPA with one of the Federal Services have been rebuffed based on inadequacy of the consultation package or been forced to advance via litigation-related deadlines.

None of these consultation efforts has resulted in a single, practical change to a pesticide product label. Second, the ESPP county bulletins for Intrepid* 2F were the first to be activated and implemented via EPA's "Bulletin's Live!" system. Development of these 22 bulletins for Intrepid* 2F and the Karner blue butterfly has set an important precedent for the immense future task whereby EPA will consider potential impacts of more than 700 pesticide active ingredients for nearly 2,000 threatened and endangered species across some 3,143 U.S. counties. Listed below are some of the lessons and implications that may be drawn from the case of cranberry pest management and the KBB in Wisconsin for the broader topic of pesticide regulation and the ESA.

The ESA Section 7 consultation process for a pesticide can result in protection of both endangered species and agricultural interests if the appropriate stakeholders are involved. The end result of the KBB case study was that effective Section 7 consultation between EPA and USFWS led to adoption of practices that allowed cranberry growers to utilize an improved pest management tool while safeguarding recovery efforts for the KBB. Success required involvement of all important stakeholders including federal agencies (EPA, USFWS), state agencies (DNR, DATCP), growers and the registrant. This is exemplified by the early failure to identify feasible use restrictions when the USFWS, state agencies, and growers were excluded. To make progress on further implementation of ESA for pesticides, the consultation process must be designed in such a way that all key stakeholders are involved.

Regional consultation efforts will be greatly facilitated by the availability of both a Species Recovery Plan (SRP) and a Habitat Conservation Plan (HCP). For the KBB, successful consultation was enabled by having both a HCP (*11*) and a species recovery plan (SRP) (*8*) in place. The BO and ITP developed for the HCP ensured that agricultural impacts and private landowners were include in the appropriate species conservation efforts. For the KBB and most other endangered species, the greatest threats to recovery involve habitat conversion or adverse modification (e.g., cessation of fires and other disturbances that fostered growth of wild lupine in the case of the KBB). Agricultural land owners who use pesticides are part of the HCP's "Volunteer" landowner group and as such are covered by the ITP for take of the KBB; they are also encouraged to voluntarily protect the KBB and its habitat. WI DATCP, a partner to the HCP, plays a lead role in providing information and guidance to the agricultural community (including cranberry growers) on conservation measures that can be taken for the butterfly. Having both a SRP to provide overall guidance and a statewide HCP to provide for coordinated local implementation of conservation practices helped facilitate a successful consultation.

Development of practical and protective pesticide use restrictions must involve both growers and relevant state agencies. As endangered species effects determinations are made and consultation occurs, there may be many possible "theoretical" or "ivory tower" options to consider with respect to use restrictions. In the case of KBB protection, EPA initially assumed that doubling the one-half mile spray buffer for area-wide, aerial applications of Bt already in use in Wisconsin was protective and could be readily implemented for use of Intrepid* 2F in cranberry pest management. When growers and the WI DATCP received EPA's labeling, however, they immediately recognized this was not feasible. In stimulating state agencies and the USFWS to appeal to EPA, the growers came forward with a number of suggestions of alternate practices they were already implementing or could feasibly implement. It seems clear from this case that restrictions developed in the absence of on-the-ground, grower and state official feedback may be impractical. Both the action agency and the consulting Service must find ways to bring the local knowledge of these key stakeholders into the process for developing species-protective, but agriculturally feasible restrictions.

The EPA ESPP county bulletin system <u>can</u> be an effective way of communicating geographic-specific restrictions to pesticide users. For the first time, EPA's "Bulletins Alive!" concept was demonstrated to provide a practical way of implementing endangered species-related restrictions. In the case of the KBB, the bulletins provided information on geographic restrictions on pesticide use that could not be adequately communicated via the product label. Since reference to bulletins from product labels is a new practice for growers, it is important that training efforts accompany the implementation of the "Bulletins Live" system. In the case of the KBB, having the UW/WSCGA-sponsored "Wisconsin Cranberry School" include specific training on the new bulletins was critical (*17*).

Effective consultation takes time and resources and at the core it is a local process. The consultation process for the KBB and Intrepid* 2F took some 31 months to complete (from EPA's initial effects determination in Oct-2006 to formal consultation request in Jan-2007 to bulletins in May-2009), and this followed an initial registration process of a couple of years and built on availability of a preexisting BiOp associated with the HCP (*11*). The KBB effort required intensive assessment efforts, a number of stakeholder meetings and exchanges of information. Considerable resources were invested in the process at both the federal and state levels. Some of the time and effort involved stemmed from the need to take Wisconsin- and cranberry-specific considerations into account, and in this case the involvement of the WCGA, the DATCP and Wisconsin field office of the USFWS was critical. This regional/local involvement allowed important aspects of local management practices in the 15 affected WI counties and via the HCP to be factored into federal regulatory decisions on labeling restrictions and county bulletins. With the thousands of consultations that may result from consideration of all pesticides, crops, counties and endangered species, it is clear that a massive effort remains ahead. There may need to be creative approaches developed and perhaps a new paradigm implemented for progress to be made in our lifetime.

For endangered species to truly benefit from pesticide regulation, the ESA consultation process must incorporate consideration of the entire portfolio of pest management products. A challenge for pursuit of implementation of ESA obligations on a piecemeal, product-by-product basis, is that resulting restrictions may offer no actual benefits and instead be negative or neutral for endangered species. In the case of the KBB, EPA initially applied such onerous restrictions on use of a new, reduced risk product that growers had to continue to rely on older, broad-spectrum insecticides which had not been assessed for KBB impacts and may have posed greater risks. If only newer products, many of which have been designed to be more selective and offer reduced risk benefits, are critically evaluated for ESA and broad restrictions are adopted, how can species benefit? EPA has indicated that older products will be evaluated for ESA impacts via the Registration Review process during the period 2007-2022, but so far little progress has been made. It realistically may take 20 or 30 years for Registration Review to be completed and ESA to be considered for existing products, and meanwhile there must be ways devised to ensure that new compounds or "unlucky" ones which appear early in the Review schedule are not differentially restricted to the detriment of the species being targeted for protection.

Acknowledgments

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Chapter 9

Endangered Species Assessments Conducted Under Registration Review: Fomesafen Case Study

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Fomesafen is an herbicide currently being evaluated by the United States Environmental Protection Agency under the Registration Review program, and is being used as one of the pilot projects to develop processes and methodology for conducting nation-wide endangered species assessments. In this chapter, the history, current status, and science of the fomesafen endangered species assessment conducted under Registration Review is discussed. In addition, methods for refining endangered species assessments in regard to environmental exposure, geospatial analyses and biological aspects of the listed species are described.

Introduction

The Endangered Species Act of 1973 (ESA) requires that all federal agencies conserve and recover listed species, and the ecosystems upon which they depend. Under the ESA, the United States Environmental Protection Agency (EPA) must conduct assessments to determine whether a pesticide will potentially affect any threatened or endangered species or their habitat critical to survival. If EPA determines that the pesticide registration may affect a threatened or endangered species, it must consult with the National Marine Fisheries Service (NMFS) and/or the Fish and Wildlife Service (USFWS). EPA is conducting endangered species assessments for pesticides during Registration Review, a program required

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by the Food Quality Protection Act (FQPA) of 1996, under which EPA reviews and updates all pesticide registrations on a 15-year cycle (*1*). One pesticide currently being assessed under Registration Review is the herbicide fomesafen. Fomesafen is one of the active ingredients EPA is using in a pilot project to develop the assessment methodology that will be used for all pesticides being assessed through Registration Review.

The purpose of this chapter is to present the history, current status, and science of the fomesafen endangered species assessment conducted under Registration Review. The first part provides background on fomesafen and EPA's Registration Review program, and discusses the history of fomesafen under Registration Review, including the consultation process. The second part describes the endangered species assessment scheme used by EPA in the draft assessment, identifying areas where refinements can be made and providing recommendations for improving the overall assessment scheme.

Fomesafen Pilot and EPA's Registration Review Program

This section provides the history and status of the fomesafen Registration Review. At the time of this writing, this Registration Review case is in progress, and updates to the case study are likely. The information in this section covers the time from initiation of Registration Review in 2007 to mid- 2012.

Fomesafen

Fomesafen is an active ingredient in 27 currently registered products (*2*), five of which are registered by Syngenta Crop Protection, LLC (Table I). Fomesafen is a protoporphyrinogen oxidase inhibitor that is used for weed control in cotton, soybeans, dry beans, snap beans, peppers, tomatoes and potatoes. This herbicide is a key agricultural tool for controlling devastating weeds such as palmer amaranth, waterhemp, giant ragweed and lambsquarter. Recently, products containing fomesafen have shown to be instrumental in controlling weeds that have developed resistance to the commonly used herbicide glyphosate, such as palmer amaranth, giant ragweed and horseweed (*3–5*). Glyphosate-resistant weeds have appeared in many southeastern states over the past few years, posing a threat to the economic stability of cotton production and cropping systems (*6*, *7*).

EPA's Registration Review Program and the Fomesafen Pilot

As required by FQPA, EPA must update the registration for all pesticide active ingredients on a 15-year rolling cycle. During this process, the EPA will review the data base for each active ingredient, and if necessary, issue a formal Data Call-In (DCI) to fill any data gaps associated with the toxicity and/or fate of the compound in the environment and deemed necessary to assess the safety to humans and the environment. Once all of the data are received, EPA will update the pesticide registration based on new scientific data, and any new pesticide regulations or requirements that might have arisen since the pesticide's last review and registration. EPA also will conduct comprehensive endangered species assessments under Registration Review to determine whether the pesticide may affect endangered species that inhabit areas where use of the pesticide might occur.

Table I. Syngenta Herbicides Containing the Active Ingredient Fomesafen

Product Name	***EPA Reg. No.***	***Summary of Uses***
Flexstar®	100-1101	Preplant, preemergence or postemergence for control or suppression of broadleaf weeds, grasses and sedges in soybeans
Prefix Herbicide®	100-1268	Control of broadleaf weeds and grass, including glyphosate and ALS-resistant weeds, in cotton and soybeans. Pre-mix of fomesafen and S-metolachlor
Flexstar® Gt Herbicide	100-1325	Pre- and post-emergence control of weeds in cotton and soybean that are difficult to control with glyphosate alone or are resistant to glyphosate and ALS-inhibitors. Pre-mix of fomesafen and glyphosate.
Flexstar Gt® 3.5 Herbicide	100-1385	Preplant or preemergence burndown application in cotton or a postemergence directed application in certain glyphosate-tolerant cotton and as a preplant or preemergence burndown in soybeans or as a postemergence over-the-top application in certain glyphosate-tolerant soybeans to control labeled broadleaf, grass and sedge weeds. Pre-mix of fomesafen and glyphosate.
Reflex® Herbicide	100-993	Pre- and post-emergence control of difficult weeds, including glyphosate-resistant Palmer pigweed and ALS-resistant pigweed, grasses and sedges in cotton, dry beans, snap beans, soybeans and potatoes

The process that EPA is following under Registration Review includes three phases for each product reviewed: Phase I – Opening of the docket, Phase II – Case development, and Phase III – Registration Review decision (*8*). The process is generalized in Figure 1.

Phase I starts with the opening of an electronic docket that will contain a preliminary work plan. The projected timing of the Registration Review case is provided. EPA also includes a problem formulation for the active ingredient being considered. In the problem formulation, EPA describes the specific approach to risk characterization for the active ingredient. EPA can also provide other documents addressing the pesticide's potential effects on humans and the environment relevant to the assessment.

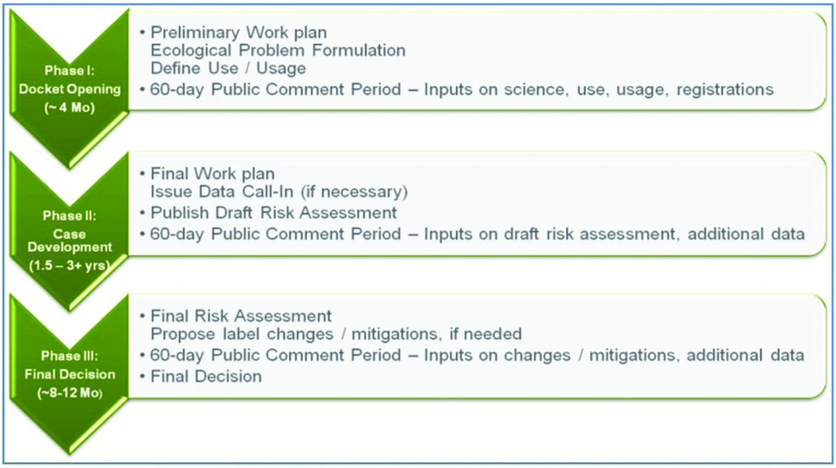

Figure 1. Summary of the Process for Registration Review.

In the fomesafen case study, the initial docket was opened in March 2007. EPA issued documents to the docket, including general overview documents related to fomesafen, human health and environmental fate and effects problem formulations with their respective appendices, use and usage information, and a summary of incident reports (*9*). EPA predicted it would take approximately three years for the fomesafen Registration Review to be completed, concluding in March 2010. Table II highlights some of the key information provided by EPA upon opening the fomesafen Registration Review docket.

As part of the normal Registration Review process, EPA solicits comments from the public on the initial material in the docket. They request comments on the preliminary work plan and rationale, ask for input on the active ingredient's use and usage such as history and location of use, application methods and timing, local use restrictions, actual use rates used at national, state and county levels, and other use and usage information important for the assessments conducted under Registration Review. The conclusion of the public comment period ends the first phase of Registration Review. In the fomesafen case study, the Phase I comment period was opened on March 28, 2007. Public comments were received from two parties, the FIFRA Endangered Species Task Force (FESTF), and Syngenta Crop Protection, LLC. FESTF noted that the registrants are task force members and can rely on FESTF data, and Syngenta provided comments on various scientific aspects of the preliminary analysis.

The second phase of Registration Review starts with the issuance of the Final Work Plan. In this phase, any studies required by EPA to fill data gaps as part of the DCI will need to be conducted to update the data base for the active ingredient. The data generation phase can take two or more years, depending upon the duration of the required studies. If new studies are submitted, EPA reviews the studies and incorporates the information into the risk assessment. The draft risk assessment is issued in this phase, and public comments are sought on the assessment and any changes or mitigations that might be required by EPA.

Table II. Summary of Information Provided by EPA with the Initial Fomesafen Docket Opening

Area	*Summary of Information*	*Reference*
Use and Usage	Fomesafen is a preplant, preemergence and post-emergence herbicide used in numerous products and crops to control broadleaf weeds, grasses, and sedges; no residential uses; applied through aerial or ground spray equipment, FIFRA Section 3 and 24(c) registrations listed;	Fomesafen Summary Document Registration Review: Initial Docket March 2007 (*11*)
Environmental Fate and Effects Problem Formulation	Available ecological toxicity studies summarized, environmental exposure characterized, incident reporting summarized, conceptual model for ecological risk provided, and preliminary risks summarized. No additional ecological effects or environmental fate data noted.	Registration Review Ecological Risk Assessment Problem Formulation For: Fomesafen (*12*)
Health Effects Problem Formulation	Potential areas that may necessitate a new human health risk assessment explored; cancer classification, FQPA safety factor, dietary and occupational exposure, and incidence reporting. It was concluded that no new data were required and a new risk assessment was not likely needed for fomesafen Registration Review.	Fomesafen Sodium: HED Registration Review Problem Formulation Document (*13*)

As mentioned in Table II, no data were required for fomesafen, either for the human health or the environmental risk assessment. Therefore, no DCI was issued and there was no timeline associated with data generation or review (Note: Since the time of this assessment, EPA has required numerous ecological and toxicological studies as conditions of registration for new uses. A number of the studies that were required as conditions of registration for fomesafen are now typically requested for other compounds during Registration Reviews). On April 22, 2009, EPA issued the draft endangered species assessment, entitled

"Environmental Fate, Ecological Risk and Endangered Species Assessment in Support of the Registration Review of Fomesafen Sodium" (*10*). Also issued to the docket were the Federal Register Notice announcing the issuance of the assessment and request for public comments, a transmittal letter associated with the assessment, and a second transmittal letter initiating consultation with USFWS and NMFS.

The fomesafen draft assessment was a screening-level assessment. EPA concluded that fomesafen had the potential to directly or indirectly adversely affect endangered birds, amphibians, reptiles, small mammals, monocot and dicot plants, algae, and fish. EPA proposed draft mitigation as follows:

- For ground application of products containing fomesafen, setbacks from endangered species locations or their critical habitats at 350 feet for plants and 10 feet for animals
- For aerial application of products containing fomesafen, setbacks at 1,000 feet for plants and 100 feet for animals

The open comment period for Phase II of the fomesafen Registration Review ran from April 22 – August 21, 2009, including an extension of the time period that was granted by EPA (*14*). A total of 132 comments were submitted to the docket during this comment period. The majority of the comments were made by individuals or organizations that use products containing fomesafen. The primary registrant, Syngenta Crop Protection, LLC., submitted comments on the scientific aspects of the draft assessment. Because EPA used a lower-tier screening approach for the assessment, numerous refinements using the best available science were provided as part of Syngenta's comments. These are discussed in more detail in the second part of this chapter. The closing of the comment period ended Phase II of the fomesafen Registration Review.

In Phase III, EPA will address public comments received in Phase II, revise and finalize the draft risk assessment, and issue a proposed Registration Review decision. EPA will seek public comments on the decision, especially on label changes or mitigation that might be implemented. At the time of the writing of this chapter, EPA had not issued a revised assessment or Registration Review decision for fomesafen. The summary of the fomesafen Registration Review and its current status is presented in Table III.

Endangered Species Act Section 7 Consultation During the Fomesafen Registration Review Program

As shown in Table III, EPA initiated formal consultation under section 7 of the Endangered Species Act concurrently with issuance of the draft endangered species assessment during Phase II of Registration Review. NMFS responded in a letter on May 22, 2009 stating that request for formal consultation was premature, and expected that revisions to the fomesafen registration review package might trigger subsequent consultations (*16*). NMFS also stated that EPA's effects determination for fomesafen did not contain the information necessary to initiate formal consultation. Missing information listed by NMFS included:

- Description of the “action” and “action area”
- A description of any listed species or critical habitat that may be affected by the action
- Cumulative effects analysis
- Analysis of potential mixtures
- Information on direct lethal or sublethal responses
- Information on indirect effects on prey, primary producers, riparian vegetation
- Other relevant available information: on the action, the affected species, or critical habitat

Table III. General Registration Review Chronology that EPA has Followed for Fomesafen (as of July 2012)

Action	*EPA Final Work Plan Estimated Date (15)*	*Actual Date*
Docket Opened	March 2007	March 28, 2007
Phase I Public Comments	March – June 2007	March 28, 2007 – June 26, 2007
Final Work Plan	August 2007	August 29, 2007
Preliminary Risk Assessment	1st Quarter 2009	April 22, 2009
Phase II Public Comments	1st – 2nd Quarter 2009	April 22, 2009 – August 21, 2009
EPA Initiates Formal Consultation Under Section 7 of the Endangered Species Act	Not anticipated in Final Work Plan	April 22, 2009
NMFS Responds to EPA Consultation Initiation	Not anticipated in Final Work Plan	May 22, 2009
Final Risk Assessment	3rd Quarter 2009	Not yet issued
Phase III Public Comments	3rd – 4th Quarter 2009	Not yet opened
Final Decision and Begin Post Decision Follow-Up	1st Quarter 2010	Not yet issued

EPA’s attempt to initiate consultation during Phase II of the fomesafen Registration Review therefore did not result in a comprehensive consultation process. As no pesticides have completed formal consultation during Registration Review at the time of the writing of this chapter, it is unclear the optimal time for section 7 consultations to occur. Figure 2 describes the points at which consultation could potentially occur.

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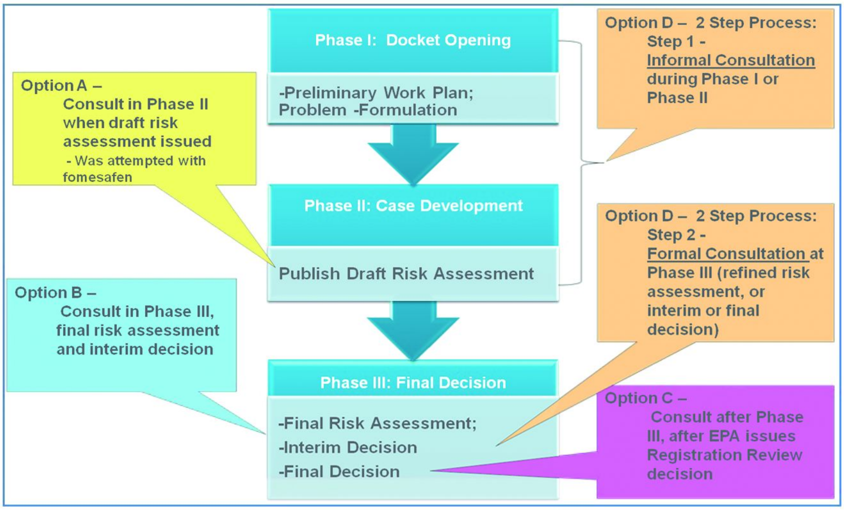

Figure 2. Options for Consultation Timing During Registration Review.

Option A (Figure 2) involves EPA initiating formal Section 7 consultation when the preliminary endangered species assessment document is issued, as was attempted with fomesafen. The goal of this approach would be inclusion of consulting agencies' inputs (NMFS and/or USFWS) prior to revision / finalization of the assessment. Potential disadvantages include the need to have multiple consultations for each Registration Review as was expressed in the NMFS letter of May 2009 (*16*). This might require NMFS and/or USFWS to issue interim biological opinions followed by final biological opinions.

Option B (Figure 2) would have EPA initiate consultation when the interim decision is issued. This approach would have the advantage of consultation just prior to issuance of a final decision, allowing for changes from both the public comments and the biological opinion to be considered in the final decision. It is unclear if the Services would be able to consult on an interim decision.

Option C (Figure 2) involves consultation after EPA has issued the final decision for Registration Review. This option would facilitate one single consultation step. However, it is unclear how EPA will work inputs received from NMFS and/or USFWS into a final decision. This option affords the possibility of EPA using the "optional formal consultation" provision of the counterpart regulations, where EPA would provide an environmental effects determination, complete with judgments on jeopardy and an incidental take statement, for the Services to review. The Services can adopt EPA's environmental effects determination as the biological opinion, or if the Services do not agree they can modify and then adopt the effects determination or write their own biological opinion (*17*, *18*).

Option D (Figure 2) would involve a multi-step process, where the consulting agencies are involved informally during the early phases of registration review, and formal consultation would occur, if necessary, upon issuance of either an interim or final Registration Review decision. Such a process would allow for early identification of areas of concern to the Services, and addressing of these areas in the assessments conducted by EPA. The prospect of submission of a mitigated action for consultation exists with this option.

Fomesafen Registration Review Draft Endangered Species Assessment and Scientific Refinements

The draft endangered species assessment for fomesafen prepared by EPA (*10*) was conducted using lower-tier modeling and exposure scenarios designed to be conservative in estimating risk. However higher-tier models and environmental exposure scenarios are available that could have been implemented into the draft assessment and would have provided a more realistic estimate of potential exposure and risk on which to establish mitigation measures to protect endangered species. This part of the chapter will describe some of the potential higher-tier modeling and other biological and geospatial information that can be used to refine both direct and indirect effects assessments for endangered species.

Direct Effects

Refinements to endangered species assessments for direct effects on listed species are possible through higher-tier exposure modeling, use of geospatial data and comparative biological and taxonomic analyses of listed species. Although the information in this chapter focuses primarily on plants, application of these and other refinements for other taxa in endangered species assessments could be implemented as well. Examples of potential refinements will be given in this chapter related to the endangered species assessment conducted by the EPA for fomesafen (*10*).

Exposure Refinements: Runoff

Potential risks to listed and non-listed terrestrial plants are evaluated by the EPA using the TerrPlant model. TerrPlant is a Tier 1 screening-level terrestrial plant exposure model that evaluates pesticide exposure. This model predicts estimated environmental concentrations (EECs) within adjacent dry and semi-aquatic areas as a function of pre-defined drift and pesticide runoff fractions. Runoff estimates are based on application rate, chemical solubility, and assumptions about drainage and receiving areas. TerrPlant does not consider environmental fate characteristics, but rather assumes a fixed, persistent concentration of runoff based on chemical solubility. Pesticide edge-of-field runoff load estimates should account for, at a minimum, environmental behavior and fate of the compound following application and temporal variability of exposure associated with runoff events. Rather than assuming an arbitrary edge-of-field runoff concentration of as much as 5% of the application rate (for compounds with a water solubility >100 mg/L), the Pesticide Root Zone Model (PRZM) edge of field flux data can be used to refine worst-case runoff estimates and consequently EECs for calculating terrestrial plant risk quotients (RQs). PRZM output provides a more thorough accounting of mass flux by accommodating multiple applications per year, whereas TerrPlant uses only the highest rate for a single application. Thus, the use of runoff flux data is appropriately conservative, and provides more realistic estimates of exposure.

Table IV. Comparison of Fomesafen Runoff Exposure Values Determined Using PRZM Runoff Flux and TerrPlant

Crop	*Cotton*
PRZM Scenario	TX Cotton
Rate (lbs a.i./A)	0.375
Date Applied	10-May
Yearly Maximum 21-d Average Runoff Flux (g/cm^2 x 10^{-5})	0.00097
Yearly Maximum 21-d Average Runoff Flux (lbs a.i./A)[a]	0.00087
TerrPlant Runoff (lbs a.i./A)	0.01875

[a] Maximum daily runoff flux (g/cm^2 x 10^{-5}) was converted to lbs a.i./A using the following equation:

$$\text{Runoff flux (lbs a.i./A)} = \frac{[\text{Runoff flux (g/cm}^2 \times 10^{-5})]\cdot[4.047 \times 10^{7}\ \text{cm}^2\text{/A}]}{453.6\ \text{g/lb}}$$

To demonstrate how PRZM affects interpretation of fomesafen behavior, Syngenta calculated PRZM runoff flux values using the PRZM/EXAMS model (shell pe5.pl, version 5.0, November 15, 2006) and the same environmental fate and physical-chemical property inputs used in the draft EPA assessment (*10*). As an example of this approach, the TX cotton ground spray scenario was assessed and resulting runoff flux exposure concentrations (converted from g/cm^2 X 10^{-5} to lbs a.i./A) were compared with runoff exposure concentrations calculated using TerrPlant (Table IV). Daily flux results were obtained by subtracting the previous day's cumulative flux from the current day's cumulative flux for each day of the 30-year (10,957 days) simulation. Since terrestrial plant effects endpoints from seedling emergence and vegetative vigor studies were determined for 21-day exposures, the runoff flux values were then calculated based on 21-day rolling averages (averages of days 1-21, 2-22, 3-23 etc.). Maximum 21-day rolling averages for each year (365 or 366 days) of the simulation were calculated, and from these 30 yearly maximum values, the 90th percentile level, was derived. The results indicate that fomesafen exposure to terrestrial plants through runoff is not as severe as predicted with the Tier 1 TerrPlant model, where the PRZM edge of field flux estimate was only ~5% of the TerrPlant exposure estimate.

Exposure Refinements: Drift

In addition to runoff estimated in TerrPlant, EPA assesses potential drift onto non-target plants using the AgDRIFT model. The AgDRIFT model was an initial model developed to predict drift but does not accommodate many factors that are known to greatly impact drift. AGDISP was developed to account for some of these factors. Tier 1 modeling with AgDRIFT produces a highly conservative estimation of spray drift deposition fractions using default and generic assumptions that can be refined using realistic model adjustments and alternatives. The only inputs available to the user in Tier 1 AgDRIFT are boom height and data percentile (for ground spray), and droplet size distribution (for ground and aerial applications). No further information about the spray material, equipment or climate conditions is considered. Furthermore, an analysis of model performance indicates that AgDRIFT over-predicts deposition fractions in the far field (>50 meters), by a factor of 4 (*19*). Therefore, for aerial applications, use of the AGDISP model is more appropriate. AGDISP, while also known to over-predict deposition fractions in the far field, is not as severely affected by this problem as AgDRIFT since the AGDISP model switches to a Gausian particle distribution at 50 m downwind. Thus AGDISP is a better model to use when estimating potential exposure levels in the far field. The following refinements should be incorporated into AGDISP to assess drift potential for aerial applications; examples are given using fomesafen:

- Region-specific use rates: Fomesafen has five distinct regional application rates specified on the label. Maximum application rates range from 0.375 lbs a.i./A in the southeastern US to 0.1875 lbs a.i./A in the northern Midwest.
- Minimum spray volume: For fomesafen, 5 gallons per acre (gpa) which is the required minimum spray volume for aerial applications as indicated on the label (vs. 2 gpa AgDRIFT default value).
- Appropriate evaporation rate: For fomesafen, 42.38 µm^2/deg C/sec (vs. 84.76 µm^2/deg C/sec AgDRIFT default value). The refined evaporation rate was selected based upon information contained in The Spray Drift Task Force Report entitled “Droplet Evaporation of Spray Drift Test Substances” (*20*). This report indicates that high salt-containing substances have reduced evaporation rates due to the high salt loading (see page 34 of (*20*)). Therefore, given that fomesafen is applied in the sodium salt form, the evaporation rate was reduced by a factor of 2 to the more realistic value of 42.38 µm^2/deg C/sec after determining the evaporation rates of all of the salt containing formulations that were tested and listed in the AgDRIFT spray material library.
- Other appropriate refinements identified for fomesafen such as drift mitigation language, spray nozzle selection and droplet size should also be included.

For ground applications, AgDRIFT is the only model available; however, some potential refinements are possible:

- Boom height: For fomesafen, approved ground applications are low boom (preplant surface, pre-emergence and/or early post-emergence). Fomesafen product labels caution against overlapping spray swaths, which can only be achieved by using a boom height no greater than 20 inches.
- Droplet size: For fomesafen, the label indicates that nozzles should be set to deliver medium quality spray (ASAE standard S-572).
- Use of 50th percentile data: The Spray Drift Task Force collected downwind deposition data in a series of ground-based field trials. These deposition data were collected into the far field for hundreds of feet from the end of the spray line in the field trials. At these far field distances, the deposition data become variable, due to outliers in the data set, leading to significant over-prediction of deposition and potential exposure. Taking into account the over-prediction of spray deposition in the far field, along with screening level assumptions at each step of the risk assessment (TerrPlant exposure modeling, NOAEC for the most sensitive test species, spray drift model inputs), use of the 50th percentile option as the most realistic estimate is recommended. This approach is similar to how the endangered Pacific salmon and steelhead species assessments were conducted for N-methyl organophosphates and carbamates (*21*, *22*).

A comparison of the reduction in deposition achieved with the different models and refinement inputs is illustrated in Table V. The use of higher-tier drift modeling that includes available refinements such as those listed above result in reduced exposure levels.

Table V. Comparison of drift deposition using AgDRIFT and AGDISP models[a]

Application Rate (lbs a.i./A)	*Distance (ft.)*	*AgDRIFT deposition[b] (lbs a.i./A)*	*AGDISP deposition[c] (lbs a.i./A)*	*AGDISP deposition with refinements[d] (lbs a.i./A)*
0.25	300	0.0037	0.0035	0.0021

[a] Spray quality for both models was medium-coarse [b] Default values for AgDRIFT are as follows: Boom height = 10 ft, canopy = 0 ft, Temp = 86°F, Wind speed = 10 mph, Swath displacement = 22.3 ft; Used Reflex formulation with water carrier (all densities assumed to be 1 g/mL); Spray volume = 2 gal/A, Evaporation rate: active fraction = 0.015 and nonvolatile fraction = 0.0625 [c] Used AgDRIFT default values where applicable [d] Used AgDRIFT default values where applicable with refinements to spray volume (5 gal/A) and evaporation rates (active fraction = 0.006, nonvolatile fraction = 0.025).

Geospatial Refinements

In the draft EPA assessment for fomesafen (*10*), information related to the proximity of fomesafen use sites relative to listed plant locations was not considered to accurately characterize the potential exposure of fomesafen to the listed plants. In addition, all listed plants in the United States were considered to be potentially affected by fomesafen, even though fomesafen use is restricted geographically based on the label. In order to get a more realistic understanding of what species could potentially be exposed to pesticides; comprehensive spatial refinements need to be incorporated into endangered species assessments. For fomesafen, a Tier 1 screening-level proximity analysis was conducted incorporating science-based clearance distances as determined using AgDRIFT for ground applications and AGDISP for aerial application. Relevant refinements as previously described in this chapter and regional application rates as described on the label were incorporated. The clearance distances provide the minimum distance between cultivated crops and the listed species location or critical habitat where exposure to fomesafen is evaluated to be below corresponding levels of concern for listed plants. Cultivated crop locations were obtained from 2001 National Land Cover Data (NLCD) class 82 (cultivated crops) (Multi-Resolution Land Characteristics (MRLC)). Locations of listed species were obtained from the Federal Insecticide, Fungicide, and Rodenticide Act Endangered Species Task Force (FESTF) Multi-Jurisdictional Dataset (MJD) ((*23*, *24*); http://www.festf.org/) and designated critical habitat information was obtained from the USFWS Critical Habitat Portal (http://criticalhabitat.fws.gov) and Syngenta internal data for those species in which spatial data were not available via the USFWS critical habitat portal. Species and/or critical habitat that were in close proximity (i.e. closer than the clearance distance) to cultivated crops were identified and assessed for potential use of further refinements including biological refinements and protections that could exclude these species from exposure.

Geospatial Refinements: Biological Aspects

Biological and ecological characteristics of some listed species preclude their presence near pesticide use sites; therefore, exposure is not likely to occur. Some examples of biological refinements that would exclude listed species from being exposed to pesticides are:

- The species might be restricted to high elevation habitats where pesticide-labeled crops are not grown.
- The species might not be present or might be dormant in a particular area when the pesticide is applied.
- The species might only be located in wooded or forested areas.
- The species might only be able to grow under certain soil conditions that do not match optimal soil conditions for growing crops where the pesticide could be used.

For example, in the refined fomesafen assessment, the rock gnome lichen, *Gymnoderma lineare*, which is only found in humid conditions in high elevations or rock gorges in low elevations, could be excluded from the assessment based on its habitat requirements. Information and documentation used to support such refinements include Federal Register Notices, Recovery Plans, NatureServe, species experts (such as State Chief Biologists, USFWS Species Experts, State Data Services Coordinators, State Endangered Species and Natural Heritage Botanists), open literature and soil survey data (SSURGO; Natural Resources Conservation Service (NRCS)).

Geospatial Refinements: Protections

In some instances, restrictions or practices (protections) are in place that would prevent exposure of listed species to pesticides. Protections might be established by a government agency or administration, by a federal, state, or local legislative body, or by a private party. These protections might apply to a single species or taxonomic group, or to several species or taxonomic groups. In some cases they might apply to an entire state or region. Examples of species management practice protections include:

- EPA management practices protect this species in the specified county.
- Federal (non-EPA) management practices protect this species in the specified county.
- State public management practices protect this species in the specified county.
- Local public management practices protect this species in the specified county.
- Private management practices protect this species in the specified county.

For fomesafen, ten species of plants in close proximity to cultivated crops (i.e., within the established clearance distance) have federal, state or private management practices that protect these species, therefore these species could be excluded from the assessment.

Geospatial Refinements: Subcounty Level

Additional refinements can be made in regard to the location of specific crops. Fomesafen is only used on specific crops as listed on the label; therefore, proximity of listed species or critical habitat to certain crops might not be relevant. Multi-year Cropland Data Layer (CDL) (United States Department of Agriculture - National Agricultural Statistics Service (USDA-NASS)) can be used to identify specific crops and rotated crops in areas near listed species and their critical habitat.

Taxonomic Refinements

In addition to the toxicity data provided in the required vegetative vigor and seedling emergence studies for registration purposes, toxicity data are often available from other studies such as efficacy screening trials for weeds and non-target assessments on crops and woody plants that can greatly expand the number of plant species tested. Through taxonomic comparison of the data from the tested species with the potentially affected listed plants, a more specific set of endpoints could be developed as opposed to using the results from the most sensitive species in non-target plant guideline studies to represent all species. The caveat to this form of analysis is the necessity for robust data. For example, in order to calculate reliable EC_{25} or NOEC values, replicated data with comprehensive archival and study reporting are desirable.

Table VI. Listed Species Related to Monocot and Dicot Test Species Showing Tolerance to Fomesafen at the Family-Level

Family	*Listed Species*	*Related Tested Species*	*EC_{25}[a] (lbs a.i./A)*
Cyperaceae	*Rhynchospora knieskernii* (Knieskern’s beaksedge)	*Cyperus esculentus* (Yellow nutsedge)	0.162 - 0.232
Liliaceae	*Helonias bullata* (Swamppink)	*Allium cepa* (Onion)	0.089 - >0.5
Fabaceae	*Aeschynomene virginica* (Virginia jointvetch)	*Glycine max* (Soybean)	0.022 - >0.5
	Astragalus robbinsii (Jesup’s milvetch)		
	Lespedeza leptostachya (Prairie lespedeza)		
	Trifolium stoloniferum (Running buffalo clover)		

[a] EC_{25} values for tested species were determined from vegetative vigor, seedling emergence and/or primary profile screening tests.

In the example for fomesafen, taxonomic data were compiled using the USDA Natural Resources Conservation Service Plants Database (http://plants.usda.gov) in order to compare taxonomic relatedness between listed species with all available pertinent species effects data. The resulting data base was comprised of 26 monocot and 26 dicot species tested in various studies. These data were compared to the listed species for taxonomic relatedness, which was limited to Family-level classification. The listed species identified were taxonomically compared to the 26 monocot and 26 dicot species tested. As indicated in the EPA draft assessment (*10*), the taxonomic comparison demonstrates that monocot species are considerably less sensitive to fomesafen than many dicot species.

However, sensitivity varied markedly within the dicot class. For example, members of the pea Family (Fabaceae), which includes 4 listed species, also demonstrate low sensitivity to fomesafen (Table VI). Soybeans are in the Family Fabaceae, and since fomesafen is applied safely to soybeans with no effects on growth or yield, it is unlikely that unacceptable effects would occur in other related members of this Family. Taxonomic relatedness at the Family level encompassed over half of the identified listed species. Given that monocots, as well as target crop species members from the Mallow (Malvaceae) and Pea (Fabaceae) Families within the dicot class, display low sensitivity to fomesafen, it is considered unlikely that fomesafen would have a significant impact on the viability of listed monocots or dicots within these particular Families.

Road Map for Evaluation of Direct Effects on Terrestrial Plants and Other Species

The following is a recommended approach for assessing the potential risks of pesticides on listed terrestrial plants. While the example below addresses effects to terrestrial plants, this approach could also be applied to other species from other taxonomic groups.

- *Stage 1.* Refine EECs generated from TerrPlant and AgDRIFT models used in conjunction with the NOAEC for the most sensitive species from either the seedling emergence or vegetative vigor studies in order to more accurately characterize potential risks to listed species. Refined exposure modeling using AGDISP for determining deposition from aerial applications and PRZM for determining runoff estimates is recommended. Furthermore, considering that the spatial bounds, which define the listed species potentially encompassed in the assessment, are influenced by exposure modeling predictions, the higher-tier AGDISP model should be used for establishing clearance distances.
- *Stage 2.* Once the spatial bounds have been established, they are applied to the use area. Inclusion of listed species potentially affected is dictated via spatial analysis of possible co-occurrence within the use area. For this purpose it is recommended to consider proximity analysis using Cropland Data Layer (CDL) information in conjunction with spatial database information for listed species derived from FESTF - MJD - IMS in order to define the listed species to be considered in the assessment.
- *Stage 3.* Once the initial compliment of listed species is compiled, it is recommended that the data be evaluated based on more refined biological and taxonomic considerations. Species-specific data should be considered from all available sources. These can include guideline studies, robust efficacy trials, recovery studies, literature studies, or any other applicable species-specific data. These data can be compared taxonomically to the listed species identified in stage 2. Provided taxonomic relatedness is demonstrated at the appropriate level, then the sensitivity value of the most taxonomically related species should be

used instead of a default value. For species where taxonomic relatedness cannot be established, then the most appropriate values based on class, nature of the effect in the study, and temporal considerations should be used.

- *Stage 4.* Subsequent to the identification of listed species, and appropriate assignment of sensitivity values, further refinements are recommended for consideration. Specifically, spatial analyses at the sub-county level using CDL data and other additional information such as soil type, elevation, current protections, temporality of applications and relation of applications to the critical stage of plant development should be considered to more appropriately establish proximity of listed species to potential use areas and define the potential for exposure.

Indirect Effects

Refinements previously described for direct effects also can be applied for assessing indirect effects. All listed species and their respective critical habitats within the clearance distances established from refined drift modeling for direct effects are included in the indirect effects assessment. Species information can be obtained from NatureServe data sets through the FESTF-MJD-IMS. The number of species potentially indirectly affected can be refined by assessing the diets and habitat requirements of each species to determine if the species is an obligate on the directly affected taxon (e.g., an endangered butterfly that relies solely on one species of plant for food and that plant is directly affected). Information on the diets and habitat requirements including critical habitat can be obtained from the FESTF MJD and the USFWS critical habitat portal, respectively. If the listed species does not rely solely on the directly affected taxon for food or habitat, it will likely not be indirectly affected and can be excluded from the assessment. Even a listed species identified as being an obligate on a specific taxon might not be indirectly affected if species within that taxon show differential sensitivity. For example, the Karner Blue butterfly relies solely on wild lupine for its food source. However, wild lupine is in the Family Fabaceae, which as previously mentioned, contains plants that are tolerant to fomesafen and therefore the Karner Blue's food source will likely not be adversely affected.

Many aquatic species depend on the services of riparian communities for maintaining their habitat (e.g., vegetated riparian areas minimize erosion and sediment input into streams). In the EPA draft assessment for fomesafen (*10*), indirect effects to listed aquatic species were determined based on the modeled direct effects of fomesafen on terrestrial plants in riparian areas. However, riparian areas are typically composed of a diverse plant community including herbaceous and woody species rather than a single sensitive species. To indicate that riparian areas, and consequently ecosystem services provided to the stream (i.e., erosion prevention and chemical filtration), would not be severely impacted by fomesafen exposure, data indicating the lack of sensitivity of woody species, monocots and certain dicots to fomesafen were used in addition to data from a plant recovery study as weight of evidence. Runoff refinements, as previously described for direct effects, were also used to refine EECs and when compared with the toxicity data from vegetative vigor and seedling emergence studies, RQs for several of the test species were below the level of concern (LOC) further demonstrating low potential impact at the community level. Additional data related to species sensitivity distributions (SSDs) and other probabilistic analyses of non-target plant toxicity data could also be used to better assess potential effects at the community level as compared to individual species.

Conclusions

The endangered species assessment process under Registration Review, at the time of the writing of this chapter, is still being structured. The appropriate timing and approach for consultation with the Services by EPA needs to be addressed to help streamline the process for efficiently completing these assessments. Refinements, as described in this chapter, should be implemented into the assessments prior to consultation so that the most accurate depiction of risk for listed species is determined.

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Chapter 10

FIFRA Registration Review and the Endangered Species Act: Clomazone Case Study

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As directed by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(g), and mandated by the Food Quality Protection Act, the U.S. Environmental Protection Agency (EPA) established a program, referred to as Registration Review, to review all pesticide registrations every 15 years. The program is intended to ensure that registered pesticides do not cause unreasonable risk to human health or the environment. The active ingredient clomazone was one of the first conventional pesticides reviewed under this program to have a national-level federally listed species assessment conducted by the EPA, and independently, data to support this assessment submitted by the registrant, FMC Corporation. EPA conducted the clomazone assessment as a pilot to explore methods to identify federally listed species that may be affected by the pesticide's uses. The U.S EPA's endangered species effects determination for clomazone conducted under the Registration Review program is reviewed and supportive data submitted by the registrant is discussed. Recommendations on how the endangered species assessment process in Registration Review can be further enhanced through reliance on data of this nature are also presented.

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
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Introduction

As directed by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(g), the U.S. Environmental Protection Agency (EPA) is required to establish procedures to periodically review all pesticide registrations. Each pesticide's registration will be completed every 15 years with the first cycle completed by October 1, 2022. The program, referred to as "Registration Review", was published in the Federal Register on August 9, 2006, with an effective date of October 10, 2006 (*1*). As stated in the Federal Register notice, "Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment".

As described in the Federal Register Notice, and on the Registration Review website (*2*), a pesticide's Registration Review case is initiated by establishing a docket and placing in this docket information, such as current registrations and registrants, risk assessment documents, incident data, a preliminary work plan explaining what EPA knows about the pesticide, and other information pertinent to the types of data the Agency may consider in the course of Registration Review. The EPA will publish a Federal Register Notice announcing the opening of the docket and a 60-day public comment period. After comments are received, the EPA issues a Final Work Plan which responds to comments, explains risk assessment and data needs, and provides an expected timeline for the Registration Review. During the public comment periods, interested parties may submit data or information to the EPA for consideration.

In conducting Registration Review for a given pesticide, the EPA reviews data and information and assesses changes since the pesticide's last review. A new or revised risk assessment is conducted if needed. The risk assessment may include an analysis of pesticide uses relative to any potentially affected species listed as endangered or threatened under the Endangered Species Act of 1973 (hereto forth referred to as "federally listed species"). A conclusion, referred to as an "effects determination", will be reached regarding the potential for the pesticide's uses to affect federally listed species and result in the destruction or adverse modification of designated critical habitat. If a new or revised risk assessment is conducted, a Federal Register Notice will announce its availability along with a 30-day public comment period. At the time of the publication of the Registration Review Federal Register Notice, the EPA envisioned that when the 30-day comment period opened, the risk assessment and effects determination would be sent to the U.S. Fish and Wildlife Service and National Marine Fisheries Service (collectively referred to as "the Services") in order to initiate consultation if warranted.

It was the EPA's intent that, after consultation with the Services is completed, if warranted, the EPA then would make a Registration Review decision as to whether a pesticide meets, or does not meet, the standard for registration under FIFRA. When this happens, a notice will be published in the Federal Register announcing the availability of a proposed decision, with a 60-day comment period. After considering comments on the proposed decision, the EPA will issue a Registration Review decision.

As described in letters from the EPA initiating formal consultation with the Services (*3*, *4*), the herbicide active ingredients clomazone and fomesafen were the first two conventional pesticide national ecological risk assessments and effects determinations conducted within the context of the Registration Review program. These two assessments and effects determinations were conducted as pilots to explore efficient and effective methods to identify federally listed species that may be affected by the pesticide's uses. In determining what species might and might not be exposed to the pesticide's uses, the clomazone pilot "utilized proximity analyses" as a primary component. Proximity analyses compare locations of federally listed species and designated critical habitat with locations of potential use sites. The fomesafen pilot "utilized to a large degree, biological characteristics," such as species diet and habitat information, as a primary component in determining what species might and might not be exposed to the pesticide's uses.

The clomazone docket was opened in February, 2007 (Docket ID: EPA-HQ-OPP-2009-0113) and clomazone was the first Registration Review major product to have a federally listed species assessment conducted by the EPA, and independently, data to support this assessment submitted by the registrant, FMC Corporation. The registrant's data collection process was conducted and a report was submitted to provide the EPA with information to support the Registration Review of clomazone under FIFRA (*5*). Specifically, the objective was to provide the EPA with information on the location of federally listed species and their proximity to sites where clomazone might be used. Information was also provided on site-specific and species-specific factors that may influence the exposure of listed species to clomazone and the potential direct effects, indirect effects, or effects on designated critical habitat. The information in the registrant's data submission is supported by full documentation, including original sources and was developed, organized, and documented using the Information Management System (FESTF IMS (*6*, *7*);), a work product of the FIFRA Endangered Species Task Force (FESTF). FMC Corporation is a full member of the FESTF.

The registrant's data submission is in the clomazone docket and available to the EPA and the Services for use in the conduct of federally listed species risk assessment and effects determination. The registrant's data are also available to support the EPA's determination of final risk management decisions. Reliance by the EPA and the Services on registrant-submitted proximity and potential exposure data transfers a large portion of the national assessment burden to the registrant without relinquishing the EPA's responsibilities to complete the risk determination and reach risk management decisions. However, because clomazone entered Registration Review as the first major product to be assessed, the registrant's data provided to the EPA are not yet fully addressed by the EPA's assessment.

This chapter will review the EPA's federally listed species effects determination for clomazone conducted under the Registration Review program, discuss data submitted by the registrant for use in the EPA's effects determination, and provide recommendations on how the federally listed species assessment process in Registration Review can be further enhanced through reliance on data of this nature.

Clomazone Registration Review Timeline

The docket for clomazone was opened and a Preliminary Work Plan was posted in February, 2007. After a public comment period, the Agency produced a Final Work Plan (FWP), which was signed on July 2, 2007 and revised to correct errors in the timeline on August 27, 2007 (*8*). The FWP stated that "the planned ecological risk assessment will allow the Agency to determine whether clomazone's use has "no effect" or "may affect" for a federally listed threatened and endangered species (listed species) or their designated critical habitat." It goes on to further state that if the assessment indicates "may affect" a listed species, or its designated critical habitat, the assessment will be refined to determine "likely to adversely affect" or "not likely to adversely affect" the species or critical habitat. When an assessment concludes in a "may affect", the EPA will consult with the Services as appropriate.

A full preliminary risk assessment, including a federally listed species assessment, was completed by the EPA and posted to the docket on April 22, 2009 (*9*). The Agency requested public comment and initiated formal consultation with the Services (*3*). A month after the EPA requested formal consultation, NMFS requested additional information for consultation (*10*). In the letter requesting consultation, the expected completion date was September, 2009 and the final decision was expected in January, 2010. As of the date of this chapter, the final decision is still pending while the EPA and the Services work to establish a consultation process.

The clomazone assessment continues to be considered by EPA as a pilot for developing a process for consultation between EPA and the Services. Registration Review is an emerging process which is experiencing delays in delivery of final decisions for the first products through the program.

EPA's Effects Determination for Clomazone

As mentioned previously, the EPA completed a preliminary risk assessment for clomazone, including a federally listed species effects determination and posted it to the clomazone docket on April 22, 2009 (*9*). The EPA's effects determination included an analysis for federally listed species identified as potentially at risk based on the results of the risk assessment. The analysis was based on the direct and indirect effects conclusions from the analysis of risk estimates. This covered a total of 1,360 distinct federally listed species (the total count of distinct species was obtained by compiling unique species names (common name and scientific name pairs) from the tables in Appendix I, J, and K (*9*)). An evaluation of potential effects on designated critical habitat was also conducted. Each species and its designated critical habitat were analyzed based on the approach described below, summarized from the assessment (reproduced from reference (*9*)).

Overall Approach

As stated on page 88 of the EPA's risk assessment (*9*), "The effects determination considers all available lines of evidence including estimates of risk, probability of mortality, type, degree, and magnitude of indirect and direct effects to listed and nonlisted species within the action area to make an effects determination for a specific listed species and [to evaluate the] potential for habitat modification to critical habitat."

To obtain the list of species to be considered in the effects determination, the EPA estimated exposures and compared the risk quotient (RQ) to the endangered species level of concern (LOC) for each species general taxonomic group (such as fish). Based on the risk estimation, if the endangered species LOC was exceeded, indicating a potential direct effect, all federally listed species in the species group were assigned a preliminary "may affect" determination. If the endangered species LOC was not exceeded for a particular species group, indicating no potential for direct effects, then the potential for indirect effects was assessed. If no potential for indirect effects was determined, all species in the species group under consideration were assigned a "No Effect" (NE) determination. If a potential for indirect effects was determined, then the species in the species group were assigned a preliminary "may affect" determination. Indirect and direct effects to listed species and the preliminary effects determination for species groups were compiled in summary tables.

A co-occurrence analysis was then conducted, using proximity data developed by the FESTF as the primary component, for all species assigned a preliminary "may affect" determination to evaluate if each species is within the Action Area. Based on the results of the co-occurrence analysis, a designation of No Effect (NE), May Affect but Not Likely to Adversely Affect (MA/NLAA), or May Affect and Likely to Adversely Affect (MA/LAA) was assigned to federally listed species occurrences and a designation of Habitat Modification of No Concern (HMONC) or Habitat Modification of Potential Concern (HMOPC) was assigned to species with designated critical habitat.

Action Area

The Action Area is defined by the furthest distal extent for any effect. As explained in EPA's risk assessment (*9*), in the case of clomazone, there are differences in the off-field distal extent between the micro-encapsulated (ME) and emulsifiable concentrate (EC) or wettable powder (WP) formulations. Due to the role that formulation plays in the size of the affected area, and potential consideration for mitigation options, EPA conducted an effects determination for the ME formulation separately from the EC and WP formulations. In addition, rice, which is only registered with the ME formulation, versus non-rice uses were also evaluated separately due to the differences in potential downstream distal extent of aquatic species effects.

For terrestrial species, the action area for the assessment was defined based on the furthest distance from treated fields for which effects to non-target plants were reported in the incident report database (OPP Incident Data System (IDS)).

Distances reported for alleged off-site clomazone movement were two miles for the EC formulation and one mile for the ME formulation. EPA assumed that the WP formulation has the same potential as the EC formulation to move offsite (two miles). For aquatic species, EPA determined that there are no effects or effects do not extend beyond the edge-of field for non-rice and dry-seeded rice uses. For wet-seeded rice, the action area for the assessment was extended to the ocean. These extreme distances and other overly conservative exposure estimates by EPA were rebutted by the registrant; the registrant's rebuttal arguments are posted in the clomazone docket (*11*).

Co-Occurrence Analysis

Based on the furthest extent projected by U.S. EPA for expected direct and indirect effects, the action area evaluated for the co-occurrence analysis for EC and WP formulations equated to a two mile radius out from any non-rice clomazone use site. For ME formulations, the action area evaluated for the co-occurrence analysis equated to a one-mile radius out from clomazone use sites in the terrestrial environment which then further extends to adjacent flowing waters downstream to the ocean for wet-seeded rice uses.

For this pilot, the FESTF IMS, a work product of the FIFRA Endangered Species Task Force (FESTF) (see Section below on Registrant Submitted Data for an overview of the FESTF IMS) was "used to identify counties with specific crop use and adjacent counties, and was used to perform an analysis of listed species that occur within 1 mile of use sites for ME formulation and that occur within 2 miles of use sites for the EC and WP formulations" (*9*). At the time of this assessment, counties with specific crop uses in the FESTF IMS were based on data from the Census of Agriculture (2002) and county-level species location data were based on data from: 1) EFED (June, 2003), 2) the NatureServe Multi-Jurisdictional Database (MJD) licensed by FESTF (the FESTF MJD (*12*, *13*);), and 3) publically available species by county presence lists from the U.S. Fish and Wildlife Service (for example, see http://www.fws.gov/mountain-prairie/endspp/CountyLists/Colorado.pdf).

To investigate individual co-occurrences identified by the FESTF IMS, EPA explained that sub-county spatial data from the FESTF MJD were used to determine the proximity of species occurrences (Element Occurrences, EOs) to potential clomazone use sites. The area where clomazone is used was defined as all cultivated land (from the NLCD, 2001 class 82) in counties having at least one clomazone registered crop (as reported by the Census of Agriculture). The only exception was in California where clomazone is only registered for use in wet-seeded rice. In California, rice field sites were defined as all cultivated land (from the NLCD, 2011 class 82) in counties having rice cultivation. For each species occurrence, the nearest distance to the area where clomazone could be used, in the county where the occurrence exists, as well as to the nearest area where clomazone could be used in each neighboring county, was calculated. Distances were calculated from the outermost point of the species occurrence to the nearest point in the land cover representing the clomazone use area. In addition to proximity data, the EPA noted that "results were evaluated to remove species in groups having NE or May affect but NLAA from risk estimation, independent of co-occurrence" and used additional lines of evidence to assign effects determinations. For example, species defined as subterranean ground insects/arachnids and mold insects were assigned NE due to no direct or indirect effects.

To evaluate critical habitat, spatial data from the U.S. Fish and Wildlife Service Critical Habitat Portal were utilized to generate proximity of critical habitat to potential clomazone use areas (represented by NLCD, class 82).

Results

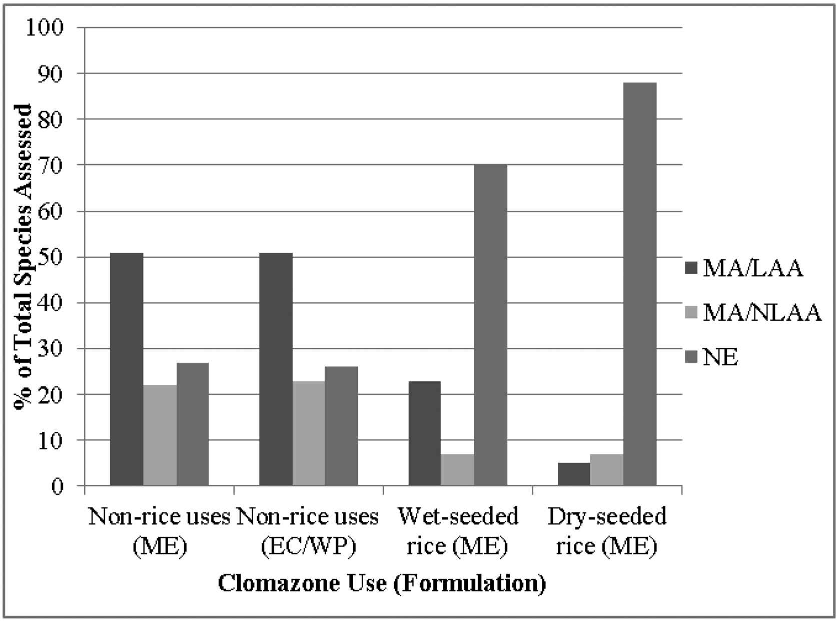

Figure 1. Percentage of Species Assigned to Each Effects Determination in EPA's Risk Assessment and Effects Determination for Clomazone.

Based on the proximity analysis and a few other additional lines of evidence, a species designation and a critical habitat modification determination was assigned by U. S. EPA to each species for the different use/formulations evaluated: non-rice uses/ME formulation, non-rice uses/EC and WP formulations, wet-seeded rice/ME formulation, and for dry-seeded rice/ME formulation. Where the action area did not overlap with a listed species occurrence or critical habitat (>1 mile from use sites for ME formulations and >2 miles from use sites for EC, WP formulations), based on the proximity analysis, a NE designation was assigned. Where at least one occurrence of a species overlapped, NE, MA/NLAA, or MA/LAA was assigned based on analysis of direct and indirect effects. The results of EPA's analysis are summarized in Figure 1. Effects determinations for all species assessed by EPA can be found in the risk assessment (*9*).

As shown in Figure 1, the majority of species were assigned a species effects determination of NE for rice (dry and wet-seeded) uses. These species will likely not require further evaluation. However, about 73% of species were assigned either a MA/NLAA or a MA/LAA determination for non-rice uses. Based on the EPA screening level approach to date, and without further refinement, further evaluation or risk management related to all of these species will draw heavily on resources from either the EPA's Office of Pesticide Programs or the Services.

Supportive Data Submitted by the Registrant

To support the EPA's effects determination, the registrant, FMC Corporation compiled proximity data as well as site-specific and species-specific information, in the FESTF IMS, a warehouse for the accumulation and storage of data relevant to endangered species and potential pesticide exposure. The FESTF IMS houses aggregated county-level location data and provides a system to document sub-county details that are documented through the collection process. A detailed written report was submitted to the clomazone docket by the registrant along with an electronic submission of supporting information in the FESTF IMS in February of 2009 (*5*). Reliance by EPA and the Services on registrant submitted proximity and potential exposure data transfers a large portion of the burden of the national assessment to the registrant without relinquishing the EPA's responsibilities to complete the risk determination and risk management decision. However, because clomazone entered Registration Review as the first major product to be assessed, the data provided to the EPA are not yet fully addressed by the EPA's assessment.

Because the EPA did not have the opportunity to use all information available to it in its federally listed species effects determination for clomazone, the number of "may affect" determinations is not fully informed and thus overconservative, resulting in potential consultation where none is actually necessary. The use of all available biological and other data contained in the registrant submitted data (*5*) will allow the Agency to greatly refine its effects determinations by presenting a more accurate effects determination, and providing scientific justifications that can be relied on to greatly reduce the number of "may affect" determinations by the EPA. Reducing the number of "may affect" determinations will allow consultation to focus only on those species having a reasonable expectation of exposure to levels of clomazone that present a potential risk, in specific local areas wherein that potential risk is not mitigated by current labeling or other biological or geographical circumstances.

Best Available Data

The information and conclusions presented in the registrant submitted data were based on a careful analysis of the best available scientific and commercial data relating to species, crops, and pesticide use. The submission utilized nationally aggregated data sources for species names, listing status, species locations, species attributes, crop locations and use practices. In utilizing such data, a balance must be reached between what is readily available and meaningful versus what might be more obscure data, the procurement of which is tedious. To the extent possible, known data gaps were either filled or documented as gaps, recognizing that certain isolated or highly specific data points are impossible to gather at the national assessment level. The logical place to further fill such data gaps might be at the implementation of the mitigation, as described by EPA's Endangered Species Protection Program (*14*).

Before being incorporated into the FESTF IMS, national data sources were validated and checked for quality and completeness, and, when feasible, augmented with additional data available at the regional or state level. The sections below discuss each data source in detail and describes the verification and supplementation (if required) process to which each data source was subject.

Taxa of Concern

The taxa of concern were stated in EPA's screening-level ecological risk assessment for clomazone, presented in the Ecological Risk Assessment Problem Formulation in the Registration Review Summary Document (*15*). The EPA problem formulation indicated that the following taxonomic groups are potentially at risk from clomazone uses:

- **Terrestrial plants**: Listed species in this taxonomic group are the primary focus of the registrant submitted data for direct effects.
- **Aquatic non-vascular plants**: No species of aquatic non-vascular plants are listed as threatened or endangered, so this taxonomic group was not addressed in the registrant submitted data.
- **Aquatic invertebrates**: Although levels of concern for aquatic invertebrates were slightly exceeded, the problem formulation noted that the screening-level risk assessment for aquatic taxa is based on the Generic Estimated Exposure Concentration (GENEEC) model, a tier 1 exposure model, and that refinement using EPA's tier II exposure models (PRZM/EXAMS) was expected to indicate that acute levels of concern are not exceeded. However, EPA informed FMC that the refined exposure modeling did indicate potential risk to aquatic invertebrates, and this taxonomic group was therefore included in the registrant submitted data for direct effects.
- **Small and medium-sized herbivorous mammals**: According to the EPA problem formulation, the concern for potential risk to mammals (chronic effects on small and medium-sized short grass consumers only) resulted from an incomplete screening-level assessment. The Environmental Fate and Effects Division (EFED) Science Chapter for clomazone (*16*) stated that "minimal acute risk is anticipated from the registered use of clomazone for … mammals. Minimal chronic risk is anticipated to mammals." However, at EPA's request, the data submitted by the registrant included mammals.

The registrant submitted data addressed the potential for direct effects on all federally listed (threatened and endangered) terrestrial plants, including monocots, dicots, conifers and cycads, and ferns and allies, as well as aquatic invertebrates and small- to medium-sized herbivorous mammals.

In addition, the clomazone Summary Document (*15*) stated, "Because of the potential risk to listed and non-listed plants, unicellular algae, aquatic invertebrates, and small and medium herbivorous mammals (short grass consumers only), should exposure occur, listed species in all taxa may potentially be affected indirectly due to alterations in their habitat (e.g., food sources, shelter, and areas to reproduce)" (emphasis added). The registrant submitted data that evaluated the following taxonomic groups for potential indirect effects: fish, crustaceans, mollusks, amphibians, reptiles, birds, mammals, insects, and aquatic vascular plants as well as terrestrial plants.

The FESTF IMS includes all federally listed (threatened and endangered) species within each taxonomic group, as indicated by the U.S. Fish and Wildlife Service's (USFWS) Threatened and Endangered Species System (TESS (*17*);). Species names in the FESTF IMS conform to those in the TESS.

Data Sources

Species Locations

The core species location data in the FESTF IMS were provided by EFED in June, 2003. To update the species location data with the most current information, location data from the NatureServe Multi-Jurisdictional Database (MJD) licensed to and received by FESTF on March 15, 2008 (FESTF MJD (*13*);), were added to the FESTF IMS before the information was compiled for the registrant submitted data. In the biological data for each Element Occurrence (EO, representing an individual record of species presence in a defined area) the FESTF MJD lists the county or counties in which that EO occurs. To supplement this biological information and ensure that all counties potentially having a species present were included, the accompanying spatial data (shape file) in the FESTF MJD was overlaid with county boundaries, and all counties that overlap with each shape file were determined. The lists derived from the biological data and spatial data were both incorporated into the FESTF IMS, and both were used in the registrant submitted data.

Because some taxonomic and geographic gaps exist in the FESTF MJD dataset, the MJD-based information was supplemented using county occurrence data issued by the USFWS for each state. For validation purposes, each USFWS Regional office was contacted to determine whether the state list was adequate or could be supplemented by more detailed readily available data (verification details were also submitted by the registrant in the FESTF IMS). The data source for each species location (i.e., the FESTF MJD and/or a USFWS county list) is indicated in the FESTF IMS for each co-occurrence through the use of a species location data source code.

Locations of Critical Habitat

The spatial extent of designated critical habitat for all available listed species was obtained from spatial data files (shape files) downloaded from the USFWS Critical Habitat Portal (*18*) on October 2, 2008. At the time of downloading, the Critical Habitat Portal contained spatial data files for 491 species.

An extensive analysis and data processing methodology was developed to: 1) determine which features from the shape files represent final critical habitat, and 2) associate each shape feature with the TESS scientific name or names to which the feature applies. With this process complete, a nation-wide critical habitat dataset was produced along with an efficient process for updating this dataset as needed to respond to the provision of new data by the USFWS.

Locations of Use

Counties containing specific clomazone labeled crop use sites were determined from the 2002 Census of Agriculture (*19*). The Census of Agriculture is described by the USDA as "the only source of uniform, comprehensive agricultural data for every state and county or county equivalent in the United States." The Census is conducted every five years, and the 2002 Census was the most recent that had been published at the time of the registrant data submission. This data set constituted the "best available data" for crop locations in the U.S. and Puerto Rico.

To account for potential exposure via environmental processes, counties adjacent to counties with potential use sites were also identified. A list of counties physically adjacent to each county in the U.S. (including counties that touch another county only at the corners) was incorporated into the FESTF IMS, separate from the list of counties containing use sites. This approach could be considered conservative because the registrant submitted data not only included counties with a species of concern and a potential use site, but also neighboring counties with a species of concern but no potential use site.

Land Cover

Specific crop location data within counties were not uniformly available for use in the registrant submitted data for clomazone. However, high-resolution spatial data on the location of cultivated land throughout the U.S. was available from the U.S. Geological Survey (USGS) 2001 National Land Cover Database (NLCD (*20*);). Landcover locations for potential clomazone use sites were represented by the class 82, cultivated crops. Grid cells were extracted from the NLCD and converted to polygons for spatial analysis in the registrant submitted data.

Co-Occurrence Data Collection

The data sources described above were aggregated in the FESTF IMS and utilized to generate county-based co-occurrences. Each co-occurrence represented a listed species with a clomazone-labeled use site in the same or neighboring county (included to account for movement of the pesticide across county borders). For each co-occurrence, information was compiled and reviewed for relevancy to the potential for direct or indirect effects on federally listed species in that county as a result of clomazone use on that crop in the same or a neighboring county. All supporting information contributing to a risk characterization was summarized in a statement of "finding" that is linked to all original documentation supporting that finding. A finding is a standardized conclusion statement about the species/use site intersection. Based on the information collected, findings provide a conclusion about potential risk, either excluding a species from concern, indicating that protections exist or that further research is needed. The findings were recorded, as appropriate, in the FESTF IMS along with original source documents and other resources as described below.

Resources Provided in the Registrant Submission

In the development of findings in the registrant submission, various reference sources were consulted, including USFWS species accounts, Federal Register Notices, county bulletins, federal and state level inventories and departments, consultations with species and site experts, and the NatureServe database (*13*). The NatureServe database provided information on species habitat, risk factors, location data (both on a county and sub-county level) and other species-specific information. Data occurring in the NatureServe database are often similar to data found in USFWS species accounts or in USFWS Redbook entries, although these latter accounts and/or entries are not always available.

Each finding developed in the FESTF IMS and electronically submitted by the registrant includes links directing users to immediate access to original source documents, so that the captured data can be readily verified. Thus, all supporting details are available for further review by the EPA or the Services. In addition, any contact with species or site experts was recorded in the FESTF IMS, with adequate information to allow verification of the expert's qualifications or further contact with that expert.

In addition, Access databases with proximity data for federally listed species (from reference (*13*)) and critical habitat (from the U.S. FWS CH Portal as described above) locations to cultivated crops (NLCD, 2001, class 82) were attached to the FESTF IMS and included in the registrant's electronic submission. Where available, sub-county data were also provided as static maps displaying species locations (from reference (*13*)) and potential clomazone use sites, represented by cultivated crops (NLCD, class 82). Maps were uploaded to the appropriate finding in the FESTF IMS and included in the electronic submission.

Results

The findings for each co-occurrence were based on the most current data available and included proximity data, as was utilized by the EPA in their risk assessment, and a wealth of additional spatial and non-spatial lines of evidence. Additional lines of evidence included biological and ecological factors that may preclude exposure such as habitat characteristics, elevation separation between species and crop locations, species' diet and dependencies (lack of dependency on plants for diet, shelter, reproduction), survey data indicating when a species was last observed in a particular location, information from the Census of Agriculture reporting which use sites occur in each county, as well as information from registrant submitted field data and clomazone product label language. In addition, information on existing protections such as measures or land owner agreements that are in place and provide protection for federally listed species, was collected and included in the registrant's submission of supportive data. These data make major contributions to clarify the relationship between potential clomazone use sites and species locations, thus reducing the subset of interactions that must be further evaluated or considered for risk management. Examples of the types of additional spatial and non-spatial information available in the registrant submission follow.

Example 1: The Little Kern golden trout was assigned an MA/LAA for wet-seeded rice uses in the EPA risk assessment (*9*). The proximity data submitted by the registrant indicates that all locations of this species and NLCD class 82 (representing potential clomazone use areas) are separated by more than seven miles. However, rice is the only use registered in California and the closest NLCD class 82 to occurrences of Little Kern golden trout in a county where rice has been reported by the Census of Agriculture (2002), is at least 22 miles. Furthermore, data collected and a map generated by the registrant shows there is an elevational separation between the species and potential clomazone use sites; the species is known only from the Little Kern River in Tulare County which occurs at high elevations in the Sierra Nevada mountain range (*13*, *21*), significantly up river from any potential rice use sites. This information could support changing the determination from MA/LAA to NE.

Example 2: The Puritan tiger beetle was assigned an MA/LAA for non-rice uses in the EPA's risk assessment (*9*). Data collected and submitted by the registrant indicates that this species is a predator in open areas. It is not reliant on plant species and would therefore not be subject to indirect effects. This information could support changing the determination from MA/LAA to MA/NLAA or NE.

Example 3: The Florida grasshopper sparrow was assigned an MA/LAA for non-rice uses in the EPA risk assessment (*9*). The registrant submission provides information to support an NE determination for some locations of the sparrow because the species has not been observed in over 30 years and is therefore no longer present in those locations (*13*). Other locations of the sparrow are more than two miles from NLCD class 82, representative of clomazone use sites, as supported by registrant-submitted data. An NE determination would be supported for these locations as well because they are beyond the Action Area for non-rice uses. For the remainder of sparrow occurrences, the registrant submission supports an MA/NLAA determination. Data collected suggest it is unlikely that clomazone would reach the bird's habitat, consisting of large blocks of fire-prone habitat, in amounts to cause adverse modification. Also, it is unlikely that clomazone would cause adverse modification to the bird's diet, consisting of a wide variety of insects and plants.

As further discussed in comments posted to the clomazone docket by the registrant (*11*), when the supportive data submitted by the registrant is considered and relied upon, the number of species for which EPA chooses to assign a MA/LAA for non-rice uses could be reduced by ~74%, from 685 to 177 for the ME formulation (see Figure 2). Likewise, species assigned a MA/LAA in the EPA risk assessment for these uses of the EC and WP formulations could be reduced from 697 to 179. Similar reductions in the number of MA/LAA species remaining after reliance on registrant submitted data are seen for the rice uses, as shown in Figure 2.

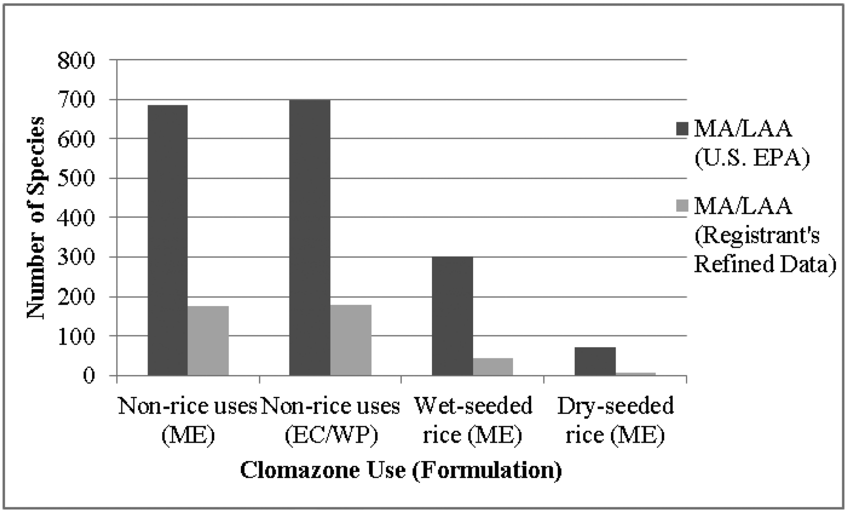

Figure 2. Number of Species Assigned MA/LAA Effects Determinations in EPA's Risk Assessment and Number of MA/LAA Species Remaining After Reliance upon Registrant Submitted Data.

Recommendations for Use of Registrant Data

In response to EPA's ecological risk assessment and effects determination for clomazone, the registrant submitted comments consisting of: 1) an evaluation of EPA's risk assessment and recommendations for correcting or refining it, 2) the consultation process as implemented by EPA at this point in Registration Review, and 3) EPA's effects determinations and how they may benefit from use of registrant submitted data (*11*). These comments were posted to the clomazone docket and will be used in this section as instructional towards the goals of this chapter; that is, to discuss lessons learned to date from the clomazone process, from the registrant's viewpoint, and to make suggestions on how the pesticide assessment process can be further enhanced.

Lessons Learned: Registrant Viewpoints

During the registrant's collection and submission of supportive data and review of the EPA's risk assessment and effects determination for clomazone, many lessons became apparent. First, as illustrated by the discussion of the registrant submitted data, there is a wealth of information available to support and enhance the EPA's effects determination. Early reliance by EPA on these data would focus the effects determination and, if necessary, the resulting consultation on species that truly have a potential for exposure, thus conserving Agency resources and shortening the consultation process. Second, meeting with the registrant early and frequently throughout the Registration Review process would help to minimize time-consuming errors. This would also keep the registrant informed of the status of Registration Review. Similarly, lack of participation of the registrant in the consultation process or pre-consultation meetings leaves uncertainty about status and next steps, and deprives the process of knowledge that the registrant can contribute to the process.

FIFRA-ESA Process Recommendations

It is recognized that Registration Review and the consultation procedures for FIRFA were, at the time of the clomazone assessment, and still are, an emerging process. It is also recognized that the process is driven by strict timelines. As this process emerges, one recommendation is that EPA and the registrant should meet prior to EPA's initiation of product review to support EPA's understanding of current uses and available or expected data. This would eliminate time spent analyzing uses that are no longer supported by the registrant and allow for the registrant to start compiling any needed data as early as possible. Another recommendation is that the applicant, as defined under the ESA, should be fully engaged by EPA in pre-consultation communications. This would enhance transparency in the process and allow the applicant to provide supportive data to the process. A final recommendation is that, as an applicant, the registrant should be included in critical points in Services and EPA interactions. This would allow the registrant to be engaged in communications and aware of the status and potential next steps.

While the clomazone pilot Registration Review/consultation process has not yet reached the point of the consideration of whether local use restrictions (per the ESPP process (*14*);) are needed for protection of federally listed species considered to be at potential risk, it is useful to envision how the more detailed data provided by the registrant might contribute to interactions between state and local entities if county bulletins are needed. For example, because the FESTF IMS is a web-based system, with data grouped by county, it is feasible that FESTF IMS access could be shared with a state or federal authority for their region only. This would put consolidated information at the fingertips of all regulating authorities and might ease the workload and facilitate bulletin development by providing further details about species-use relationships at the local level. These details, and additional state or regional input, would build a strong localized profile for the purpose of implementation of any necessary mitigations.

Registration Review Recommendations

It is clearly recognized that the schedule for Registration Review of clomazone limited the ability of EPA scientists to fully consider all data available to them. However, as illustrated by the registrant submission of supportive data for clomazone, these data make major contributions to document the relationship between potential use sites and species locations, and need to be available to EPA early in their review process, and potentially, at the implementation of any necessary mitigations. The supportive species findings developed by registrants are fully documented, with original source documents and other resources fully and immediately accessible for verification by EPA. It is recommended that EPA should rely on such findings and can do so with confidence. Also, EPA and the Services should take advantage of best available data submitted by the registrant to reduce the subset of species that must be considered for risk management. This will help to conserve the EPA's and the Service's efforts for the species that are truly at risk, not only benefiting these organizations but also the at-risk species.

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Chapter 11

Use of Simple Stream Modeling Methods To Assess the Potential Risks of Malathion to Salmonids

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This paper considers the potential effects of malathion to salmonid populations in the Pacific Northwest. It refines a previous assessment by accounting for stream dilution with the AgDRIFT model for pesticide spray drift. A generalized Haber's Law model was used to model toxicity for different concentration-time profiles. Risk was considered for salmonids directly and to a sensitive prey species, *Daphnia magna,* assuming a 100 foot buffer distance between the field edge and the water body. Assuming that the limited ecotoxicology data available to characterize the Haber's Law exponent are representative, the analysis showed that direct effects to salmonids are highly unlikely. There is a small possibility of effects to *Daphnia magna* for streams with shallow depths and relatively still water. However, most other invertebrates are much less sensitive to malathion and salmonids have a diverse diet. Therefore, infrequent effects to a small number of prey species are very unlikely to affect salmonid populations.

Introduction

In recent years, there has been significant interest regarding the potential effect of pesticides on Pacific salmonids. Under the Endangered Species Act (ESA), the National Marine Fisheries Service (NMFS) has produced a series of biological opinions (BOs) that have assessed the potential risks to salmonids from organophosphorous and carbamate pesticides. This paper is focused on the assessment for malathion, which was included in the first BO along with

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chlorpyrifos and diazinon (*1*). The BO included an assessment of potential risks to salmonids in 28 evolutionary significant units (ESUs).

The concentrations of malathion in salmonid habitat are generally much too low to directly affect salmonids even with extreme methods of estimating concentrations. However, among several lines of evidence in the BO, one of the key conclusions was that salmonid prey, particularly invertebrates, were more sensitive and could be impacted by malathion, and the loss of prey was determined to have a significant effect on salmonid populations.

One of the key sources of information developed in the BO was an estimate of potential concentrations of malathion in salmonid habitat. The estimates were derived using both aquatic water modeling and from a review of historical environmental measurements. While the environmental measurements were predominantly very low, NMFS placed more emphasis on the modeling estimates, which allowed a consideration of worst-case scenarios potentially not captured in the measurement programs.

One of the key sources of modeling estimates was derived with the AgDRIFT model (*2*). AgDRIFT is a commonly used tool that allows the estimation of concentrations in a downwind water body following a pesticide application. The model accounts for a variety of factors, including the application rate, the application method, the droplet size, and the size of the water body. Bogen and Reiss (*3*) found that the methods used in the BO were flawed because salmonids generally reside in flowing water bodies. However, the AgDRIFT modeling estimates did not consider stream dilution. Instead, the AgDRIFT estimates were based on the instantaneous concentration of pesticide at the moment that a plume hit the water body (assuming instantaneous mixing). This estimate was compared with ecotoxicology data where the organisms were exposed for 48 to 96 hours, which represents a mismatch of exposure and toxicity. If stream dilution was taken into account, Bogen and Reiss (*3*) estimated that the resulting concentrations for pesticides were about 50- to 300-fold less.

This paper applies the stream modeling methodology of Bogen and Reiss (*3*) to malathion and includes a risk assessment using malathion ecotoxicity data.

Material and Methods

While it was not used in the BO, the AgDRIFT model includes a Stream Assessment Tool that allows the user to estimate stream dilution after a pesticide plume first enters a water body. This module within AgDRIFT uses an advection-diffusion equation to estimate the dispersion of pesticide as it travels downstream. The use of this tool enables a calculation of the longer-term average concentrations to which salmonids and prey would be exposed, allowing a more accurate comparison with the ecotoxicity data.

The AgDRIFT model provides estimates of concentrations at different distances downstream of the plume impact point. The downstream distance that yielded the highest concentration was used in the analysis. Counterbalancing this conservative assumption, only a single application is considered. It is possible that multiple applications in the same general area could affect stream concentrations.

Before applying the average concentrations derived by the AgDRIFT Stream Assessment Tool, there is a significant toxicological issue to address. It is conceivable that a short-term pulse exposure might have a different magnitude of effect than a much smaller but constant and longer lasting exposure that has an identical average concentration over time. The effect that the time pattern of exposure has on toxicity is modeled using a generalized version of Haber's Law (*4*):

$$L = C^n T \qquad \text{(I)}$$

where *L* is the toxic loading, *C* is concentration, *T* is time, and *n* is the toxic load exponent. When ecotoxicological data are available with the same outcome and different time durations, the toxic load exponent can be estimated. Equation I can then be used to estimate toxicity for different concentration-time regimes.

Bogen and Reiss (*3*) applied the AgDRIFT model to a range of salmonid habitat characteristics accounting for depth and stream velocity. An exponential decline in concentration over time was observed, allowing the model results to be easily characterized mathematically. Applying the exponential concentration decline formulation and the generalized Haber's Law, Bogen and Reiss found that the dilution ratio, ρ, (initial concentration/equivalent constant concentration) can be estimated as:

$$\lim_{kT \to \infty} \rho = (n\, k\, T_{con})^{1/n} \qquad \text{(II)}$$

where *k* is the first-order rate constant for the concentration decline, and T_{con} is the duration. The equivalent constant concentration represents the time-averaged concentration (over T_{con}) that is equivalent in toxicity to the initial pulse concentration, accounting for the Haber's Law exponent. Thus, the equivalent concentration can be compared with an ecotoxicity effect value for a study with duration of T_{con}.

Results

Estimation of Haber's Law Exponent for Malathion

Bogen and Reiss (*3*) searched the literature for ecotoxicology studies that included measurements over multiple time durations and fitted the data using Equation I to derive Haber's Law exponents for malathion and other pesticides. Several studies with adequate data were identified.

Ren et al. measured the LC_{50} of malathion to *Daphnia magna* over 24 and 48 hours with exposures up to 10 ppb (*5*). *Daphnia magna* was the most sensitive invertebrate species for malathion in the studies conducted by the registrant and was the key basis for the NMFS BiOp conclusions. The registrant *Daphnia magna* guideline study (*6*) also included two time points (24 and 48 hours), but did not have a sufficiently robust dose-response (i.e., a range of responses at different doses) to estimate the Haber's Law exponent with Equation I. However, the registrant study does show a dramatic difference in response at 24 and 48 hours. At the highest exposure of 1.3 ppb, 10% of the organisms were immobilized at 24 hours, while 80% were immobilized at 48 hours. Applying a non-generalized Haber's Law (i.e., with $n = 1$), a 40% immobilization would have been predicted at 24 hours based on the 48-hour measurement. The actual immobilization was 4 times lower. The results from Ren et al. (*5*) and the registrant study were consistent. The 48-hour EC_{50} in the registrant study was 0.72 ppb, whereas the LC_{50} in Ren et al. (*5*) was 0.9 ppb.

Gries and Purghart was another registrant-sponsored study for rainbow trout (*Oncorhynchus mykiss*), a salmonid species (*7*). In this study, the rainbow trout were exposed to five doses up to 1.6 ppm and observed at six time points up to 96 hours. The 96 hour LC_{50} was 0.18 ppm (180 ppb). Thus, rainbow trout were about 200 times less sensitive to malathion than *Daphnia magna*.

Legierse et al. measured the LC_{50} of malathion for guppies (*Poecilia reticulate*) for 14 different time points up to 336 hours (14 days). While not a common salmonid prey item, this study provides the most extensive dose-response vs. time data that were identified (*8*). There would be less uncertainty in the analysis if studies were available with as many time points as included in Legierse et al. for more common salmonid prey. The LC_{50} for malathion ranged from 3.8 ppm at 24 hours to 0.83 ppm at 336 hours.

Table I shows the fitted Haber's Law exponents for each of the three studies. The estimated values were 0.48 (*Daphnia magna*), 1.8 (rainbow trout), and 0.91 (guppies). A Haber's Law exponent of 1 indicates that the toxicity at two time points can be estimated as the inverse ratio of the time values. For example, if the LC_{50} is 10 ppb at 48 hours, the LC_{50} would be 20 ppb at 24 hours with $n = 1$. For Haber's Law exponents less than 1, the ratio of toxicity at different time points is greater than the ratio of durations. At Haber's Law exponents greater than 1, the inverse ratio of toxicity at different time points is less than the ratio of the durations.

Table I. Estimated Haber's Law exponents (*n*) for three studies for malathion

Study	***Species***	***n***
Ren et al. (*5*)	Water flea (*Daphnia magna*)	0.48
Gries and Purghart (*7*)	Rainbow trout (*Oncorhynchus mykiss*)	1.8
Legierse et al. (*8*)	Guppy (*Poecilia reticulate*)	0.91

To illustrate the effect of a Haber's Law exponent of less than 1, Figure 1 shows the equivalent constant concentration to cause the same effect for different durations of exposure for $n = 0.48$ (estimated value for *Daphnia magna*). A toxic loading factor of 2 was assumed so that the concentration at 2 days is set a 1 ppb. For a 0.1 hour (6 minute) duration, an exposure of 513 ppb will cause the same effect as an exposure of 1 ppb for 2 days. Similarly, the equivalent effect concentrations are 76 ppb at 15 minutes, 18 ppb at 30 minutes, and 4.2 ppb at 1 hour. This dramatically shows how important it is to account for the duration of exposure.

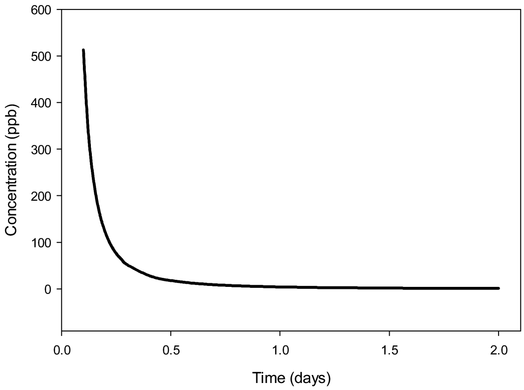

Figure 1. Equivalent effect concentrations for Haber's Law exponent of n = 0.48.

Estimation of Time-Averaged Exposures in Salmonid Habitat

A survey of salmonid habitat in Oregon found that salmonids may sometimes reside in non-flowing types of habitat, such as backwater pools, damned pools, and beaver ponds, accounting for about 20% of the total juvenile salmonid capacity (*9*). The remainder reside in flowing water bodies, which is the focus of this analysis. It should be noted that even water bodies such as backwater pools will have some dilution over time from either direct exchange of water with the main water body or from hyporheic flow, which is a mixing of shallow groundwater and surface water.

Bogen and Reiss (*3*) considered a range of habitat stream scenarios with different depths and velocities. The depths ranged from 0.1 to 0.5 meters and the velocities ranged from 0.0213 m/sec to 0.5 m/sec. It is important to consider that both very shallow habitat (0.1 meters or about 4 inches) and very slow stream velocity (0.0213 m/sec or about 4 feet per minute) assumptions were included in the analysis.

To estimate concentrations in the streams, the AgDRIFT model was used. The application rates allowed for malathion range from less than 1 lb active ingredient (ai)/acre to 2.5 lb ai/acre, with most application rates being between 1 and 2 lb a.i./acre. Aerial applications lead to significantly more drift than other types of applications. To consider a range of possible scenarios, aerial application rates of 1 lb ai/acre and 2.5 lb ai/acre were considered.

Table II summarizes other relevant parameters in the AgDRIFT modeling. Of note, the distance between the edge of the field and water body was assumed to be 100 feet. This value was chosen for demonstration purposes, but the methods in the paper can be applied for other distances. At this distance, it is assumed that runoff is not a significant loading factor to the stream. It is also means that the calculations essentially are testing the reliability of a 100 feet buffer zone for controlling impacts of spray drift. Tier 1 AgDRIFT default values were used for all parameters except the application rate, buffer distance, and stream depth and velocity. Of note, among the many conservative assumptions, the wind is assumed to be moving directly from the field to the pond. Any deviation from this assumption would result in lower concentrations and even no impact on the stream for many wind directions.

Table II. Parameters for AgDRIFT modeling

Parameter	***Values***
Application rate	1.5 or 5 lb ai/acre
Distance between edge of field and water body	100 feet
Stream depth	0.1 to 0.5 meters
Stream velocity	0.0213 to 0.5 m/sec
Stream width	30 m
Flight lines	20
Swath width	60 feet
Riparian interception factor	0.2
Droplet size	Fine-to-medium distribution (volume median diameter or 255 μm)
Wind speed	10 miles per hour
Wind direction	Directly from field to stream
Temperature	86°F
Humidity	50%
Atmospheric stability	Neutral

Tables III and IV summarize the estimated equivalent concentrations over 48 hours (*Daphnia magna*) and 96 hours (rainbow trout) using Equation II and applying the AgDRIFT Stream Assessment estimates compiled from Bogen and Reiss (*3*). The equivalent concentration is a time-weighted average concentration that accounts for the Haber's Law exponent. Table III provides the results for an application rate of 1.0 lb ai/acre and Table IV provides the results of application rate of 2.5 lb ai/acre. The concentrations for *Daphnia magna* and rainbow trout are different because the averaging duration is different (48 hours for *Daphnia magna* and 96 hours for rainbow trout) to allow comparison with standard ecotoxicity test, and because the Haber's Law exponent is factored in, which is why the term "equivalent concentration" is used.

The estimated equivalent concentrations for *Daphnia magna* range from 0.0002 to 0.38 ppb for a 1.0 lb ai/acre application rate and from 0.001 to 0.94 ppb for a 2.5 lb ai/acre application rate. For rainbow trout, the estimated equivalent concentrations range from 0.2 to 6.3 ppb at 1.0 lb ai/acre and from 0.5 to 15.7 ppb at 2.5 lb ai/acre.

Table III. Equivalent concentrations using Equation II for an application rate of 1.0 lb/acre (100 foot buffer distance)

Depth (m)	*Velocity (m/sec)*	*k (hr^{-1})*	*C_o (ppb)*	*Equivalent Concentration*	
				Daphnia magna [(a)]	*Rainbow Trout* [(b)]
0.1	0.0213	0.57	80.4	0.38	6.3
0.1	0.1	1.9	55.8	0.021	2.2
0.1	0.2	3.2	46.2	0.006	1.4
0.1	0.3	4.5	41.2	0.003	1.0
0.1	0.5	6.5	36.8	0.001	0.74
0.25	0.0213	0.79	37.4	0.089	2.4
0.25	0.1	3.0	27	0.004	0.84
0.25	0.3	7.0	20.2	0.001	0.39
0.5	0.0213	1.1	20.4	0.024	1.1
0.5	0.1	4.6	15.02	0.001	0.37
0.5	0.3	8.0	11.24	0.0002	0.20

(a) Equivalent concentration over 48 hours accounting for Haber's Law exponent of $n = 0.48$. (b) Equivalent concentration over 96 hours accounting for Haber's Law exponent of $n = 1.8$.

Estimation of Risk Quotients for *Daphnia magna* and Rainbow Trout

From the equivalent concentration estimates in Tables III and IV, the risk quotient (RQ) can be estimated using the LC_{50} of 0.9 ppb for *Daphnia magna* and the LC_{50} of 180 ppb for rainbow trout, as summarized in Table V. The RQ is defined as the exposure divided by the toxicity level. Thus, lower numbers mean that the exposure is relatively less than the level that may cause an effect.

Table IV. Equivalent concentrations using Equation II for an application rate of 2.5 lb/acre (100 foot buffer distance)

Depth (m)	*Velocity (m/sec)*	*k (hr^{-1})*	*C_o (ppb)*	*Equivalent Concentration*	
				Daphnia magna [(a)]	*Rainbow Trout* [(b)]
0.1	0.0213	0.57	201	0.94	15.7
0.1	0.1	1.9	139.5	0.05	5.6
0.1	0.2	3.2	115.5	0.01	3.5
0.1	0.3	4.5	103	0.01	2.6
0.1	0.5	6.5	92	0.00	1.9
0.25	0.0213	0.79	93.5	0.22	6.1
0.25	0.1	3.0	67.5	0.01	2.1
0.25	0.3	7.0	50.5	0.001	1.0
0.5	0.0213	1.1	51	0.06	2.8
0.5	0.1	4.6	37.55	0.002	0.9
0.5	0.3	8.0	28.1	0.001	0.5

(a) Equivalent concentration over 48 hours accounting for Haber's Law exponent of $n = 0.48$. (b) Equivalent concentration over 96 hours accounting for Haber's Law exponent of $n = 1.8$.

At 1.0 lb ai/acre, the RQs are all below unity, indicating that the exposure is less than the LC_{50}. The highest RQ was 0.42 for scenario 1 (a shallow depth and low stream velocity scenario) for *Daphnia magna*. The highest RQ for rainbow trout was 0.035, which shows that the exposures do not approach the LC_{50} level at 1.0 lb ai/acre for the assumptions used in this analysis.

At 2.5 lb ai/acre, the highest RQ for *Daphnia magna* was 1.0. For rainbow trout, the highest RQ was 0.087. Thus, direct effects to rainbow trout are unlikely. Even for *Daphnia magna*, the RQs for 9 of 11 scenarios are less than 0.07, indicating a very large margin of safety. Nonetheless, effects to *Daphnia magna* cannot be ruled out for extreme circumstances of shallow depth, low stream velocity, and winds from the field to the water body.

Discussion

The analysis in this paper shows that is very unlikely that malathion concentrations in salmonid habitat could ever reach levels that would directly impact salmonids. However, it is possible that malathion concentrations could occasionally reach a level that could impact the most sensitive salmonid prey item, *Daphnia magna*, but only under extreme circumstances of very shallow water depth and virtually still water.

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Table V. Estimated risk quotients for *Daphnia magna* and rainbow trout

Application Rate = 1.0 lb ai/acre		*Application Rate = 2.5 lb ai/acre*	
Daphnia magna	***Rainbow Trout***	***Daphnia magna***	***Rainbow Trout***
0.42	0.035	1.0	0.087
0.024	0.012	0.059	0.031
0.0066	0.0077	0.016	0.019
0.0029	0.0057	0.0072	0.014
0.0012	0.0041	0.0030	0.010
0.098	0.014	0.25	0.034
0.0044	0.0047	0.0110	0.012
0.0006	0.0022	0.0014	0.0054
0.027	0.0061	0.067	0.015
0.0010	0.0020	0.0025	0.0051
0.0002	0.0011	0.0006	0.0028

Malathion has a wide range of sensitivity to invertebrate species. Considering the ecotoxicity data summarized by the U.S. Fish and Wildlife Service (*10*) and the EPA (*11*), the range of LC_{50} values for invertebrates is 0.5 to 10000 ppb. In this assessment, a *Daphnia magna* LC_{50} of 0.9 ppb was considered, which is at the low end of the range of invertebrate toxicity. This leaves the question of whether some infrequent effects to a small part of the invertebrate population will incur any significant effects to salmonids.

Higgs et al. provided an extensive review of salmonid diets by lifestage (*12*). In particular, the publication reviews numerous studies that analyzed the stomach contents of salmonids. One of the overarching conclusions was that salmonids are opportunistic feeders with significant diversity in prey, which includes a wide variety of insect species, crustaceans, other fish, algae, eggs of fish and insects, etc. Thus, even if some sensitive invertebrates were to be affected by malathion, the salmon would have alternative species as prey. Therefore, some infrequent effects to daphnids or other similarly sensitive species are not likely to harm salmonid populations.

This assessment has a number of uncertainties that should be considered. First, there is relatively limited data on the characteristics of salmonid habitat. To account for this uncertainty, very shallow depths with extremely slow stream velocities were considered. However, even less data are available on other types of habitats like backwater pools.

The Haber's Law exponents in the paper were derived from relatively limited data. Most ecotoxicity studies do not contain data with robust dose-responses at multiple durations of exposure. Future ecotoxicity studies would benefit from observations at more time points and higher exposure concentrations that cause effects for very short durations. Such data would help to more accurately apply the generalized Haber's Law concept.

Future analyses could build on these methods using more complex stream dynamics, modeling the simultaneous contribution of runoff and spray drift, and evaluating the impact of multiple applications affecting a stream.

Conclusions

A risk assessment was conducted for potential malathion effects to Pacific salmonids. A time-varying exposure profile was constructed using the AgDRIFT model. A generalized Haber's Law model was used to estimate toxicity. Direct effects to salmonids are highly unlikely due to the relatively low toxicity of malathion to salmonids. There is the possibility of infrequent effects to sensitive invertebrate species in very shallow water habitats with low water velocities. However, most invertebrate species are much less sensitive to malathion than *Daphnia magna* and the available literature shows that salmonids have a diverse diet. Therefore, infrequent effects to sensitive invertebrates are not likely to impact salmonid populations.

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Chapter 12

Use of the Joint Probability Distribution Analysis for Assessment of the Potential Risks of Dimethoate to Aquatic Endangered Species

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The joint probability distribution analysis (JPDA) utilizes the full exposure distribution and the dose-response curve to determine the probability of an adverse effect occurring and the magnitude of the effect. It accounts for uncertainty from variations in exposure concentrations and species sensitivities and can better address the probability of risks of pesticides than the standard, Environmental Protection Agency regulatory risk quotient (RQ) method. In this application, the concern is for effects of dimethoate on salmonid prey which have differing sensitivities. Thus, accounting for variability in response is important. While use of the RQ method indicated potential risks to aquatic invertebrates, results of JPDA showed minimal risks, despite using an exposure model that likely significantly overestimates water concentrations. This paper demonstrates the application of the JPDA methodology to refine an ecological risk assessment and develop more accurate risk estimates.

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Introduction

As part of its mandate to assess the potential effects of pesticides on endangered species, the U.S. Environmental Protection Agency (EPA) and the National Marine Fisheries Service (NMFS) are engaged in a consultation regarding potential effects to salmonids in 26 Evolutionary Significant Units (ESUs) in the Pacific Northwest (http://www.epa.gov/oppfead1/endanger/litstatus/final-batch-3-opin.pdf). In analyzing the risks of pesticides to endangered species, EPA and NMFS have routinely applied conservative assumptions and based risk characterizations on single point estimates (risk quotients [RQs]). The analysis provides limited information about the probability of an unacceptable risk or the magnitude of risk, nor does it scientifically consider many of the uncertainties in individual sensitivity and species sensitivity. In commenting on EPA's current procedures for risk assessments, the FIFRA Science Advisory Panel (SAP) recommended that EPA develop methodologies to conduct probabilistic assessments of risks. The SAP specifically emphasized that "while these current procedures can serve as a screen to identify possible environmental damage, they often provide less information on the likelihood of the damage and the uncertainty in such estimates as is desirable in balancing risks and benefits as required under FIFRA" (*1*).

Addressing issues of probability of risk requires incorporation of the full exposure distribution and the concentration-effect relationship. A more refined, higher tier risk assessment is therefore warranted, such as the joint probability distribution analysis (JPDA) that was recommended in the ecological risk assessment process (http://www.epa.gov/oppefed1/ecorisk/aquareport.pdf). In this approach, both the exposure and the effect are treated as probabilistic distributions instead of point values, and the two probabilistic distributions are then integrated to create a joint probability distribution, which describes the probability that an effect (response) exceeding any given magnitude will occur under the range of exposure scenarios used to generate the exposure distribution. Thus, the joint probability distribution provides information on the relationship between the magnitude of effect and the probability of that effect occurring.

Contrary to the EPA RQ method in which only one point on the exposure concentration distribution is used in risk characterization, the JPDA utilizes the full exposure concentration distribution, which alleviates the uncertainty due to variation in ranges of exposure concentration. Since the concentration-effect relationship can be derived from any effect endpoints for developing the joint probability distribution, the JPDA can also address the probability of risks of a pesticide to various species, with the probability of an effect being predicted across the range of sensitivities of the species in question. Depending on the number of species included in the analysis, the resulting joint probability distribution can better characterize potential pesticide impact on communities and ecosystems than an assessment based on an individual test species. Therefore, the joint probability distribution is especially useful for an endangered species risk analysis, such as the Pacific Northwest salmonid risk analysis. Because the joint probability distribution reflects the uncertainties in the risk characterizations for both exposure and effects, it provides a better description of the risks of pesticides to ecosystems for decision making than a simple quotient, as EPA currently uses.

The objectives of this study were to evaluate the potential risk of dimethoate (*O,O*-dimethyl *S*-[2-(methylamino)-2-oxoethyl] dithiophosphate) to federally-listed Pacific Northwest salmonids using the JPDA and to compare the results of such an analysis to those of EPA in their risk assessments.

Material and Methods

Risk Assessment Using the Joint Probability Distribution Analysis

With the JPDA, the exposure and toxicity are both estimated probabilistically. The exposure assessment is undertaken by using the concentrations predicted by the linked PRZM/EXAMS model (PE 5.0, http://www.epa.gov/oppefed1/models/water/) with EPA standard scenarios (http://www.epa.gov/oppefed1/models/water/przmenvironmentdisclaim.htm) for higher-tier ecological risk assessment. All these scenarios were developed assuming a 10-ha treated field draining into an adjacent, 1 ha by 2 meter deep, stagnant pond, with no outlet. Each scenario represents a unique combination of climatic conditions, crop-specific management practices, soil-specific properties, site-specific hydrology, and pesticide-specific application and dissipation processes. The scenarios are supposed to represent a high-end exposure for the crop of interest. The modeling scenario is also expected to produce runoff greater than would be expected at 90% of the sites where the crop of interest is grown. The exposure is modeled for 30 years to provide a meaningful distribution of the predicted concentrations for probabilistic exposure characterization. Contributions from spray drift to exposure are included in PRZM/EXAMS and are dependent on the method of pesticide application (e.g., ground equipment, aerial, airblast). The model generates probability distributions of pesticide concentrations in the water column for various durations of exposure.

For acute exposure assessment, the probability distribution of the daily peak concentrations over a period of 30 years is used to construct the joint probability curve. Chemical specific PRZM/EXAMS model input parameters are presented in Table I.

For toxicity, the concentration-effect relationship is derived from two effect endpoints. One effect endpoint is the percent of species affected by dimethoate, expressed as the species sensitivity distribution (SSD). In this case, we would use toxicity levels for invertebrate species that salmonids may consume. The 48-hour, acute toxicities of dimethoate (LC_{50}/EC_{50}) to 9 freshwater and marine invertebrates determined in 11 studies (Table II) were used to construct the SSD using the EPA Species Sensitivity Distribution Generator (SSD_Generator_V1. xlt). This generator produces an SSD by fitting the most commonly applied distribution, the linearized log-normal distribution, to laboratory toxicity data, such as LC_{50}/EC_{50} or other toxicity endpoints. The fitted distribution for the central tendency was then used to construct the JPD curve. When multiple test data are available for the same species, the geometric mean of the measured toxicities for the species is used. The acute toxicities for freshwater and saltwater species were combined because only two saltwater species toxicity data are available, which makes it impossible to construct the SSD for saltwater species alone. Furthermore, salmon can reside in either habitat depending on life stage. Therefore, it can feed on both saltwater and freshwater invertebrates.

Table I. PRZM/EXAMS input parameters for dimethoate[1]

Parameters	*Dimethoate*
Water solubility (mg/L)	3,200
Henry's Law Constant (atm-m^3/mole)	$8.0e^{-11}$
Linear adsorption coefficient (L/kg)	0.3 (K_d)
Photolysis half-life (days)	353.0
Aerobic aquatic metabolism half-life (days)	16.4
Anaerobic aquatic metabolism half-life (days)	40.9
Aerobic soil metabolism half-life (days)	6.2
Neutral hydrolysis half-life (days)	6.8
Foliar decay half-life (days)	2.9
Application method	Aerial
Application rate (kg/ha)[2]	0.28
Number of application	3
Application efficiency	0.95
Spray drift fraction	0.05

[1] These parameter values were obtained from the EPA effects determination (http://www.epa.gov/espp/litstatus/effects/redleg-frog/dimethoate/analysis.pdf) for the California red-legged frog. [2] This use rate was for the California lettuce scenario. Application rates for other scenarios were obtained from the same EPA effects determination.

The second effect endpoint is the dose-response relationship derived from the acute mortality data for daphnids. The dose-response data measured by Song et al. (*6*) at 20–21°C, Hertl et al. (*9*), and Anderson et al. (*10*) are combined and used. The measured concentration-mortality data for dimethoate were fitted to a logarithm function to derive the concentration-effect relationship.

The exposure distribution is then integrated with the concentration-effect relationship to develop a joint probability curve for analysis. The risk is then characterized according to the magnitude of the risk product (RP), which is calculated as the product of the exceedance probability and magnitude of effect. This risk product can also be interpreted numerically as the area under the exceedance curve (*13*). Four categories of RPs have been used, following Giesy et al. (*14*) and Giddings et al. (*15*), to characterize the effects of dimethoate on aquatic animals. For comparison and consistency with the EPA RQ method, all categorizations are based on the 90th percentile RP.

- If the calculated 90th percentile RP is less than 0.25%, then the risk is characterized as minimal;
- If the calculated 90th percentile RP is greater than 0.25% but less than 2%, then the risk is characterized as low;
- If the calculated 90th percentile RP is greater than 2% but less than 10%, then the risk is characterized as intermediate; and
- If the calculated 90th percentile RP is greater than 10%, then the risk is characterized as high.

Table II. Acute (48-h) toxicity of dimethoate to various aquatic salmon prey species for construction of species sensitivity distribution (SSD)

Species	*LC_{50} or EC_{50} (mg/L)*	*Sources*
Stonefly (*Pteronarcys california*)	0.14	(*2*)
Snowbug (*Asellus aquaticus*)	2.96	(*3*)
Scud (*Gammarus lacustris*)	0.2	(*4*)
Midge (*Chironomus tentans*)	0.249	(*5*)
Yellow fever mosquito (*Aedes aegypti*)	5.0, 6.4	(*6*)
Saltwater mysid (*Mysidopsis bahia*)	22.0	(*7*)
Brine shrimp (*Artemia*; Crustacea)	15.73	(*6*)
Marsh mosquito (*Aedes taeniorhynchus*)	0.031	(*6*)
Daphnid (*Daphnia magna*)	6.4	(*8*)
Daphnid (*Daphnia magna*)	2.0	(*9*)
Daphnid (*Daphnia magna*)	1.1	(*10*)
Daphnid (*Daphnia magna*)	1.5, 1.8, 1.7, 2.0	(*11*)
Daphnid (*Daphnia magna*)	3.32, 3.12	(*6*)
Daphnid (*Daphnia magna*)	6.4	(*12*)

Risk Assessment Using the EPA Risk Quotient Method

The same exposure concentration distribution generated by PRZM/EXAMS model as in the JPDA is used for exposure assessment using the deterministic RQ method. However, unlike the JPDA in which the entire concentration probability distribution is used, the EPA RQ method only uses the 90th percentile concentration of the daily peak concentration distribution to calculate the RQ for acute risk characterizations. Practically, the RQ is calculated by dividing the exposure concentration at the 90th percentile by an appropriate measurement endpoint (e.g., LC_{50}/EC_{50}) obtained from the standard toxicity tests. Usually the lowest toxicity endpoint (e.g., LC_{50}/EC_{50}) is used for the RQ calculation. The RQ is compared to a set of risk criteria to determine whether there is a potential regulatory concern.

Three categories of regulatory concern above minimal risk to non-target aquatic animals have been established for acute risks—acute high risk, acute restricted use, and acute endangered species. Each category comes with a prescribed level of concern (LOC) defined by EPA for risk characterizations. For aquatic animals, the LOCs are 0.5, 0.1 and 0.05 for acute high risk, acute restricted use, and acute endangered species, respectively. If the risk criteria (LOCs) are not exceeded, it is concluded that there will be minimal ecological concern from the proposed use of the product and the aquatic risk assessment process is judged complete. If the risk criteria are exceeded, the risk assessment process advances to a higher tier analysis, but only for those taxa and application scenarios that continue to be of concern. Note that although an entire dose-response curve can normally be derived from the standard toxicity test, only one point on this curve, the concentration corresponding to 50% mortality (LC_{50}/EC_{50}), would be used in toxicity assessment and risk characterizations with the EPA deterministic RQ method. Ignoring the rest of the curve in risk characterizations may result in uncertainty due to variation in ranges of exposure concentrations. This is an apparent limitation of the RQ method compared to the JPDA method in which the entire dose-response curve is utilized for risk characterizations.

Results and Discussion

Risk Characterizations Using the Joint Probability Distribution Analysis

Figure 1 shows the SSD of dimethoate constructed based on data in Table II using the EPA Species Sensitivity Distribution Generator. The measured 48-hour acute toxicities (LC_{50}/EC_{50}) of dimethoate to nine invertebrate species are included.

The sensitivities of the nine species to dimethoate vary significantly (Figure 1), with the marsh mosquito (*Aedes taeniorhynchus*) being the most sensitive and saltwater mysid (*Mysidopsis bahia*) being the least sensitive to dimethoate. The 90th percentile dimethoate peak concentrations in the ecological pond predicted by PRZM/EXAMS for seven sites are also included in Figure 1 for comparisons. These sites cover the major use patterns of dimethoate in the U.S. and some were used by EPA in endangered species effects determinations (http://www.epa.gov/espp/litstatus/effects/redleg-frog/ dimethoate/analysis.pdf). These predicted concentrations (the vertical lines on the tail side of the SSD curve in Figure 1) incorporate site-specific field and environmental information and can serve as the upper bound concentrations expected under the specified conditions, especially when the site-specific information (e.g., the site-specific monitoring results and the results from mesocosm studies) is not available. Putting together these predicted concentrations with the SSD in one graph has the advantage of helping visually determine the potential impacts on the examined species from different use sites. This is important because one of the primary goals of aquatic ecological risk assessment, whether it is at the screening-level or at higher levels, is to prioritize the potential risks at different locations and to eliminate from further considerations those species and locations that are unlikely to be at risk (*13*). It can be seen from Figure 1 that for all invertebrate species, dimethoate uses on Oregon pear and wheat, and California alfalfa, citrus, corn, cotton, and lettuce have minimal impacts on the invertebrates. Of the seven scenarios modeled, the California lettuce scenario predicted the highest peak daily concentration (Figure 1), which is 2-3 times higher than those of the two Oregon scenarios, and even it does not exceed the LC_{50} of the most sensitive invertebrate (marsh mosquito), indicating that uses of dimethoate would not impose significant impacts on salmon prey invertebrates.

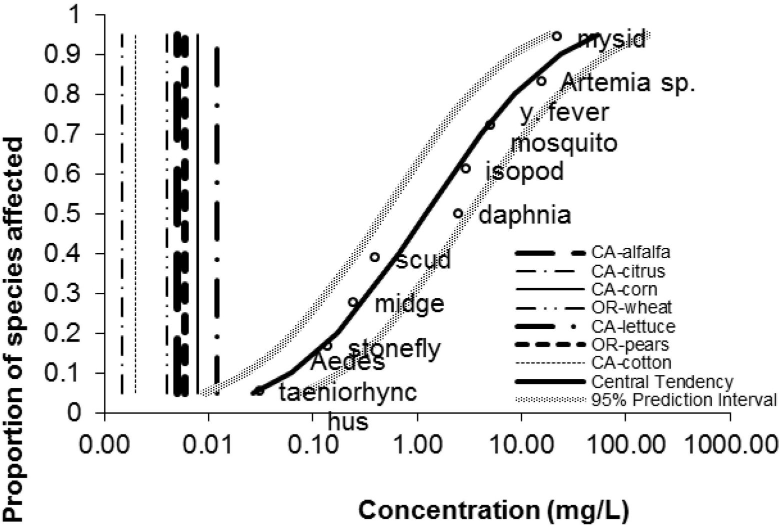

Figure 1. Acute species sensitivity distribution (SSD) to dimethoate, with site-specific 90th percentile peak daily concentrations for representative crop uses predicted by PRZM/EXAMS.

The SSD is then combined with the probability distribution of exposure concentrations predicted by PRZM/EXAMS for the California-lettuce use scenario to create the joint probability curve for dimethoate risk (Figure 2). This use scenario generates the highest dimethoate peak daily concentrations in the hypothetical EPA (Environmental Fate and Effects Division) farm pond (Figure 1) and the JPDA based on this use scenario is more protective of invertebrate species. The joint probability curve (Figure 2) clearly indicates that there is no predicted adverse effect on a wide variety of salmon-feed invertebrate species from the dimethoate use on California lettuce. The calculated RPs for the same exposure concentration range are also included in Figure 2 (the secondary *Y-axis*). The 90th percentile RP is 0.118% and the maximum RP is 0.144%, which is significantly less than 0.25%, indicating that uses of dimethoate pose minimal risk to salmon-feed invertebrate species according to the risk categories described previously.

In its recent Biological Opinions (BiOps) (http://www.epa.gov/ oppfead1/ endanger/litstatus/final-batch-3-opin.pdf), NMFS reported that dimethoate use might adversely affect salmonid prey communities in some areas and jeopardize the Pacific Northwest salmon-feed species based on the AgDrift model estimates and the EPA screening-level GENEEC model estimates. EPA also reported that dimethoate use "May Affect" steelhead and salmon in the Pacific Northwest in its risk analysis for these listed species (http://www.epa.gov/oppfead1/endanger/litstatus/effects/dimethoate/dimethoate_analysis.pdf) based partly on GENEEC and PRZM/EXAMS models. The higher level JPDA for dimethoate including its use in the Pacific Northwest clearly indicates that those jeopardy determinations were overstated.

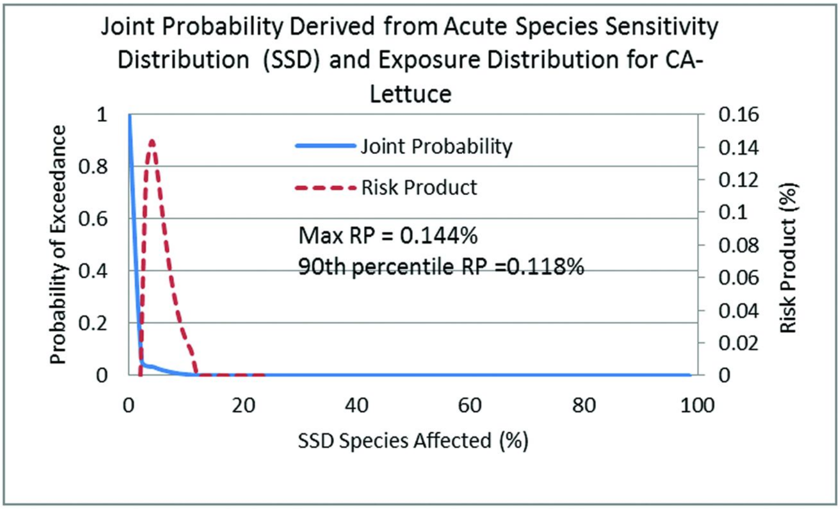

Figure 2. Joint probability curve derived from the acute species sensitivity distribution (SSD) and exposure distribution predicted by PRZM/EXAMS for dimethoate use on California lettuce (CA-Lettuce).

A joint probability curve was also constructed for daphnids alone by integrating the same probability distribution of exposure concentrations as above with the concentration-effect relationship between *Daphnia magna* and dimethoate. The latter was obtained by fitting the measured concentration-mortality data for *Daphnia magna* (Table II) to a logarithm function. The resulting joint probability curve is shown in Figure 3, along with the RPs for the same exposure concentration range (the secondary *Y-axis* in Figure 3). Like the joint probability curve constructed based on the SSD, this joint probability curve shows that there is a very low probability for dimethoate to impact *Daphnia magna* at the maximum label rate on California lettuce. Since the peak daily concentration for dimethoate use on California lettuce is the highest among the seven scenarios modeled, it is expected that uses of dimethoate would have minimal impact on *Daphnia magna*. The calculated RPs ($<10^{-15}$%) are much less than the minimal RP of 0.25%, indicating that use of dimethoate poses minimal risk to the salmonid prey *Daphnia magna*.

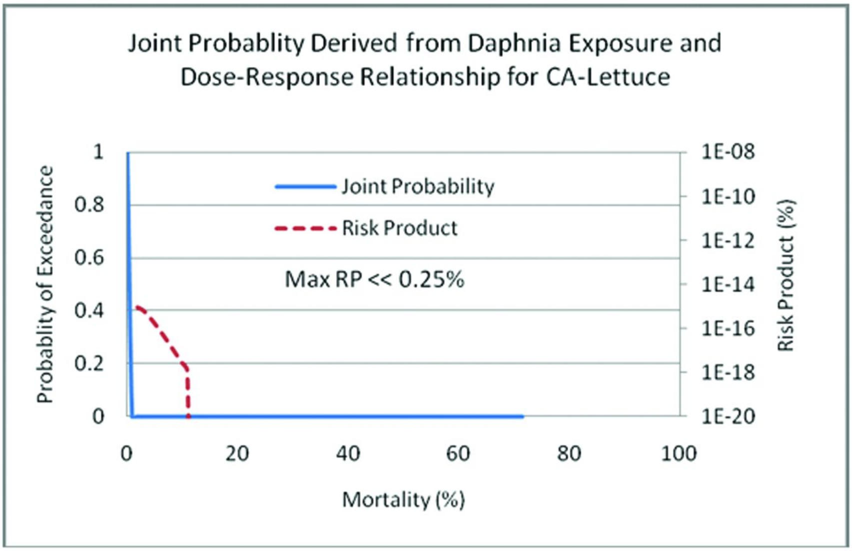

Figure 3. Joint probability curve derived from the dose-response relationship for daphnia magna and exposure distribution predicted by PRZM/EXAMS for dimethoate use on California lettuce (CA-Lettuce).

Risk Characterizations Using the Risk Quotient Method

For consistency and for comparison with the risk determined using the joint probability approach, the 90th percentile daily peak concentration from the same exposure concentration distribution generated by the PRZM/EXAMS model as in the JPDA was used to calculate the RQ for acute risk characterizations. The acute

(48-h) toxicity endpoint value for the most sensitive invertebrate species is 0.031 mg/L (Table II) and the 90th percentile peak daily concentration for California-lettuce is 0.012 mg/L. The resulting acute RQ is 0.39. The EPA LOCs for aquatic animals are 0.5, 0.1, and 0.05 for acute high risk, acute restricted use, and acute endangered species, respectively. Therefore, based on this RQ, dimethoate would be considered to pose acute risk for two of the three risk categories according to the EPA RQ method. This is in great contrast to the conclusion obtained from the more refined JPDA, which shows that use of dimethoate poses minimal risk to aquatic animals. The bias of the RQ method lies in its use of a single point on the toxicity-effect curve while ignoring the range of sensitivity to prey species and the range of possible exposures. As a result, the RQ method results in overestimation of the potential risks to salmonid prey items. Salmonids feed on different invertebrate species and it is unlikely for salmon to consume only the most sensitive species, therefore, the actual risk is even smaller. On the other hand, if we know the probability of the distribution, it may help us further define the likelihood of the occurrence.

It is important to recognize that the exposure distribution predicted by the PRZM-EXAMS model is very conservative. Therefore, the JPDA that is based on such an exposure distribution likely overestimates the true exposure and risk. As described previously, each PRZM scenario represents a site expected to produce runoff greater than 90% of the sites where the appropriate crop is grown. The aquatic system modeled by EXAMS is also a static farm pond adjacent to the treated crop, and the default assumption is that spray drift goes directly into the pond. In reality, spray setback or buffer zones exist, which may reduce pesticide drift into a nearby water body. Moreover, the 90th percentile concentration in the pond predicted by PRZM/EXAMS is used to compare against ecotoxicological levels of concern. This scenario does not approximate the typical habitat for salmonids (e.g., a flowing stream).

Conclusions

The probability of risks of dimethoate to Pacific Northwest salmon prey invertebrates was determined using the JPDA and the results of this analysis were compared to those using the EPA RQ method as well as the risk calculations performed by NMFS. The joint probability curve was constructed using the full exposure distribution and the toxicity distribution, neither of which are considered in RQ calculations. The latter was derived either from the SSD or from the dose-response relationship. Nine salmon prey invertebrate species for dimethoate were used to generate the species sensitivity distributions. Both the exposure distribution and the toxicity distribution are treated as probabilistic distributions in constructing the joint probability curve, thus alleviating the bias of a deterministic approach, such as the RQ method.

The exposure distribution from the use site that produces the highest peak daily concentrations was used for the JPDA, which revealed that there is minimal risk to prey for Pacific Northwest salmon across the major dimethoate use regions, while the RQ method indicated potential risks for two out of three EPA risk categories. The difference was a result of the bias of the RQ method in which only two point values, one from the exposure distribution (90th percentile peak daily concentration) and the other from the toxicity distribution for the most sensitive species (LC_{50}/EC_{50}), were used to estimate the potential risk. Use of the JPDA SSDs provides valuable information to allow for prioritization of the potential risks at different locations and addresses many of the uncertainties in aquatic risk assessment. Thus, it is recommended that this approach be used by EPA and NMFS for jeopardy and habitat modification determinations in the BiOps when a product and use combination fails the initial screening-level assessment.

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Chapter 13

A GIS-Based Approach To Quantifying Pesticide Use Site Proximity to Salmonid Habitat

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Characterizing and quantifying the proximity of potential pesticide use sites to endangered species habitats are integral components of pesticide exposure risk assessments. One region of interest has been the salmonid evolutionarily significant units (ESUs) and distinct population segments (DPSs) in the Pacific Northwest and California. The availability of spatial datasets that classify stream and river segments by salmonid habitat type, combined with high resolution crop datasets, has allowed for refined estimates of potential use areas within these regions. Automated Geographic Information System (GIS) procedures were applied to 28 endangered or threatened ESUs/DPSs to characterize proximity and magnitude of potential use areas to defined salmon habitats within different ESUs, for different crop uses, and the different types of habitats. The results demonstrated that the GIS-based approaches used in this study could produce refined, best available quantification of potential pesticide use areas in relation to the salmon habitats in the 28 ESUs/DPSs.

Introduction

The potential effects of agricultural pesticides on threatened or endangered salmonid species in the Pacific Northwest and California has received increased attention over the past decade. Within the past several years, the National Marine

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

Fisheries Service (NMFS) has produced biological opinions concerning the potential impact of several groups of pesticides on salmonid species that have been listed as threatened or endangered under the Endangered Species Act (*1–3*). These assessments have included spatial analysis components that sought to address the intensity of agriculture within the Evolutionarily Significant Units (ESUs) and Distinct Population Segments (DPSs) potentially affected, as well as within large buffers around specific salmonid habitat areas. Valuable data were generated during these assessments which provide a general interpretation of agricultural land use within the salmonid ESUs; however, for crops specific to individual pesticides, for analysis of different salmonid habitat classifications, and for analysis of potential pesticide use sites within a broad range of buffered distances, additional analysis was necessary.

Here an approach detailing a more refined assessment of the proximity of potential agricultural pesticide use sites to water bodies identified as supporting salmonid habitat was performed. The analysis focused on the ESUs and DPSs of five different salmonid species found in California and the Pacific Northwest (ID, OR, and WA). These species included chinook, chum, coho, sockeye, and steelhead. In total 28 ESUs/DPSs were assessed.

The objective of this assessment was to use the best available crop location and species habitat location data to more comprehensively characterize pesticide use site location proximity relative to habitat identified by NMFS as consequential to the species of interest. This chapter describes the data sources used in the assessment, provides details on how these data sources were used the spatial analysis methodology applied in assessing pesticide use site proximity to salmonid habitat, and provides a comprehensive summary of the results. While this approach was developed for a specific pesticide, the approach presented is applicable to all pesticides.

Materials and Methods

Analysis Approach

The objective of the analysis was to evaluate the proximity of pesticide-labeled crops to water bodies supporting salmon habitat within the threatened and endangered ESUs and DPSs in California and the Pacific Northwest. The approach was designed to be flexible in terms of allowing the assessment of a wide range of distances around the water bodies of interest. Another requirement of the approach was to allow mapping of the proximity of pesticide-labeled crop-growing areas to the salmon habitat-supporting water bodies. To accomplish these objectives, a raster-based Geographic Information System (GIS) proximity analysis methodology was designed that would calculate the distance of every cropped pixel to the nearest water body of interest. The datasets resulting from this analysis met the goals of allowing a flexible assessment of crop acreage within a range of distances, and allowing detailed mapping of the proximity of the areas to salmon habitat.

Data Sources

Spatial data for ESU and DPS boundaries were obtained from the NMFS website (*4*). These boundaries, developed by NMFS, depict watershed boundaries by which distinct salmon populations are tracked and managed. This spatial data contained attributes describing the protection status of the salmon population within each unit. The 28 ESUs and DPSs with either "endangered" or "threatened" status were included in this analysis. The ESU/DPS boundaries obtained from NMFS were originally delineated from USGS 1:250,000 scale hydrologic unit boundaries. To ensure consistency throughout the spatial analysis, the NMFS boundaries were re-delineated using the higher resolution 1:100,000 scale National Hydrography Dataset (NHD) Plus dataset (*5*).

The NHDPlus datasets represent the highest resolution nationally available catchment boundary dataset. The hydrography and catchment boundaries are based upon the medium resolution NHD dataset. For each NHD reach, a catchment boundary is defined, resulting in millions of small watersheds across the United States. The NHDPlus catchments were used to create refined delineations of the ESU boundaries in order to preserve consistency between ESU boundaries and the hydrography used in the proximity analysis.

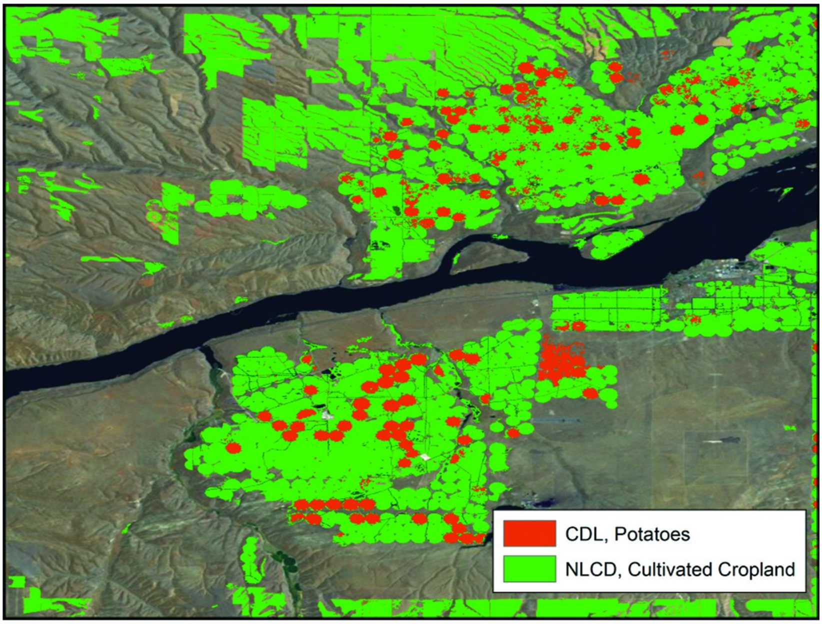

Figure 1. Comparison of CDL and NLCD for Potatoes, Washington State. Sources: Potatoes, 2009 CDL; Cultivated Cropland, NLCD 2006; Imagery, ESRI. (see color insert)

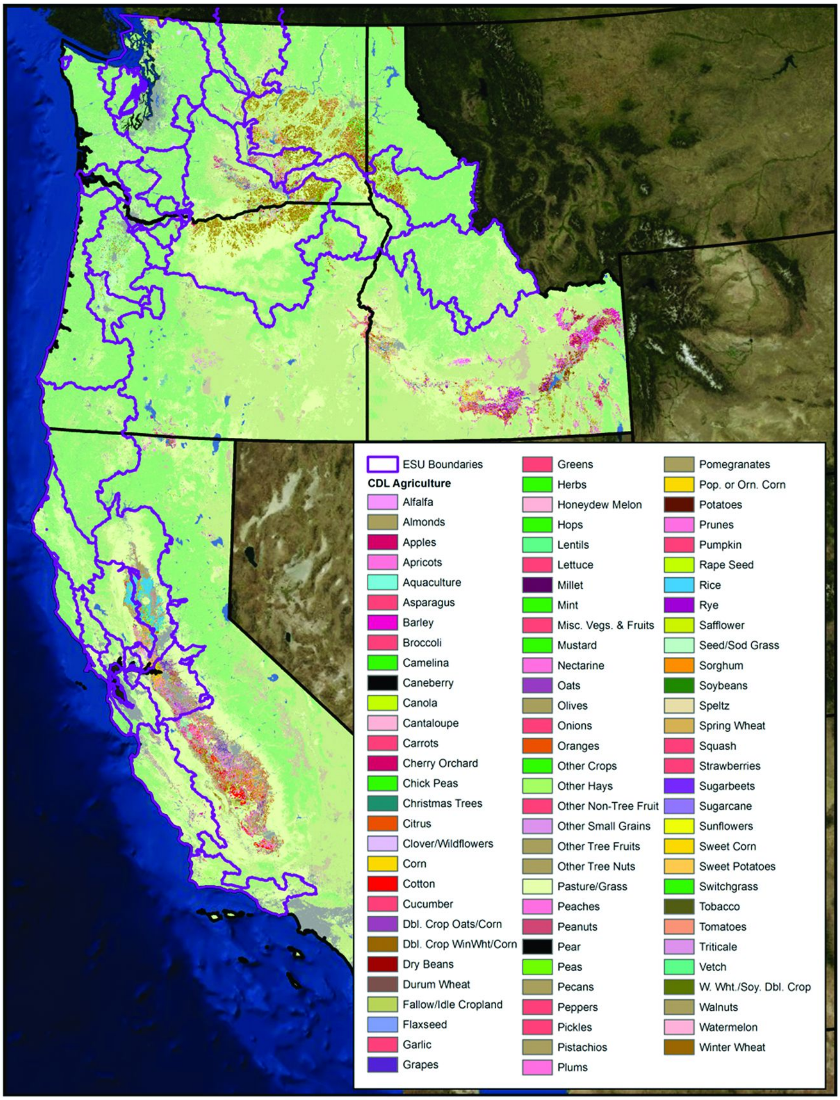

Figure 2. Cropland Data Layer and ESU/DPS Boundaries. Data Sources: Land Cover, 2009 CDL; ESU Boundaries, NMWFS; Imagery, ESRI. (see color insert)

The National Agricultural Statistics Service (NASS) Cropland Data Layer (CDL) was used to identify the areas within the salmonid ESUs/DPSs where crops with labeled uses of the pesticide of interest are grown. The CDL dataset is a crop-specific land cover/land use dataset that includes 122 different land cover and crop classifications (2009 CDL version). The CDL dataset is a relatively recent and important advancement in estimating potential pesticide use sites. Prior to widespread availability of the CDL dataset, the National Land Cover Dataset (NLCD) represented the best available dataset for conducting national assessments requiring identification of pesticide use site locations. The limitation of the NLCD agricultural land cover classes is that it does not distinguish between specific crops and it represents the land cover and use at the time of satellite image data collection (2001 in the case of the NLCD 2001 dataset). For pesticides that are used on a limited group of crops, this led to potential misrepresentation of the extent of pesticide use sites; an example is shown in Figure 1. In this section of Washington State, the areas associated with potato crops from the CDL are compared with the NLCD cultivated cropland class. This example shows clearly how NLCD would over-represent the extent of pesticides applied to potato crops.

At the time of this study, CDL data were available for the states in the salmonid ESU area (CA, ID, OR, and WA) for the years 2007 and 2009. The year 2009 was chosen as the primary dataset for this assessment; however, 2007 data was also used to evaluate one ESU (Critical Habitat Areas in California Central Valley Steelhead DPS) in order to evaluate the temporal sensitivity of crop proximity calculation. A map showing the CDL dataset and the ESU boundaries for the states included in the study area is shown in Figure 2.

There are several different data sources and designations for salmonid habitat-supporting water bodies. This includes data from NMFS (*6*) and data from independent organizations including StreamNet (*7*), which provides fish habitat data in the Northwest, and CalFish (*8*), which provides fish habitat data in California. In this study several different classifications of salmonid habitat were evaluated in order to gain an understanding of the variability of potential risks for salmonid exposure to the pesticide in different types of habitat areas. In this study, we sought to assess the following types of habitat areas: (1) Designated Critical Habitat Areas, (2) General Habitat Areas (using spatial data available from the NMFS website or other independent sources), and (3) Specific Habitat Type Areas (migrating, rearing, and spawning). An example of the different habitat types for the California Central Valley Steelhead DPS is shown in Figure 3.

Spatial Analysis

The process and methodology followed in the spatial analysis of pesticide-labeled crop proximity to salmonid habitat water bodies is described in this section. Discussions on pre-processing of the source datasets are provided to aid in the methodological understanding of how the ESU/DPS boundaries, crop cover, and habitat datasets were developed as inputs to the proximity analysis. Details of how the spatial analysis was conducted are provided, as well as assumptions and limitations of the approach and their corresponding effects on the interpretation of results.

The salmon ESU/DPS boundaries evaluated in this assessment were re-delineated using NHDplus data in order to ensure consistency with the NHDPlus hydrography and to help facilitate future analysis at the NHDPlus catchment level. The NHDPlus-based ESU/ DPS boundaries were designed to be consistent with the area originally delineated in the NMFS boundaries. Minor differences may exist along the perimeter of the boundary as a result of the differences in scale of the source datasets, however these are not considered as significantly impactful to the interpretation of the assessment or the conclusions.

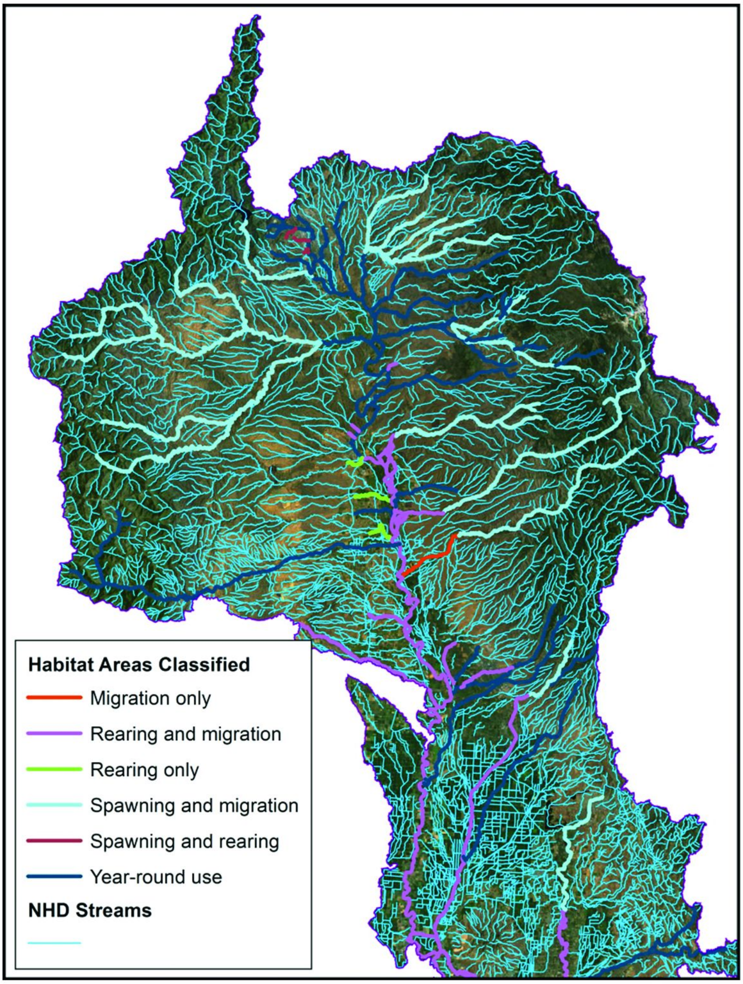

Figure 3. Salmonid Habitat Classifications for California Central Valley Steelhead DPS. Sources: Habitat Areas, NWFS; Hydrography, NHDPlus; Imagery, ESRI. (see color insert)

The 2009 CDL datasets for California, Idaho, Oregon, and Washington were merged into a single raster dataset covering the four state region and re-projected from a local Universal Transverse Mercator projection into the North American Albers Equal Area projection. This dataset was then re-sampled from the original 56-meter (184 ft.) resolution to a 28-meter (92 ft.) cell size. This re-sampling was done so that the crop proximity to water body analysis would be conducted at a finer resolution, which is important for assessing the crops within closer proximity to habitat-supporting water bodies (i.e., within a few cell widths). Although an even higher resolution resampling could improve the precision of the proximity calculations, this resolution would make analysis at the multi-state level impractical.

Three different sets of water bodies supporting salmonid habitat were identified for the crop proximity analysis; critical habitat areas, general habitat areas, and specific habitat type areas including migrating habitat, rearing habitat, and spawning habitat. For the proximity analysis, a raster dataset representative of the water bodies of interest for each species and ESU/DPS was created. The process followed in the creation of these raster datasets was very similar for all three scenarios and the steps in this process are outlined as follows (different or additional steps, where taken, are noted):

- Identification of Water Body Features: Individual linear feature classes of water body habitat for each salmonid species were created for each habitat scenario. These datasets were created independently for each species because the habitat classification for a given water body varies for each species. Once the linear habitat features were selected for each species and each habitat scenario, additional area features from NHDPlus were selected to represent the wide rivers and impoundments that the linear habitat features flow through.
- Creation of Water Body Rasters: The approach developed for the proximity analysis required that the habitat water body features be represented as a gridded raster dataset. The linear and area features selected for each species and habitat scenario, described in the previous section, were converted to raster datasets with a 28-m cell size and "snapped" to the 2009 CDL dataset.

The spatial analysis performed in this assessment was designed to allow for the consideration of cropland acreage impacted by a continuous distribution of possible distances to surface water. The most practical and efficient approach for performing such an analysis is through an evaluation of distances between landscape features (i.e., agricultural land use and salmonid habitat areas) in a raster processing environment. The resolution for raster analysis is an important consideration, as features in the analysis cannot be represented at a finer resolution than the analysis resolution. The raster cell size chosen for this analysis was 28-meters. This was chosen because it represented an equal interval of the native cell size for the CDL dataset (56-meters) and, because it represents a practical cell size in which to perform spatial analyses over the large, multi-state region which the salmonid ESU/DPSs encompass. The next smaller cell size that was considered, (14-meters (46 ft.)), was impractical for analysis at the scale of the salmonid ESUs/DPSs. It is acknowledged that many water bodies are narrower than 28 meters, the minimum width that water bodies are represented in this analysis. This indicates that for bodies narrower than 28 meters, our approach is conservative in the distances it calculates from crop areas to the edge of the water body. The impacts of the cell size assumption on this analysis are minimal and will be discussed in the "Analysis Assumptions and Limitations" section that follows. For wider rivers, lakes, and impoundments, the 28-meter cell-based representation of these water body surfaces results in less distortion than occurs for narrow flowing water bodies.

The spatial proximity analysis was performed using ArcGIS 9.3.1 and the Spatial Analyst extension. The steps in the analysis can be summarized as follows:

- Generation of a raster representation of the ESU of interest.
- Extraction of crop classifications of interest within the ESU from the CDL dataset.
- Performing of Euclidean distance operation between the CDL crops of interest and the habitat water body scenario raster. This operation generates a new raster dataset where each pixel (for crops of interest only) contains its distance to the nearest habitat pixel.
- Processing the data contained in the distance raster to calculate and summarize the area of cropland associated with every possible distance to the nearest habitat water body.
- Generation of spatial and tabular output datasets.

The analysis was performed independently for each ESU crop scenario and habitat scenario assessed. The crop scenarios are defined by the different crops or groups of crops whose proximity to the habitat areas were assessed. In evaluating the critical habitat areas, each of the crops was assessed individually, as well as lumped together to represent all possible use sites. For the other two habitat scenarios (general and specific types), the crops were evaluated as a lumped group only.

In order to make this process efficient, a geo-processing script was written to automate the spatial analysis steps described above. A version of this geo-processing script is available at the GeoSTAC web site (*9*). The tabular output results from the geo-processing script were then imported into an MS Access database for analysis and post-processing.

Analysis Assumptions and Limitation

The raster analysis approach is the only practical method for performing this type of proximity analysis which evaluates a continuous range of distances from surface water. The primary limitation associated with a raster-based assessment is that some of the water features whose proximity is being evaluated are not as accurately represented as a raster as they are by a vector feature. The primary example of this is a smaller stream, whose width is considerably less than a 28-meter pixel. The result of this is that for water bodies whose width or area is less than that of a single 28-m pixel, the acreage estimates for a given proximity may be slightly inflated: that is the acreage within this distance will be an overestimate. This will primarily be a limitation when evaluating the proximities of less than a few pixels in width (e.g., ≤ 90 m). To account for this, the distance calculated by the raster Euclidean Distance operation is adjusted when the tabular summary data is produced. The adjustment is to increase the distance by one half the cell size

(14 meters in this assessment). In cases where a habitat water body is considerably narrower than the 28 meter cell size, this adjustment provides a more realistic estimate of the distance of a cropland pixel to that particular water body.

The extent of pesticide use sites was represented using individual crop classifications from the CDL dataset. The CDL data developers acknowledge the uncertainty in classification of each crop type in their metadata accuracy assessments. The results for the crop use site proximities reported in this chapter will have less uncertainty when considering the "lumped" crop group than when considering individual crops. As this chapter is being written, approaches are under development that account for uncertainty in CDL crop classifications by combining multiple years of data and lumping crops into more generalized categories. The methodology presented in this chapter can also be applied using other use site datasets such as the more generalized CDL ones being developed.

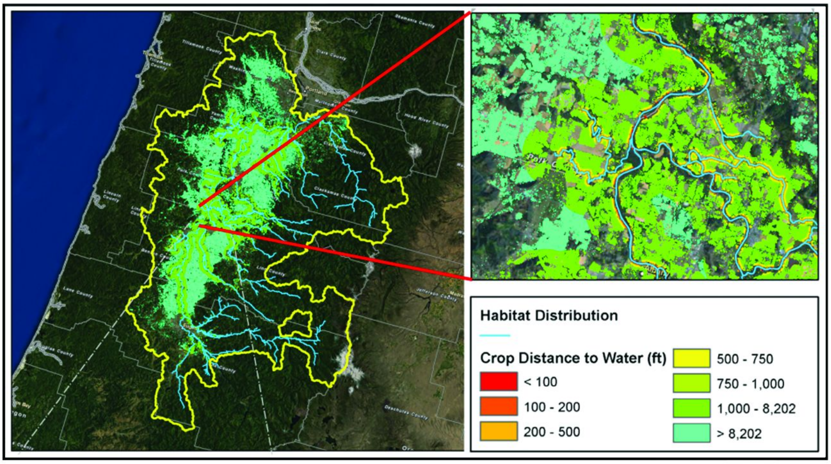

Figure 4. Spatial Distribution of Use Site Proximity within Upper Willamette Chinook ESU. Data Sources: Habitat Distribution, NMFS; Crop Proximity, Stone Environmental. (see color insert)

Results and Discussion

This section presents the results of the proximity analysis of pesticide use site crops to salmonid habitat for each of the crop and habitat scenarios. The discussion first considers the characteristics and variability of the "General Habitat Areas" across all 28 ESUs/DPSs assessed, and subsequently considers the variability of the proximity to different habitat classifications. While both individual crops and all crops combined were assessed in this study, only the combined crops analysis will be discussed here.

Summary of Use Site Proximity to All Habitat Areas

For each ESU/DPS, the results of the proximity analyses provided a visual depiction of the variability in use site proximity in the form of maps. In addition, for each ESU/DPS, the complete cumulative distribution of proximities was created. Examples of both of these outputs are shown in Figure 4 and Figure 5 respectively. Figure 4 shows that over 65% of the use sites are beyond 8,200 ft., with over 86% of the potential use site area beyond 1,000 ft.

Figure 5 shows the cumulative distribution of use site proximity to salmonid habitat for the Southern California Steelhead DPS. Figure 5 shows that approximately 800 acres of potential use sites are within 1,000 ft of salmon habitat with about 1,600 aces within 4,000 ft.

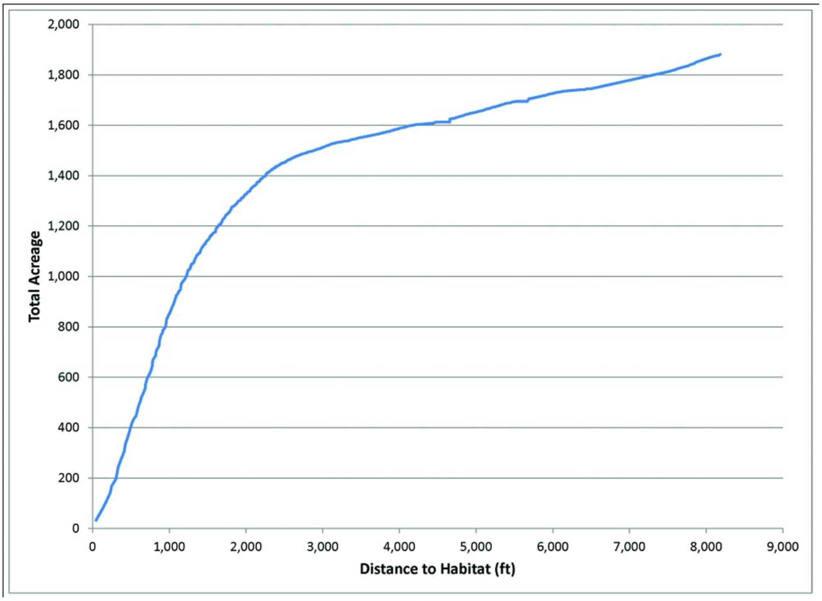

Figure 5. Cumulative Distribution of Use Site Proximity within Southern California Steelhead DPS.

A trend observed when reviewing the entire group of ESUs/DPSs was that potential pesticide use sites represent a relatively small percentage of area within a given proximity to the habitat areas (i.e., if there are 2,000 acres within 100 ft. of salmon habitat, only 20 acres are potential pesticide use sites). This data is summarized in Figure 6. The data in this figure shows the fraction of total area within different proximity that is covered by potential pesticide use sites. The data is summarized by showing the number of ESUs/DPSs that fall into different classifications of proximity and percent area. For example, in 21 ESUs potential pesticide use site areas represent ≤ 0.5% of the area within 100 ft of salmonid habitat. Looking at the area within 1,000 ft of salmonid habitat, potential pesticide use sites represent ≤ 1% of the area in 22 of the 28 ESUs. There are two ESUs where the pesticide use site areas are considerably higher, covering > 10% of the area within 500, 750, 1000, and 8,202 ft. These two ESUs are the Upper Willamette Chinook ESU and the Upper Willamette Steelhead DPS.

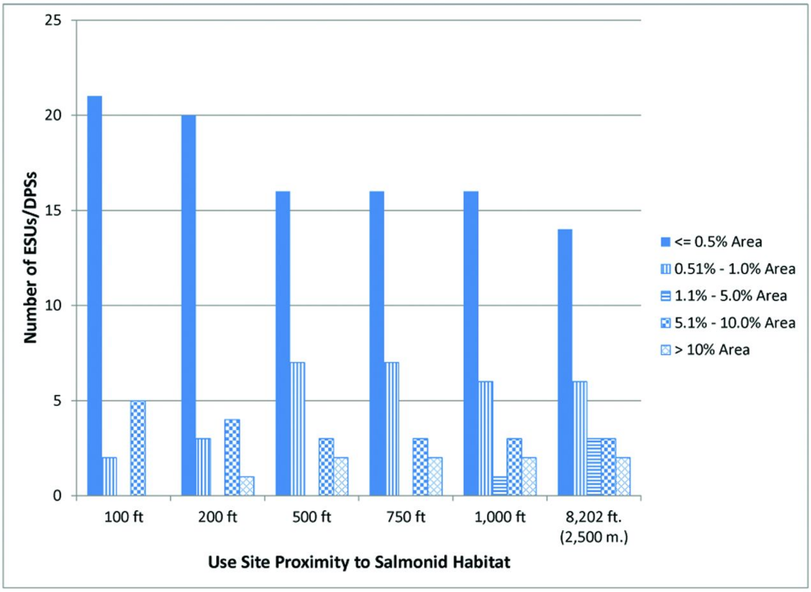

Figure 6. Summary of Pesticide Use Site Acreages for All ESUs/DPSs.

Pesticide Use Site Proximity to Different Habitat Types

Three different habitat types for salmonid species of concern were assessed in this study. These included the designated critical habitat areas, the general habitat areas, and the specific habitat types (migrating, rearing and spawning areas). The proximity analysis was run independently for each habitat type to allow an evaluation of the relative occurrence of pesticide use sites within close proximity to each habitat classification. An evaluation of the Puget Sound Chinook ESU is shown in Figure 7. In the figure, the cumulative distributions of use site proximity are shown for five different habitat areas, plus the proximity to all water bodies in the NHDPlus dataset (NHD All Water). The "NHD All Water" group is shown to put into context the importance of identifying which water bodies are supportive of salmonid habitat and which ones are not. The data shows clearly that acreages of potential pesticide use sites within a given proximity are significantly higher when considering all water bodies in the NHDPlus dataset. This strongly supports the incorporation of more explicit habitat data when performing proximity assessments. In addition, the data shows the difference between use proximity for water bodies that support salmonid habitat at different life stages (migration, spawning, and rearing). For the Puget Sound Chinook ESU example shown in Figure 7 it is clear that, given the lower potential pesticide use site acreages in close proximity to rearing and spawning habitat, there would be less potential pesticide exposure risk to salmonids in these life stages. In addition, for Puget Sound Chinook ESU, the acreage distribution of use sites to Critical Habitat is very similar to the General Habitat areas.

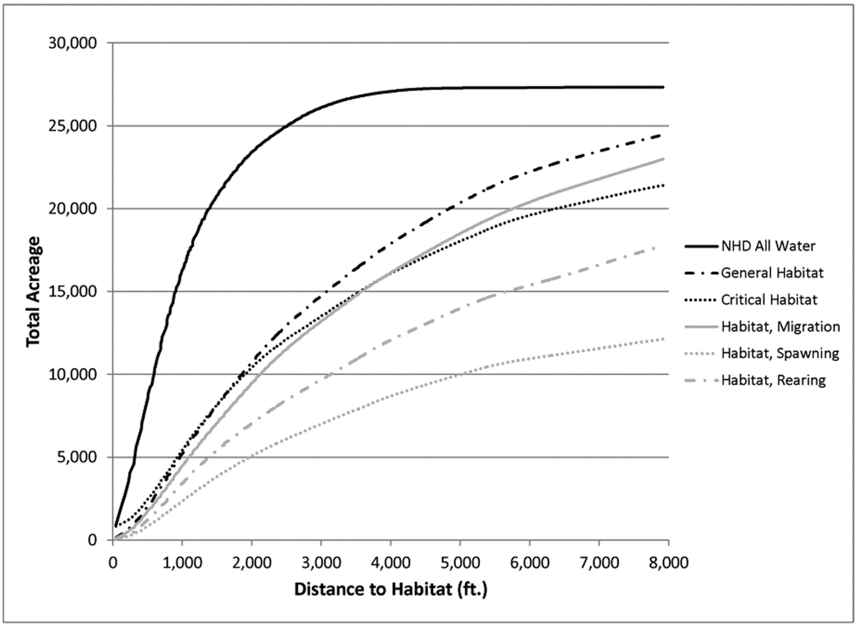

Figure 7. Comparison of Pesticide Use Site Proximity Cumulative Distributions for the Puget Sound Chinook ESU.

The pesticide use site proximity assessments for migrating, spawning, and rearing habitat classifications were summarized over the 28 ESUs/DPSs to further assess differences in potential exposure risk to the various salmonid life stages. For each ESU/DPS, the use site percent area within a given proximity to each habitat type was calculated. Next, these percentages were averaged over all of the ESUs/DPSs (where data were available). These results are shown in Figure 8. This summary shows a clear difference between the acreages potentially affecting spawning habitat versus rearing and migrating habitat area. The use site intensities for the migrating habitat areas are consistently higher than both rearing and spawning areas, with use intensities for rearing habitat areas close to that of the migrating habitat areas. For the 100 ft through 1,000 ft distances, the pesticide use site intensity within the spawning habitat distances are only 20% to 25% of that for the migrating and rearing habitat distances. This suggests that the areas around the water bodies supporting salmonid spawning are less likely to be cropped than the areas surrounding the rearing and migrating water habitat areas.

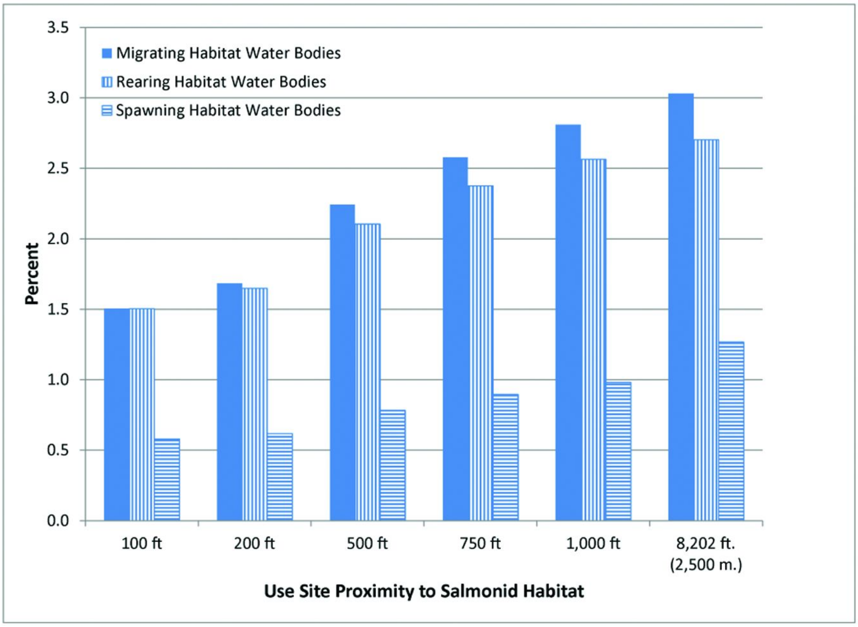

Figure 8. Pesticide Use Site Intensity within Different Setbacks to Salmonid Habitat Classifications, Averaged Over All ESUs/DPSs.

Conclusions

A GIS-based methodology for quantifying potential pesticide use site proximity to salmon habitat was developed that used the best available spatial datasets and an automated spatial processing approach. The data generated from this analysis allowed a detailed evaluation of the pesticide use site characteristics within a broad range of proximities to salmon habitat. The assessment evaluated different habitat classifications independently in order to gain a more comprehensive understanding of the potential pesticide exposure risk to salmon species at different life cycle stages. The results of this analysis showed the strength of the GIS approach for large-scale proximity assessments and the importance of considering spatially explicit habitat data when relating pesticide use site proximity to species exposure potential.

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Chapter 14

Ecological Risk Assessment for Salmon Using Spatially and Temporally Explicit Exposure Modeling: Moving Forward

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Applying well-understood aspects about the spatial and temporal distribution of salmon in a watershed can lead to more ecologically realistic and substantially different estimates of their exposure to agricultural pesticides compared with worst-case assumptions. Use of a spatially and temporally specific framework has other implications for regulatory decision-making, specifically: 1) a requirement to account for the sources and magnitude of model uncertainty, and 2) the determination of population effects requires accounting for multiple exposure levels. The increased complexity of the framework pays off by informing decision-makers of the range of risk agricultural pesticides pose to salmon and of targeted opportunities for efficient risk mitigation. Use of spatially and temporally explicit exposure models face several obstacles which can be overcome with education, outreach, and further development of these model frameworks. Such efforts are recommended given the gains these models provide.

Introduction

Pacific salmon (*Oncorhynchus* spp.) exhibit repeatable patterns of movement and habitat use during their life in freshwater (*1*). They are diadromous: they spawn and rear in freshwater streams, migrate to sea where they grow and mature, and then return when mature to their natal stream to spawn. The cold,

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

gravel-bottom streams to which salmon are adapted are generally found in forested areas in the upper portions of river basins, and often several hundred kilometers from the ocean (*1*). The migratory life history of salmon is an adaptive strategy that takes advantage of secure and productive opportunities for spawning and early rearing in freshwater, while also harnessing high growth opportunities in the ocean. As mature salmon return to freshwater to spawn, they home accurately to their natal area within a watershed. Many juveniles remain in these natal areas throughout their freshwater rearing, while others exercise a range of migratory patterns within freshwater to seek out seasonal opportunities that are advantageous elsewhere in the basin (non-natal areas). Migrations that redistribute juveniles within freshwater are timed to avoid seasonally unfavorable circumstances, such as low flow and high temperatures during summer, so migrations typically occur in spring and fall (*1*, *2*). The lower elevation and valley bottom portions of river basins that may provide good rearing opportunities during fall through spring are often inhospitable and avoided by juveniles during summer. These lower portions of the basin are also where the floodplain is generally broadest and where agriculture is a common land use. Juvenile salmon also show fine-scale habitat preference when rearing—in response to factors such as water velocity and prey availability (*3*, *4*). In short, it is fairly well-understood when and where salmon occur and how this pattern changes throughout the freshwater portion of their life cycle.

Because the presence of both pesticides and fish vary independently over time and space, we would expect the exposure of fish to pesticides in their natural habitats to vary widely over time and space. However, ecological risk assessments typically have not accounted for the spatial and temporal distribution of Pacific salmon in freshwater. Instead, they have been based on the simplifying worst-case assumption that 100% of a salmon population is exposed to an environmental stressor of interest (e.g., agricultural pesticides at a given concentration). They do not consider that, due to the spatial and temporal variability of fish distribution *and* environmental stressors, exposure may be less than 100%. And, by assuming the worst-case, they do not provide decision-makers with information about the range of exposure that could occur. This simplifying assumption underlies ecological risk assessments in two recent Biological Opinions (*5*, *6*) which will be a focus in this chapter.

In this chapter, we provide a brief recap of the recently published Intersect model (*7*, *8*) which accounts for the spatial and temporal variability of salmon exposure to agricultural pesticides in freshwater. This model was used to predict the exposure of juvenile spring Chinook (*O. tshawytscha*) to the organophosphorous insecticides chlorpyrifos, diazinon, and malathion, and the carbamate insecticides carbaryl, carbofuran and methomyl in the Willamette Basin, Oregon. We demonstrate here how such models can provide information about the range of pesticide exposures and how this information can be used to better represent population effects. We also address several obstacles these models face for acceptance as regulatory models.

Model Overview

This section provides a brief recap of the Intersect model (*7*, *8*). Readers should consult the original publications (*7*, *8*) for a detailed description and demonstration of the model. Development of Intersect involved adapting an existing exposure analysis framework (*9*) to consider fish migration among habitat units and fish use of habitat proportional to its quality (Figure 1). Temporally, we accounted for differences in juvenile life-history pathways and their use of natal and non-natal streams over an entire brood year in 42 biweekly time steps. We used estimates of juvenile passage at migrant trap locations to track the differing proportions of juveniles that emigrate from natal streams in which they were spawned downstream to non-natal stream reaches where they reared or passed through, and ultimately outmigrate to the ocean in the spring and fall. In the Willamette Basin, for instance, most spring Chinook complete their juvenile rearing in natal streams in the upper portions of the basin before emigrating downstream. Spatially, we accounted for differences in the extent of fish use in 859 distinct reaches covering 8 tributary subbasins and 3 mainstem subbasins. Within each reach, we accounted for preferences exercised by spring Chinook salmon for specific types of habitat. Key determinants included stream area, habitat type (e.g., pools, riffles, backwater), and stream width. Combined, this information was used to account for the proportion of adult-equivalent juveniles (juveniles that will survive to become spawning adults) produced in the basin that can be found in any habitat during any time-step.

This information was then integrated with spatially and temporally explicit information about agricultural pesticide concentrations to determine the proportion of juvenile adult-equivalent salmon co-occurring with high pesticide concentrations during any time-step. As a first approximation, we estimated the proportion of juvenile salmon that rear in habitats where higher pesticide concentrations could occur (i.e., low velocity habitats near areas where agricultural pesticides are used and could be transported to the stream via drift or runoff). The recent Biological Opinions (*5*, *6*) assume that higher pesticide concentrations would occur in off-channel, backwater habitat occurring within 1,000 ft of agricultural land cover. Based on this assumption, we estimated that 13% of all juvenile adult-equivalents in the Willamette Basin used such habitats (*7*). Practically, this represents an upper bound to the probability of exposure. This outcome is substantially different than the worst-case assumption of exposure to agricultural pesticides (i.e., 100%).

A key reason for this outcome is that most agricultural pesticide use in the Willamette Basin occurs along streams crossing the valley floor, and not natal to spring Chinook. Most juvenile spring Chinook rear in their natal streams upstream of agricultural lands (Figure 2). In the valley bottom where the broad floodplain provides most of the agricultural land, high stream temperatures during summer, lower habitat quality, and predation are among factors contributing to avoidance of non-natal reaches (*10–13*). Those juveniles that do rear in non-natal reaches prefer to rear in off-channel, backwater habitat; however, such habitat is limited. Stream surveys indicate that backwater habitat accounts for only about 5% of total rearing habitat in non-natal streams (*14–16*). Thus, most juveniles use higher velocity, edge habitat along the main channel. Because the amount of backwater habitat is limited in the Willamette Basin, the proportion of the population rearing in backwaters is, therefore, limited. Overall, such detail about patterns of fish and pesticide use in the Willamette Basin provides the regulatory decision-maker with more information relevant to risk assessment than when assuming 100% exposure.

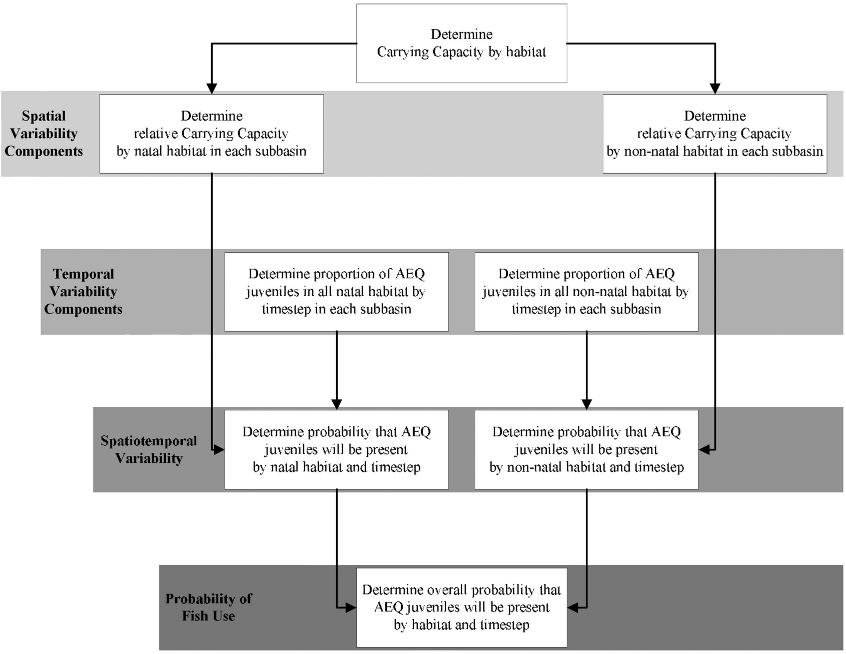

Figure 1. The Intersect modeling framework for determining the probability of juvenile salmonid presence (adult-equivalents) across time and space.

Example Application for Evaluating Direct Effects

When evaluating direct effects, the question becomes: what fraction of juveniles co-occurs with pesticide concentrations expected to result in adverse effects through direct contact? We answered this question in the Willamette Basin (*7*) using a pesticide concentration profile derived from the National Water Quality Assessment program (*17*). We chose a station that occurred in low-velocity habitat that was adjacent to and draining from the highest concentration of agricultural land use in the basin, and recorded the highest pesticide concentrations in the basin. The monitoring record covered up to 13 years of observations from which we derived the return frequency of occurrence for several pesticide concentrations. Readers should consult the original publications (*7*, *8*) for a detailed description of the derivation of this profile. Generally, peak concentrations occur in the late fall and winter during periods of greater precipitation and surface runoff.

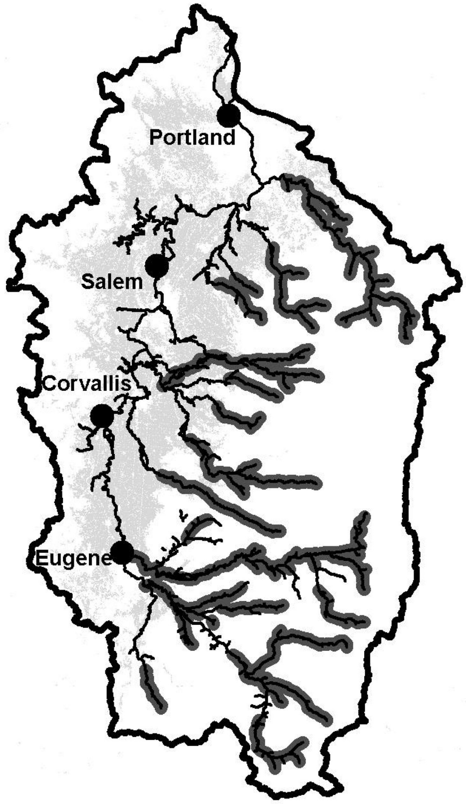

Figure 2. Natal (shaded lines) and non-natal streams used by spring Chinook salmon in the Willamette Basin relative to agricultural land (shaded areas).

While this timing of peak concentrations generally coincides with peak emigration from natal streams in the Willamette Basin, exposure was capped by the 13% of salmon predicted to use off-channel, backwater habitat adjacent to agricultural lands. We predicted that nearly all of these juveniles co-occurred with at least the lowest detectable concentration of these pesticides. However, the probability of exposure to successively higher levels decreased rapidly to 2% at 0.5 µg/L, and none at 1.0 µg/L. Co-occurrence with elevated concentrations was greatest in the late fall and winter during periods of greater precipitation and runoff (leading to higher pesticide concentrations) which coincide with peak movement of spring Chinook salmon to rearing habitat in non-natal streams.

Example Application for Evaluating Indirect Effects

When evaluating indirect effects, the question becomes: what fraction of the juvenile population co-occurs with pesticide concentrations expected to adversely affect components of the environment that fish rely on? We answered this question in the Willamette Basin (*8*) by evaluating reductions in aquatic invertebrates on which juvenile salmon feed. Recognizing that the extent of habitats expected to yield higher pesticide concentrations was limited, we chose to evaluate indirect effects via reduction in carrying capacity in backwater, off-channel habitats—rather than a reduction in growth as would be appropriate if exposure were 100%. Several studies demonstrate a strong relationship between carrying capacity and prey abundance (*18–21*).

Our framework considered the reduction in relative abundance of prey taxa comprising the spring Chinook diet in the Willamette Basin. We accounted for the spatial and temporal distribution of prey taxa (*22–24*) and estimated effects using species sensitivity distributions normalized to the most toxic compound, assuming additive toxicity and similar sensitivity across taxa. Using the pesticide profiles described above, we estimated that prey base reduction in off-channel, backwater habitats could be as much as 30%. Co-occurrence of this reduced prey base with fish use was greatest in the late fall and winter when higher pesticide concentrations coincided with peak rearing in non-natal streams *and* when the predominance of prey were from more sensitive taxa. Overall, we found that the basin-wide reduction in carrying capacity was about 5%. We posited that this lost capacity is probably compensated elsewhere via increased occupancy (emigration to other habitats) not accounted for in the model.

Implications for Decision Making

By applying well-understood aspects about the spatial and temporal distribution of juvenile salmon, the Intersect model provides a reasonable basis to find that the exposure of juvenile salmon to agricultural pesticides could be less than 100%. A recent workshop devoted to spatially explicit exposure models (*25*, *26*) asserted that such estimates are “more ecologically realistic”. Use of such a framework has other implications for decision-making. One is that by using a more complex model, informed by disparate data sources, the question of model uncertainty becomes relevant. The other is that the determination of population effects now requires accounting for multiple exposure levels across the basin. We address both of these in this section.

Evaluating Model Uncertainty

There are two main sources of uncertainty that can underlie spatially and temporally explicit exposure models. One is the variability about the many model inputs used to characterize patterns of fish use, prey effects, and pesticide concentrations. Some variability is natural within these systems and some variability reflects errors in the data used to inform these models. The second key source of uncertainty is our lack of complete understanding about how these systems work. The patterns of fish use, pesticide use, and prey response can be more complex than an already complex model represents. Ostensibly, the recent

Biological Opinions (*5*, *6*) compensate by assuming the worst-case scenario (100% exposure). However, more detailed assessments are possible.

Detailed sensitivity analyses were conducted for our demonstrations in the Willamette Basin (*7*, *8*). We evaluated uncertainty in several key parameters influencing patterns of fish use (extent of natal habitat, percentage of juveniles rearing in non-natal habitat, and percent area of backwater, off-channel habitat) as well as prey reduction (diet composition, prey availability, and toxicity effects). We found that although there were statistical uncertainties, these factors varied within physical or biological limits. Extent of natal habitat, for instance, is fairly well-understood in the Willamette Basin. While it can vary year-to-year as climate variability affects stream conditions, it is limited by the availability of suitable substrate and cool temperatures which generally decrease from the headwaters to the mouth (*10*, *11*). Readers should consult the original publications (*7*, *8*) for a detailed description of limits bounding key parameters. By varying these factors one-at-a-time within these limits, we found that the fraction of juvenile adult-equivalents that rear in habitats where high pesticide concentrations occur would vary less than 5% and that reduction in overall carrying capacity under such circumstances would also vary by less than 5%.

Greater concern about model uncertainty tends to be expressed where pesticide use varies among crops and among years, and because low-frequency monitoring programs may not detect peaks in pesticide concentrations. Detailed sensitivity analyses were conducted for our demonstrations in the Willamette Basin (*7*, *8*) that evaluated statistical uncertainty in the monitoring record. We did this by calculating tolerance limits (confidence limits about percentiles in the data distribution) to assess a range of upper-end exposure outcomes. We found that it could affect exposure estimates substantially. We found, for instance, that no juvenile adult-equivalents co-occurred with average pesticide concentrations exceeding 1.0 μg/L (this is because the monthly average never exceeded this concentration threshold in the monitoring record). In contrast, if concentrations everywhere were at the 95% upper confidence limit of the 95th percentile (estimated from the monitoring record), nearly 12% would exceed the 1.0 μg/L threshold. These analyses are instructive, but are not necessarily realistic because they assume that a given concentration level occurred everywhere agricultural land is present, all the time.

To overcome this simplifying assumption, in this chapter we instead evaluated exposure outcomes when pesticide concentrations vary in accordance with the frequency of concentration levels observed in the monitoring record. We used the same monitoring record as in our Willamette Basin study (*7*, *8*) and conducted 1,000 simulations where we randomly chose monthly values representing the upper extent of the 25th, 50th, 75th, and 100th percentile of the frequency distribution. For our simulations, we still assumed that concentrations would occur everywhere when they were simulated to occur. With these simulations, we were able to characterize the range of exposure levels—not just point estimates—occurring at various concentration thresholds (Figure 3). We found that nearly all fish in off-channel, backwater habitats near agricultural lands are exposed to detectable concentrations of the six agricultural pesticides in mixture. As the concentration threshold increases, exposure decreases but the average exposure level calculated from the simulations is greater than the point estimate we calculated assuming an average concentration level. Such a detailed assessment is made possible using the Intersect framework and is more useful for understanding the potential range of exposure outcomes.

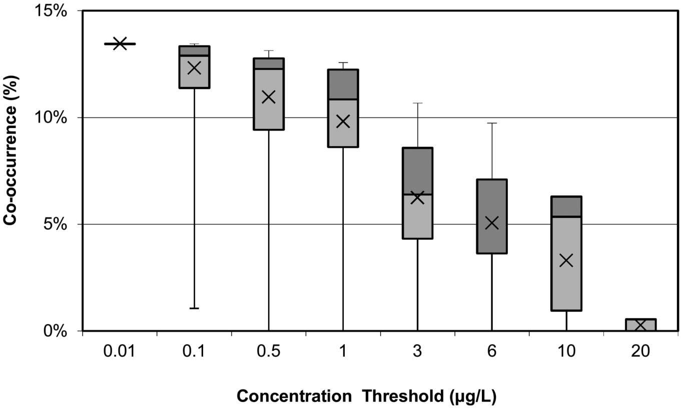

Figure 3. A range of exposure outcomes at various concentration thresholds resulting from stochastic simulation of monthly pesticide concentration levels.

Evaluating Population Effects

The recent Biological Opinions (*5*, *6*) use the change in lambda, the intrinsic population growth rate, as a key determinant of ecological risk. If the difference between lambda for an exposed population and that for an unexposed population exceeded one standard deviation for the unexposed population, then the exposed population was determined to be at significant risk. In their analysis, lambda was affected by first-year survival. First-year survival was determined for several individual pesticide concentrations assuming 100% exposure of juvenile salmon. Several endpoints were evaluated. Conducted over a range of concentration levels, these analyses yielded a range of lambda values, each representing the effects of 100% exposure to a single pesticide concentration. These analyses are instructive, but are not necessarily realistic because they assume that the entire population is exposed to a single concentration level.

To determine population effects when a substantial fraction of juvenile salmon is unexposed, and when the remaining fractions are exposed to multiple concentration levels, a similar but different approach must be employed. As we can interpret from Figure 3, a large fraction of juvenile adult-equivalents could be exposed to no or low pesticide concentrations (where survival would be relatively unaffected) but lesser fractions could be exposed progressively higher concentrations levels (where survival could be affected). To account for this, we have to consider the fractions exposed to different concentration levels and the direct and indirect effects to these fractions. For this chapter, we demonstrate this concept via calculation of an exposure-weighted first-year survival rate. We use the first-year survival rates reported for several concentration levels in the recent Biological Opinions (*5*, *6*) as representative of effects occurring at each concentration level. Use of these survival rates in this manner requires several simplifying assumptions that warrant further research; however, they remain useful for demonstration. For progressively higher concentration levels, we first determine the fraction of the population co-occurring with each concentration. We then multiply these fractions by the first-year survival rates reported for each concentration level. Finally, we sum these products over all concentration levels to yield an exposure-weighted first-year survival rate. By weighting, we yield an overall survival rate that is more representative of population-level effects in a system where fish use and pesticide use vary in time and space.

For instance, using the range of pesticide concentrations in Figure 3 and first-year survival rates reported for 60-day exposure to chlorpyrifos reported in the recent Biological Opinion (*5*), we calculated an exposure-weighted first-year survival rate of about 0.51%. To get this result, we first calculated the fraction of the unexposed population (100% - 13% = 87%). Of the 13% that are exposed, we calculated the fractions exposed to 0.01 μg/L, 0.1 μg/L, and so on up to 20 μg/L. For this demonstration, we used the maximum values reported in Figure 3 for our calculations. For example, the fraction of the total population exposed to 0.1 μg/L is <<1%. These fractions were multiplied by first-year survival reported in the Biological Opinion (*5*) that ranges from about 0.56% for the unexposed population down to 0.21% when 100% of the population is exposed to 20 μg/L. For example, the contribution of the unexposed population to the exposure-weighted first-year survival rate is approximately 0.87 * 0.0056 = 0.0048. This accounts for a large fraction of the overall survival rate. Only a small fraction of the population is exposed to concentration levels with relatively low survival rates. Hence, the exposure-weighted survival value decreased only a little from that for the unexposed population.

To interpret the effect on lambda, we used the relationship between first-year survival and intrinsic population growth rate as reported in the recent Biological Opinions (*5*, *6*) (Figure 4). Use of this relationship in this manner also requires several simplifying assumptions that warrant further research; however, it remains useful for demonstration. Using it, we determined that the lambda value for the exposure-weighted first-year survival rate of 0.51% was about 1.06. This value of lambda was only 0.03 less than that reported in the recent Biological Opinions (*5*, *6*) for an unexposed population (1.09), even though it accounted for those portions of the population that were exposed to concentrations up to 20 μg/L. The reduction in lambda using the exposure-weighted survival rate did not exceed the standard deviation of lambda for the unexposed population (0.08). According to the criteria employed in the recent Biological Opinions (*5*, *6*), the exposed population would not be considered to be at significant risk. In contrast, when 100% of the population was assumed to be exposed to single pesticide concentration levels, significant decreases in lambda occurred (see Figure 5). Though more complex, accounting for multiple exposure levels is more representative.

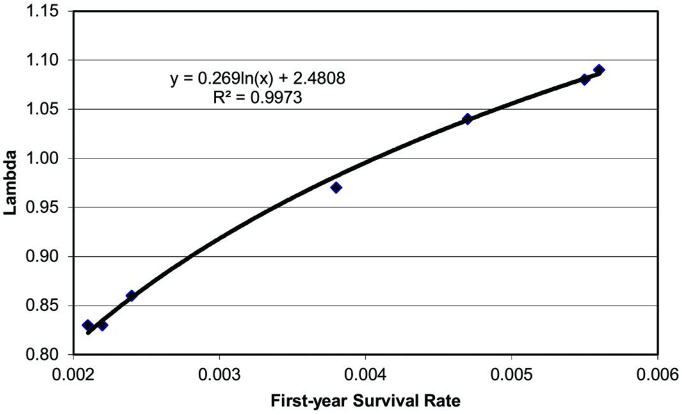

Figure 4. Relationship between lambda and first-year survival reported for ocean-type spring Chinook exposed to chlorpyrifos (5).

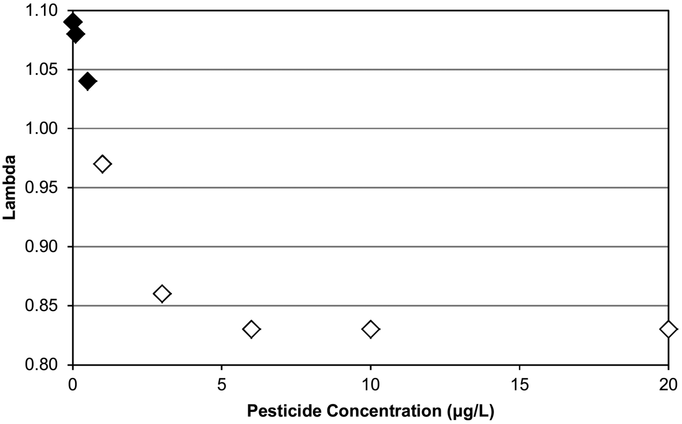

Figure 5. Lambda values reported for 100% exposure of ocean-type spring Chinook salmon to different concentrations of chlorpyrifos (5); significant changes in lambda are indicated by open diamonds.

Overcoming Impediments To Use

Despite the arguably positive gains that spatially and temporally explicit exposure models can provide to decision making, there are numerous scientific, technical, and cultural obstacles to overcome (*25*, *26*). Scientifically, there have been two major concerns. One is that, because of the uncertainty underlying the many parameters used in these models, model estimates are unreliable. The response to this concern can be drawn from our discussion above. Yes, uncertainty does exist, but there are systematic ways to evaluate its influence on modeled outcomes. The Intersect framework enables the estimation of the probability for a range of outcomes. Instead of a relying on a single point estimate, decision-makers can test the implications of the various assumptions underlying the model. Done probabilistically, such analysis provides insight into the chances that significant population effects could occur. This is not possible when assuming 100% of the population is exposed to a single pesticide concentration. Better information will lead to better risk management.

Another scientific concern is that spatially and temporally explicit models "dilute" exposure estimates. The concern is that one could understate the rate of exposure of salmon to pesticides by factoring in area or time that does not have high pesticide concentrations. More correctly, the spatial and temporal accounting assigns the full rate of exposure wherever it occurs, and eliminates the systematic misassignment (bias) of exposure where there is none. Risk assessments that can be rolled up to population-scale improve ecological relevance (*27*). Our framework evaluates spawning and rearing use of juvenile spring Chinook salmon within an evolutionary significant unit (ESU). This is, by definition of an ESU, a population-scale assessment. Spatially and temporally explicit models may have mathematical uncertainty, but they increase accuracy by reducing the systematic bias created by assuming that the entire population experiences a single exposure level. The spatial and temporal accounting is more ecologically realistic. Overcoming the "dilution" misperception requires on-going education.

Many have expressed that spatially and temporally explicit exposure models are too complex to apply over the entire range of an ESA species. There are two responses that could help alleviate this technical concern. One is that the model frameworks described above (*7*, *8*) are proof-of-concept and we could reasonably expect future generation models to be much simpler. As proof-of-concept, the Intersect model was built to demonstrate how, by applying well-understood patterns of fish use, we can gain more ecologically realistic exposure estimates that could improve regulatory decision-making. We felt that the best way to demonstrate this would be to build the models at the finest spatial and temporal resolutions supported by the available data. However, as we did this, we discovered that such fine resolutions are not always necessary. For instance, fish distribution does not have to be accounted for at a habitat unit scale within each reach. In our demonstration, we accounted for fish in each of thousands of habitat units across the basin. Instead, it would probably be adequate to simply use summary-level information about the relative carrying capacity in each sub-basin, in natal streams vs. non-natal streams, and in its allocation among different habitat types. Instead of an array of nearly 10,000 values, we would be accounting for an array of only about 100 values. Whereas, it may take an analyst the same amount of work to populate either array, an array of 100 summary values *is* easier to comprehend than one of 10,000. As the approach matures, this technical concern regarding complexity will be overcome.

Another response to this concern is to emphasize that the data used to populate these models is widely available throughout most of the range of ESA salmon species. Programmatic data sets are available on the extent of salmon fish use, habitat quality preferred by juvenile salmon, choice of juvenile life-history pathways, and timing of emergence, emigration, and outmigration. Where they are not, reasonable approximations can be made. Predictive models can be built from the available data to fill data gaps. We successfully accomplished this in our demonstration (*7*). Alternatively, data gaps can be filled through the expert opinions of biologists working in the area. Although expert opinions may have great uncertainty, sensitivity analysis can reveal the effect of this uncertainty on model outcomes. In the few instances when uncertainty substantially affects decision-making outcomes, it can become a focus of additional information gathering. For instance, we found in our demonstration that two variables had the greatest influence on predicted exposure—downstream extent of natal habitat and extent of backwater, off-channel habitat. Consultation with local biologists would be a very reasonable means to gather local knowledge about these variables. This technical concern regarding data gaps can be overcome in systematic fashion.

After a number of examples have been assessed with this modeling approach, it may be possible to generalize the typical fraction of a population that could be impacted by agricultural pesticide use. If so, then the generalized estimate could be applied to outcomes from simpler risk evaluations that are not spatially and temporally explicit to interpret risk in a more realistic manner for Pacific salmonids. For example, if a screening-level exposure model predicts a concentration value in an agriculturally dominated water body that may affect fish directly or indirectly through effects on aquatic invertebrates, then the risk assessor can interpret the severity of the risk by considering that only X% of the population will be exposed. Such factors are currently considered in risk assessments for listed migratory terrestrial animals such as birds, where proximity of chemical use to occupied habitat also has a variable spatial and temporal profile. Although this usually involves a simple presence/absence analysis, there is no reason that minor exposure potential cannot also be included in an assessment involving best professional judgment. From this perspective, it is not necessary to conduct spatially and temporally explicit assessment for every new situation if there is sufficient knowledge transferable from previous similar cases.

Finally, there is the cultural perception that there is little precedent for the use of spatially and temporally explicit exposure models in ecological risk assessment. This perception is largely a matter of resolution. The recent Biological Opinions (*5*, *6*), in fact, do consider spatial and temporal variability—just at a very coarse resolution. Finer resolution formulations are mostly beyond the experience of the regulatory and risk assessment community. It will require continued outreach to educate the regulatory and risk assessment community to "unveil" how these models are constructed and how they can be put to work. This symposium has provided an effective forum for this kind of outreach. Published, peer-reviewed work documenting these frameworks has been an important step as well. Such outreach should continue. It would be of great value to package these models and put them in the hands of stakeholders, along with packaged datasets, training materials, and workshops. Not only do these measures further educate both managers and stakeholders, but they also provide the opportunities for important feedback. Overall, there is room for improving the accessibility and visibility of spatially and temporally explicit exposure models, which should increase their use in risk assessments.

Recommendations

By applying well-understood aspects about the spatial and temporal distribution of juvenile salmon, more ecologically realistic exposure estimates are possible. These improvements can lead to improved regulatory decision-making. In some instances, they can affect risk determinations. For this reason alone, these models warrant consideration in the ecological risk assessment process. Further, the added detail included in these models is useful for identifying where and when management actions pose the greatest potential, and when they lack potential, to mitigate damaging levels of un-intended exposure to pesticides. The dramatic increase in environmental monitoring, both of physical and biological attributes, now makes the inputs needed to inform such models more readily available, and the growing scientific literature on examples of spatially and temporally specific ecological models provides the know-how to assemble such models. Thus, resource managers should push past lingering resistance to application of such models, and strongly support such actions as education, outreach, and refinement of modeling tools that will lead to their broader adoption. It is time to recognize that application of best available science requires that available details of spatial and temporal differences in ecological function be integrated into analytical tools supporting management decision-making. Thus, we recommend that application of this modeling approach be expanded, which will lead to better stewardship in the management of our natural resources.

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Chapter 15

Advancements in Endangered Species Act Affects Determination for Pesticide Registration Actions

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The United States Environmental Protection Agency is beginning the review of pesticide registrations under the Registration Review provisions of the Food Quality Protection Act. This process will include the completion of effects determinations and consultation for federally listed threatened and endangered species under Section 7 of the Endangered Species Act. The spatial, biological and temporal complexity of effects determinations and consultation for pesticide regulatory decisions, often made at a nationwide geographic scale, necessitates the movement toward a process that automates and standardizes many aspects of pesticide risk assessment. This development raises important scientific issues between the EPA and the U.S. Fish and Wildlife and National Marine Fisheries Services.

Introduction

The Food Quality Protection Act mandated a new Registration Review program for the United States Environmental Protection Agency (EPA). All pesticides except those exempted under the Federal insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 259(b) that are distributed, sold, and used in the United States must be registered by EPA, based on scientific data and analysis showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The Registration

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Review program makes sure that all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects.

Changes in science, public policy, and pesticide use practices do occur over time. Through the Registration Review program, the EPA will reevaluate pesticides to ensure that as changes occur, pesticide products can still be used in an acceptable manner consistent with the available information of chemical hazard, exposure, and public policy. The Registration Review program challenges EPA to continuously improve its processes, science, and information management while maintaining a collaborative, transparent and open public process for decision-making.

As part of the Registration Review process, EPA will be evaluating pesticide regulatory decisions in the context of provisions under the Endangered Species Act. Section 7(a) (2) of the ESA requires federal agencies to ensure that any action they authorize, fund, or carry out, will not likely jeopardize the continued existence of any listed species, or destroy or adversely modify any critical habitat for those species. In fulfilling these requirements, each agency must use the best scientific and commercial data available. Pesticide regulatory decisions made by the EPA are federal actions subject to compliance with these requirements.

As EPA embarks on a multi-year process of Registration Review there are key factors that the Agency must consider:

- Seven hundred and thirty-nine pesticide cases comprising 1,155 active ingredients are being re-evaluated through Registration Review.
- Many pesticide active ingredients are formulated in numerous pesticide products.
- Pesticide products may be registered for numerous sites of use encompassing a range of application rate, method, and interval as well as a variety of target pests.
- The spatial scale of pesticide application may involve a few to millions of acres of land either highly localized or nationwide in scale.
- Review of existing pesticide registration decisions must be publically transparent.

The resultant combinations and permutations of pesticide active ingredients, products, and use areas results in a complex matrix of environmental and use parameters pertinent to exposure estimation. This is on varied geographical levels of resolution that pose challenges for assessing the impacts of the regulatory decisions on listed species for which occurrence may range from highly localized sites to distributions that are dispersed across many states.

To meet the demands of high throughput of regulatory decisions, large scale analysis, high resolution decision-making, and multiple legal mandates requiring the consideration of best available information, EPA is challenged with meeting both FIFRA and ESA requirements through the development of a risk assessment and listed species effects determination process that will:

- Improve efficiency
- Enhance transparency
- Improve spatial representation of exposure/risk
- Engage in independent scientific review of issues and processes

Efficiency Improvements

As stated earlier the regulatory scope of a pesticide active ingredient may involve a complex matrix of registered formulations involving one or more sites of use distributed across the landscape of the United States and its Territories. Ecological risk assessments to support Registration Review and listed species effects determinations must make use of a variety of environmental fate and effects data (including publically available data) for pesticide active ingredient, formulations (when available) and pesticide degradates. These data are then used in a suite of environmental exposure and risk integration models that consider the pesticide formulation, and the site, rate, method, timing, and interval of application. These models may be run numerous times, incorporating geographic differences in soils, meteorology, and in the case of agriculture, local cultivation differences as well as regional and local differences in pesticide use. The results of these models are presented as taxonomically specific risk conclusions, which are assigned geographic areas within and around the various use sites. These areas of expected effects are then associated with best available information on the locations of listed species and their biological characteristics to address the basic questions:

- Are there listed species within the areas of expected effects?
- Are any of the taxonomically–based effects directly or indirectly applicable to each species within the effect areas?
- Can risk mitigation measures be undertaken in specific geographic areas to reduce or preclude effects on listed species?

Performing such an information and modeling intensive assessment with a high degree of spatial and biological specificity and simultaneously accessing the best available information from a variety of sources is beyond the manual calculation capabilities of a risk assessor for any but the most limited pesticide suites of formulations and sites of use. For the more complex matrices involving variations in pesticide use combined with varied physical features of use sites, and accounting for the spatial and biological characteristics of individual listed species across all those use sites, EPA must turn to a more automated process employing an assessment integration tool that can:

- Interface to available EPA and other federal and state agency databases (e.g., use site locations, rates of pesticide use, species locations, and species biology) and models
- Automate computation of risk assessment metrics
- Automate spatial cross-referencing of risk outcomes with listed species location
- Identify situations favorable for risk mitigation exploration
- Provide real-time assessment of mitigation impacts to effects determinations

It is important to understand that the envisioned automated process should be capable of rapidly identifying areas where initial modeling and risk assessment efforts suggest potential adverse affects to resources targeted for protection. However, it should be recognized that such standardization runs the risk of inappropriately applying models and assumptions to situations where alternative methods of analysis would be more appropriate. For example, concerns for false negative outcomes (i.e., no adverse effects predicted, though adverse effects may actually occur) can be reduced through careful and reasonably conservative assumptions and model parameterization.

Therefore the overall assessment process must be flexible enough to incorporate additional lines of information for locations where initial assessment efforts have triggered concerns. Though not clearly defined at present, the process must be capable of additional tiers of analysis, either during Registration Review or during consultation under ESA so as to address additional lines of information as they are made available to EPA.

Such a tiered approach has been supported by the National Academies of Science in *Science Decisions: Advancing Risk Assessment*:

> *The committee recognizes that EPA has the technical capability to do two-stage Monte Carlo and other very detailed and computationally intensive analyses of uncertainty and variability. But such analyses are not necessary in all decision contexts, given that transparency and timeliness are also desirable attributes of a risk assessment, and given that some decisions can be made with less complex analyses (1).*

Figure 1 depicts this information access, calculation, and integration process conceptually for both terrestrial and aquatic organism risk assessment under the present suite of tools and methods used by EPA. The diagram shows:

- Information sources
- Modeling steps (including pesticide environmental monitoring data considerations) for establishing risk calculations
- Off site transport process models to extend exposures and risk estimates beyond the pesticide use site
- Species location and biological integration
- Development of spatially specific mitigation measures to reduce or avoid listed species effects

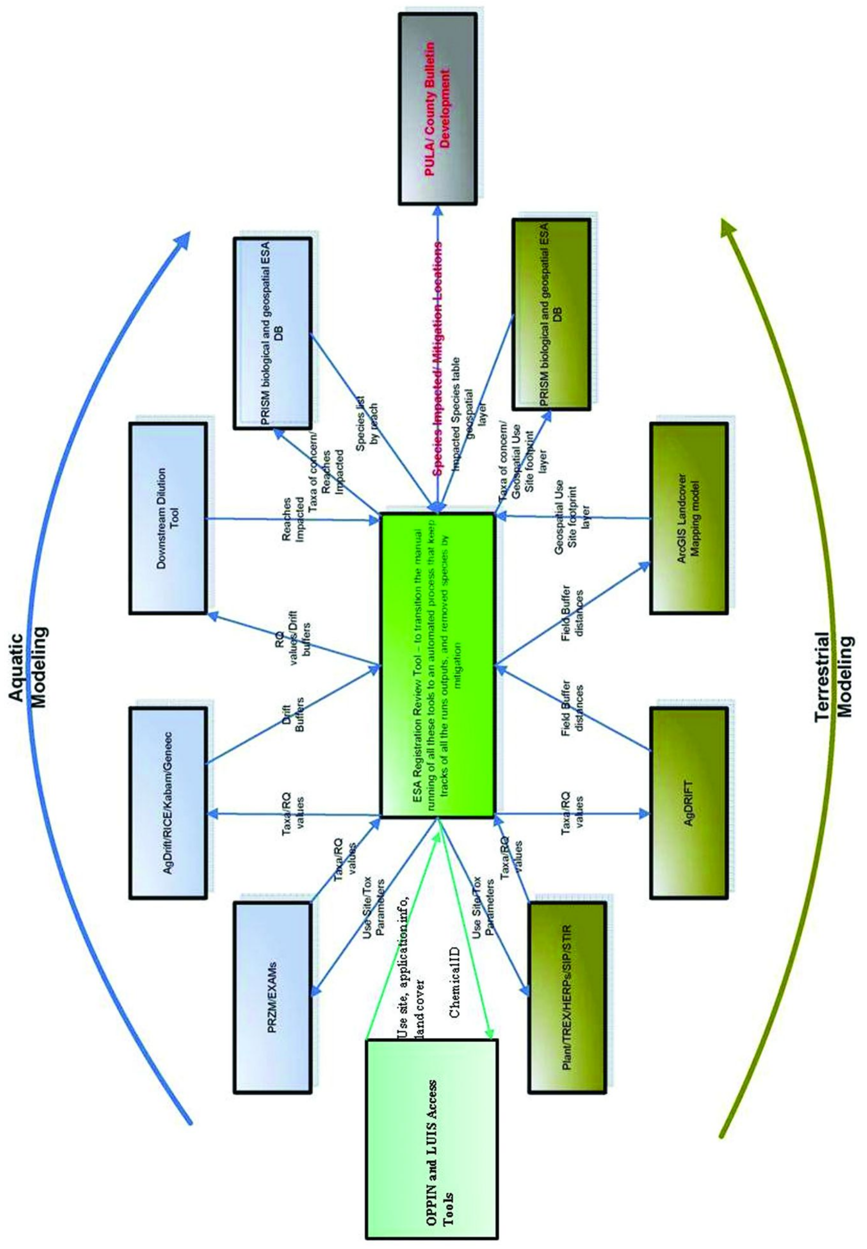

Figure 1. Integration Tool Conceptual Information Flow Diagram.

Transparency Enhancement

In order to maximize the opportunity to receive public perspective and knowledge, EPA produces risk assessment products that adhere to the principles outlined in the Science Policy Council Handbook on Risk Characterization (*2*). The Handbook calls for a risk assessment process that is transparent, clear, consistent and reasonable. Under this guidance the Registration Review risk assessment process to support listed species effects determinations is intended to be an explicit, well described approach that discusses assumptions, extrapolations, model use, plausible alternative assumptions, and gaps in the available data, uncertainties, and the relative strength of the risk assessment.

The Registration Review process is intended to provide a number of points of entry for public and stakeholder participation to benefit the quality of risk assessments supporting effects determinations. Perhaps the greatest opportunity for transparency and public input is available during the Problem Formulation stage of the ecological risk assessment. The Problem Formulation is intended to direct the risk assessment process through (1) a clear discussion of protection goals, (2) a statement of the hypotheses to be tested in the risk assessment, (3) presentation of the conceptual model relating pesticide use, exposure, effects, and consequences to attributes requiring protection, and (4) a discussion of the analysis plan to test the hypotheses using the available information on pesticide use as well as environmental fate and effects. An important goal for enhanced transparency is to seek public input to ensure that the data used by EPA is the best available and that protection goals are consistent with societal objectives. During this process the following decisions are reached which will influence the conduct of the risk assessment:

- Understanding the use and usage patterns of the pesticide
- Identification of the stressors of concern to include active ingredient, formulated products, and degradates
- Identification of the available environmental fate and effects data to be used in the quantification of exposure and risks
- Identification of exposure, fate and effects data gaps
- Discussion of risk assessment assumptions in the face of gaps
- Identification of exposure routes of potential concern and consistent rationale for routes not of concern
- Description of any models and environmental monitoring to characterize exposure
- Description of the exposure and effects integration methods to assess risk at determined taxonomic, spatial, and temporal levels of resolution

The initial drafting of a risk assessment and effects determination follows the problem formulation step. It is anticipated that, for many registration actions, the public review and data generation activities addressing the Problem Formulation's description of the approach to the risk assessment will reduce the potential for drastic risk assessment revision. However, the risk assessment process following the draft stage must be amenable to modification. Should additional evidence become available between draft and final risk assessment, the incorporation of more specific information on pesticide use and species can be assessed for the potential to reduce or avoid adverse effects to listed species.

The final risk assessment is intended to incorporate the best available information regarding the use of the pesticide, its fate and effects properties, and an understanding of the location and biological requirements of a listed species within areas of expected effects. The final risk assessment is also intended to include all proposed modifications of pesticide use intended to reduce or avoid adverse effects on listed species. This final risk assessment should contain the necessary information to initiate informal and formal consultation with the Services of any listed species judged to be likely or not likely adversely affected by the proposed regulatory action.

Improved Spatial Representation of Exposure/Risk

EPA is in the process of improving the spatial representation of pesticide use sites. Early preregistration review approaches followed assessment methods employed in a number of single species effects determinations in which agricultural use sites were conservatively assigned to appropriate GIS (Geographic Information System) shape files in the National Land Cover Data, a joint United States Geological Service and EPA geographical information data set (www.epa.gov/mrlc/nlcd-2006.html). However, based on public input to effects determinations relying on this type of spatial assignment for uses, EPA realizes that better, more refined data sets may be available to improve analytical resolution while accounting for uncertainty in future changes in use sites. EPA is actively engaged in external scientific peer review with the National Academies of Science regarding the use of geospatial and pesticide use information to focus analyses appropriately, taking into account:

- The dynamic nature of pesticide exposure
- Variability in pesticide usage
- The possibility that pesticide use may change in the future
- The limitations of available data on current usage
- Which existing data sets are appropriate to consider and the data characteristics that are relevant for various scales

Ecological risk assessment processes have relied on runoff and drift loading models that use a suite of scenarios as conservative representations of soils, meteorological conditions, agronomic practices and pesticide use. EPA has, up to now utilized regional use site scenarios to represent comparatively large areas of the nationally distributed uses sites and crops. This has been necessary because of the computational resource limitations of the Agency. However, the high degrees of variation across the landscape for the input parameters associated with the Agency's exposure models, when placed in the context of often limited geographic ranges of listed species, suggests that reliance on conservative regional scenarios for surface water modeling may assign concern for effects to listed species in areas where application of the best available information using more highly resolved spatial distributions of the parameters would not.

The information and approaches described above are important considerations when conducting an assessment of risks in the pesticide application area. However, The Endangered Species Consultation Handbook (*3*) and 50 CFR Section 402.02 indicate that Section 7 effects determinations and consultations with the Services must consider the entire action area. This is specifically defined as "all areas affected directly or indirectly by the Federal action and not merely the immediate area involved in the action." To accomplish this task, EPA is exploring ways to advance the risk assessment process to make use of new modeling approaches that account for downstream transport of pesticide loads to surface water, and spray drift to surface waters and terrestrial environments remotely distant from the pesticide use site. EPA is focusing its downstream transport analysis efforts to:

- Integrate multiple uses of a pesticide across watersheds
- Follow pesticide loads downstream
- Follow the resultant change in the risk picture with pesticide transport

Figure 2 is a conceptual depiction of the application of spray drift and downstream transport considerations in the context of the locations and biology of listed species. Figure 3 is a similar conceptual depiction of the use of spray drift transport considerations for defining the action area in terrestrial systems.

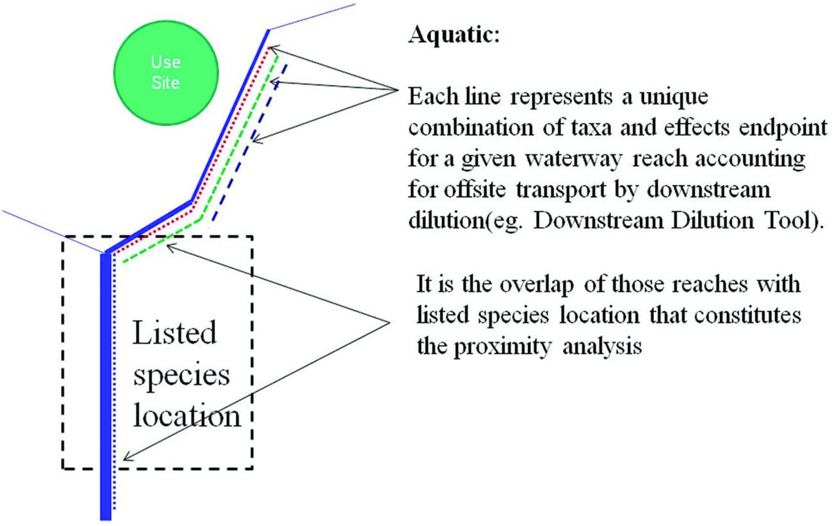

Figure 2. Conceptual depiction of downstream transport and dilution of pesticides when defining the Action Area.

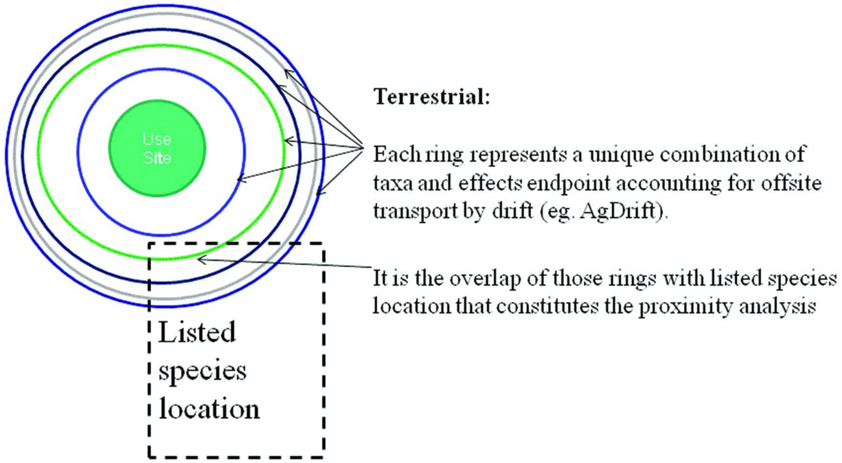

Figure 3. Conceptual depiction of spray drift transport of pesticides when defining the Action Area.

Independent Scientific Peer Review of Issues and Processes

In the spring of 2011 the National Academy of Sciences' National Research Council was requested by EPA and the Departments of Agriculture, Commerce, and Interior to convene a panel of independent experts to consider a suite of scientific and technical issues that have been identified as the federal agencies exercise their joint responsibilities under the Endangered Species Act and FIFRA.

The federal agencies' experience in completing consultations under ESA for FIFRA-related actions has identified several scientific issues (http://www8.nationalacademies.org/cp/projectview.aspx?key=49396). The agencies are seeking the Academy's advice on approaches for assessing the effects of proposed FIFRA actions on endangered and threatened species and their critical habitats. Among the topics identified for Academy review are:

- Identifying best available scientific data and information
- Methods to consider sub-lethal, indirect, and cumulative effects
- Approaches for assessing the effects of chemical mixtures and inert ingredients
- The use of models to assist in analyzing the effects of pesticide use
- Incorporating uncertainties into the evaluations effectively
- The use of geospatial information that can be employed by the agencies in the course of these assessments

In addition to this current effort, the National Academies have provided past guidance to the EPA, especially in the critical area of accounting for uncertainty in the risk assessment process. Pertinent to the EPA's current effort to automate and standardize improvements to computation and information access Science *Decisions: Advancing Risk Assessment* offered the following:

> *...it is important to recognize that there are some uncertainties in environmental and health risk assessments that defy quantification (even by expert elicitation)...and that inconsistency in approach will be an issue to grapple with in risk characterization for some time to come. The call for homologous treatment of uncertainty should not be read as a call for "least-common-denominator" uncertainty analysis, in which the difficulty of characterizing uncertainty in one dimension of the analysis leads to the omission of formal uncertainty analysis in other components (1).*

With completion of the National Academies of Science recommendations it is anticipated that EPA and the Departments of Commerce and the Interior will renew efforts to establish an effects determination and ESA consultation process that will reflect the practical application of available information in the above specific technical areas with appropriate measures to address sources of uncertainty to ensure that FIFRA federal actions will not jeopardize listed species or their critical habitat.

It is possible that incorporation of the National Academies of Science recommendations will involve the development of additional methods to characterize uncertainty and utilize new data sources, and new methods to characterize exposure and effects beyond those currently employed by EPA in reach FIFRA regulatory decisions. The EPA will likely seek scientific peer review of any new methods through its FIFRA Scientific Advisory Panel, which is chartered to provide advice on recommended improvements in the effectiveness and quality of scientific analyses made by EPA (http://www.epa.gov/scipoly/sap/pubs/charter.pdf).

Acknowledgments

This publication expresses the opinion of the author. It has not undergone Official Environmental Protection Agency peer review and may not be considered as the official opinion of that agency.

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Chapter 16

Data Quality, Reliability, and Relevance Standards for Ecological Risk Assessment: Recommendations for Improvements to Pesticide Regulation in Compliance with the Endangered Species Act

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Risk assessment procedures used by the U.S. Environmental Protection Agency (EPA) for pesticides have been worked out over a period of years and are now well-established and well-known by the regulated community. Similarly, the nature of the database needed to support a standard EPA risk assessment for a pesticide is well-established and well-known. These procedures and data are used to make assessments for endpoints that are deemed relevant to the questions at hand for a particular pesticide. In contrast, no instructional guidelines for evaluating data reliability or relevance for the purpose of endangered species assessments for pesticides are in place. This circumstance has resulted in considerable confusion and uncertainty in the overall consultation process. In this paper, we begin with an overview of some methods used to ensure that high quality data are selected for a risk assessment and we then examine what criteria might be applied to whether data are in fact relevant for a given assessment. Finally, we provide examples of how improperly selected data can strongly influence the conclusions of an assessment, if such data are not of high quality or solid relevance. But we also provide guidance

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on how to decide which studies beyond guideline studies may (and should) be incorporated into the risk assessment. This paper concludes that no instructional guidelines for evaluating relevancy and reliability are in place, and shows that peer review does not always serve that purpose. Consequently, the risk assessor must use due diligence to consider risk assessment and protection goals in light of data reliability and relevance. Suggestions provided here on how a risk assessor might weigh data for use in a given risk assessment hopefully enhance the assessor's ability to utilize or question data and give it the proper role in the given risk assessment exercise.

Introduction

In 2002, the Office of Management and Budget (OMB) set forth guidelines for all federal agencies to ensure and maximize the quality, objectivity, utility and integrity of information they disseminate. The agencies that administer pesticide regulation and species protection have processes to address data quality, but not necessarily agreement on a standard approach to qualifying data used in an assessment with respect to its "reliability," and "relevance." Data of the best methodology and quality performance standards may serve well in one assessment role but poorly in another. A robust ecological risk assessment must assemble and depend upon data that is reliable and relevant in order to address its protection goals.

Ecological risk assessments are performed on pesticides by a variety of federal entities, as well as by pesticide registrants. The U.S. Environmental Protection Agency (EPA) has the responsibility to ensure that the basic procedures for risk assessment, which have been set out and generally agreed upon (*1*), are employed for federal risk assessment purposes. In brief, ecological risk assessment is performed in 3 phases: problem formulation, analysis, and risk characterization. In the problem formulation phase, risk assessors evaluate protection goals and select assessment endpoints, which are characteristics to be protected for a valued entity. Protection goals addressed by the risk assessment (also referred to as risk management goals) are the societal values that are to be protected or managed. For example, a protection goal might be protection of fish species and their habitat, and assessment endpoints would be selected for their relevance to this protection goal (e.g., survival, growth and reproduction of fish, abundance of food items for fish). In this example, measurable endpoints that could be evaluated in a risk assessment would include laboratory or field study endpoints that measure the impact of a stressor on mortality, length, weight, and fecundity. In order to properly formulate the risk assessment, then, inputs from risk managers and other interested parties are critical at this stage to ensure that the assessment and measurement endpoints are relevant to the protection goals.

With a clear understanding of assessment goals and endpoints, risk assessors can prepare a conceptual model of potential exposure pathways and ecological entities that may be exposed and an analysis plan on how the assessment is to proceed. The execution of the analysis plan involves estimation of exposure and definition of the relationship between such exposure and ecological effects, both of which are related to an assessment endpoint, which in turn relates to the ecological entity or characteristic that is to be protected. The final phase, risk characterization, involves the integration of exposure and effects profiles and discussing the lines of evidence and determining if potential adverse effects exist.

A robust risk assessment, framed to address protection goals, relies upon (1) the quality of the studies that support it; (2) the relevance of study endpoints to the risk assessment with respect to their measures of effect or measures of exposure, and; (3) the quality and relevance of the chosen assessment endpoints to the attributes being protected. A robust ecological risk assessment should be supported by what is variously described as "high quality" or "best available" scientific information, selected with respect to its relevancy to the risk assessment at hand.

During problem formulation, all reasonably available data are collected to inform the subsequent assessment, and in the assessment process data appropriate for use are incorporated into the derivation of risk conclusions. The problem, however, is the lack of a universal regulatory meaning for data qualification criteria, and a described framework for relevancy of such data to a given endpoint. Without this, it is difficult to define the appropriate role for and weight of a given finding when risk characterization is undertaken. Given the fact that there are various methods for defining the use of high quality data, this paper focuses on ensuring that these high quality data are selected and applied reliably and with relevance, giving emphasis to standards that ensure contextual reliability. We also examine data attributes related to relevancy, mainly in the context of pesticide regulation under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA).

Federal Actions for Ensuring Data Quality

The OMB (*2*) guidelines mentioned above were promulgated through the Paperwork Reduction Act, and therefore all federal agencies must adhere to them. Furthermore, the guidelines incorporate the quality principles applied by Congress to the risk information used and disseminated pursuant to the Safe Water Drinking Act amendments of 1996 (*3*). The intent of the OMB to apply the guidelines to ecological risk assessments is clear in that "a risk assessment prepared by the agency to inform the agency's formulation of possible regulatory or other action" is specifically mentioned as an example of the information dissemination covered by the guidelines (*2*). Therefore, risk assessment is required by law to utilize and meet these data quality standards.

According to the guidelines (*2*), the term "quality" subsumes the characteristics of "utility," "objectivity," and "integrity," which have the following definitions:

- Utility: The usefulness of the information to its intended users (that is, reliability). And, when considering the usefulness of information it disseminates, an agency is required to consider not only the uses of the information from the perspective of the agency, but also from the perspective of the public.
- Objectivity: Includes two elements: "presentation" and "substance." The element "presentation" requires that information be presented in an accurate, clear, complete, and unbiased manner, and includes the information being presented in a proper context (that is, with relevancy).
- Integrity: The security of the information. Is the information protected from unauthorized access or revision, so that it is not compromised through corruption or falsification? In applying this term to the use of data in risk assessment, ensuring integrity would mean the referenced data is complete and used in its whole, within the context (relevance) it can scientifically apply.

It should also be noted that the issue of data reliability has surfaced in other contexts. For example, in March, 2009, President Obama issued a Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity. As a follow-up to this Memorandum, in December 2010 John Holdren of the Office of Science and Technology Policy issued a Memorandum on Scientific Integrity (*4*). In that memo, in point 2, on pages 1 and 2, a key feature of scientific integrity is stated as "ensuring that data and research used to support policy decisions undergo independent peer review by qualified experts, where feasible and appropriate, and consistent with law."

The various guidelines and policies cited above provided necessary, but not sufficient, conditions for qualifying data for use in ecological risk assessment. They do not ensure that data utilized in a risk assessment is consistent with the assessment's goals and endpoints. The guidelines and policies on quality per se do not specifically address the need for data to be relevant to the risk assessment itself. Relevancy varies from one type or scope of risk assessment to another. There are thus two conditions that need to be fulfilled before information can be used in a given risk assessment: relevancy and reliability as they relate to the risk assessment process (that is, protection goals and assessment endpoints). Even if a particular study fulfills the quality standards of utility, objectivity, and integrity, and is reproducible, the issue of applying data specific to protection goals and assessment endpoints must be addressed. One way to do so is to employ data quality objectives (DQOs) (*5*).

The DQO process is a strategic approach based on the scientific method that guides a data collection activity. It gives a systematic procedure for specifying, ahead of time, the criteria for a data collection design, including when to collect information, where to collect information, tolerable level of decision errors, and how much information to collect (*6*). This process includes identification of issues and stakeholders, as well as the participation of stakeholders (*6*). EPA (*7*) includes a brief discussion of the use of data quality objectives in ecological risk assessment. FIFRA studies conducted under Good Laboratory Practices (GLP) obviously fulfill the "relevancy" intent of DQOs because they exist as a suite of data intentionally developed to serve a specific risk assessment process. McCarty et al (*8*) recently reviewed information quality in peer review versus GLP studies. The authors note that GLP is best at data quality, documentation and ensuring reproducibility, but is not "foolproof." Journal peer reviewed studies bring forth new science and data, but peer review "…is currently not a reliable process for establishing data quality, nor does it represent an unequivocal metric for establishing relative merit of data or interpretation and conclusions drawn from those data." (*8*). The authors conclude that neither process (GLP or peer-review) can stand alone in determining the relevancy or reliability of a study to be used in a risk assessment process, but that only a sound weight of evidence scheme can fulfill this need.

Problem formulation for the risk assessment on a registration action requires a baseline set of data, as outlined in pesticide data requirements that have evolved over time (40 CFR Part 152). However, EPA may and often does determine that it is necessary to collect additional data to address important components of the protection goals. When pesticide data are used in alternate risk assessment programs, such as that for ESA, a DQO assessment could make the case for inclusion or exclusion of additional relevant and reliable data, because in that regulatory setting other types of studies may have contextual relevancies or irrelevancies that affect usefulness.

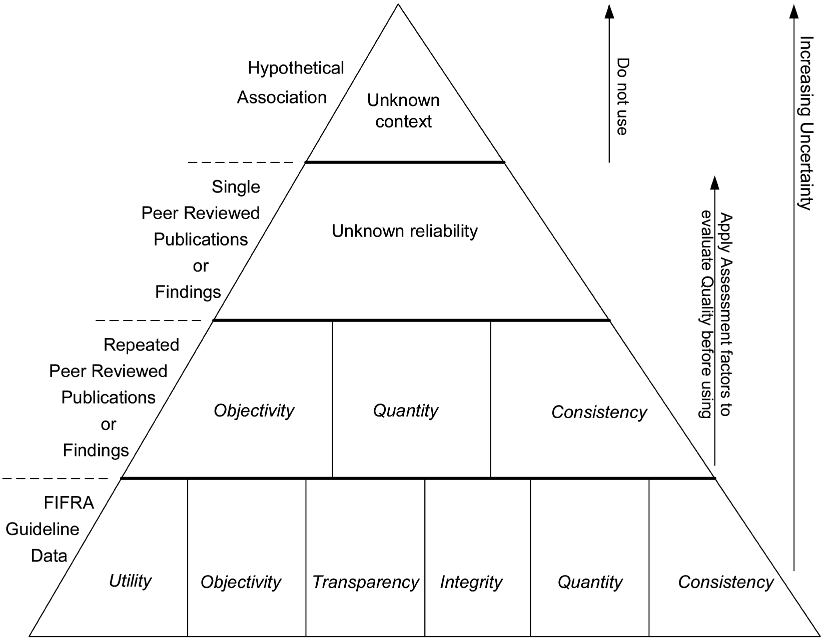
For pesticides, the basic relevance, reliability, and quality decisions have already been addressed through the 40 CFR Part 158 data requirement tables, which describe the core data necessary to performing a risk assessment on a proposed registration action. For ecological risk assessments under FIFRA, EPA primarily relies on results from these core studies, as performed under GLP standards, but EPA also reviews and evaluates other data for its reliability in and relevance to the assessment. The required FIFRA studies, which have been through a validation program, are described by specific details for conducting them (EPA's harmonized test guidelines (*9*), especially Series 850 (Ecological Effects Test Guidelines) and Series 835 (Fate, Transport, and Transformation Test Guidelines)). Although OMB (*2*) does not mention the FIFRA pesticide review process that EPA uses to evaluate required studies, it is clear that the EPA process for data submission, study review, risk assessment, and ultimately, registration, functions as a peer review, and complies with the OMB guideline. Subsequent to the promulgation of the information quality standards by OMB, EPA, NOAA, and USFWS, there was an independent verification that FIFRA, GLP studies fulfill the criterion of "best available scientific information." In their review of EPA's approach to assessing the ecological risks of pesticides, the U.S. Fish and Wildlife Service (USFWS of the U.S. Department of Interior) and National Marine Fisheries Service (NMFS of the U.S. Department of Commerce), specifically identified FIFRA guideline, GLP studies as "best available scientific information" (*10*).

Additional Approaches To Ensure Data Quality

To accommodate the relevance and reliability aspects of data quality, a step that can be considered is a "relevancy ranking" exercise on individual studies, as a prelude to their use in an ecological risk assessment. For example, EPA (*11*) provided guidance for determining the adequacy of existing data in the context of EPA's high production volume chemicals program. In that program, EPA makes it clear that their preferred choice is for hazard studies that are conducted under optimal conditions, following good laboratory practice (*11*). However, where only alternate types of studies, not meeting GLP requirements, are available, EPA (*11*) discusses the use of the classification system developed for populating the International Uniform Chemical Information Database (IUCLID). This system was developed by Klimisch et al. (*12*). The system provides a formalized way to consider reliability, relevance, and adequacy. "Adequacy" is defined as "the usefulness of the data for risk assessment purposes." Under the system of Klimisch et al. (*12*), studies are classified as: 1, or reliable without restriction; 2, or reliable with restrictions; 3, or not reliable, and; 4, or not assignable. This ranking concept can be taken one step further by defining the usefulness of the data for a given risk assessment purpose.

McGaughey (*13*) combines features of the guidelines, data quality objectives, and a study classification system to produce a data quality pyramid for study evaluation and selection (Figure 1). The pyramid establishes what components of the data provide the strongest base for the use of the data by describing 6 attributes that must be considered when evaluating a study or data (*13*). The 6 attributes correspond to the general attributes of "quality" as described in the Data Quality Act (utility, objectivity, transparency (as in the Act); and integrity, quantity, and consistency). As these attributes are lost, the strength of the base of the pyramid is diminished and the study or data will lose its reliability for ecological risk assessment. Giving integrity, quantity and consistency equal weight in establishing the base of the quality pyramid opens the opportunity to ensure relevancy and reliability. Data relevance and reliability come into question if referenced data are (1) not rectified to the objective at hand (opposite having integrity), (2) scarce (opposite abundant data in agreement), or (3) inconsistent (opposite high levels of consistency in all other studies).

In the context of using existing data for ecological risk assessment, Markweise (*14*) sets out a tiered procedure for collecting data and for analyzing the quality of that existing data. The process begins with an explicit statement of the problem, followed by an information survey to include the maximum amount of pertinent information. The result is the identification of key data. Once the data are identified, they go through a practical screen to eliminate unrepresentative or incomparable data. This screen is followed by a methodological screen to evaluate data quality, which includes ranking by experts, according to quantitative criteria. Criteria to be considered are termed soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review (= data validation, experimental replication).



"Best available" loses reliability as it sheds its components of quality

FIFRA Guideline Data: Has its *utility* defined by FIFRA testing guidelines; has its *consistency* defined by EPA review; has its *quantity* defined by FIFRA data requirements; has its *objectivity, transparency* and *integrity* assured by GLP requirements.

Repeated Peer Reviewed Publications or Findings: Has *consistency* defined by replication; demonstrates *quantity* based on the statistical design of the studies ; has its *objectivity* from peer review; has *ultility* to the extent it supports risk assessment; but loses its *integrity* and *transparency* because methods are not documented to the degree GLP's require.

Single Peer Reviewed Publications or Findings: Has limited *objectivity* depending on the level of peer review but has its *utility* defined by one circumstance and may not have been deigned for purposes of risk assessment; and loses its *transparency b*ecause methods are not documented to the degree GLP's require, loses its *quantity* by its isolation and is of unknown *consistency*.

Hypothetical Association: Has vitually no *utility;* loses its *objectivity* to subjective speculation; has no *transparency* in methodological scientific application; is not supported by any *quantity* of data; and has no measure for *consistency.*

Figure 1. Data Quality Pyramid for Risk Assessment Processes and risk Management Decisions.

Breton et al (*15*) developed an electronic scoring system (eco-QUESST, Ecotoxicological Quality Evaluation System and Scoring Tool) to assess the quality and usability of aquatic ecotoxicology studies (fish, daphnid and algae) for the New Substances Notification Regulations in Canada. The electronic system takes the evaluator through a series of questions (largely based on (*12*)) that are weighted for their importance. Similarly Hobbs et al (*16*) and Markich et al (*17*) developed a rating scheme to evaluate the studies in the Australasian Ecotoxicology Database (AED). Both approaches use a numeric scoring system to document the quality evaluation of studies. Breton et al (*15*) provides a comparison of the 2 approaches.

Recently, EPA's Office of Pesticide Programs (OPP) released an internal guidance document: "Evaluation Guidelines for Ecological Toxicity Data in the Open Literature" (*18*). This paper provides their procedures for screening, reviewing and using published open literature toxicity data in Ecological Risk Assessments. The primary source for open literature are those articles that have been included in the EPA ECOTOX Database, for which there are defined criteria that must be met in order for them to be included in the database. However it should be noted that these criteria are somewhat basic and only focus on a few quality aspects of the data. Once it has been determined that a paper meets these minimal criteria, then OPP would classify it into one of 3 categories:

- Quantitative – appropriate for use quantitatively in risk characterization. These studies must be scientifically valid and demonstrate a relationship between the measurement and assessment endpoints stated in the risk assessment.
- Qualitative – not appropriate for quantitative but sufficient quality, relevant to issues of concern in the risk assessment, and can be used descriptively in risk characterization.
- Invalid – inappropriate for use in quantitative or qualitative and lacks scientific defensibility.

The OPP approach recognizes that not all scientific studies are appropriate for risk assessment; it could however be more explicit in recognizing the factors that can be used in making judgments on study categories.

Building Blocks for Defining Relaibility and Relevancy

It is clear from the above regulatory and procedural examples that the elements of quality as defined by the integrity of a given report or publication are generally agreed. However, the decisions on which studies to include for a specific assessment endpoint have no similar common thread of definition. Such selections need to be made through a thoughtful process that will allow the assessor to reach sound scientific conclusions about potential risks with respect to protection goals. It is not easy to qualify an item of data with regard to its relevancy or unique reliability, because the dynamics of the assessment come fully into play in defining the useful database. Since the dynamics of an assessment will vary based on the setting, there seemingly is no single set of definitions that would provide guidance. Instead, it is the biology and logic of the assessment itself that drives what data are indeed reliable in it and relevant to it.

Table I sets forth a series of questions that address either data quality or data relevancy issues, within the context of a risk assessment (*19*). If these questions are used as a weight of evidence approach to incorporate data reliability and relevance into the assessment process, the result will be a body of information upon which the assessment relies, selected in a manner that reduces the uncertainty of the final conclusions. Within each quality measure (utility, objectivity, transparency, quantity, consistency and integrity) the more answers that can be given as a "yes" inform the ultimate weighting factor applied.

Table I. Questions to be used in a weight of evidence approach for data quality and relevance (*19*)

Quality and Relevance Criterion	*Definition or description*	*Key Questions – Study Quality*	*Key Questions – Study Relevancy and Reliability*
Utility	Usefulness to its intended purpose	--	• Does the endpoint under consideration relate to the assessment endpoint in the risk assessment? • Is it likely that the study endpoint will significantly impact the assessment endpoints under relevant field conditions? • Can the study endpoint be detected or measured in the field? • Is the exposure route in the study relevant to the conceptual model? • Is the study duration consistent with potential exposures in the field? • Is the testing strategy (organism, exposure scenario) aligned with the occurrence and the persistence of the test substance in the environment (target compartment)? (*12*) • Are physical/chemical properties of the test substance (hydrolytic, photolytic aerobic and anaerobic stability, volatility, solubility) fully considered before planning the test design? (*12*)
Objectivity	Information being presented in a clear, complete,	• Is there full disclosure of sources of information? • Has the study been conducted under accepted testing guidelines or test	--

Continued on next page.

Table I. (Continued). Questions to be used in a weight of evidence approach for data quality and relevance (*19*)

Quality and Relevance Criterion	***Definition or description***	***Key Questions – Study Quality***	***Key Questions – Study Relevancy and Reliability***
	contextually appropriate and unbiased manner	procedure? • Has the study been peer-reviewed either through a regulatory review or through published literature?	
Transparency	Identification of data sources, methods, assumptions, criteria for data acceptance and scientific justification for use of the methods	• Has the study met all data quality and reporting criteria? For example ○ Clear documentation of test procedures ○ Test substance identity and purity ○ Identification of test species and relevant life history parameters ○ Feeding of test organisms pre- and during the test ○ Acclimation of test organisms ○ Definition of measured parameters/endpoints ○ Methods for determining effect concentrations ○ Exposure duration ○ Use of emulsifiers/stabilizers or other solvents ○ Appropriate control groups ○ Neutralization of samples ○ Test substance dosing mechanisms ○ Analytical verification of test substance concentrations ○ Physical and chemical test conditions (pH, light intensity and photoperiod, temperature, hardness)	• Have sources of uncertainty and potential errors been identified?

Continued on next page.

Table I. (Continued). Questions to be used in a weight of evidence approach for data quality and relevance (*19*)

Quality and Relevance Criterion	*Definition or description*	*Key Questions – Study Quality*	*Key Questions – Study Relevancy and Reliability*
Quantity	The magnitude of the effect influencing the amount of data needed to validate the effect and sample and study replication	• Are there appropriate number of organisms, replication and statistical power in the study?	• Do the study endpoints relate to the available suite of data? • Is the effective concentration higher, lower, or within the same range of other endpoints/
Consistency	The extent to which similar findings are reported and to which similar methods and analyses were used.	• Has the study been replicated?	• Is there supporting or refuting data available? • Are the endpoints consistent with other findings? • Is there an explanation for differences in findings from other studies?
Integrity	Protection of information from unauthorized access or revision	• Has the study been conducted under Good Laboratory Practices? • Are the data available for further analyses?	--

Each of the criteria can be weighted to facilitate decision making as to the appropriateness of endpoints and studies, in a fashion similar to that done for general quality (*12*). Table II gives an example of how weighting might be applied in the assessment process, if one combined the weighting mechanism put forth by Klimisch et al. (*12*) with a weighting process for relevancy and reliability. Studies of the highest value to a given risk assessment would be nearest the perfect score of 1-1-1 for quality-reliability-relevance. Studies of least value to the assessment would be nearest the 3-3-3 score, and those which should not be used in the assessment would be at or near the 4-4-4 score. If any of the criteria (quality, reliability or relevance) obtain a low score of 4, then it is likely that the study is not appropriate for the ongoing risk assessment.

Table II. Weighting quality, relevance, and reliability in building a database for risk assessment

Weight	***Klimisch et al (12) – General Quality***	***Hall et al (19) - Reliability***	***Hall et al (19) - Relevance***
1 (Highest)	Reliable without restriction	Study endpoint directly relates to assessment endpoint	Study endpoint contextually parallel with protection goal
2 (next to highest)	Reliable with restriction	Study endpoint indirectly relates to assessment endpoint	Study endpoint contextually similar to protection goal
3 (lowest)	Not reliable	Study endpoint unrelated to assessment endpoint	Study endpoint contextually different from protection goal
4 (not useful)	Not assignable	No association between study endpoint and assessment endpoint	Study endpoint cannot be placed in context

Examples of Data Reliability and Relevance and How They Affect Risk Assessment Conclusions

In this section, we present examples of how data reliability and relevance affect the qualification of studies for use in ecological risk assessments, and ultimately, affect the conclusions from those assessments.

Reliability

As an example of the evaluation of reliability, Hall and Anderson (*20*) reviewed the procedures that EPA used to establish draft water quality criteria for the insecticide diazinon (*21*). An unusually low criterion was set that did not reflect the expected values known for the product. The water quality criterion was set using the lowest mean acute values that occur in four different genera, as available from published studies and FIFRA data. One the values for a genera (the 200 ng/L LC50 for the amphipod *Gammarus fasciatus*) appeared anomalous for this genus, in that reported toxicity values for other amphipods range from 2000 ng/L to 184,000 ng/L (*22*). Reliability of the data is put in question when Hall and Anderson (*20*) point out study attributes:

- The study was conducted in 1966
- The product was impure (89% technical diazinon)
- Results were based on nominal, not measured, concentrations
- The concentration of diazinon was not verified in the test systems
- The study is well outside the range of toxicity values observed for similar species.

One would expect peer-reviewed publications to reliably reflect the underlying study data. However, when Hall and Anderson (*20*) were able to obtain the raw data sheets for this study, they learned that the concentration units were not reported correctly and that the actual LC50 was 2000 ng/L, in the range observed for other amphipods. Furthermore, a repeat of the study confirmed the 96 hour LC50 for this amphipod was 16,820 ng/L. When the more reliable value for G. *pseudolimnaeus* was used to replace the questionable value, the final water quality criterion for diazinon increased from 100 ng/L to 165 ng/L.

This example illustrates the power and importance of documentation, and in particular of having access to the raw data for a study, for knowing the purity of the test substance, and for basing results on measured concentrations. All of these features would be known in a Pesticide Assessment Guideline study, done under GLP's. We point out that many peer reviewed studies would not have the level of documentation and standardization inherent in a FIFRA GLP study or a study essentially having those elements. Consequently, a study not having those elements which produces an anomalous result should be carefully considered with respect to its reliability. It should also be noted that the original, flawed, study was influential data in the context of the assessment. But that study, in itself, ultimately did not support the reliability standard. In our data weighting exercise, the questions in Table I and the score assignments in Table II would likely have resulted in a very low quality score (a 3-3-1 or, given examination of the raw data, a 4-4-1).

Relevance

The examples above speak to study reliability. The other criterion, study relevance, is an issue when, for example, dose routes or dose volumes are not comparable to those found or expected in the environment and thus not relevant to the assessment goals. Dose routes that bypass normal exposure and metabolism may not be relevant to assessment goals, for example. When metabolic pathways are overwhelmed, or a product that normally would not be absorbed from the gastrointestinal tract is introduced intraperitoneally or intravenously, the resulting toxicological response is possibly not directly relevant to environmental risk assessment. While these dose routes may be helpful in identifying modes of action, they do not necessarily translate to use in characterizing environmental risk.

An example of these circumstances is given in a paper by Seiler (*23*) on the mutagenicity of benzimidazole and benzimidazole derivatives in bone marrow of the mouse and Chinese hamster. Many types of fungicides are mutagenic in mammals and other vertebrates when administered by intraperitoneal injection or directly into target tissue (egg yolks, for example). A finding of mutagenicity is not necessarily relevant for use in risk assessment, however. In the case of findings reported by Seiler (*23*), the dose route would not be encountered, and under expected exposure routes and conditions, the product is metabolized such that mutagenic activity would not be expressed. Note that this study also found that a threshold was demonstrated for this type of mutagenic activity, but this blood threshold would never be reached based on predicted environmental exposures. So, the questions and weighting in Tables I and II would place such a study in its appropriate role with respect to using or not using it in a given risk assessment, with a potential score of 1-2-4.

Relevancy also must take into account advances in scientific investigation. Carmichael et al. (*24*) point out how our increased knowledge of toxicological mechanisms shapes how in turn we can better design and interpret studies intended to assess the toxicity of agricultural chemicals. In traditional mammalian toxicity studies, doses are set by selecting levels expected to produce no effect, a minimal effect and a toxic effect. However, selection of very high chemical doses that overwhelm metabolic detoxification and/or clearance pathways, and that are widely separated from real-world environmental or worker exposure, can produce test results that are not relevant to human or other organism risks.

In the EPA OPP open literature guidance, an example of relevance for nontarget terrestrial plants is provided (*18*). Two GLP nontarget plant tests are required for pesticide registrations, a seedling emergence test that is initiated with seeds being planted in soil, and a vegetative vigor test that is conducted with small emerged plants. EPA notes that if a risk assessment is to be conducted on ferns, the most relevant test to consider is the vegetative vigor study since ferns lack seeds.

2,4-D, a widely used herbicide, provides another example. The minimally toxic effects of 2,4-D in rat animal toxicity tests are generally limited to dose levels known to saturate the metabolic clearance of 2,4-D from the body by the kidney (*25*). Rodents and humans share the same renal clearance mechanism, and extensive human biomonitoring data of 2,4-D indicate that doses leading to saturation of renal clearance in rats are in fact widely separated from actual human exposures to 2,4-D. Therefore, toxicities in the rat at dose levels at or above the saturation of renal clearance are not relevant for human risk assessment (see for example (*25*)). Thus, the case of 2,4-D illustrates how investments in understanding toxicological mechanisms can result in improved, science-informed risk assessments, given the ultimate score of the study with respect to general quality, relevance and reliability.

Another example of the importance of matching the test system and endpoint to the risk assessment objective is provided by the mechanistic study of Heimeier et al. (*26*). The authors studied the effects of bisphenol A (BPA) on embryos of *Xenopus laevis* to assess T3–dependent development at the morphological and molecular levels. They found that after 4 days of exposure to 0.1 and 10 μM BPA with the addition of T3 to the test system BPA inhibited T3-induced intestinal remodeling in premetamorphic X. laevis tadpoles. No effect on metamorphosis was observed in the BPA treatment groups (without T3). This paper may be scientifically interesting in examining gene regulation (i.e., the proposed mechanism for the apparent inhibition was the antagonizing the regulation of many T3-response genes, adversely affecting T3-signaling pathways). However, the results from the study have questionable relevance to risk assessment. The presence of additional T3 hormone during the frog metamorphosis process would not occur in nature. Consequently, the relevancy and reliability standards in Table I may have resulted in a lower total weighting for this study when Table II weighting factors are applied.

Conclusions

Data reliability and relevance are cornerstones supporting robust risk assessments. Data reliability, under the monikers “best available” or “high quality,” has received considerable attention. The importance of using “best available” scientific information has been fully appreciated, and several governmental organizations have set forth criteria and procedures to ensure that data can be identified and defended as “best available.” In this publication, we examine how reliability and relevance of data used in risk assessment must address the assessment and protection goals of the risk assessment by examining federal actions dealing with data quality and data quality in risk assessment. We introduce questions to aid in establishing data reliability and relevance, and a data quality pyramid that illustrates how the base of data reliance is strengthened by components of reliability and quality. These pieces of the puzzle are combined in a potential weighting scheme (as suggested by McCarty et al (*8*)) that can form the basis for study selection in a given risk assessment. To illustrate various challenges that lack of relevancy and reliability bring, we introduce examples of influential data that are not relevant or reliable in a given risk assessment setting.

In the realm of pesticide regulation, we argue herein that studies done (data developed) according to the Pesticide Assessment Guidelines and Good Laboratory Practices meet the standard of “best available,” on the grounds of utility, reproducibility, and integrity and therefore are appropriately relied upon in pesticide risk assessments We provide examples of how reliance on less robust studies can significantly alter measurement endpoints for risk assessment. But also provided is guidance on how to decide which studies beyond the guideline studies may (and should) be incorporated into the risk assessment.

In discussing the design of studies on agricultural chemicals, Carmichael et al (*24*) state objectives that can be modified to point to relevance:

- Utilize that information which can be applied to a range of relevant expected exposure situations
- Characterize potentially induced effects at exposure levels approximating those that might be encountered in the use of the compound
- Carefully interpret effects induced by studies with high dose levels that may overwhelm the exposed organism
- Utilize data from studies having an adequate number of test organisms housed under conditions that do not cause undue stress
- Consider carefully the relevance of results in studies having no control groups or deaths in the control group of organisms

Ultimately, risk assessments for pesticides benefit from a core data set driven by federal FIFRA and Good Laboratory Practice requirements, which address the protection goals of the registration process. However, additional data, when available needs to be examined with full consideration of its relevancy or reliability to the assessment goals at hand. It is therefore imperative to apply relevance and reliability standards to the data examined. This paper concludes that no absolutely instructional guidelines for evaluating relevancy and reliability are in place, and shows that peer review does not always serve that purpose. Consequently, the risk assessor must use due diligence to consider risk assessment and protection goals in light of data reliability and relevance. Suggestions provided here on how a risk assessor might weigh data for use in a given risk assessment hopefully enhance the assessor's ability to utilize or question data and give it the proper role in the given risk assessment exercise.

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Chapter 17

A Causal/Risk Analysis Framework for Informing Endangered Species Jeopardy Reviews for Pesticides

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A framework is proposed for evaluating the relative importance of select pesticides as sources of risks to the viability of endangered species. The framework is based on a causal/risk analysis approach that has been modified to be more specific to pesticides and endangered species matters. A step-wise process is proposed that involves the identification of candidate stressors including the pesticides in question, development of a comprehensive conceptual model that illustrates how the stressors may impact the endangered species (directly or indirectly), and application of criteria for judging the weight-of-evidence. The process yields outcomes that rank stressors. This allows for evaluation of pesticides in relation to other stressors to determine whether the select pesticides are affecting or may pose a risk to population viability and also to guide the development of species conservation plans. An example is provided for the kit fox, an endangered species, and a suggestion is made to conduct a collaborative project involving the Services (U.S. Fish and Wildlife Service, National Marine Fisheries Service), the U.S. Environmental Protection Agency, and the pesticide industry.

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
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Introduction

This paper presents a framework for using formal causal/risk analysis to evaluate the potential importance of pesticides as stressors that may increase the risk of extinction of endangered species in areas where there is overlap between those populations and the influence of the pesticides. The approach includes causal elements, because it presumes that historical or existing stressors have contributed to the endangerment of a species; the approach also includes risk elements, because some applications concern whether or not a pesticide could contribute further to endangerment. In some cases, the pesticides under evaluation are already present, while in others, they may be introduced. The purpose of the framework is to provide a means of judging the potential significance of particular pesticides under regulatory review. Such reviews are of particular import when considering potential effects on endangered species, and the framework is designed to provide a means of classifying such effects. It is also intended to highlight actions that may be most valuable for conservation plans. The proposed framework is intended to be used for evaluations that would benefit from greater structure, quantification, and clarity. There may be instances where simpler methods of evaluation suffice to answer management questions.

The framework is premised on the recognition that time to extinction can be influenced by a number of stressors, some of which may be especially important, while others may be less important and still others may be negligible (*1*, *2*). The relative importance of existing stressors can be assessed using causal analysis, an approach that has a long history of assisting health and environmental professionals in differentiating among causes of an illness or environmental impairment (*3*–*5*). A well-structured causal analysis can guide the collection and use of information needed to answer questions about causes/stressors, as well as their relative importance (*5*). With regard to questions concerning the viability of endangered species and the assessment of pesticides and other stressors, a causal analysis serves to: 1) guard against gaps in logic concerning candidate causes and effects; 2) provide transparency for "professional judgment" and scientific opinions; 3) identify principal causes/stressors that affect population viability and that could be mitigated; and 4) distinguish among negligible, minor, and major causes/stressors. A causal analysis enables stakeholders to be more easily engaged in the assessment of information and using it to support conclusions or guide mitigation measures. In cases where a new stressor such as a pesticide is introduced, the framework can guide the risk assessment aspects of the analysis and help answer questions as to whether the introduced stressor would be negligible, minor, or a possible major stressor. This aspect of the risk assessment for a pesticide would account for the existing stressors and the role they have played or are playing with respect to endangerment.

The proposed application of causal/risk assessment to pesticide assessments is derived from existing causal analysis methods that have been used to judge biological impairments in water bodies and have been used in one case to evaluate potential chemical stressors on the kit fox, an endangered species (*6*). We recognize that stresses on salmonids in the Pacific Northwest has been a matter of great interest with regard to the role that pesticides may play in influencing the risk of extinction. It is notable that causal analysis has been applied in a limited way to this matter. Wiseman et al. (*7*) explored seven candidate causes of biological impairment involving salmonids in the Touchet River (Washington, USA): 1) unspecified toxicity, 2) warmer temperature, 3) increased sedimentation, 4) decreased DO, 5) increased pH, 6) reduced detrital food, and 7) reduced habitat complexity.

In this paper, we first provide an overview of the proposed framework. We then provide an example of an actual application of causal analysis to an endangered species matter.

Proposed Framework

We propose an approach that ranks the contribution of pesticides to extinction risk for selected endangered species. For example, the pesticides could be sorted into three categories based on their contribution to extinction risk: “negligible cause/stressor,” “minor cause/stressor,” or “major cause/ stressor.” These categories and terms are simply suggestions, and greater discussion is needed to agree on a classification system. However, the principle idea is to have a classification system that allows regulators and others to understand the relative importance of a particular pesticide to a specified endangered species. This provides more insight than a binary-risk vs. no-risk conclusion.

The proposed seven-step causal/risk analysis framework (Figure 1) is patterned after that developed by EPA (*4*) for assessing causes of environmental impairments in water bodies. The framework is intended to support Section 7 consultations with the Services (U.S. Fish and Wildlife Service, National Marine Fisheries Service) regarding endangered species and the EPA regulatory process for pesticide registration. To that end, the framework lays out a process for categorizing stressors with respect to their influence on the time to extinction of the endangered species. Non-pesticide stressors with a potentially high impact are included, so that the added stress or risk from pesticide exposure can be appropriately and parsimoniously evaluated. As noted, the casual analysis framework is intended to support judgments concerning the relative significance of pesticides; this can involve classifying pesticides as negligible, minor, or major with respect to the stress or risk they pose for time of extinction of an endangered species. While the ultimate focus is on the role that pesticides have played or may yet play with respect to the time to extinction of a species, it is helpful, whenever possible, to identify all major stressors and to have an understanding of their roles. An explicit consideration of these alternative causes is valuable, because it makes the casual/risk analysis approach beneficial beyond the immediate question of answering specific questions regarding whether or not a pesticide is a contributing factor. A broader process that considers the range of alternative causes is more likely to be accepted than a process focused exclusively on one stressor. That said, the intent of the process is to enable a determination to be made about pesticides and their contribution to endangerment. The steps in the process are described in the following sections.

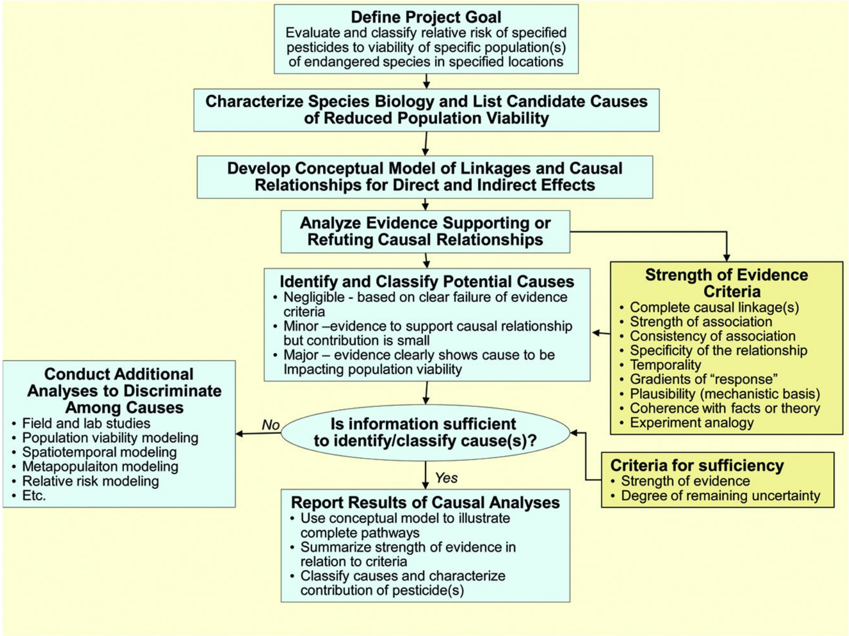

Figure 1. Causal/risk analysis approach.

This first step of the causal/risk analysis describes the goals and objectives of the assessment. It further specifies several key aspects of the assessment. These include: 1) identification of the endangered species, 2) identification of the pesticides being evaluated, 3) descriptions of the spatial and temporal characteristics of the assessment with regard to the species populations and the influences of the pesticide(s), and 4) an overview of the plan for applying causal/risk analysis. This step is similar in many respects to the problem formulation step used in ecological risk assessment (*8*), and guidance that has been developed for that purpose can be helpful for completing this step of the analysis.

The second step is to characterize the species' biological characteristics and ecological requirements. This step helps identify a species' vulnerabilities to various stressors. Relevant information used at this step includes life history characteristics and ecological and habitat requirements, with an emphasis on the characterization of critical habitat. Demographic information should also be included. The characterization of the species biology should include information on what is known about the cause(s) of the decline in the species population (required detail in the species listing document or recovery plans).

The identification of candidate causes of population declines, along with stressors that might influence recovery, is a key part of the second step of the analysis. For pesticide evaluations, including Section 7 consultations, the pesticides in question would be included along with the other candidate causes/stressors. The list should include the most obvious causes/stressors, as well as those that may be possible based on general knowledge or that may be of particular concern to trustees and/or stakeholders but whose causal relationship is not known. For most threatened and endangered species, a starting list of stress factors can be found in the species recovery plan drafted by the U.S. Fish and Wildlife Service. For guidance on development of a list of candidate causes, the following categories from the Endangered Species Act are helpful: 1) the present or threatened destruction, modification, or curtailment of its habitat or range; 2) overutilization for commercial, recreational, scientific, or educational purposes; 3) disease or predation; 4) inadequacy of existing regulatory mechanisms; and 5) other natural or manmade factors affecting its continued existence. Other categories that are relevant to the assessment of chemicals would include "pesticides" and "other toxic chemicals." These should be included among the basic categories because of the need to consider toxic chemicals in the assessment of potential stressors.

Once the comprehensive list of potential causes/stressors related to a species decline has been prepared, a conceptual model is developed to illustrate the relationships between the causes/stressors and the species of concern; this is key to the process of prioritizing the stress factors. Life history stages should be examined separately, because vulnerability to a stress factor may differ as a result of different physiology and/or behaviors associated with different life stages. Temporal aspects are important for determining whether the stressor is present when the organisms are present, which life stage is likely to be most exposed, and if the cause/stressor is expected to persist indefinitely. The relative magnitudes of the stressors on life stages are also identified in the conceptual model. For example, if one stressor has a slight effect on a life stage but not necessarily on overall lifespan, while another has a substantial effect in shortening lifespan, then the latter is considered to be a potentially more significant stressor than the former. If known, the causal mechanism by which a stressor affects a life stage should also be stated at this step. This provides insight into the significance of the stressor and can be important for identifying stressors that have potential additive, antagonistic, or synergistic effects. This statement could be relatively general, such as, "Toxicant reduces survival of eggs and larvae." Such statements should be supported by references to the relevant literature. Both direct effects of stressors (those that act directly on the species of concern) and indirect effects (such as reducing the species' food supply or increasing predators) should be included in the conceptual model and evaluation. Only those causes/stressors that are known to affect the species of concern either directly or indirectly should be included.

Following the development of a list of potential causes/stressors that have a reasonable possibility of affecting a threatened or endangered species, including the pesticide in question, it is necessary to establish a relative ranking of threats, so that time-to-extinction estimates can include influences of the most important stressors. New and emerging threats such as climate change can also be quantified and prioritized at this time. Population declines for endangered species are usually related to combinations of stressors, and the proposed framework is designed to distinguish among causes/stressors that are major, minor, and negligible in either reducing populations of endangered species and/or limiting the ability of these populations to recover. The premise for judging a pesticide as a negligible stressor is that it will not decrease the time to extinction for the relevant endangered species under the current management plans. To implement the method, we propose criteria for the classification of stressors. We recognize that this is an initial classification and will need to be reviewed and modified by stakeholders. However, it serves as a starting point.

- **Major Cause/Stressor**—there is convincing evidence that this is one of the causes/stressors that has led to the decline of the species population, is impeding the recovery of that species, or may cause further decline and/or impede recovery.
- **Minor Cause/Stressor**—there is convincing evidence that this is not a Major Cause/Stressor. However, there is some evidence that this cause/stressor has or may contribute to a population decline by causing a small negative change in a demographic characteristic that is ecologically meaningful to the species in question. Because this is a minor cause/stressor, manipulation of exposure or stress will not change the extinction risk in the absence of management of major causes/stressors.
- **Negligible Cause/Stressor—**there is convincing evidence that stress is too small to cause a change in demographic characteristics of the population.

The causal/risk analysis approach should also consider the possibility of cumulative risks from multiple stressors and distinguish which of the existing or potential future stressors are most likely to interact adversely with the proposed action. The preferred approach for accomplishing this is to relate all stressors to changes in fitness parameters, specifically to reproduction and survival rates, as well as those that potentially influence dispersal. However, this approach requires knowledge of the stressor-response relationship; i.e., how a particular magnitude of the stressor produces a specific change in the survival or reproduction of the species of concern, which is not always available in a quantitative fashion. The relative risk model (*9*) or a formal weight-of-evidence approach (*10*) can be used for initial ranking of the stress factors on a qualitative basis. Menzie et al. (*5*) have also outlined a step-wise approach for considering the cumulative effects of multiple stressors, and that methodology has been adapted to the proposed framework.

The approach uses a “+” and “–” scoring system based on the degree of confidence in the supporting weight of evidence (*6*, *11*):

+++	convincingly supports
– – –	convincingly weakens
++	strongly supports
– –	strongly weakens
+	somewhat supports
–	somewhat weakens
0	neither supports or weakens
NE	no evidence

The framework relies on Hill's criteria, as adapted by Wickwire and Menzie (*12*) and Suter et al. (*13*), as a means of evaluating the strength of evidence for ecological applications. These criteria and their application to pesticides and other stressors are described below.

- **Complete causal linkage(s)**: A complete causal linkage requires evidence to support the various linkages that connect pesticides and other stressors as candidate causes with demographic factors believed to contribute to the decline of the species (i.e., reductions in reproduction, survival, growth, or dispersal rates). Spatial and temporal considerations are important for judging causal linkages.
- **Strength of association**: This criterion refers to the degree to which population declines can be related to one or more of the stressors. This is typically an analysis informed by knowledge of the association, as well as statistical analysis that can be supported by models. Some stressors may be strongly associated with population abundance or with changes in demographic characteristics related to population viability, while others may be weak and still others may be negligible. The types of evidence used to judge relationships will vary among stressors and will be guided by the nature of the causal relationships illustrated in the conceptual model.
- **Consistency of association**: This refers to the larger body of scientific observation concerning the relationships among candidate causes/stressors and the demographic factors that have been identified as contributing to the decline of populations of the endangered species and species that share biological and ecological characteristics. Evidence is stronger if the relationship has been observed elsewhere. If there is a lack of field observations on relationships between particular causes/stressors and the decline of a species and/or ability to recover, then the evidence for the particular cause is weakened. Care must be taken to distinguish between hypotheses and demonstrated relationships. The former are weaker than the latter.
- **Specificity of the relationship**: Specificity of effects can be useful for distinguishing among causes/stressors. For example, if a pesticide has a very specific effect on a demographic factor, and that type of effect may be contributing to the species' decline or reducing its ability to recover, that would be stronger evidence than an effect that could be caused by a number of candidate stressors.
- **Temporality**: This criterion relates to the need for the candidate cause/stressor to precede or be coincident with the effect. This is especially important for distinguishing major causes/stressors from minor or negligible causes/stressors. For example, in the case of pesticides, if population declines preceded the use of particular pesticides, then it cannot be concluded that the pesticides were a major source of that decline. They could still, however, influence the ability of the species to recover. Temporality is also important to consider with regard to the

timing of stressors—such as seasonal or pulse stressors—and the timing of demographic factors that are important to the species (spawning, reproduction, growth of young, and survival of adults). Evidence is stronger if the candidate cause/stress precedes the response and/or is occurring coincident with the demographic characteristics considered most important for sustaining or increasing population viability. If the cause/stress follows the decline, and/or if it is out of phase with factors influencing population viability, then the evidence is considered weak.

- **Gradients of "response"**: This relates to spatial considerations between candidate causes/stressors and the responses of the population. In the case of pesticides, this would typically involve examining the spatial patterns of either measures of exposure or effects in relation to the distribution of the pesticides. For other candidate causes/stressors, the analyses would involve similar evaluations. For example, patterns of predation pressure or losses of spawning areas resulting from habitat modification are amenable to spatial analysis. GIS and other mapping methods are typically used to examine spatial patterns.
- **Plausibility (mechanistic basis)**: Evidence is stronger if the relationship between the cause/stress and the effect on the endangered species includes a plausible mechanism. This is especially important for cases where time and space relationships appear to be present, but the nature of the connection is otherwise unclear. Plausible effects can be direct or indirect (e.g., through reduction in food). For a mechanism to be plausible, evidence needs to point to an explanatory basis for population decline or constraint on recovery and how the cause/stressor relates to that explanation. More specific explanations provide stronger lines of evidence. In contrast, if there is not a plausible explanation (especially considering other criteria), then the lack of evidence would weaken the nexus between cause/stressor and effect.
- **Coherence with facts or theory**: This criterion relates to the larger body of information about how particular causes/stressors affect populations. In general, these reflect comprehensive studies related to developing facts about population-level effects and theories related to the decline of populations of particular species.
- **Experiment**: This criterion relates to manipulations and experiments that have been carried out to examine responses. For example, there may be recovery plans or control measures that provide insight into population responses following specific removal or modification of causes/stressors. An example is the coyote control program in the case of the kit fox example discussed later in this paper. This control program was followed by an increase in kit fox abundance. The manipulation lent credence to the conclusion that reduced prey abundance caused by the presence of coyote was the primary cause of kit fox decline.
- **Analogy**: This criterion draws from experience that may be considered analogous to the current evaluation.

While we outline a particular set of criteria, these are not the only ones that might be used. Cormier et al. (*14*) recently identified six fundamental causal characteristics that are similar to Hill's criteria and that could support an evaluation for the potential significance of stressors on endangered species. These could serve as an alternative means of evaluating information related to pesticides and other causes/stressors:

- **Time Order**: The effect cannot precede the cause. Logically then, the causal event occurs before the event that constitutes the effect.
- **Co-Occurrence**: Because the causal agent/stressor and affected entities must have interacted, they must have co-occurred in space and time. Co-occurrence does not require physical contact, and it may refer to co-occurrence with the absence of something. Also, time lags and movements of organisms are important considerations when evaluating co-occurrence.
- **Preceding Causation**: Each causal relationship is a result of a larger web of cause-and-effect relationships. Evidence of the network or pathways that preceded the causal relationship under investigation increases confidence that the causal event actually occurred.
- **Sufficiency**: The intensity, frequency, and duration of the cause/stressor are adequate to produce the magnitude of the effect, given the susceptibility of the entity.
- **Interaction**: The cause/stressor physically interacts with the entity in a way that induces the effect.
- **Alteration**: The entity is changed by the interaction with the cause/stressor. The alteration defines the effect that prompted the causal assessment and may provide evidence in the form of symptoms or other characteristic responses.

Example Application of Causal Analysis for an Endangered Species

To illustrate the methodological concept of causal analysis, we use as an example the application of causal analysis to evaluate a decline in the population of the endangered San Joaquin kit fox population on the Elk Hills Naval Petroleum Reserve #1 in California (*6*), which was observed between 1981 and 1986. This precipitous decline was a cause for concern at the time because of its magnitude and because it was associated with an increase in oil production on the site.

The causal analysis followed the methodology described above. However, we use the terms major, minor, and negligible in the case example and base these designations on the explanatory text in the EPA case study (*6*). Fifteen types of evidence were used to evaluate the contributions from the six categories of stressors. Based on this analysis, the overall weight of evidence supported the conclusion that predation by coyotes was the major cause of the decline. Road kills contributed to the high mortality of foxes, but were much less common and are considered a minor cause. The decline in prey probably contributed to mortality by making the foxes more susceptible to predation and, as such, was a major indirect cause. However, the decline in prey with respect to food availability was considered a minor cause. As a model for causal analysis at contaminated sites, this study was successful at sorting the causes into categories useful for management. Contaminants were found to be a negligible cause, and an alternative cause—predation by coyotes—was strongly supported by the evidence.

EPA (*6*) summarized their analyses in a table that presented the weight of evidence for or against the various candidate stressors contributing to the decline of the kit fox population (Table I). Evidence supporting a candidate stressor as a cause of kit fox population decline was designated with one or more plusses (+), while evidence against a stressor was designated with one or more minuses (–). Four of the stressors—predation, toxics, accidents, and disease—act directly on the kit fox population, because they remove animals from the population and thereby reduce reproductive success. For this case study, there was a particular interest in the potential role of toxics, because this candidate stressor prompted the causal analysis. The stressors of prey and habitat could affect the kit fox population indirectly, because these reflect basic needs of the kit fox population. EPA distinguished between habitat-related stressors that were associated with disturbance and climate (*6*). This type of distinction can be important for identifying proximal causes.

The weight-of-evidence table is interpreted, in part, by examining the consistency of the evidence across each candidate cause. For example, positive or neutral pieces of evidence would support a candidate cause to a greater degree relative to causes for which the evidence is mixed or negative. Consistent negative evidence can be used to eliminate a cause. As Table I shows, with the exception of predation, the evidence was somewhat inconsistent for all of the candidate causes. The consistency of evidence for predation contributed to the conclusion that this was a major cause.

Interpretation of the table also includes considering explanations for the inconsistencies. If inconsistencies in evidence can be explained for a particular candidate cause, that can help strengthen the basis for a conclusion regarding that cause. To that end, EPA developed explanations for three candidate causes—habitat modification, prey abundance, and vehicular activity—that involved converting them from candidate causes to contributors to the most likely cause.

Table I. Example presentation of evidence for an endangered species causal analysis: Decline of the kit fox (*6*)

Comparison of the Strength of Evidence for the Candidate Causes. Types of evidence with no evidence for any candidate cause were excluded.

	Prey		*Habitat*		*Predation*	*Toxics*	*Accidents*	*Disease*
Types of Evidence	*Disturbance*	*Climate*	*Disturbance*	*Climate*				
Evidence that Uses Data from the Case								
Spatial/Temporal Co-occurrence	++		+	−	+	+	+	−
	+	−						
Temporal Sequence	0		0		0	0	NE	NE
Evidence of Exposure or Biological Mechanism (pathway independent)	++		NE	NE	++	++	++	− −
Evidence of Exposure or Bio-logical Mechanism (by pathway)	−	+						
Causal Pathway	+	−	++	−	+	+	+	0
Stressor-Response Relationships from the Field (pathway indep.)	+++		− −	0	NE	NE	NE	NE
Stressor-Response Relationships from the Field (by pathway)	−	+						
Manipulation of Exposure	+		NE	NE	+	NE	NE	NE

Continued on next page.

Table I. (Continued). Example presentation of evidence for an endangered species causal analysis: Decline of the kit fox (*6*)

Comparison of the Strength of Evidence for the Candidate Causes. Types of evidence with no evidence for any candidate cause were excluded.								
	Prey		*Habitat*		*Predation*	*Toxics*	*Accidents*	*Disease*
Types of Evidence	*Disturbance*	*Climate*	*Disturbance*	*Climate*				
Symptoms, Starvation	−		NE	NE	NE	NE	NE	NE
Symptoms, Reproductive (pathway independent)	+							
Symptoms, Reproductive (by pathway)	+	−						

We applied our parlance to the EPA case study (*6*) and, based on EPA's interpretations, designated candidate causes as either a major cause, a contributing but minor cause, or a negligible cause. An initial step in the causal analysis approach is to eliminate causes based on the available evidence. Disease as a candidate cause was considered negligible, because the evidence from the site was negative, and very few of the trapped or dead foxes were observed to be diseased. In contrast, there was strong and consistent evidence for predation (Candidate Cause 3) as the major cause. Based in part on literature and work with Tom O'Farrell, EPA learned that predation by coyotes is the major cause of death in kit foxes. They also found that this is the case elsewhere, an observation that further supported coyote predation as a major cause. In contrast, while evidence for vehicular accidents is also positive, the mortality rate for kit foxes due to accidents is much lower than for predation, and EPA determined from modeling that it was not sufficient to account for the decline. For this reason, EPA considered vehicular accidents a contributing minor cause.

EPA concluded that the evidence for environmental contaminants was inconsistent and complex and that there was no evidence that toxic exposures could account for the high mortality rates that caused the decline. Thus, toxics were considered a negligible cause.

Because trapped or dead kit foxes did not exhibit signs of starvation, EPA concluded that prey availability was not a likely cause for the sudden decline in the kit fox population. In addition, there was no evidence to indicate that kit fox fecundity was influenced by spatial patterns in prey availability. However, EPA did conclude that reduced prey availability could be a contributing major cause that forced kit foxes to spend more time foraging and thus exposed them to predation and to being killed by vehicles.

Habitat quality is an especially important factor for survival of kit foxes, but EPA found that the evidence was ambiguous that change in habitat quality was a factor affecting survival of kit foxes and causing their decline. While there is some evidence that shifts from undeveloped to developed areas could affect abundance, contributions of vegetated and unvegetated areas to the decline of the kit fox remain largely unknown.

Based on their review of the body of evidence (Table I), EPA concluded that predation by coyotes was the major cause of the decline in the kit fox population. Notably, the kit fox decline ended after a coyote control program was instituted and coyote numbers declined.

The example is illustrative of the potential value of a formal causal analysis for an endangered species matter. The elimination of toxicants and diseases as causes has practical management implications. No additional measures need be taken to eliminate exposures to toxicants or to reduce the introduction of pathogens. EPA (*6*) reported that the use of a formal causal analysis method provides greater assurance of the quality of the results, and that identification of the likely proximate cause provides increased confidence that the negative results for contaminants were not a result of inadequate data or analysis.

Discussion

The proposed causal/risk analysis framework provides a means of organizing and evaluating scientific information related to potential risks of anthropogenic stressors to endangered species, upon which to build an assessment of whether pesticides contribute significantly to shortening the time to extinction. Based on our experience with other applications of causal analyses, we believe that application of the framework will help with the transparency of the evaluation process and will provide a means of understanding the relative significance of stressors, including pesticides. The framework presented in this paper is largely based on that developed by EPA as part of stressor identification and the CADDIS system. That approach incorporates a variety of qualitative and quantitative information to support the overall weight of evidence. There are a number of weight-of-evidence approaches that could be used to supplement the approach, but we envision those as tools that may be used for specific applications. We do think that Bayesian approaches may prove useful for organizing and quantifying the weight of evidence, and we are currently working on such applications. Within a management context regarding whether or not to use a pesticide, and perhaps how to use it, multi-criteria decision analysis (MCDA) may also prove useful. Linkov and Moberg (*15*) have described the application of this methodology to a broad range of case studies.

Although causal analyses have been applied to endangered species, we are unaware of an application that is linked to the pesticide regulatory review process and Section 7 consultation. A logical next step is to carry out such an application of causal/risk analysis of a pesticide as a pilot project. While this can be accomplished as a technical exercise for illustration purposes, we envision that the most effective applications will be those that occur as part of a collaborative assessment effort involving the Services, EPA, and the pesticide industry. This can be accomplished by following the steps outlined in this paper. A collaborative approach will involve identifying and agreeing on criteria for judging information and on judging how to rank stressors. Based on experience elsewhere, this type of collaboration has been shown to be effective for developing a shared understanding of the assessment process and of the analyses.

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Chapter 18

Demography and Modeling To Improve Pesticide Risk Assessment of Endangered Species

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The present ecological risk assessment process for pesticides as practiced by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) consists of developing short-term toxicity data for a few select species and comparing these data to expected environmental concentrations to develop risk quotients (RQ). Risk quotients are then compared to "levels of concern" (LOC) which vary depending upon the type of pesticide being evaluated and the type of organisms likely to be exposed. The LOC is supposed to account for all of the types of uncertainty associated with the risk assessment. There are several problems associated with this process. For example, populations do not respond the same way to toxicant exposures as do individuals. Populations, if thinned may compensate for losses and actually grow faster than expected. Furthermore, exposure to pesticides can result in a proportion of a population dying while the remaining individuals are impaired due to multiple sublethal effects. Another issue is that the few species that are used for the development of toxicity data may not be good representatives of the many species they are supposed to protect. These species are often chosen based on ease of rearing and evaluation, not because they are good representatives of many species. Susceptibility of a population to pesticides is influenced by life history traits and differences in life history traits are not considered in the current risk assessment process.

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It has also been shown that populations of organisms often exist as mixtures of life stages. The makeup of the population structure can greatly influence susceptibility to pesticides and this is also not considered in the risk assessment process. Furthermore, different life stages may exhibit vastly different susceptibility to toxicants, yet usually only one life stage is evaluated. In this chapter, the current risk assessment process and new approaches to improve risk assessment of pesticides are discussed. The new approach consists of developing population-level measures of toxicant effect that incorporate the total effect (lethal and multiple sublethal effects) followed by population modeling to determine the probability that specific concentrations of pesticides will drive populations to extirpation or whether populations will recover.

Introduction

The pesticide industry is a large and important industry with an estimated value of $39.4 billion worldwide in 2007 (*1*). There are great benefits to the use of pesticides, particularly with regard to food production, protection of homes and other structures, as well as protection of human and animal health. The reduction of malaria transmission alone saves many lives each year. The down-side to pesticide use is the potential to have negative impacts on non-target organisms, including humans. By definition, pesticides are designed to kill pest species. Because pest species share similar, if not identical physiological systems with other organisms, it is impossible to not affect certain non-pest species if they are exposed (*2*, *3*). Therefore, there are risks associated with the use of pesticides. In this chapter, the focus will be on how the United States Environmental Protection Agency (EPA) develops ecological risk assessments for pesticides. The problems associated with the EPA process will be discussed and a new approach involving population-level estimates of effect followed by population modeling will be outlined that may improve our ability to estimate potential pesticide risks.

The EPA Risk Assessment Process

The ecological risk assessment process for pesticides is used to estimate the potential risk that pesticides might have on non-target species, including endangered species (*4–6*). The approach used by the EPA involves a comparison of toxicity endpoints developed for a select number of species to an estimated environmental concentration. The toxicity endpoints are measured in individuals and are almost always measures of acute mortality or effects on reproduction. The Expected Environmental Concentration (EEC) is estimated through modeling (*5*, *6*). A risk quotient (RQ) is developed by dividing the EEC by the toxicity endpoint. The following equation is used for the development of a risk quotient:

$$RQ = EEC/LC50$$

Table I. EPA risk presumptions for ecological risk assessment of pesticides

Risk Presumptions and LOCs		
Risk Presumption	***RQ***	***LOC***
Birds[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or $LD_{50} < 50$ mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or $LD_{50} < 50$ mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
Aquatic Animals[2]		
Acute Risk	EEC/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOEC	1
Terrestrial and Semi-Aquatic Plants		
Acute Risk	EEC/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1
Aquatic Plants[2]		
Acute Risk	EEC/EC_{50}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1

[1] LD_{50}/sqft = (mg/sqft) / (LD_{50} * wt. of animal) LD_{50}/day = (mg of toxicant consumed/day) / (LD_{50} * wt. of animal) [2] EEC = (ppm or ppb) in water.

The LOC is used to account for uncertainty in the risk quotient. Uncertainty stems from many sources. For example, data is only developed for a small number of species that are used to represent many species. Data developed for Bobwhite quail and mallard ducks are used to represent all birds and reptiles. Data for a few fish species are used to represent all fish and amphibians. The honey bee is used to represent all insects. Other sources of uncertainty include differences in susceptibility among other unstudied organisms, individual-to-population-level extrapolation, laboratory-to-field extrapolation, variability among the data, and uncertainty in the actual amounts of pesticides in ecosystems. The LOC varies depending upon the type of pesticide being evaluated as well as the type of organism potentially exposed (Table I) (*7*). If the LOC is exceeded, then action(s) must be taken to reduce the risk. These actions may include the development of additional data or changes in the amounts of pesticides applied, frequency of applications, and where they are applied.

The toxicity data for pesticides is developed for a standard group of organisms. These organisms are supposed to be representative of different functional groups in an ecosystem, but are chosen based on the ease with which they can be reared and maintained in the laboratory.

The data required for the registration of a pesticide in the United States can be found via the EPA web site (URL http://www.epa.gov/pesticides). For example, the terrestrial and aquatic non-target data requirements for a pesticide applied outdoors are:

- Two avian oral LD_{50} studies
- Two avian dietary LC_{50} studies
- Two avian reproduction studies
- Two freshwater fish LC_{50} studies
- One freshwater invertebrate EC_{50} study
- One honeybee acute contact LD_{50} study
- One freshwater fish early-life stage study
- One freshwater invertebrate life cycle study
- Three estuarine acute LC_{50}/EC_{50} studies -- fish, mollusk and invertebrate

It is important to point out that the freshwater invertebrate life cycle test listed above is not a demographic study (see below) but instead is a longer term reproduction study, for example the 21 day *Ceriodaphnia dubia* test (*8*).

Problems with the EPA Risk Assessment Process

The ecological risk assessment process for pesticides as practiced by the EPA has several short-comings. Some of these issues are discussed below.

Multiple Toxic Effects

The EPA approach does not take into account the “total effect” of a pesticide. Exposure to pesticides can result in a proportion of a population dying while the remaining individuals are impaired due to multiple sublethal effects. In other words, the survivors may have a reduced life span, behavioral changes that reduce their ability to find food, home to breeding grounds, and find a mate. Thus, not one but several sublethal effects may occur in individuals exposed to pesticides. This results in a population that is much more susceptible than predicted by measurements of acute mortality and reproduction only. Therefore, what happens to individuals does not necessarily translate to what happens at the population level. Stark (*9*) published examples of populations being more or less susceptible than predicted by individual measures of effect. Stark (*9*) exposed populations of the water flea, *Daphnia pulex*, to the acute LC50 for several pesticides and adjuvants and let the populations grow and reproduce. At the end of the study, population size was recorded. None of the populations were 50% smaller than the control. The majority of the populations had gone to extinction and the population exposed to diazinon was 91% of the control, which was much higher than predicted.

Individuals Versus Populations

With the current ecological risk assessment process, individuals are evaluated with toxicity tests. However, populations do not respond the same way to toxicant exposures as do individuals (*10*). Populations, if thinned may compensate for losses and actually grow faster than expected. This process is called “population compensation” (*11*).

The Surrogate Species Issue

It is obvious that toxicity data cannot be developed for all species. Therefore, surrogate species must be evaluated and data for these few select species is used to protect all others. Furthermore, because of the “take” clause in the Endangered Species Act (ESA) (*12*) threatened and endangered species cannot be tested in the Unites States. The problem with surrogate species is that no one knows whether the species chosen as representatives are actually good predictors of pesticide impact on the vast majority of other species. The species that are evaluated have quite often been chosen based on their ease of rearing in the laboratory and not because they represent an average species or a protective species. Two issues come into play with surrogate species. The first is that different, even closely related species can exhibit vast differences in susceptibility to pesticides (see below for a discussion of this topic). The second issue is that species have developed different strategies that maximize their survival (*13*). Some species have long lives, produce few offspring, and make a major investment in nurturing their offspring (e.g., humans). Other species do not nurture their young, have short life-spans, and produce large numbers of offspring often throughout their life span.

These differences in life history traits can have a large impact on susceptibility of a population to pesticides. One way to envision this is to consider what I have called the “rat-elephant phenomenon”. This phenomenon is quite simplistic and is best understood with the following example. If we have two populations, one consisting of 100 rats and the other consisting of 100 elephants and you kill 50% of each population, which population should recover the fastest to reach its initial population size of 100? The answer, obviously, is the rat population. Rats will recover much faster than elephants. The reason for this difference in population recovery is that the rat population reproduces at a much younger age, and produces many more offspring and broods of offspring than the elephant population. This is obviously an extreme example, but differences in life history strategies have implications for ecological risk assessment of pesticides. As mentioned above, uncertainty factors (LOC) are used to account for many types of uncertainty, including differences in life histories. However, how can we be sure that use of toxicity data developed for one species (e.g., Bobwhite quail) is protective of all bird and reptile species when these species have a wide range of life history strategies?

Of course the rat-elephant example is extreme and a risk assessor is much more likely to compare toxicity data developed for a rainbow trout to protect endangered salmon species. However, Banks et al. (*14*) evaluated several fish species used to develop toxicity data as surrogates to protect Pacific salmon. Interestingly, the species most closely related to anadromous salmon in this study, the cutthroat trout, was one of the least protective species; the Round Goby was the most protective. In an attempt to come up with protective fish models, Hanson and Stark (*15*) have developed an average and a protective fish model. Furthermore, Stark et al. (*16*, *17*) evaluated the response of closely related arthropod species to the same levels of stress (mortality, reductions in the number of viable offspring, or a combination of both of these factors). They found that populations of these species recovered at very different rates indicating that use of one species to protect others is risky.

Population Structure

It has also been shown that populations of organisms often exist as mixtures of life stages. The structure of a population can greatly influence susceptibility to pesticides and this is not considered in the risk assessment process. Stark and Banken (*18*) evaluated two arthropod species, the two-spotted spider mite, *Tetranychus urticae* (Koch), and the pea aphid, *Acrythosiphon pisum* (Harris), with different starting population structures to determine whether different population structures would influence population-level susceptibility to pesticides. The three differently structured populations evaluated were (1) eggs or neonates for *A. pisum* and *T. urticae,* respectively, (2) stable age distribution, and (3) young adult females only. Population growth rate was the endpoint of interest in this study for both unexposed and pesticide-exposed populations. Populations of *T. urticae* were exposed to 100 µg/l of the pesticide dicofol while the populations of *A. pisum* were exposed to 200 µg/l azadiracthin, the active ingredient in Neemix. Population growth rate for the three control populations in a closed system converged on days 16 and 17 days after the start of the study, for *T. urticae* and *A. pisum*, respectively. However, population growth rate for populations of *T. urticae* and *A. pisum* started as eggs of neonates were significantly lower than populations with the adult and mixed-age populations. These results indicate that the population structure of a population has a significant influence on the impact of pesticides.

Differential Susceptibility

As mentioned above, even closely related species can exhibit vastly different susceptibilities to toxicants. An example of how different susceptibility can be was presented by Deardorff and Stark (*19*). They determined the acute toxicity of the insecticide, spinosad to three species of Water fleas (Cladocerans), *Daphnia pulex*, *D. magna* and *Ceriodaphnia dubia*. Their results showed that *C. dubia* was 72 times more susceptible than *D. pulex* to spinosad.

Does the Risk Quotient-Level of Concern Approach Work?

The obvious question after this discussion is: "Does the Risk Quotient-Level of Concern method protect species"? Little work has been done to answer this question. We have found that in some cases the method is over-protective and in other cases it is under-protective. Hanson and Stark (*20*) evaluated the Toxicity Exposure Ratio (TER), the analogous method to the risk quotient used in the European Union, for *Daphnia pulex* exposed to the insecticide spinosad. They found that the TER was overprotective by a factor of 6 for *D. pulex*. In other studies we have found that the RQ-LOC does not provide protection of certain species when they are evaluated at the population level using the demographic toxicity approach (see below). For example, Chen et al. (*21*) evaluated the effects of the insecticide imidacloprid on the water flea, *Ceriodaphnia dubia*. The EPA EEC for imidacloprid in surface water systems is 17.4 µg/l and this concentration is considered safe for aquatic organisms. However, Chen et al. (*21*) found that exposure of population of *C. dubia* to an imidacloprid concentration of 0.3 µg/l, a concentration that is well below the EEC, resulted in a 27% reduction in population size. Therefore, a population approach using demographic parameters proved that the current risk assessment process may not work.

How Do We Improve the Ecological Risk Assessment Process?

The above mentioned issues that are problematic with the current ecological risk assessment process for pesticides can be dealt with if actual populations exposed to pesticides are monitored over longer periods of time where reproduction occurs. One way to do this is with demographic toxicity studies followed by population modeling.

Demography and Modeling

Demography is the study of populations and the processes that shape them (*22*, *23*). Life tables are a major component of demography and are usually developed from detailed measures of individual survival and reproduction. Life tables have been used by the life insurance industry to determine the probability that a person will die and by ecologists to develop information on basic population biology. A number of population parameters are derived with life tables. The most important of these is the population growth rate which comes in two forms, the intrinsic rate of increase (r_m) (the rate of natural increase in a closed population) and lambda (λ) (the population multiplication rate) which is the anti-log of r_m. Growth rates are important because they tell us about the health of a population. A lambda value of 1 indicates that a population is stable (neither increasing or declining) a growth rate greater than 1 indicates that the population is increasing exponentially, and a growth rate less than 1 indicates that a population is declining and heading towards extinction.

Other demographic parameters developed in a life table are the net reproductive rate (R_0) (the per generation contribution of newborn females to the next generation), the intrinsic birth rate (b) (the per capita instantaneous rate of birth in the stable population), intrinsic rate of death (*d*) (the per capita instantaneous rate of death in the stable population), doubling time (*DT*), the time it takes a population to double, and generation time (*T*), the time required for a newborn female to replace herself *Ro*-fold.

Demographic data can be developed for unexposed and pesticide-exposed populations. These data have a great advantage over traditional toxicity data which is developed as single measures of effect in individuals. The advantage is that a measure of total effect (lethal and multiple sublethal) at the population level is obtained.

Studies using demography to evaluate the effects of toxicants on populations have been published for a long time, but this approach has still not been widely used by environmental toxicologists (*24–30*).

Another advantage of demographic toxicity data is that it can easily be incorporated into more sophisticated mathematical models that enable one to analyze population outcomes over time (*31*).

Matrix Models

Several types of population models have been developed that can be used to interpret effects of toxicants on populations (*31*, *32*). However, matrix models which are based on linear algebra theory are the most commonly used by ecologists and population biologists (*30*, *33*, *34*). Matrix models have been used to make management decisions to protect threatened and endangered species (*35–37*). Matrix models have also been used in the past to estimate the impact of toxicants on populations (*38–40*).

Matrix models are simple to construct and understand. The data required for their development are probability of survival, reproduction, and whether individuals remain in a stage or age class or move to the next one. These data may be obtained from laboratory studies or from observations of populations in the field.

A typical matrix equation is presented below in equation . Survivorship values (*P*) are placed on the subdiagonal while fecundity values (*F*) are placed along the top of the matrix. The vector, $n_{(t)}$, represents the starting condition of the population and consists of numbers of individuals in each stage or age category (n_1, n_2, n_3 etc.).

Equation 1. Matrix model example

$$\begin{pmatrix} n_1 \\ n_2 \\ n_3 \\ \vdots \\ n_z \end{pmatrix}(t+1) = \begin{pmatrix} F_1 & F_2 & F_3 & .. & F_z \\ P_1 & 0 & 0 & .. & 0 \\ 0 & P_2 & 0 & .. & 0 \\ \vdots & .. & .. & .. & \vdots \\ 0 & 0 & .. & P_{z-1} & 0 \end{pmatrix} \begin{pmatrix} n_1 \\ n_2 \\ n_3 \\ \vdots \\ n_z \end{pmatrix}(t)$$

An example of how a matrix model works is presented below. In this example, the initial vector at the beginning of a study is a stage-structured population consisting of three stages, eggs, juveniles, and adults. The starting total number of individuals in the population is 24. The survivorship values (shown on the diagonal) show that 100% of the eggs hatch but that only 50% develop into juveniles. Additionally, the fecundity values (on the top line) show that the eggs and juveniles do not reproduce (both zeros) but that 12 offspring are produced by the adults. This species reproduces once per year and therefore the time step is one year.

A matrix multiplication example is shown below in Table II:

Table II

Stage	*Starting Vector (Nt)*	*x*	*Matrix*	*=*	*Multiplication*	*New Vector (Nt + 1)*
Egg	12		00 00 12		12x0 8x0 4x12	48
Juvenile	8		01 00 00		12x0 8x0 4x12	12
Adult	4		00 0.5 00		12x0 8x0 4x12	4
Total No. of Individuals	24					64

After one time step (multiplication), the population consists of 64 individuals and we now have a new vector (*Nt*+1). This new vector is then multiplied against the matrix to obtain a third vector (*Nt*+2) and this process is continued projecting the population into the future. After a number of multiplications, the proportion of individuals in each stage will become a constant. It is at this time that the stable age distribution is reached. This type of matrix model is called a deterministic model. It does not take into account stochastisity or random variation. Both deterministic and stochastic matrix models can be developed and serve different purposes. Deterministic models are often used to develop population growth rates and conduct elasticity analysis. Elasticity analysis is used to show which life stage is the most sensitive with regard to contribution to population fitness (*36*, *41–43*).

Stochastic models are much more complicated and are often developed for use as decision models for the protection of threatened and endangered species (*34*, *36*).

An Example of a Deterministic Population Model

Using the example above, where we have a hypothetical species with 12 eggs, 8 juveniles and 4 adults, deterministic matrix models were constructed where the first population is an unexposed control. The second population has been exposed once yearly to a pesticide and the only effect is 25% mortality. A third population

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has been exposed to a pesticide yearly and 25% of the population dies while the remaining 75% produce 25% fewer offspring than the control. Again the time step is one year and the model was run for 10 years. In this example, we see that the control population, which started as 24 individuals, increased to 13,632 individuals after 10 years (Fig. 1). The population that had a 25% mortality rate grows to 1,527 individuals over 10 years, and the population that is reduced 25% and has a 25% reduction in offspring only grows to 1,000 individuals after 10 years. Therefore, the population that experienced 25% mortality was actually reduced 89% and the population that experienced 25% mortality and a 25% reduction in offspring was reduced 89% compared to the control population over a 10 year period. Clearly, these types of results cannot be obtained using the risk quotient-LOC method.

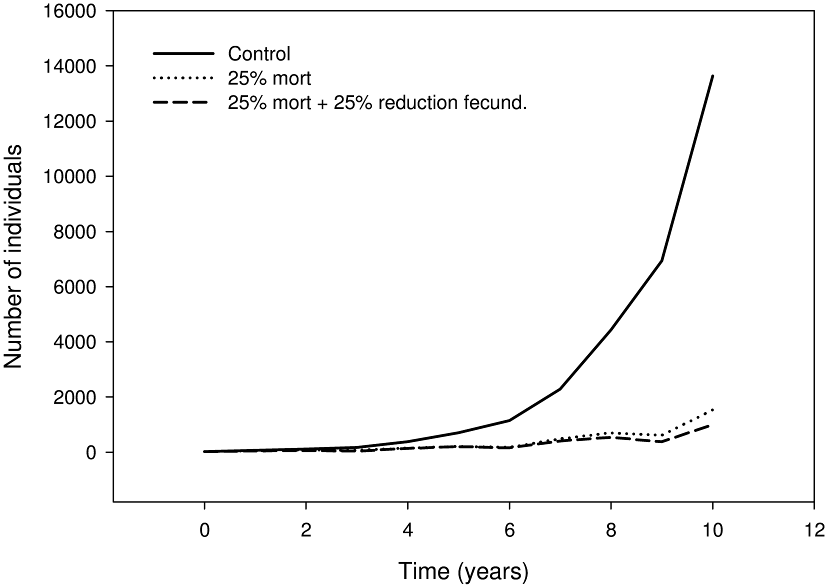

Figure 1. Population trajectories for a hypothetical species unexposed (control) and exposed to a pesticide that either causes mortality only or mortality and a reduction in fecundity.

Conclusions

The ecological risk assessment process used by the EPA for pesticides involves a comparison of an expected environmental concentration to a toxicity endpoint leading to development of a risk quotient. Risk quotients are developed for a few select species. The risk quotient is then compared to a level of concern which varies depending on the type of pesticide being evaluated and the species of concern. Levels of concern are supposed to take in account all of the uncertainty associated with the risk assessment process. The current risk assessment process does not consider population-level processes, differences in life history traits, multiple effects (lethal and sublethal), population structure and other issues.

Demographic toxicity data gives a complete picture of the total effect of pesticides on populations. These data can be used in various population models to determine when and if populations will recover from exposure to pesticides and the probability of extinction. Use of demographic data and population modeling should improve our ability to protect the environment.

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Chapter 19

Consideration of Nontraditional Endpoints in the Assessment of Ecological Risk under the Endangered Species Act

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As the field of environmental toxicology progresses, research is revealing effects on species that expand beyond the traditional endpoints of survival, growth, and reproduction as measured in single organism lab studies. Exposure to contaminants can result in adverse effects to endocrine function, olfaction, behavior, and other physiological impairments that may be exacerbated in combination with ecological stressors. Decisions regarding the management of species listed under the Endangered Species Act necessitate an examination of the best available data regarding all the effects of stressors on the conservation of those species, as well as treatment of uncertainty that is inclusive of all potential risks and is commensurate with their protected status. Analysis of potential linkages between sublethal responses of pesticides to higher-order responses in individuals and populations often requires extrapolation of incomplete data sets to provide protection to vulnerable species facing a myriad of potential threats. The adverse outcome pathway model provides a useful framework for the incorporation and use of currently available data, as well as a means to identify vital data gaps to be filled through future research and monitoring.

Introduction

Effects of pesticides on fish and wildlife species can span beyond those which are readily measured in laboratory tests required for pesticide registration. Under the current data requirements for the Federal Insecticide Fungicide and Rodenticide Act (FIFRA; 40 C.F.R. Part 158), registrants must submit to the U.S. Environmental Protection Agency (EPA) reproductive and acute lethality studies for as few as six species depending on the intended use of the product (e.g., indoor vs. outdoor). Toxicity values derived from these studies (e.g., LC50/LD50 for acute tests, NOEC, no observable effect concentration, for reproductive tests) typically define the "traditional" assessment endpoints of survival, growth, and reproduction used by EPA in its ecological risk assessment of pesticides. However, the necessity of taking a more refined approach when analyzing the effects of contaminants on species has long been recognized, although not always practiced. In *Silent Spring*, Rachel Carson (*1*) noted that: "We are accustomed to look for the gross and immediate effect and to ignore all else. Unless this appears promptly and in such obvious form that it cannot be ignored, we deny the existence of hazard." In 1970, Friend and Trainer (*2*), writing on the influence of insecticides to reproduction, behavior, and disease state, spoke of sublethal effects as "less obvious, but probably more significant." They lamented the reliance on direct mortality as the sole response considered: "it represents the crudest type of end-point being characterized by an all or none response: it is easily measured and readily observable but conveys a minimum amount of information." The obligation to consider all of the effects of chemical exposure is not only ecologically relevant, but also a requirement when assessing effects to species listed under the Endangered Species Act of 1973, as amended [16 U.S.C. 1531 et seq.] (ESA). While datasets relevant to nontraditional endpoints often lack the robustness of those generated under FIFRA, they can provide valuable insights into potential threats to vulnerable species. Vigorous use of available data should continue while methods to both extrapolate these endpoints to higher level effects and validate assumptions are developed.

Analysis of Risk under the Endangered Species Act

The purpose of the ESA is to provide for the recovery of threatened and endangered species. Specific federal agency responsibilities are described in section 7 of the ESA and include requirements for interagency cooperation to conserve federally listed species and designated critical habitats. Section 7(a)(1) directs all federal agencies to develop programs for the conservation of listed species. Section 7(a)(2) directs federal agencies to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. In fulfilling these requirements, each agency must use the best scientific and commercial data available [16 U.S.C. 1531 et seq.]. The procedures for completing section 7(a)(2) consultation are elaborated in regulation (50 CFR §402), which describes the pertinent definitions and the framework for analyses with respect to the effects of the federal action on the survival and recovery of the species as a whole. All regulatory authorizations under FIFRA, including the registration of pesticides under Sections 3, 4, 18, and 24(c), are subject to these interagency cooperation requirements.

Federal agencies must complete one or more decision points in fulfilling procedural requirements of consultation on their proposed actions. A federal agency must determine whether its action *may affect* (or have *no effect* on) any listed species or designated critical habitat. An action *may affect* a listed species or critical habitat if the species or critical habitat is likely to co-occur with the stressors of the action. If a proposed action may affect a species or critical habitat, then consultation is required even if the response is wholly beneficial. A federal agency must then complete an ecological risk assessment (biological assessment or evaluation) to determine whether the proposed action is *likely* or *not likely to adversely affect* any listed species or designated critical habitat. A spectrum of responses is possible, with varying consequences to the fitness of the individual(s) affected (see Figure 1 for examples). Formal consultation is required if *any* adverse effect is likely to *any* individual of a listed species or critical habitat.

While all ecological risk assessments contain elements of uncertainty, how that uncertainty is handled is a function of the management goal for which the assessment is performed. Under section 7(a)(2) of the ESA, agencies are mandated to insure that actions are not likely to jeopardize the continued existence of any threatened or endangered species. In 1995, the National Research Council (NRC) spoke extensively to the topic of making decisions under the ESA in the face of uncertainty (*3*). In their discussion, they note that as scientists, we are trained to minimize "Type I error" (erroneously concluding that an effect exists). However, they caution, that while this choice may be appropriate for advancing scientific knowledge, it may not be the optimal choice when making management decisions. Approaches that minimize Type I error typically come at the expense of increasing "Type II error" (erroneously concluding that no effect exists). In performing risk assessment under the ESA, we must consider that the cost of missing an effect may have irreversible consequences (i.e., species loss). As such, a fundamental distinction in ecological risk assessments performed for ESA compliance lies in the overall importance placed on having strong evidence that an effect is likely to occur before such an effect is included in the assessment. Reliance on data with unknown or high risk of Type II error does not provide strong support for the substantive requirement to avoid jeopardizing threatened and endangered species. When there is uncertainty in the existing data or uncertainty due to significant data gaps, biased decisions that would work to the detriment of listed species are avoided (*3*).

In fact, Congress has given specific guidance to provide the benefit of the doubt to the species when there is uncertainty in the existing data or uncertainty due to significant data gaps [H.R. Conference Report No. 697, 96th Congress, 2nd Session 12 (1979)]. When the U.S. Congress amended the ESA in 1979, both the House and the Senate debated the proper course of action that should be taken when writing biological opinions in the face of uncertainty; that is, when action agencies "cannot guarantee with certainty that the agency action will not jeopardize the continued existence of the listed species or adversely modify its critical habitat: [H.R. Conference Report No. 697, 96th Congress, 2nd Session

12 (1979)]. The Congress amended the ESA to allow for biological opinions to be framed on the best evidence that is available or can be developed during the consultation process and concluded that the language "continues to give the benefit of the doubt to the species, and it would continue to place the burden on the action agency to demonstrate to the consulting agency that its action will not violate Section 7(a)(2)" [H.R. Conference Report No. 697, 96th Congress, 2nd Session 12 (1979)].

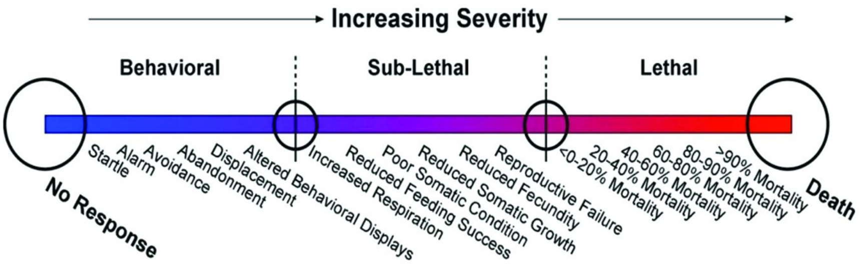

Figure 1. An illustration of the range of animal responses to physical, chemical, or biotic stressors.

Nontraditional Endpoints of Pesticide Exposure

Nontraditional (i.e., sublethal) effects of contaminants, including pesticides, have been widely documented in the 50 years since publication of *Silent Spring*. The types of responses that can be elicited from contaminant exposure are too numerous to list and are constantly growing as researchers evaluate new chemistries and measure novel endpoints. Physiological responses from contaminant exposure that have been documented in wildlife range from biochemical changes like endocrine disruption, immune suppression, enzyme induction, and altered hematological parameters to more gross effects like histopathological changes and organ damage. Behavioral changes resulting from contaminant exposure are well-documented and examples include alterations in behaviors such as schooling, locomotive ability, nest building, courtship, and natal homing (*4*–*6*). Behavioral indicators of toxicity in particular have been described as ideal for the assessment of effects of pollutants as they provide a link between physiological function and ecological processes (*6*).

However, despite substantial documentation in the literature that contaminant exposure can result in sublethal responses, some argue that these effects are not relevant assessment endpoints for ecological risk assessment as they do not rise to the level of affecting an organism's survival, growth, or reproduction. In analyses for FIFRA registrations, one justification for their dismissal are findings of no significant effects to survival, growth or reproduction in a life-cycle study, such as is required for pesticides that have potential to reach water (*7*). Specifically cited is the belief that test organisms able to successfully complete the life-cycle as tested have compensated for any adverse sublethal effects along the way. However, these standard types of single stressor/single species toxicity tests, such as are required under FIFRA, are generally not designed to capture and illustrate the consequences of sublethal responses to individual fitness. While life-cycle tests evaluate chronic effects of pesticides over a full generation, they and other standard toxicity tests required under FIFRA do so under conditions designed to rule out the effects of all other stressors: food is accessible, mates are proximate, predators are absent, no migration is required, and so on. Sublethal responses such as decreased olfactory ability, altered schooling behavior, etc. may affect behaviors that cannot adequately be measured in these tests (e.g., feeding, selecting a mate, escaping predation, migrating) that would otherwise be deleterious to an individual's survival and reproduction. In this sense, laboratory toxicity tests – believed to be conservative due to their constant exposures to chemicals – lose their conservatism when extrapolated to natural conditions (*8*).

Recognizing the inability of standardized toxicity tests to capture outcomes of sublethal responses from exposure under natural conditions, a number of researchers have examined the consequences of introducing pesticides into mesocosms that reflect more realistic community structures. When tested under these conditions, sublethal responses of pesticide exposure resulted in adverse effects to individuals challenged by factors such as predation, interspecific competition, and disease state (*4*, *9*). Assessing effects under the principles of community ecology allows for the analysis of more complex and realistic ecological interactions that may be influenced by the addition of the pesticide, such as keystone effects, resource competition, predator-prey effects, multi-trophic level effects, density-mediated effects, or mutualism, and can provide a predictive mechanism for risk assessment (*10*, *11*). This may be especially relevant for threatened and endangered species, which themselves may not be inherently more sensitive to toxicological effects of the pesticide, but may be made more vulnerable due to the condition of their environmental resources.

Admittedly, the ability to comprehensively describe the consequences of sublethal responses to the fitness of organisms is limited by the available data. However, repeated findings of adverse effects in mesocosm studies serve as a "proof of concept" that sublethal responses can indicate higher level fitness consequences, as could be predicted by the life history and community ecology of the species. As such, when characterizing the effects of an action under the ESA, the analysis is not limited to using only those data that quantify direct changes in survival, growth, or reproduction. To determine potential effects from sublethal responses, logical, science-based causal linkages are sought to support the extrapolation to effects at the individual level. Identification of linkages is based on the available information on a toxicant (exposure and toxicity) and on the species/taxa assessed. If appropriate data are available, sub-organismal effects may be linked quantitatively to whole organism responses (e.g., % decline in reproduction or survival). However, for the majority of pesticides, toxicity studies have not been conducted at multiple levels of biological organization (i.e., suborganismal-organism-population), and thus quantitative analyses will often not be possible. In such cases, the expertise of scientists is required to qualitatively evaluate the linkages and weigh the lines of evidence based on the best available scientific data.

For instance, in a recent consultation on the effects of atrazine to the federally endangered Alabama sturgeon (*Scaphirhynchus suttkusi*), the U.S. Fish and Wildlife Service examined toxicity data indicating the potential for olfactory effects in fish from exposure to this pesticide (*12*). While no quantitative data specifically linked these effects to survival or reproduction, we examined the role of olfaction in other sturgeon of the Acipenseridae family and found that olfaction is an integral factor in many processes that affect individual fitness. While olfaction is fundamental to feeding, mating, homing, and predator avoidance behaviors in most fish, sturgeon, which have poorly developed vision, are generally more reliant on olfactory performance than other taxa (*13*, *14*). Unlike most fish species that rely on vision for food searching behavior, sturgeon are unable to orient, make distant or near searches for food, or discover approaching objects based on visual cues and must rely on the olfactory system as the primary sensory system for feeding (*13*). For reproductive behavior, the involvement of chemical signaling in both finding a partner for spawning and determining their readiness is well studied and universal for all fish (*14*). Studies examining sturgeon specifically have documented male reactions to female sexual pheromones that suggest that males use olfaction to detect ripe females at spawning sites (*15*). This information on sturgeon physiology and life history is used to extrapolate the known toxic effects of atrazine on olfaction to the potential effects to the fitness of Alabama sturgeon individuals.

While this type of reasoning provides a link between the sublethal effect and higher order effects, in very few cases will it provide us with a precise threshold at which fitness will begin to be affected. A small number of well-studied biochemical responses have been quantified to the level of being able to define points on a continuum that are associated with higher-level effects and in few cases have been modeled to population level effects (*16*, *17*). However, for the majority of sublethal effects, it may be feasible to conclude that alteration of a biological response contains potential to affect an organism's fitness but limited ability will exist to identify the threshold at which an organism will no longer be able to compensate. There may be a threshold for the degree of a response necessary to alter fitness (e.g., 10% vs. 50% reduction of olfaction) or a threshold of temporal persistence on a scale of transience to permanence. Each of these factors is likely to be variable based upon factors such as lifestage, individual fitness, or ecological stressors. It may be more reasonable to expect that such responses are more likely to shed light on exposures or concentrations that will *not* cause adverse effects.

Such a gap in information causes a challenge in the regulation of chemicals in identifying a concentration above which an individual or population can no longer tolerate the effects of chemical exposure. And as scientists we may be put in the uncomfortable position of extrapolating beyond what may be typically justified based upon the available data. However, because we perform this risk assessment under the ESA, we may handle this uncertainty differently than when performing risk assessments for other purposes. In order to avoid missing an effect (i.e., minimizing Type II error) we employ conservatism to be inclusive of possible threats to species. In doing so, we may decrease our accuracy in determining an exact threshold, but increase the likelihood that our estimate is inclusive, rather than exclusive, of the threshold at which effects begin to manifest.

As a result, best professional judgment is used in the consideration of sublethal data and requires a unique examination of each type of response documented in the literature and its potential to affect an individual's fitness. Ultimately, interpretation of this data may vary based upon the status of the species under consultation. Some listed species are robust and the hurdles to achieving their conservation may be low (e.g., a species close to delisting). Others are critically endangered and the likelihood of their recovery is low, leaving little or no room for error. A species' degree of endangerment greatly influences the amount of risk that can be accepted such that, in the absence of data, more conservative estimates regarding effects to individuals or populations may be more appropriate for those species that are less likely to withstand additional stressors.

A New Paradigm for Regulatory Toxicity Testing?

Technological advances in the understanding of biological systems and how those systems are perturbed by chemicals have laid the ground work for fundamental changes in regulatory toxicity testing to better account for the full spectrum of responses elicited by chemicals. The NRC elucidated a vision for such changes for human health protection in their 2008 report entitled *Toxicity Testing in the 21st Century: A Vision and a Strategy* (*18*). The vision calls for a transformation from "a system based on whole animal testing to one founded primarily on *in vitro* methods that evaluate changes in biological processes using cells, cell lines, or cellular components, preferably of human origin." Central to the vision is the identification of toxicity pathways, that is, normal cellular response pathways that are expected to result in adverse health effects when sufficiently perturbed. Once toxicity pathways are identified, high throughput tests (i.e. *in silico* and *in vitro* assays) will be developed to detect where perturbations occur along the pathway. Mathematical models will link molecular and cellular responses to apical endpoints. The NRC acknowledged that a substantial research effort will be required to develop the science (e.g. toxicogenomics, bioinformatics, systems biology, epigenetics, and computational toxicology) necessary to implement such a strategy. The benefit, however, is expected to be a system that is more capable of detecting toxic effects, providing broad coverage of chemicals and chemical mixtures, reducing cost and time of testing, using fewer animals, and having a greater capacity for assessing the tens of thousands of chemicals that are currently in use.

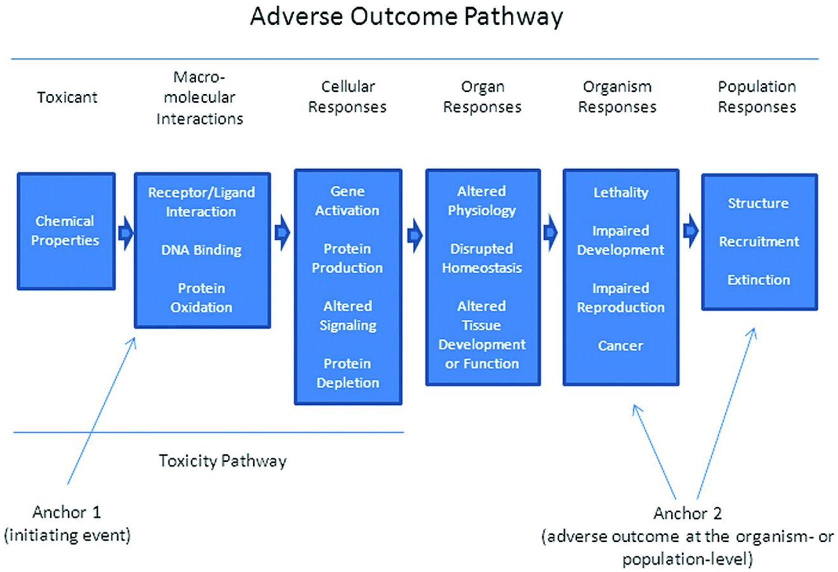

Figure 2. Conceptual diagram of key features of an adverse outcome pathway (AOP). Each AOP begins with a molecular initiating event in which a chemical interacts with a biological target (anchor 1) leading to a sequential series of higher order effects to produce an adverse outcome with direct relevance to a given risk assessment context (e.g. survival, development, reproduction, etc.; anchor 2). The first three boxes are the parameters that define a toxicity pathway, as described by the National Research Council (3). (Adapted with permission from ref. (20). Copyright 2009 John Wiley and Sons.)

Although the NRC report focused on human health, a similar paradigm shift for ecotoxicology has also been proposed (*19*). Current ecotoxicology testing programs that support implementation of environmental regulations (e.g., FIFRA and Clean Water Act) focus on measuring traditional adverse effects from whole-animal tests. By comparison, the 21st century vision for predictive ecotoxicology proposes a framework for organizing information from emerging technologies such as transcriptomics, proteomics, metabolomics, and *in vitro* assays, along with data from more traditional tests. This framework, known as the "adverse outcome pathway" (AOP) (Figure 2), is the "conceptual construct that portrays existing knowledge concerning the linkage between a direct molecular initiating event (e.g., molecular interaction between a xenobiotic and a specific biomolecule) and an adverse outcome at a biological level of organization relevant to risk assessment" (*20*). Whereas toxicity pathways described in the NRC vision for human health only consider events at the molecular and cellular levels, the AOP provides a structure for linking molecular events to higher orders of biological organization (i.e., whole organism and population-level responses). Not pictured in Figure 2 are "system nodes" which are organism-level responses that link suborganismal pathways to apical endpoints (*21*). For example, behavior is a system node that links neurotoxic pathways (e.g., acetylcholinesterase inhibition) to survival and reproduction via behavioral endpoints such as predator avoidance, feeding behavior, swimming activity, imprinting, and courtship/mating behavior (*21*). Taken together, behavior and other system nodes (immune function, development, probability of stage-specific survival, fecundity, egg quality, etc.) can be a "conduit of many types of information, including mechanistic toxicity data," to define an individual's fitness in terms that are also relevant for population modeling.

Adverse outcome pathways provide a framework for compiling current knowledge about xenobiotics in a structure that links toxic events or perturbations along a causal pathway. Depending on the available information, AOPs may differ in their level of detail. Some may be fully developed and mechanistically based (analogous to a "mechanism of action") while others may be less well defined with linkages between levels of biological organization founded on plausible or hypothetical associations (*20*). Several AOP case examples that vary in detail and complexity have recently been described: narcosis baseline toxicity, photo-activated polycyclic aromatic hydrocarbon toxicity, aryl hydrocarbon receptor-mediated toxicity, estrogen receptor-mediated activation (*20*), domoic acid toxicity (*22*), and vertebrate endocrine systems perturbations - hypothalamus-pituitary-thyroid, -adrenal, and –gonad axes (*23*). Data/information gaps revealed by AOPs are expected to help identify research needs to support implementation of the new paradigm. Other research areas identified in the vision include the development of new tests (*in vitro* and other non-apical tests), computational models (e.g., biological-based dose-response models, quantitative-structure activity relationships), tools for species extrapolation (*24*), methods for identifying new AOPs (*25*), and AOP-relevant biomarkers.

The paradigm shift for ecological toxicity testing and risk assessment described here is more in alignment with the U.S. Fish and Wildlife Service's vision of how toxicity data should be used to support ESA consultations than is the current (traditional) testing approach. The AOP framework utilizes data in a way that seems less likely to omit adverse effects. Toxicity data at multiple levels of biological organization would be used to identify relevant pathways and toxic effects (lethal and sublethal) which contribute to adverse outcomes. Because section 7 of the ESA requires the use of best *available* scientific and commercial information, endangered species consultations conducted today do not have the benefit of information expected to be generated sometime in the future. The requirement for use of best *available* allows for determinations to be made in the face of current uncertainty. Therefore, application of AOPs to structure toxicity data for ESA consultations should be grounded on the present state of knowledge, not what may be achievable in the future once research programs have contributed new information. The same approach to addressing uncertainty under ESA, described earlier, should be applied to the use and interpretation of AOPs.

Monitoring and Reporting Under ESA

Regardless of the method of analysis, consultation on proposed pesticide registration decisions requires management of risk for threatened and endangered species. In section 7 consultation on federal actions, federal agencies commonly employ monitoring, reporting, targeted research, and adaptive management of programs as a means of addressing uncertainties and minimizing burdens on the regulated community. Currently there are no comprehensive monitoring programs to measure pesticide concentrations that enter the environment, nor their effects to fish and wildlife. The detection of nontarget mortality from pesticide exposure is rare, and generally opportunistic, as opposed to a result of prescribed monitoring (*26*). In contrast, detecting effects other than mortality can *only* result from targeted monitoring. As a result, there is little opportunity to either validate assumptions made in the risk assessment process, or remove conservatism imposed from data gaps. The regulated community and the agencies regulating pesticides can be better served by advancements in the implementation of FIFRA to facilitate monitoring, reporting, and an adaptive framework.

However, even when employed, all but the most comprehensive monitoring will have its limitations. Because multiple pollutant stressors occur in almost any habitat of threatened and endangered species, teasing out effects attributable to individual pollutants presents a considerable challenge. Therefore, it is critical that potential effects to individuals – including sublethal effects – are recognized upfront, and when appropriate, properly mitigated. The history of FIFRA implementation has shown that once a pesticide is registered, the burden of proof shifts to proving the existence of adverse effects in the wild, which may be too high of a bar to surmount.

Conclusions and Recommendations

Ecological risk assessment that focuses only on the traditional endpoints of survival, reproduction, and growth in its analysis is inconsistent with characterizing the effects of the action by ESA standards. All endpoints that may affect the fitness of an individual must be considered in assessing effects to threatened and endangered species. For pesticides that have been studied beyond the standard tests required for registration under FIFRA, additional data affords us the opportunity to extrapolate those effects to the natural environment and refine our understanding of how these stressors affect species. For the vast majority of toxicological responses, decisions under the ESA will need to proceed before quantitative linkages or physiological pathways are fully elucidated. To avoid missing potential effects of pesticides where there are data which suggest their existence, a range of possible outcomes should be considered for short-term regulatory action and for longer-term monitoring and research. Only in this way will assumptions generated in the risk assessment process be confirmed or rejected, and unnecessary burdens on the regulated community arising from overly conservative assumptions be lifted.

Acknowledgments

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Chapter 20

Utilizing At-Risk Species Data To Sustain Biodiversity and Streamline Decision Making

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The projected growth of the world's human population will increase global demand for food and sustainable fuels as well as the land and water required to produce them. To be effective, efforts to conserve biodiversity from the associated potential for further habitat loss and conflicts with wildlife must be grounded in science. For nearly forty years, the NatureServe network has combined expertise and on-the-ground experience to amass credible, reliable biodiversity data used by practitioners and decision-makers from across the public and private sectors. Balancing competing uses and values requires strategic approaches that conserve important natural values, streamline regulatory processes, and deliver the scientific knowledge needed to make informed decisions cost-effectively.

Introduction

The Value of Biodiversity

Appreciation for the diversity of life on Earth has been evident from the earliest recorded times, but the past half century has seen an explosion in societal concern for plants and animals and the habitats on which they depend. Although species possess distinct utilitarian and intrinsic value, they also play essential roles in maintaining the ecological systems that provide us with food, water, and shelter. A recent study by Fairbank, Maslin, Maullin, Metz & Associates (*1*) found that American voters overwhelmingly recognize the vital benefits that nature provides for people – nine out of ten American voters rate these benefits of nature as either "extremely" or "very important."

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

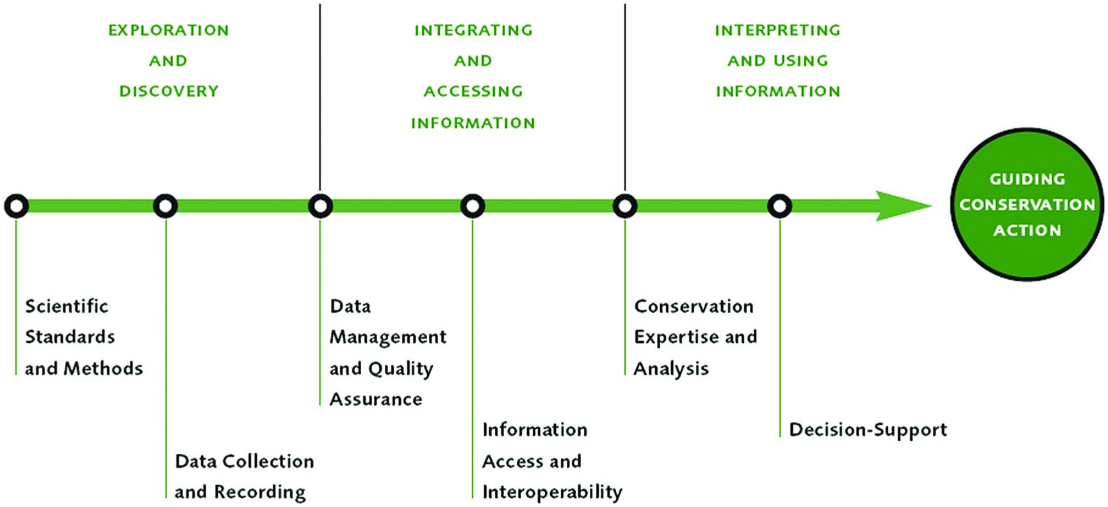

Figure 1. NatureServe's Conservation Information Value Chain. Each successive stage links to and builds upon the previous stage, adding value at each level of product or service. Reproduced with permission from NatureServe.

Increased awareness of environmental problems led to passage of a host of influential federal legislation in the late 1960s and early 1970s, including the Clean Water Act, Clean Air Act, and National Environmental Policy Act (NEPA). The Endangered Species Act of 1973 (ESA) constitutes the strongest expression of this respect and value for biodiversity, noting that "…species of fish, wildlife, and plants are of esthetic, ecological, educational, historical, recreational, and scientific value to the Nation and its People." The regulatory regimes established by such legislation increased the need for a reliable scientific basis for conservation-related decisions and policies.

The natural heritage network now overseen by NatureServe was established to create scientific methods and standards for developing and maintaining the data that conservation practitioners need to establish the status and location of species and ecosystems across the landscape. NatureServe now seeks to make this information readily accessible while developing tools in collaboration with practitioners to help them ensure the scientific validity of their conservation decisions.

Contributing to Science-Based Decision Making

NatureServe exists to build knowledge about biodiversity and apply it to conservation and resource management. The NatureServe network develops high-quality and up-to-date information about the status and distribution of species and natural ecosystems and delivers that information to guide conservation action (Figure 1). NatureServe collaborates with government agencies, industry, and other organizations to create a uniquely integrated suite of data, products, and expertise that decision-makers can trust.

Distribution of Imperiled Plants and Animals

During its nearly 40-year history, NatureServe's natural heritage network has relied on a combination of expertise and on-the-ground experience to amass credible, reliable data on biodiversity. Currently over 1,000 biologists, data managers, and other professionals constitute the NatureServe network. Through decades of careful research, analysis, and on-going inventories, these scientists have identified the species and places most important to conservation. This knowledge provides a fundamental building block for conservation action and decision-making. Where are the rare and imperiled species? How are they doing? What do they need to survive? Unique expertise and a steadfast commitment developed in pursuit of these fundamental questions has created the most comprehensive and authoritative database on the locations and status of species in the Northern Hemisphere (Figure 2).

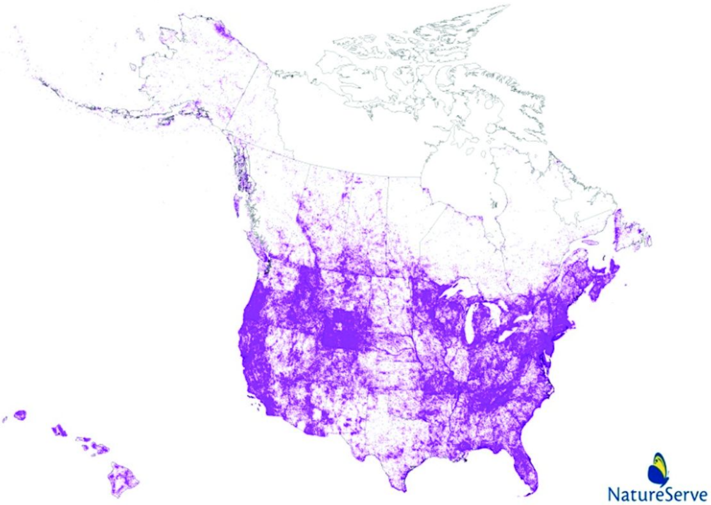

Figure 2. Distribution of At-Risk Species. This map includes 21,893 at-risk species, documented by nearly one million detailed population-level occurrences contained in NatureServe's comprehensive biodiversity databases. Reproduced with permission from NatureServe.

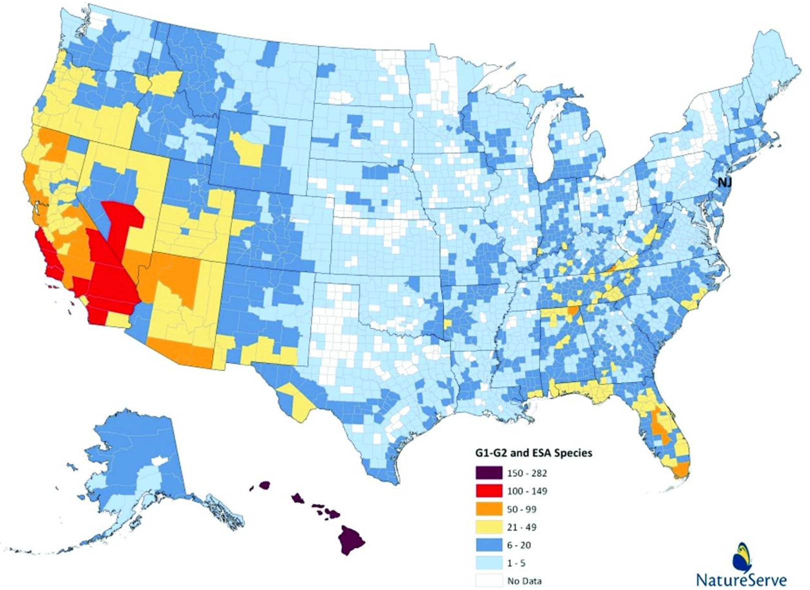

Figure 3. Known distribution by county of listed and imperiled species (G1-G2) in the U.S. Reproduced with permission from NatureServe.

To address the significant components of biodiversity that remain undocumented, NatureServe and its natural heritage network continue field inventory work, collecting information on the location of species across the United States and Canada. This data is collected and maintained according to internationally consistent standards, enabling NatureServe to aggregate this information to provide a far more fine-grained view of the geography of imperilment across the United States (Figure 3) and Canada.

How Are They Doing? The Status of Biodiversity

Ensuring the continued survival of the nation's species requires a sound understanding of their current condition. Which species are widespread, abundant, and secure? Which are rare or declining, and facing increased risk of extinction? Assessing a plant or animal's conservation status—or extinction risk—requires accurate, up-to-date information about the species' distribution, its population numbers and trends, and the threats facing those populations. In the United States, the U.S. Fish and Wildlife Service - which, along with the National Oceanic and Atmospheric Administration, has primary responsibility for administration of the ESA - is charged with assessing the condition of plant and animal life for the purpose of determining what protection is warranted under that Act. As of May 2012, 1,391 U.S. species were listed under the ESA, with 1,073 listed as endangered, and another as 318 threatened (*2*, *3*). The number of listed species is dynamic, as additional species are considered for possible listing, and other species considered for delisting due either to recovery, extinction, or reassessment of condition. The federal endangered species list, however, is insufficient to gauge the overall condition of the U.S. biota. A broader overview of the condition of U.S. species resides in the conservation status assessments carried out by NatureServe's U.S. network members.

By assessing the conservation status of every U.S. native species in the 24 widely understood groups of plants and animals, NatureServe and its state natural heritage network have been able to create a comprehensive view of the overall condition of more than 27,000 individual species. Of particular concern are the approximately 9% regarded as critically imperiled (G1) and 10% categorized as imperiled (G2). Risk trends across the various groups of plants and animals reveal some striking patterns. For example, the United States hosts the world's largest number of species of freshwater mussels in the world, yet this group of organisms also has the highest levels of imperilment: 67% of mussel species are categorized as vulnerable, imperiled, or already extinct. Flowering plants, however, contain by far the largest number of at-risk species (5,315), due both to the large number of species in this group (more than 16,000), and the fact that many are highly localized plants that occur in different regions of the country (*4*).

Knowing the status and distribution of imperiled species and their habitats enables proactive conservation and management efforts that can preclude the need for federal listing. Targeting such efforts prior to species' listings provides greater flexibility in developing management plans that can prevent or reduce future threats and impacts.

Conserving Biodiversity Associated with Agricultural Lands

Within an active landscape of competing uses and values, how do we strategically plan to conserve the natural values that are important to our community? For example, the projected growth of the world's human population will increase global demand for food and fuel, as well as the land and water required to produce them—with the potential for additional habitat loss and conflicts with wildlife. Many publications outline the impacts of agricultural practices on species and ecosystems (*5*). We know that the use of pesticides and other chemicals can impact water quality on agricultural lands (*6*), and that this, in turn, affects plant and animals species that depend on these waters to survive (*7*). Furthermore, although there is recognition that 'water quality and biodiversity are key environmental areas of concern for agriculture' (*8*), neither guidelines nor metrics have yet been fully developed and vetted to address these areas of concern.

Agro-ecosystems can provide critical pathways for biodiversity migration and adaptation. The proliferation of regulatory and market-based incentives is increasing the interest of agribusiness in more sustainable practices. We know that the size, design, and management of agriculture lands can either support or inhibit the survival of species and ecosystems, including supporting wildlife corridors (*9*) and 'stop overs' of migratory birds (*10*). Edward O. Wilson recently noted (*11*) "Agriculture is one of the vital industries most likely to be upgraded by attention to the remaining wild species. The world's food supply hangs by a slender thread of biodiversity. Ninety percent is provided by slightly more than a hundred plant species out of a quarter-million known to exist. Twenty species carry most of the load, of which only three-wheat, maize, and rice-stand between humanity and starvation. Yet some thirty thousand species of wild plants have edible parts consumed at one time or other by hunter-gatherers…..The problem before us is how to feed billions of new mouths over the next several decades and save the rest of life at the same time, without being trapped in a Faustian bargain that threatens freedom and security."

In light of these competing needs, access to reliable information about the location, condition, and needs of at-risk species and ecosystems can facilitate the management of agriculture lands in ways that also conserve biodiversity.

Making Regulatory Decision-Making Processes More Efficient and Effective

Complying with federal regulations is complicated – arguably, unnecessarily so - and can inhibit collaborative efforts to minimize the impacts on species and the environment. Data limitations, particularly geospatial data, serve as a significant barrier to the successful implementation of approaches to avoid impacts to natural resources (*12*, *13*). Results from the Transportation Research Board's Strategic Highway Research Program (SHRP) Capacity Program C06 research project (*14*) suggest that many regulatory conflicts and costly delays in delivering projects can be attributed to the poor quality or availability of natural resource data used in the planning phases of projects.

Other approaches can streamline the process and deliver the information needed to make informed decisions more cost-effectively. For example, when regulatory agencies seek to avoid impacts to threatened and endangered species, they traditionally use datasets constructed by extrapolating the distribution of species in large land areas, like counties or watersheds, from known distributions of the species in smaller areas. These maps have considerable limits from a planning perspective, because they do not predict other places where threatened resources are *likely* to occur or provide greater certainty about where species are *not likely* to occur. NatureServe's expertise in using its core data holdings to model the predicted distribution of endangered species (Figure 4) can provide game-changing tools for planning and assessment. These species distribution models (SDM) rely on a more scientifically defensible assumption that species are linked to the landscape by recognizable biotic and abiotic predictors. SDMs thus provide a more accurate method for predicting what habitat is likely occupied by a particular species than do more coarsely scaled maps of existing species ranges or distributions. In addition, SDM predictions need not be categorized simply as suitable or unsuitable, but may depict varying degrees or gradients of suitability from "high" to "low."

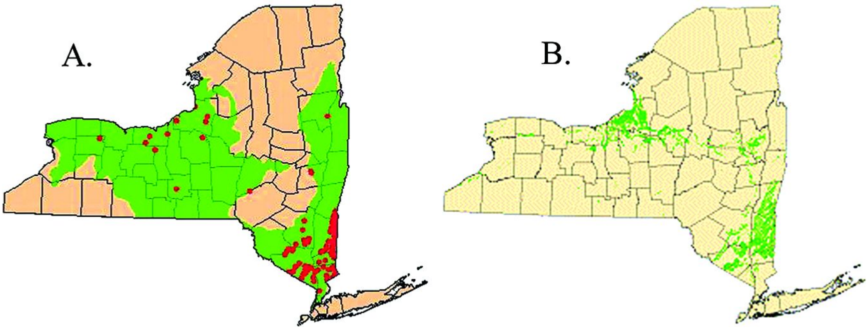

Figure 4. The current approach to mapping endangered species combines precisely known locations (red dots) with very broad estimates of where that species could potentially occur (A) whereas predictive distribution modeling (B) produces maps of where a species is likely to occur—and likely not to occur (Image: New York Natural Heritage Program). Reproduced with permission from NatureServe.

These maps have the potential to improve the data used in the regulatory process and increase the efficiency and cost-effectiveness of the processes, while improving mitigation and restoration efforts. For example, in 2003 the Oregon Department of Transportation (ODOT) formed the Oregon Transportation Investment Act III State Bridge Delivery Program (Bridge Program) to manage the repair and replacement of bridges by 2011. During this process, the Oregon Biodiversity Information Center (a NatureServe member program) provided more accurate endangered species maps such as depicted in Figure 4 along with more accurate wetlands maps. These maps served as the foundation for a multi-agency agreement on programmatic permits and approvals, environmental performance standards, and a comprehensive program for mitigating environmental impacts. Using this new process, the Bridge Program completed the permitting process for individual bridges more cheaply and quickly. ODOT's cost/benefit analysis concluded that, on average, an entire permitting package for a bridge project took 31 days to complete, as opposed to 135 days or longer under the traditional approach (*15*).

Recent guidelines under the Clean Water Act, and multi-agency initiatives like Eco-Logical, encourage use of collaborative, ecosystem-scale decision-making rather than traditional, site-driven environmental assessments and actions because the former have been shown to more effectively contribute to conservation and restoration goals. Many other regional and state-wide efforts across the country are demonstrating these improved environmental outcomes and more efficient decision-making processes; a key component of their success is the use of high-quality data on species and ecosystems (*12*, *13*).

Rather than avoiding or short-cutting regulations, the goal of these methods is to use high-quality information in coordinating environmental requirements of multiple agencies, eliminating confusion and duplication of effort caused by conflicting agency regulations, and ensuring comprehensive environmental protection. This approach enables greater degrees of focus, specificity, and confidence both for the regulators and the entities subject to their regulations.

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Chapter 21

Using GIS To Assess Pesticide Exposure to Threatened and Endangered Species for Ecological Risk Assessment

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With the listing of salmon for protection under the Endangered Species Act, the Washington State Department of Agriculture (WSDA) determined that the traditional environmental data sets for pesticide registration decisions were insufficient to accurately determine potential exposure and subsequent effects of pesticides on salmonids and other listed species in Washington State. WSDA has implemented a program to spatially determine the location and use of pesticides in relationship to salmonid habitat and monitor pesticide residues in salmon-bearing streams in Washington State. Data elements developed include a geographic information system (GIS) incorporating the location of 160 crop types grown in Washington and an estimation of state-specific pesticide use.

Introduction

The United States Environmental Protection Agency (EPA) is incorporating consultation under Section 7(a)(2) of the Endangered Species Act (ESA) into Registration Review for pesticides registered in the United States (*1*). All Federal agencies must consult with either the U.S. Fish and Wildlife Service or National Marine Fisheries Service (NMFS) if they authorize an action that will jeopardize the existence of a listed species or adversely modify a listed species critical habitat (*2*). Typically ecological risk assessment for pesticide registration is done in a tiered manner where screening level assessments based on conservative exposure scenarios are used to determine if an adverse environmental outcome is not likely

In Pesticide Regulation and the Endangered Species Act; Racke, K., et al.;
ACS Symposium Series; American Chemical Society: Washington, DC, 2012.

(*3*). It is anticipated that consultation under ESA will necessitate ecological risk assessments conducted for pesticide registration to be more spatially explicit when determining potential exposure to listed species.

Recent biological opinions conducted by NMFS have incorporated spatial analysis to determine the co-occurrence of potential pesticide use and salmonid habitat (*4–7*). The NMFS analysis focused on determining the potential for pesticide use based on the land cover categories found in the 2001 National Land Cover Database (NLCD) (*6*). However, the 2001 NLCD only has two land cover classifications for agricultural lands: pasture/hay and cultivated crops (*8*). In a minor crop state such as Washington, two agricultural land cover categories must represent over 200 commodities each with unique pest pressures and pesticide use practices (*9*). For example the NLCD does not identify the spatial extent of where caneberries, mint or hops are grown nor their relationship to habitat for a listed species.

Since Washington's agricultural lands coincide with threatened and/or endangered species habitat, the Washington State Department of Agriculture (WSDA) has instituted a program to collect state-specific pesticide use data and compile a high resolution land cover dataset of agricultural land for use in ecological risk assessment for pesticide registration. In combination, these datasets allow risk assessors to evaluate the spatial and temporal use of pesticides in relationship to listed species habitat thus reducing uncertainty of exposure estimates and allowing for development of targeted mitigation measures.

Methodology

Pesticide Use Information

Accurate pesticide use data is invaluable for assessing the potential impacts of pesticides on water resources and ESA listed species. However, comprehensive pesticide use reporting programs such as the one administered by the California Department of Pesticide Registration (*10*) are rarely implemented. Given the cost and data management infrastructure, and in the absence of stakeholder support needed to implement a program similar to California's, WSDA has developed and implemented a unique program to develop pesticide use profiles that capture the typical use patterns for pesticides by commodity.

Pesticide use data is collected by conducting detailed surveys with farmers, ranchers, land managers, pesticide applicators, and crop consultants for a specific commodity. Typically, surveys are conducted during an on-site interview with a respondent; however, telephone and e-mail correspondence may also be used. To develop the survey WSDA reviews available data for the respective commodity which includes but is not limited to the following:

- Pesticide labels
- Previous pesticide use summaries
- Washington State University Cooperative Extension recommendations (*11*)

- Pacific Northwest Pest Control Handbooks (*12*, *13*)
- Washington State University Pesticide Information Center On-Line (PICOL) (*14*)
- National Agricultural Statistics Service (NASS) chemical use surveys (*15*)
- The Compendium of Washington Agriculture (*9*)
- Sales data when available

Information gathered from the data review is incorporated into a survey guide which provides an inclusive pesticide list with abbreviated use summaries that are vetted through the interview. Data collected during the survey interview includes:

- Beginning and ending application dates
- Pounds of active ingredient applied per acre per application
- Number of applications
- Application interval
- Percent acres treated
- Application method
- Region of application
- Target pest (optional)

Anecdotal information such as opinions about product availability or trends in use of specific product are noted but are not used in developing a pesticide use profile.

WSDA pesticide use data is typically not collected annually. The frequency of data collection for a specific pesticide is determined by agency priorities and limitations in staffing or resources. Generally, WSDA expects to update data by commodity every five years.

Recognizing the qualitative nature of the pesticide use surveys, WSDA has also developed a cooperative agreement with NASS to augment their Fruit and Vegetable Chemical Use surveys to include application timing windows for data collected in Washington State. NASS gathers chemical use data based on a Multivariate Probability Proportional to Size design. This sample design accounts for approximately 90 percent of all lands in farms in the United States (*16*, *17*). Rather than typical use data, the NASS surveys are an accounting of the previous year's pesticide applications in their entirety (product, rate per acre, date of application, application region, percent of acres treated). The farms sampled in each survey are representative of the whole industry and include small, medium, and large acreage operations. The cooperative agreement calls for the final accumulated data to be provided to WSDA by active ingredient and growing region. The reported data includes the mean and median application rates per acre, month and year of application, and the coefficient of variation (CV) of the use estimates.

All pesticide use data is compiled in an Access (Microsoft) database for use within a geographic information system (GIS).

Land Cover

In 2001, WSDA began development of a high resolution land use database to better characterize crop production locations in relation to habitat occupied by federally listed salmonid species. A high resolution land use database is needed to determine the correlation of crop production locations to habitat occupied by listed species. Agricultural land use data is compiled using GIS software developed by Environmental Systems Research Institute, Inc. (ESRI). The geodatabase consists of a feature dataset containing feature classes, tables, and topology rules. Domains have been created in the attribute tables for the crop type, crop group, irrigation type, rotation crops, NLCD category, and county to minimize data entry errors. There are 160 crop types (e.g., wheat, apple, carrot) that fall into 17 crop groups (e.g., cereal grain, orchard or vegetable). Automation has been added to the geodatabase to maximize efficiency of data input. For example the township, range, section (TRS), county, NLCD land use category fields are automatically updated when creating or editing a record. All geospatial data is in Washington State Plane coordinate system with NAD83 (HARN) horizontal datum and coordinate units of meters. Depending on regulatory priorities, fields are surveyed or updated every two to five years.

Agricultural land use data collected is based on surveys of individual fields; as such the base land unit is the field boundary. Field borders are verified and drawn based upon imagery. Typically National Agricultural Imagery Program (NAIP) color mosaics or orthoquad photos downloaded from the USDA website (*18*) are used. Field boundaries are drawn at a minimum scale of 1:8000. Any field smaller than 0.5 acre is not mapped.

Timing is critical for accurate crop classification, as there must be physical evidence of the crop at the time of visual inspection. This physical evidence includes but is not limited to all stages of plant growth from seedling to maturity, post harvest crop residue, and seed. Most perennial crops (e.g., orchards, vineyards, hay, hops or mint) can be classified year around. However, annual crops (e.g., potatoes, onions or beans) need to be surveyed during the growing season.

Field survey data may be collected directly from producers. This usually occurs via onsite consultation. Electronic or hard copy maps are generated showing field boundaries with reference layers such as aerial imagery to aid in identify specific fields. Crop locations, irrigation methods, and classifications are verified by the producer via an interview as opposed to visually inspecting specific fields. This approach is beneficial when mapping large farms with limited access. Other data sources that have been used to determine field borders or identify crop type include the National Agriculture Statistics (NASS) Cropland Data Layer (*19*) and field surveys conducted by Washington State Conservation districts.

To ensure data integrity, rules are established within the crop geodatabase to maintain consistent data entry/modification and provide for quality control and quality assurances. In addition to the domains previously mentioned, topology rules prevent polygons from overlapping each other or crossing TRS boundaries. Lastly, data is selected at random for review as part of an established quality assurance and control program (QA/QC). The QA/QC review includes validation of the field survey data and field boarders by individuals who did not collect the original data. The minimum acceptable crop classification accuracy is 90%, with a target goal of 95%. The 2011 field survey work had a 4.3% error rate.

Pesticide Use Intensity

Combining pesticide use and agricultural land use data allows for the determination of a spatially explicit estimation of pesticide use intensity. Although the field border is the smallest land unit within the agricultural land use dataset, pesticide use intensity is calculated at the section level which is typically one square mile. Pesticide use intensity calculations are aggregated to the section level to normalize for the spatial variability in agricultural land use. For example, orchards, vineyards and hop yards typically remain in fixed locations, while commodities such as corn, potatoes or tomatoes are typically not grown in the same field in successive years. Aggregating use to the section assumes the commodity could be grown within section on any given year but, not necessarily in the same field. Finally, aggregating data to the section level provides continuity with the reporting unit used by the California Department of Pesticide Regulations Pesticide Use Reporting Program (*20*).

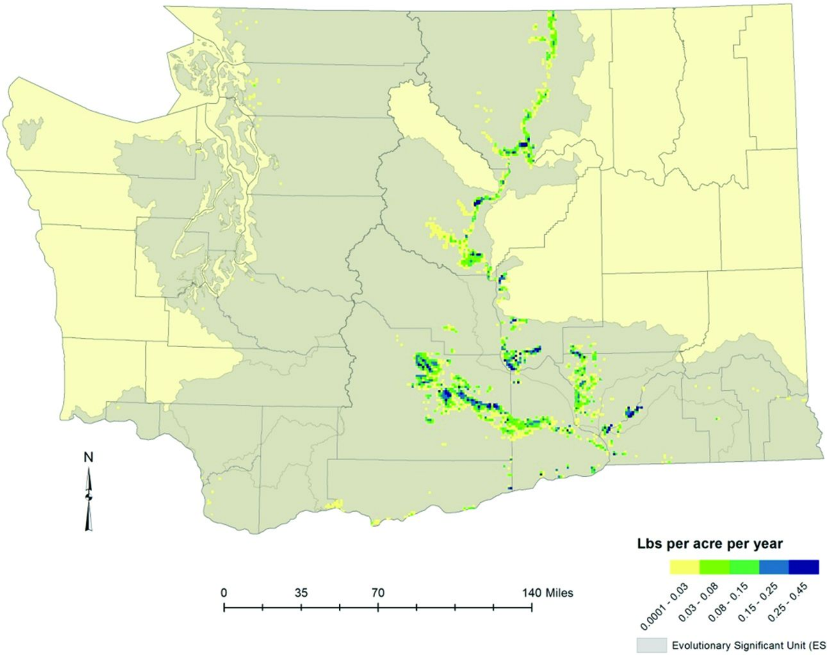

Figure 1. Oryzalin pesticide use within the ESUs of listed salmonids in Washington State. (see color insert)

Pesticide use is calculated as follows for each commodity and summed for each section:

$$Pesticide\ Use = AR \times AP \times AT$$

Where AR is application rate, AP is number of applications and AT is percent acres treated for the state. Pesticide use is calculated for the minimum, maximum or median rates determined from the pesticide use database. All crop uses are summed within each section, resulting in a loading estimate that is section specific rather than crop specific. The final map shows pesticide use intensity displayed at the section level as pounds per acre for all known uses (Figure 1). Using the application timing data, temporal use intensity by month can also be calculated.

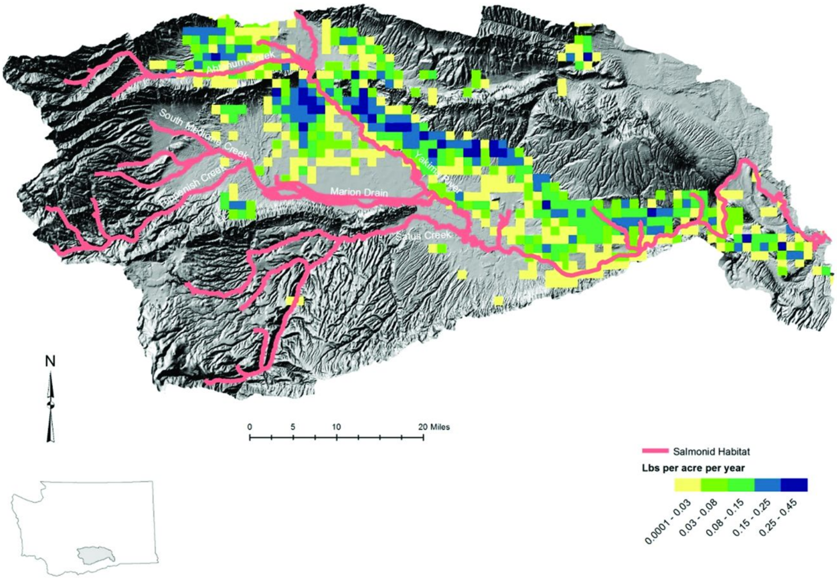

Figure 2. Oryzalin use in relationship to salmonid habitat (Lower Yakima, WA). (see color insert)

Integrating Spatial Data into Ecological Risk Assessment

Understanding the spatial and temporal distribution of pesticide use allows for refinement of exposure scenarios and improved evaluation of the spatial relevance of environmental monitoring data used for a registration risk assessments. Habitat data for threatened and endangered species can be evaluated for co-occurrence of pesticide use. Figure 2 shows the relationship of pesticide use in the lower Yakima Valley to salmonid habitat. Knowing the temporal aspect of pesticide use and habitat utilization allows for a refined exposure assessment for listed species. Spatially explicit use information also allows for determination of the relevance of environmental data such as surface water monitoring detections. Knowing the locations of sampling sites used for pesticide monitoring and pesticide use intensity within a watershed reinforces the relevance of both pesticide detections and non-detections in evaluating environmental exposure for listed species.

NMFS has noted the uncertainty of predicting pesticide use over a 15 year duration of a pesticide registration (*7*) which is the length of the federal action evaluated during consultation. Programs that continually survey and measure changes in agricultural land cover, pesticide use and environmental concentrations of pesticides can be incorporated into an adaptive management strategy for the registration granted by EPA and incorporated into the reasonable and prudent alternatives (RPA) referenced in the biological opinions to avoid jeopardy. An adaptive management approach would evaluate the exposure assumptions used during the registration and consultation process and evaluate the effectiveness of mitigation measures put into place to protect listed species. If changes of pesticide use occur or environmental exposure exceeds levels of concern identified during registration, mitigation could be tailored to meet local conditions.

Conclusions

As EPA incorporates assessments for ESA listed species into Registration Review there will be a greater need for high resolution spatial datasets that identify the relationship of pesticide use to habitat of threatened and endangered species. In minor crop states where there is high variability of commodities grown across the landscape it may be beneficial to develop high resolution land cover data that augments the generic land cover designations of national datasets such as the NLCD. Coupling high resolution land cover data with state-specific pesticide use information allows further refinement of the temporal and spatial use of pesticides and subsequently reducing uncertainty surrounding exposure assessments for listed species. Lastly, temporal and spatial data characterizing pesticide use can be integrated into adaptive management plans to tailor mitigation for local conditions. This allows risk managers to focus limited resources on areas where protection is most needed.

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Chapter 22

Development of a Spatial-Temporal Co-occurrence Index To Evaluate Relative Pesticide Risks to Threatened and Endangered Species

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A decline in pelagic species has been observed in the San Francisco Bay-Delta, triggering questions as to whether contaminants are contributing to the decline. An index method was developed to evaluate the spatial and temporal co-occurrence of pesticides and threatened and endangered species for this large ecosystem. The co-occurrence index combines monthly species abundance with statistical distributions of pesticide indicator days for 40 widely used pesticides. The frequency of co-occurrence was determined for 12 aquatic and semi-aquatic threatened or endangered species to help guide future research and monitoring priorities, and the placement of best management practices in the study area.

Introduction

A decline in pelagic species in the San Francisco Bay-Delta region has been reported (*1*), causing speculation as to whether contaminants may be playing a role in organism decline. The objective of this study was to evaluate the potential co-occurrence of pesticides with several threatened and endangered species (TES) in the Sacramento River, San Joaquin River, Bay-Delta estuary, and their

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tributaries to help guide research and monitoring priorities, and the placement of best management practices (BMPs) in the study area.

Forty pesticides (Table I) were considered in this project. The list is slightly modified from a list published by the Central Valley Regional Water Quality Control Board (*2*) of pesticides that pose the highest overall risk to aquatic life in surface water in the Central Valley based on usage in the region, aquatic life toxicity, and chemical properties.

Table I. Pesticides Evaluated

Chemical Name	*Chemical Name*	*Chemical Name*
(S)-Metolachlor	Deltamethrin	Oxyfluorfen
Abamectin	Diazinon	Paraquat Dichloride
Bifenthrin	Dimethoate	Pendimethalin
Bromacil	Diuron	Permethrin
Captan	Esfenvalerate	Propanil
Carbaryl	Hexazinone	Propargite
Chlorothalonil	Imidacloprid	Pyraclostrobin
Chlorpyrifos	Indoxacarb	Simazine
Cyhalofop-butyl	Lambda-cyhalothrin	Thiobencarb
Clomazone	Malathion	Tralomethrin
Copper Hydroxide	Mancozeb	Trifluralin
Copper Sulfate	Maneb	Ziram
Cyfluthrin	Methomyl	
Cypermethrin	Naled	

The twelve species addressed in the study include: four runs of Chinook salmon (*Oncorhynchus tshawytscha*), Central Valley steelhead (*Oncorhynchus mykiss*), Southern North American Green Sturgeon (*Acipenser medirostris*), Delta Smelt (*Hypomesus transpacificus*), Striped Bass (*Morone saxatilis*), San Francisco Longfin Smelt (*Spirinchus thaleichthys*), Threadfin Shad (*Dorosoma petenense*). California Red-legged Frog (*Rana draytonii*), and California Freshwater Shrimp (*Syncaris pacifica*). The runs of Chinook are Sacramento River winter-run, Central Valley spring-run, Central Valley fall run, and Central Valley late fall run.

Co-occurrence Method Development

Existing Co-occurrence Methodologies

Co-occurrence studies have been used to evaluate a wide variety of topics, including predator-prey relationships (*3*, *4*), invasive species (*5*, *6*), or competing species (*7–9*). Researchers have relied on a number of different methods to determine co-occurrence such as basic geographic information system (GIS) analysis (*9*, *10*), statistical approaches (*11*, *12*) or co-occurrence networks (*13*), and C-scores (*14–17*). The most common GIS assessments use standard overlay, predictive surfaces (*10*), and cluster analysis (*9*) to determine if two species co-occur. Statistical approaches to determine co-occurrence range from basic joint probability assessment (*18–20*), to more complex approaches such as multivariate logistic regression (*11*) or probabilities of occurrence based on multiple presence/absence surveys (*12*). The C-score or checker box approach, which produces a presence/absence matrix, has been demonstrated to work well for two species and for multiple paired species over a period of time (*21*).

The methods listed above function well when only a few entities are compared, but they cannot accommodate multiple species and multiple pesticides on a landscape level with a temporal component whilst ranking co-occurrence areas of concern. Therefore, a new approach was developed.

Co-occurrence Matrix

For this study, co-occurrence was determined by partitioning the landscape into discreet segments based on the likelihood that at least one pesticide is above a set benchmark and that one or more species are present at that location during the same period. The segments enabled us to account for local spatiotemporal patterns. The model assumes that species richness is sufficient to rank and determine co-occurrence for any time period. To account for temporal variability, a monthly time step was applied to the chemical occurrence and species richness. Rather than calculating a joint probability (*18–20*), the co-occurrence is expressed in a 2-dimensional unitless number in a matrix. Each part of the number expresses the contribution of the two entities considered. Higher numbers indicate greater co-occurrence and lower numbers indicate lesser co-occurrence.

The public land survey system (PLSS) section was used as the spatial computational element because historical pesticide use in California is reported at this level (*22*). For each landscape segment the potential ecological risk was calculated using the concept of a risk quotient (RQ). The RQ is calculated as the estimated exposure concentration (EEC) divided by the toxicity (*23*).

Generally in risk assessment, RQ ≥ 1 indicates pesticide exposure may adversely impact species. To avoid confusion over RQ, which implies adverse effects, the term “indicator event” is used. An indicator event is one in which toxicity has the potential to occur if the species is present.

One dilemma faced in the development of the co-occurrence matrix was whether to conduct the analysis based on the number of chemicals causing indicator events in a landscape segment on the same day or if any chemical produced an indicator event on that day. Because the effects of multiple pesticides (i.e., mixtures) not all interactions are understood (*24*), co-occurrence was evaluated using indicator days. An indicator day is a day in which at least one indicator event occurs. The rate of indicator days (I_n) was calculated for each landscape segment for each for the set time period:

$$I_n = \frac{I}{(N_y \times N_d)}$$

Where

I_n = rate of indicator days for the analysis period

I = number of indicator days per time period (month)

N_y= number of years considered

N_d = number of days in the time period

For long time periods, I_n has the potential of becoming large and meaningless. However, I_n can be expressed by percentile level. In this study 10 percentile classes were used (e.g., 10th, 20th, 90th and 100th percentiles) in order to normalize results and accommodate a range of conditions, such as a different numbers of pesticides, analysis time steps (e.g., seasons instead of months), or analysis periods (number of years).

In order to determine if the species under question were present, distribution maps were assembled that associate the aquatic TES with landscape segments. Once the maps were in place, a species richness assessment was performed to determine the fraction of species estimated to be present relative to the number under consideration in this study. That fraction is called the species richness fraction, S_n, and is calculated as:

$$S_n = \frac{M}{N}$$

Where

M is number of species present in the time period considered

N is the number of species considered in the study

Like I_n, percentile fractions (the 10th, 20th, ..., 90th and 100th) were determined for each landscape segment and time period in order to normalize results when considering a different number of species.

Both pesticide concentrations and species are dynamic in space and time. The landscape segment anchors the spatial aspect and does not influence the temporal aspect. The environmental fate models used for the analysis, which are discussed later in this document, operate on a daily time step (*25*, *26*). However, since species distribution was available on a monthly basis, the ecological risk temporal windows were up scaled from day to month. As such the co-occurrence model embeds a monthly temporal window. A monthly time step was deemed to provide sufficient temporal resolution to detect any potential trends over the course of a year.

Because I_n and S_n are expressed as percentiles at a monthly time step, a single score or joint probability would obscure some of the information. To circumvent this, a 2-dimensional co-occurrence matrix was created. The matrix is an 11 x 11 grid (Figure 1) with indictor day percentiles along the abscissa and species richness percentiles along the ordinate. The grid axes are divided into bins representing percentile intervals -- that is, the 1st to 10th percentile is bin 1, 11th to 20th percentile is bin 2, and so on. The bins are numbered 0 to 10 from left to right and from top to bottom. The matrix values are simply a two-digit juxtaposition of the bin numbers and range from 0000 to 1010, i.e., 0000 indicates that neither species nor indicators days are present and 1010 indicates that all species and indicator days are very likely to co-occur. Because the bins are scaled to the population, the maximum fractions (and thus 100th percentiles) are not necessarily 1.0, but could be smaller. This approach enables the user to determine for the considered populations areas where, relatively speaking, more frequent co-occurrences of pesticides and species are located in the landscape.

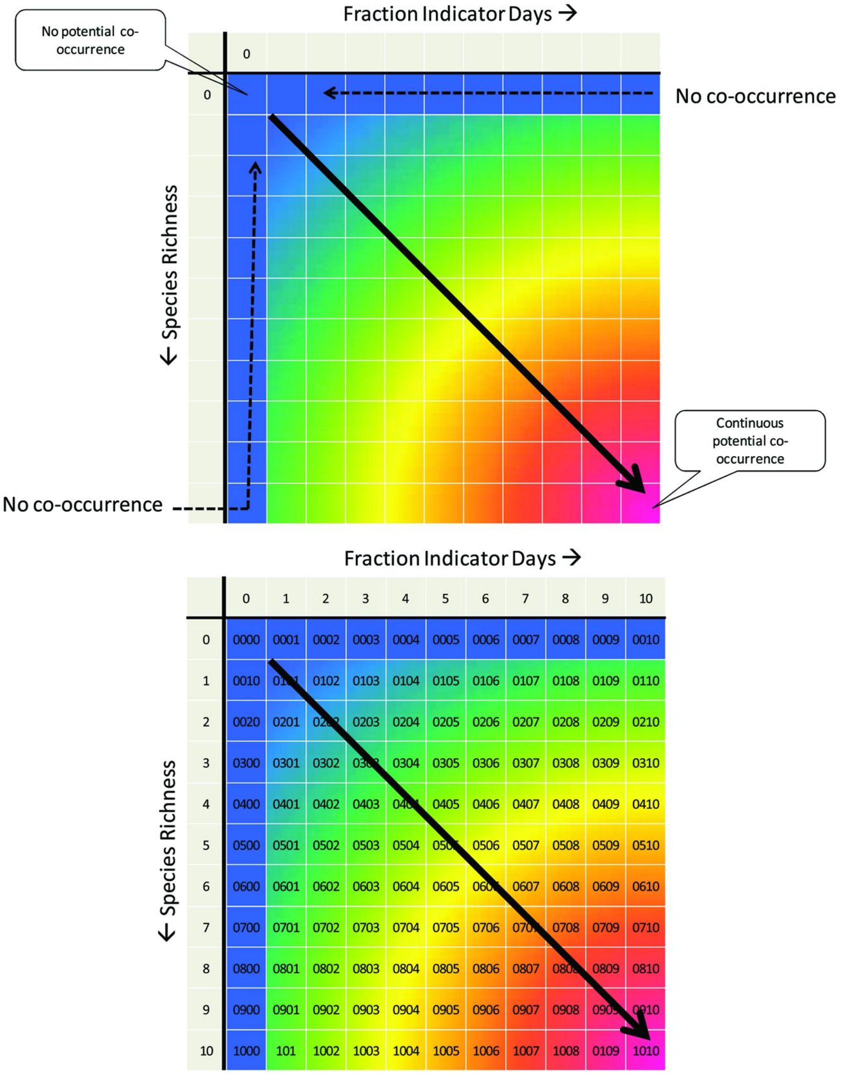
Co-occurrence Model Input Development

Modeling Estimated Environmental Concentrations

Daily pesticide loads to aquatic systems in the study area were estimated for historical applications of 40 pesticides to agricultural fields, rice paddies, and urban areas. Modeling for a ten-year period (2000 - 2009) necessitated the development of a framework to account for the dynamic aspects such as variable weather, changing application locations, and temporal changes in agricultural landscapes. The framework for this study was the PLSS section. Using a GIS, each PLSS section was further divided into hydrologic response units (HRU; (*27*)). Each HRU is uniform in land cover (e.g., agriculture, urban), soils (USDA Soil Survey Geographic Database (SSURGO); (*28*)), climate (California Irrigation Management Information System (CMIS); (*29*)), and agricultural management practices (irrigation from the California Department of Water Resources 2001 county survey; (*30*)). To account for a changing landscape, the land cover layer was updated every two years based on data from the California Farm Mapping and Monitoring Program (*31*).

Pesticide mass loadings for runoff and erosion were calculated using model simulations for each HRU. The total mass loading at the PLSS section level was calculated by aggregating the mass loadings. The sub-aggregated mass loadings were then used as input for the receiving water model, which in turn estimated environmental concentrations (EECs). Using data from California's Pesticide Use

Reporting (PUR) database (*22*), historical applications were linked to use sites (28 different crop categories and urban) for each PLSS sections for a 9-year period (2000–2008).



	0	1	2	3	4	5	6	7	8	9	10
0	0000	0001	0002	0003	0004	0005	0006	0007	0008	0009	0010
1	0010	0101	0102	0103	0104	0105	0106	0107	0108	0109	0110
2	0020	0201	0202	0203	0204	0205	0206	0207	0208	0209	0210
3	0300	0301	0302	0303	0304	0305	0306	0307	0308	0309	0310
4	0400	0401	0402	0403	0404	0405	0406	0407	0408	0409	0410
5	0500	0501	0502	0503	0504	0505	0506	0507	0508	0509	0510
6	0600	0601	0602	0603	0604	0605	0606	0607	0608	0609	0610
7	0700	0701	0702	0703	0704	0705	0706	0707	0708	0709	0710
8	0800	0801	0802	0803	0804	0805	0806	0807	0808	0809	0810
9	0900	0901	0902	0903	0904	0905	0906	0907	0908	0909	0910
10	1000	101	1002	1003	1004	1005	1006	1007	1008	0109	1010

Figure 1. Co-occurrence matrix basic design (top), filled in (bottom). (see color insert)

Daily pesticide mass loadings resulting from agriculture and urban applications were simulated using the Pesticide Root Zone Model (PRZM). PRZM is a dynamic, compartmental model developed by the U.S. Environmental Protection Agency (USEPA) for use in simulating water and chemical movement in unsaturated soil systems within and below the plant root zone (*25*). PRZM is the standard model used for ecological and drinking water risk assessments for pesticides by the USEPA's Office of Pesticide Programs (USEPA OPP; (*32*)). The model has undergone an extensive validation effort against numerous field-scale runoff and leaching studies conducted for pesticides in the United States (*25*, *33*) and the model has been integrated into several watershed assessments in the U.S., including the Sacramento River watershed, which resides in the study area (*34*).

Pesticide mass loadings from wet seed application rice agriculture were simulated using the rice water quality model, RICEWQ 1.7.3 (*26*). RICEWQ has the ability to simulate the unique water management practices associated with rice production and because of the relative ease in using the model for bulk scenario processing. The model has been validated against field and watershed applications to flooded rice paddies in Australia, Italy, Greece, Japan, and the U.S. (*35–50*).

A further issue that can impact the aquatic environment, and needs to be considered, is spray drift. Spray drift is the offsite movement of pesticide during application. The drift can end up in a water body depending on a number of factors, including application rate, method of application, pesticide formulation, wind speed, wind direction, humidity, barometric pressure, height and velocity of the application apparatus, proximity of the water body to the treated field, and presence and effectiveness of interception barriers. Unfortunately, the PUR gives only the application rate and a general description of the application method. Therefore, drift load (M_{drift}) for an application was estimated with a simple linear equation:

$$M_{\mathrm{drift}} = \mathrm{Rate} \times D_{\mathrm{FRACT}} \times \sum_{i=1}^{n} (L_i \times W_i) \times \frac{\mathrm{PUR}_{\mathrm{area}}}{\mathrm{Ag}_{\mathrm{area}}}$$

Where

M_{drift} = Mass loading (kg) resulting from drift for a single pesticide.

Rate = pesticide application rate (kg /ha^{-1}) for the pesticide.

D_{FRACT} = Drift fraction (unitless), based on values used by the USEPA for pesticide risk assessment (*51*). For aerial applications a drift of 5% of the application rate is assumed. For ground applications, a drift of 1% of the application rate is assumed.

L_i = Stream length (m) associated with the treated field.

W_i = Width of the stream (m).

$\mathrm{PUR}_{\mathrm{area}}/\mathrm{Ag}_{\mathrm{area}}$ = Area-weighted correction (unitless) for the treated area, PUR area (ha), and the PLSS land area (ha).

This equation applies only to a single event, but the daily concentration is what is of interest. So, to calculate that for a generic pesticide mass loading (M_i), a receiving water body was defined from the total stream length within each PLSS section. The volume (V) of this water body is calculated based on the linear length of each stream order in the PLSS according to the following equation:

$$V = \sum_{i=1}^{n} (L_i \times W_i \times D_i),$$

Where
L_i = length,
W_i= width,
D_i = depth,
i = one of n channel segments.

As data for a more complex stream definition was not readily available for all streams in the study area, the stream geometry was fixed by stream order, with lengths derived from the National Hydrography Dataset (NHD+; (*52*)). For a natural stream, the depth and width were obtained from USEPA Reach File 1 (RF1; (*53*)). A linear regression equation was developed based on the RF1 from streams in the study area to estimate the depth of a stream given the width. The resulting relationship was used to compute the depth of each stream order based on assumed standard width. For man-made agricultural ditches, the dimensions were obtained from expert opinion (Wrysinski, J. Yolo County Resource Conservation District, Woodland, CA. Personal Communication, 2010).

The final calculation for estimating environmental concentrations is:

$$[C_i] = \frac{M_i}{V_i},$$

where
M_i = total daily mass (kg) for a chemical i in a PLSS section,
V_i = volume of water (m3) in the PLSS section,

M_i represents the total daily off-target mass for each of the 40 pesticides determined by summing the modeled mass agricultural loadings from runoff (dissolved and adsorbed to eroded soil), releases from rice paddies, drift from spray, and runoff from urban areas, and then mixing the total off-target mass in a volume of water. The computed concentration was then compared against a reference benchmark to determine if the computed concentration is above a benchmark.

Aquatic Life Benchmarks

Benchmark values were derived for each pesticide. The primary data source was the lowest acute fish or invertebrate benchmark value from the OPP Aquatic Life Benchmarks database (*54*). The benchmarks, which contain a safety factor of 2, were divided by an additional safety factor of 10 to account for TES. The toxicity of copper is influenced by a number of physicochemical characteristics (in particular water hardness), which, influences speciation and bioavailability of copper. A representative hardness and a hardness equation acute criterion maximum concentration equation (*55*) were calculated for both copper-based pesticides. The OPP database did not contain benchmarks for abamectin, indoxacarb, cyhalofop-butyl, or pyraclostrobin; the benchmarks for these pesticides were from other sources (*56*).

Species Distribution

The next piece needed for the co-occurrence analysis is a sense of what species are at risk and where they are located. The U.S. Fish and Wildlife Service (USFWS) critical habitat data (*57*) provides some of this information. However, the USFWS only gives federally listed species; no convenient dataset existed for state listed species (e.g., the California freshwater shrimp). In addition, the critical habitat data lack a clear temporal aspect. Given these limitations, a dataset for each species was required, specifically, one which showed, for each water segment, monthly species presence or absence.

Developing these species-specific datasets required life-cycle and presence information from a variety of sources. The primary references used were from Moyle (*58*, *59*). The resultant fish species range maps are considered high water year ranges; some of the stream reaches included are ephemeral and would not contain adults or juveniles during low water years. The California Red-legged frog was a special case. The distribution and abundance representations relied only on the USFWS critical habitat data (*57*), which is likely to under represent the actual species distribution.

Co-occurrence Assessment

The first step in the co-occurrence assessment was the development of the two required input datasets: the frequency distribution of the sum of indicator days and the frequency distribution of the species richness. Results concerning the off-target mass loadings and predicted concentrations are not included in this chapter, but are included in separate report by Hoogeweg and coworkers (*60*).

Indicator Days

Indicator days provide insight into the potential of an estimated pesticide concentration exceeding the benchmark for one or more pesticides. The maximum number of indicator events in a PLSS section was 2,876 in this study. Computed indicator days for several randomly selected PLSS sections (Figure 2) demonstrate that the number of indicator days is highly variable by location and by month due to factors such as application timing relative to rainfall and irrigation practices. The modeled decrease in the number of indicator days in the months of August through October for the PLSS section shown in Figure 2 might be due harvest of the crops in that time period.

The frequency distribution for indicator days by month for the period 2000–2009 is shown in Figure 3. Overall, the distribution appears to follow a log-normal curve, but with additional peaks at roughly the 0.15 and 0.50 bins. The tri-modal pattern is caused by differences between the application schemas of pesticide use in the urban environment, on rice paddies, and on other crops. The drivers of this are differences in application timing, for example urban applications are comparatively higher in the winter and early spring. Without urban applications the graph followed a log-normal pattern. The highest and most frequent indicator days were predicted to be in the San Joaquin River watershed in June through August. In these months, a majority of the agricultural areas fall in the upper percentile range (90th–100th percentile).

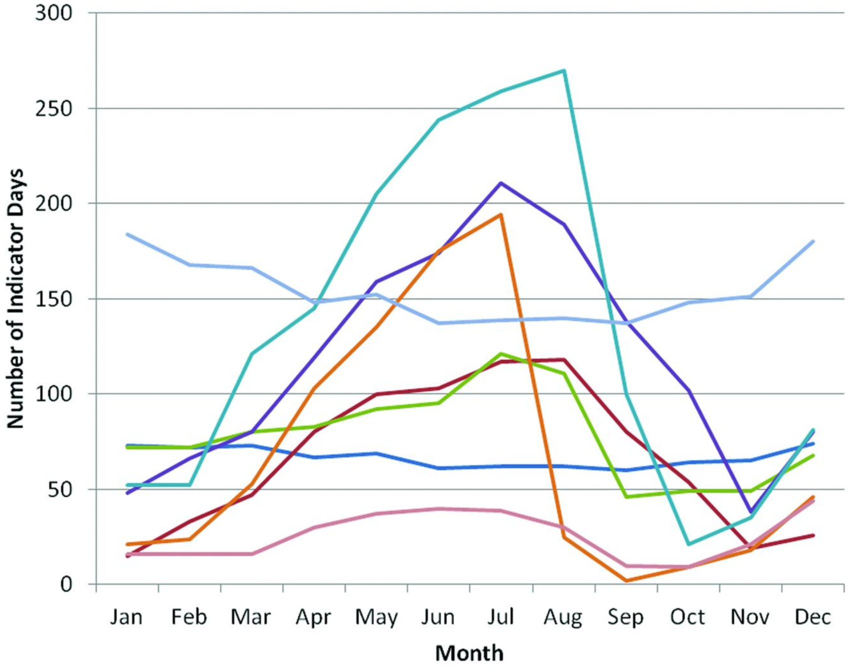


Figure 2. Temporal trend of the number of indicator days for selected Public Land Survey System sections by month for random locations in the study area. (see color insert)

In order to characterize the statistical distribution of indicator days, the frequency distribution was organized into percentile fractions (Table II). As shown in the table, the 80th percentile represents those months (and sections) where half of the time an indicator event took place. The 90th percentile is slightly higher at 0.589. The maximum value of 0.994 is noteworthy, since it indicates that there are a few instances (sections and months) in which the pesticide concentrations have the potential to be above a benchmark nearly every day of a year and month.

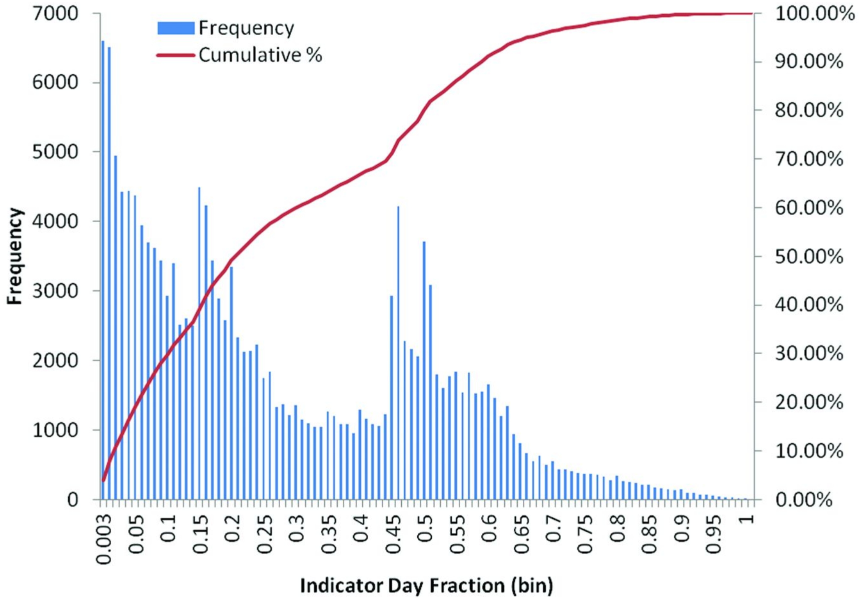


Figure 3. Frequency and cumulative distribution of all indicator days. (see color insert)

Table II. Statistics for the Indicator Day Distribution

Percentile	*Fraction*	*Bin*	*Bin Range*
10	0.017	1	0–0.017
20	0.055	2	0.018–0.055
30	0.100	3	0.056–0.100
40	0.153	4	0.101–0.153
50	0.206	5	0.154–0.206
60	0.303	6	0.207–0.303
70	0.447	7	0.304–0.447
80	0.500	8	0.448–0.500
90	0.589	9	0.501–0.589
100	0.994	10	0.590–0.994

Species Richness

The physical distribution of the species under consideration was limited by the presence of partial and full barriers (e.g., dams) that prohibit upstream or downstream movement of the species. As such, many species are not present in the streams at higher elevation and were limited to aquatic habitats within the traditional agricultural areas in the Central Valley and to lower elevations in the mountains.

Although the distribution maps indicate where the species is present, they do not show when the species is present. This is significant, since while the results show that species richness changed little throughout the year, temporal changes are present in the system (Figure 4). Salmon migrations, for example, influence the species richness at certain times of year. Irrespective of the time period considered, the highest species richness was located in the Delta and along the Sacramento River.

The frequency distribution of the species richness data (Figure 5) depicts a strong bias at the 30th and 50th percentiles. This means that up to six of the species are present in most streams throughout the year.

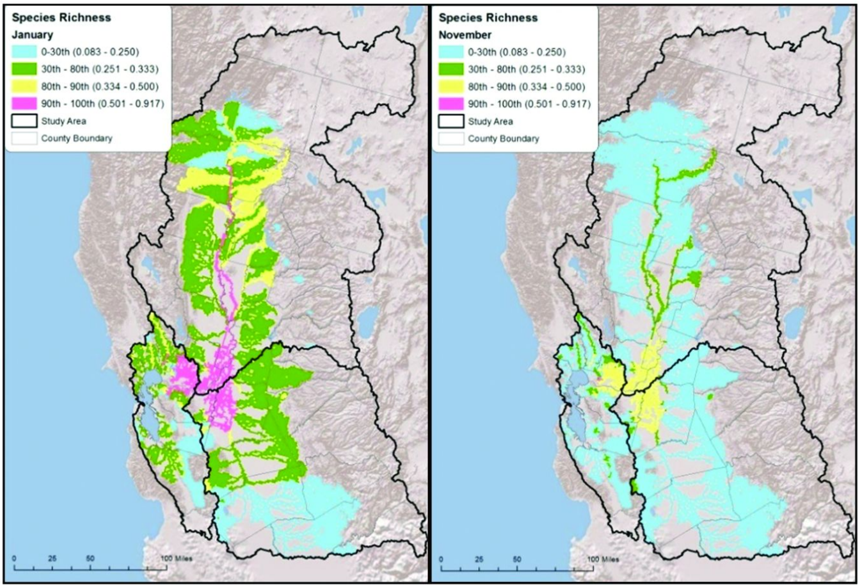


Figure 4. Species richness distribution for January (left) and November (right). (see color insert)

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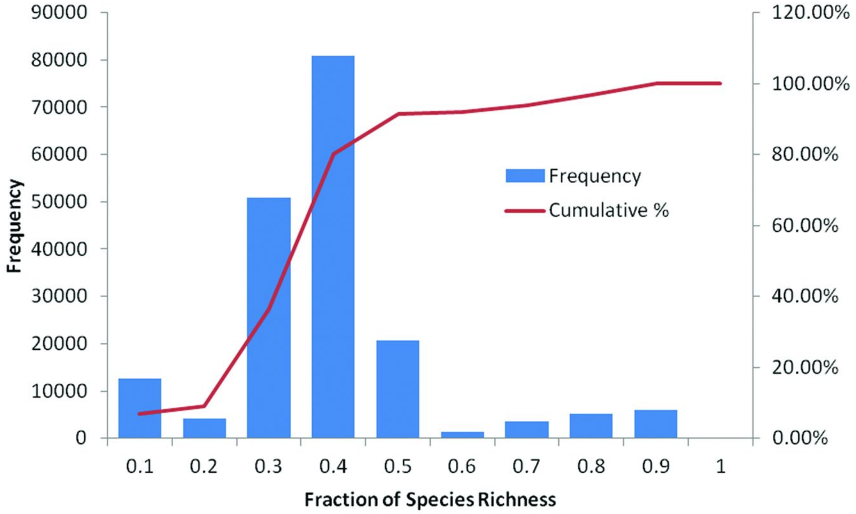

Figure 5. Frequency and cumulative distribution of the species richness. (see color insert)

Table III. Statistics for Species Richness Distribution

Percentile	*Fraction*	*Bin*	*Bin Range*
10	0.250	1	0.001–0.250
20	0.250	2	0.001–0.250
30	0.250	3	0.001–0.250
40	0.333	4	0.251–0.333
50	0.333	5	0.251–0.333
60	0.333	6	0.251–0.333
70	0.333	7	0.251–0.333
80	0.333	8	0.251–0.333
90	0.500	9	0.334–0.500
100	0.917	10	0.501–0.917

Because the frequency distribution of the species richness is dominated by the 0.3 to 0.5 range, the calculated percentiles of species richness (Table III) show little variation. For example, the 10th to 30th percentile are 0.250 and the 40th to 80th percentiles are 0.333. The maximum (100th percentile) species richness value is 0.917. This indicates that no area has all 12 species present. This is due to the fact the California Red-legged frog is not found in the Delta, and California freshwater shrimp have a very limited distribution.

Colusa Basin Drain Case Study

To demonstrate the utility of the co-occurrence matrix for assessing co-occurrence of pesticides and TES, case studies were conducted to determine where potential areas of concern. The Colusa Basin Drain (primarily agricultural) is presented in this paper as an example. As was described in the previous sections, the co-occurrence matrix uses a relative ranking based on percentile distributions. The higher the individual percentile level, the higher the likelihood of co-occurrence. However, for co-occurrence to transpire, both the species and the indicator day must coincide in same temporal window and location.

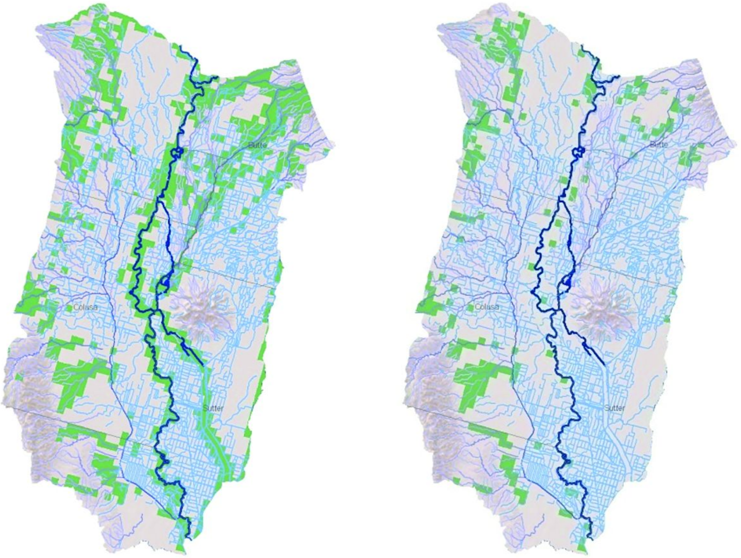

Figure 6. Percentile areas (shown in green), 50th (left) and 80th (right), for co-occurrence of pesticides and threatened and endangered species in the Colusa Basin Drain. The blue lines represent natural streams and agricultural ditches. (see color insert)

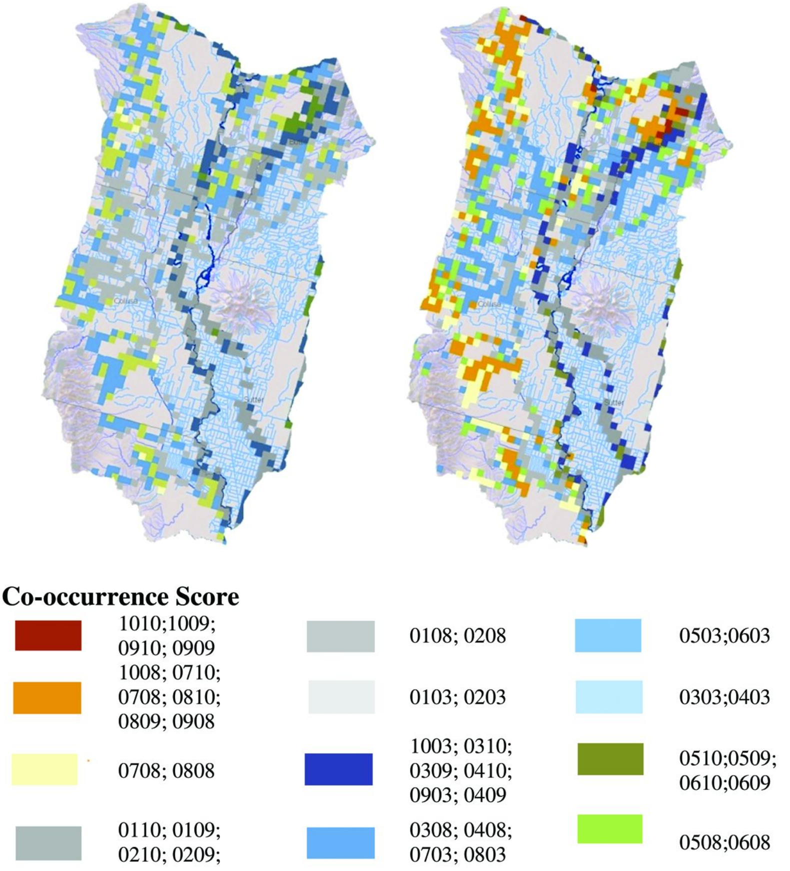

Figure 7. Co-occurrence for January (left) and May (right) of pesticides and threatened and endangered species in the Colusa Basin Drain (see color insert)

Varying Percentile Levels

To demonstrate the utility and versatility of the developed co-occurrence approach, regions were determined that adhere to predefined percentile levels using a 12-month time window. Next, the 50th, 80th, and 90th percentile levels were calculated for the Colusa Basin Drain. The 50th percentile represents the median case and had values of 0.206 for indicator days and 0.333 for species richness. However, 0.333 represents the 40th to 80th percentile range for the species richness. Therefore, the 80th percentiles for both indicator days and species richness were considered as well. The 90th percentile was used as the worst case, following the normal procedure in risk assessments (*61*). Using the co-occurrence matrix approach, the 90th percentile values are 0.5 for species richness and 0.589 for indicator days. As the percentile level increases, fewer sections adhere to the predefined 50th and 80th percentile levels (Figure 6). At the 90th percentile level (not shown) two PLSS sections were found in the Colusa Basin Drain that met this scenario.

Temporal Assessments

The final component to consider is the temporal assessment. Both pesticide use and species richness vary over time; therefore co-occurrence should be time dependent as well. Figure 7 illustrates the co-occurrence for two example months (January and May) for the Colusa Basin Drain. In January the overall co-occurrence is lower than in May. This is due to increases in both pesticide use and species richness in the month of May. Co-occurrence ranged from 0103 to 0710 in January and 0103 to 1010 in May. Areas with no co-occurrence (i.e., either no indicator days or no species present during the time period) are not shown on the maps.

The lowest co-occurrence value in both January and May was 0103, which represents the 10th percentile level for indicator days and the 30th percentile level for species richness. At the upper range, January had a co-occurrence of 0710 and May of 1010. The percentile levels for the indicator days ranges from bin 7 (60th–70th percentile level) to bin 10 (90th–100th percentile range). For both months, the species richness was in the 10th bin, which represents the 90th–100th percentile range, or near maximum likelihood that all species were present.

Because this assessment shows the intersection in time and space of aquatic species and pesticide use, there are many different potential applications for the co-occurrence matrix. Resources agencies tasked with protecting aquatic species will now be able to better predict optimal times and places to monitor within watersheds, and thus will be able to make optimal use of BMPs to mitigate pesticide loadings. The information could also be parsed out for risk managers attempting to understand the specific locations of higher co-occurrence of a particular species and a particular pesticide or the joint co-occurrence of multiple pesticides in the same class (i.e., pyrethroids).

Conclusions

The growing need to determine if pesticides may be coming into contact with threatened and endangered species prompted the creation of a new approach that juxtaposes modeled pesticide concentrations in surface water and species richness data to determine where co-occurrence is most probable. Comparing these two sets was done with a monthly timescale, as that best represented both species richness and the distribution of pesticide exposure events (indicator days).

The results of this analysis are both positive and negative. Given sufficient data, a co-occurrence assessment is certainly possible and the information it yields can be valuable on a variety of levels. In addition to that, the majority of information needed to conduct the study was publicly available or could be processed from public sources. However, there are limitations and assumptions that lead to uncertainty in predictions of co-occurrence. Degradation products, chronic toxicity, and indirect effects were not addressed. There are gaps in the data, particularly in the estimation of water volumes and channel routing that compromise the ability to estimate exposure concentrations. Therefore, predictions of co-occurrence do not mean that adverse effects will occur. As a result, they should only be used to provide a relative ranking of potential areas of risk to the threatened and endangered species in the study area and the general time of year when these risks would be most likely to occur.

Yet, the co-occurrence matrix is flexible and scalable and can be adapted to answer a variety of potential questions depending on the needs of the risk assessor. The method could easily be expanded upon to give it greater complexity and utility by incorporating more detailed information about the hydrodynamics and the temporal distribution of species abundance and presence in the watershed, and could include additional species, pesticides, endpoints, and/or other water quality constituents. While this work done was specific to California's Central River Valley, the same method could be applied to other species, geographical areas, time windows, or pesticide classes. Large watersheds are difficult to manage, requiring very large sets of both modeling and monitoring data, and the co-occurrence method can give resource managers a way to focus and refine their impact evaluations. By applying these tools, resource managers can identify higher risk areas, giving them a better idea of when and where they may occur during a year. It also gives managers a way to test solutions, such as alternative pesticide use and optimized location of BMPs. Others may find this model useful in predicting effects of changing pesticide use instructions on labels (e.g., different application rates, targeted vs. broadcast applications, use of buffer zones).

Acknowledgments

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Chapter 23

Use of Risk-Based Spray Drift Buffers for Protection of Nontarget Areas

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Regulatory authorities have begun to shift spray drift management label language from protecting threatened and endangered species and habitat to protecting non-target areas including grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas, and shrub lands”. We outline a process for using spray drift models to determine buffer distances using non-target species study endpoints (NOER’s, ER_{25}’s or ER_{50}’s). The conservatively protective nature of this approach is explored, as well as its current use in regulatory practice. Use of the presented method provides adequate protections for current or future habitat. Use of risk-based buffers should be included as part of an accepted toolbox of fixes for non-target species exposure concerns. The U.S. Environmental Protection Agency’s risk assessment and registration processes include spray drift considerations, and approved labeling may include drift reduction considerations. These considerations are based on estimates of potential exposure from drift and hazard evaluation of the chemical being applied. The potential exposure from drift is estimated using models. Stakeholders are currently sponsoring research to improve model estimates so that they more accurately reflect potential for drift with consideration of available technology.

Introduction

The Office of Pesticide Programs within the U.S. Environmental Protection Agency (EPA) is responsible for administration of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA), and has the authority to register plant protection products under the Act. Plant protection products may be registered for specific uses if those uses are deemed, by the Agency, to not represent a risk to the continued well-being of exposed individuals and if they are further deemed to have no unreasonable adverse effects on the environment. To make this latter determination the EPA conducts an ecological risk assessment. Under the provisions of the Endangered Species Act (ESA) all Federal departments and agencies must seek to conserve threatened and endangered species and must insure any "action" does not jeopardize a species or destroy or adversely modify its habitat. Because the "action" of registering or reregistering an active ingredient must be compliant with ESA, the ecological risk assessment conducted by EPA must consider the impacts on endangered species.

There are a number of ways that endangered species protections might be applied in plant protection product registration actions. One proposed method is that a more stringent protection standard for ESA would be applied only to the locations identified as habitat for a particular endangered species that could be affected by a proposed product use. In this manner the impact on production agriculture would be minimized by narrowing the land area subject to risk mitigation practices. There are challenges in identifying the range of area that requires protection for each species, potential movement of species and the fact that new species may be added to protection lists requiring revision of restrictions. Additionally, there is disagreement between EPA and the 'Services' (U.S. Fish and Wildlife Service and National Marine Fisheries Service) which administer ESA regarding what needs to be considered in an acceptable risk assessment to sufficiently estimate the potential impact on species. Despite obstacles, great strides have been made in developing a system that considers the complexity of questions to be considered. An alternative method has also been applied. EPA has started revising label language to include spray drift protections away from solely occupied threatened and endangered species habitat to protecting all non-target areas identified as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas, and shrub lands.

Examples of older label language for spray drift management can be seen in Figure 1, while an example of newer language can be seen in Figure 2. The change to protecting all non-target areas would protect both present and future habitat and remove necessity to consider 'exclusions' that may not be static and would provide protections without confirmation of species presence. While agreement on a near zero exposure estimate may be easier to attain than agreement on data requirements for risk assessment, such an approach may cause undue impacts on the grower. To achieve this scenario registrants could apply mitigation measures from an approved toolbox, (*e.g.*, no- spray buffer zones or vegetative buffer strips), to achieve a theoretical 'de minimus' exposure scenario. The size of buffers would be based on exposure estimates relative to toxicity endpoints that enable EPA to reach a conclusion of "not likely to affect". Because the risk assessment considers all non-target areas, which include all threatened and endangered species habitat, a "not likely to adversely affect" (NLAA) determination should absolve EPA of the obligation to consult with the Services and could streamline the process.

However, achieving a theoretical 'de minimus' exposure scenario may have an unacceptably high cost in terms of the amount of land taken out of production to buffer all non-target areas. To achieve an NLAA determination the EPA may choose to use a NOEC (no observed effect concentration) rather than ER_{25}/ER_{50}/ LC_{50} endpoints. This would likely be substantially more conservative than current assessments and require larger buffers.

The work presented here describes a method whereby buffers to protected areas can be calculated using spray deposition models and appropriate non-target effects data. Since the method described in this process is based on exposure calculations and properly selected and applied effects data endpoints, the method is referred to as "risk–based" buffer calculation in contrast to statutory or "expert opinion" buffers which are arbitrarily set without the benefit of scientific method. The paper further explores where improvements may be made to existing tools, using best available data, in order to improve the viability of the methods currently in use or envisioned. Any method applied to this setting must ensure that endangered species protections are adequate while minimizing the impact on production agriculture and the ability to continue to produce food, fiber and fuel for a growing global population.

Methods

In order to calculate risk-based buffers, there are two elements required for estimation. The two elements are exposure, which comes from a drift model, and an estimated effects level of concern, which comes from the appropriate non-target species study. In an example typical for the risk assessment of herbicide application, we have examined effects on non-target plants resulting from ground sprayer exposures. Figure 3 is an illustration of the process required to determine an appropriate risk-based buffer distance.

Nontarget Plant Studies

For determination of terrestrial spray buffers, data from one of two guideline studies are used which are part of all regulatory data packages. The seedling emergence study OPPTS 850.4225 (*1*) and the vegetative vigor study OPPTS 850.4250 (*2*) are part of all regulatory data packages. The decision on which of these studies is used is driven by the product use pattern and the study that demonstrates the greatest sensitivity to the plant protection product being tested. These studies include ten different plant species involving both monocots and dicots. The species included in the studies can vary but typically would be corn, ryegrass, onion, wheat, lettuce, soybean, tomato, cabbage, carrot, and canola.

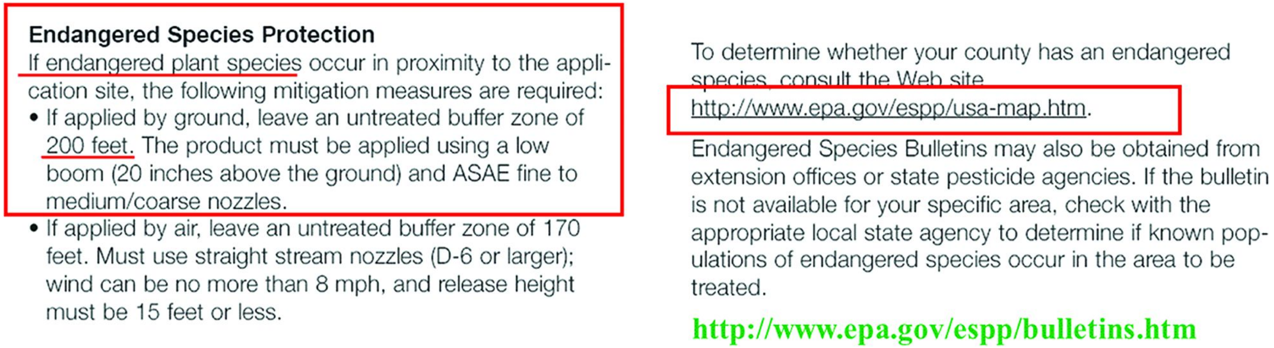
Figure 4 is a picture of plants ready for treatment in a vegetative vigor study. For the vegetative vigor study, once plants reach the proper size for treatment, they are sprayed in a spray chamber. Seeds in the seedling emergence study have the product doses placed (or administered) into the soil with water. For the vegetative vigor study, plants are evaluated at 7, 14, and 21 days for plant height, survival and dry weight. Evaluations are similar for the seedling emergence study. Figure 5 is an example table from a vegetative vigor study indicating the non-target plant endpoints.

The use of these studies has been criticized for not including weed species. However, the species tested are a cross-section of plant types and testing is done on pre-emergent or very young plants that are most sensitive to plant protection products. It is normal in this testing to see high levels of sensitivity in test species with traits similar to target weed species. In the example table in Figure 5, the no observed effect rate (NOER) for the lowest endpoint used was based on plant height.

In the risk assessment process, the effects observed in the laboratory are extrapolated to populations of all non-target plants. When calculating buffer distances, the response level appropriate to achieve a desired protection goal must be known. It is unlikely that an exposure level producing an effect in the laboratory would produce the same level of effect on a heterogeneous population in a field spray scenario. Therefore, the effects tests used represent a very conservative approximation of the effects that might be observed under field conditions, regardless of the level of protection deemed appropriate. The protection goal could be the same for threatened and endangered species as for sensitive non-target crops. An ER_{25} (25% effect rate) value has often been deemed adequate to provide a margin of safety ensuring that no unreasonable adverse effect would be observed in wild populations exposed at a comparable level. Alternatively, a much more conservative NOER value may be, and often has been, used for assessment.

Spray Drift Exposure Modeling

Spray drift exposure estimates are derived from models of empirical data which are obtained in field studies designed to determine deposition of drift under circumstances prevailing at the time of the study. For FIFRA regulation, two models are currently used predict deposition, AgDRIFT® (*3*), based on data generated by the Spray Drift Task Force, and AGDISP (*4*). In Canada, the Pest Management Regulatory Agency (PMRA) uses the Agricultural Buffer Zone Workbook (*5*) for estimating drift deposition based on data generated by Agriculture and Agri-Food Canada (AAFC) (*6*). The parameters that can be varied to adjust a buffer distance using available ground models depend on the variables monitored and controlled for in the underlying data. Typically, droplet spectra (VMD_{50}), release height, and wind speed can be changed. Aerial models have many other factors than can be adjusted to impact predicted spray drift.



Endangered Species Protection

If endangered plant species occur in proximity to the application site, the following mitigation measures are required:

- If applied by ground, leave an untreated buffer zone of 200 feet. The product must be applied using a low boom (20 inches above the ground) and ASAE fine to medium/coarse nozzles.
- If applied by air, leave an untreated buffer zone of 170 feet. Must use straight stream nozzles (D-6 or larger); wind can be no more than 8 mph, and release height must be 15 feet or less.

To determine whether your county has an endangered species, consult the Web site http://www.epa.gov/espp/usa-map.htm.

Endangered Species Bulletins may also be obtained from extension offices or state pesticide agencies. If the bulletin is not available for your specific area, check with the appropriate local state agency to determine if known populations of endangered species occur in the area to be treated.

http://www.epa.gov/espp/bulletins.htm

Figure 1. Example of older label language for the protection of threatened and endangered species. Example is from BASF's Prowl® H_2O label.

Now buffers are required for protection of all **non-target areas** which include:

"Grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas, and shrub lands."

Avoid potential adverse effects to nontarget areas by maintaining a 100-feet buffer between the point of direct application and the **closest downwind edge** of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas, and shrub lands).

Some labels just mention *all sensitive off-target areas* which would include crops as well.

Figure 2. Example of the most recent label language. Protection is wind-directional and has the expanded border areas protected. Example is from BASF's Kixor® containing product labels.

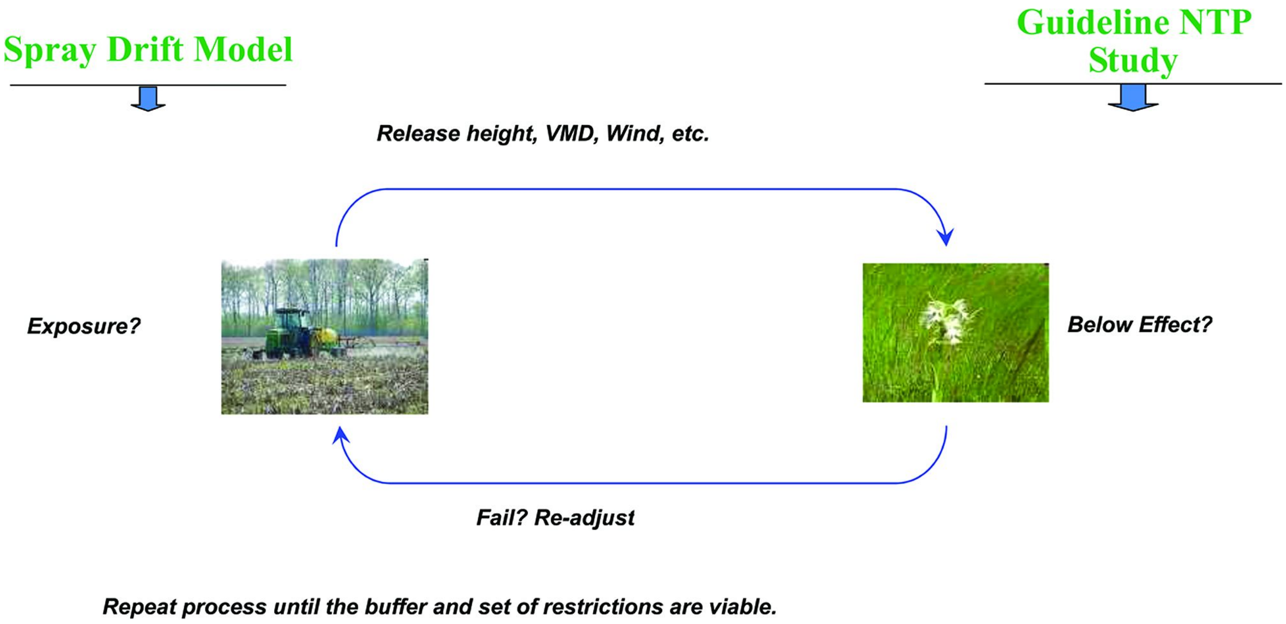
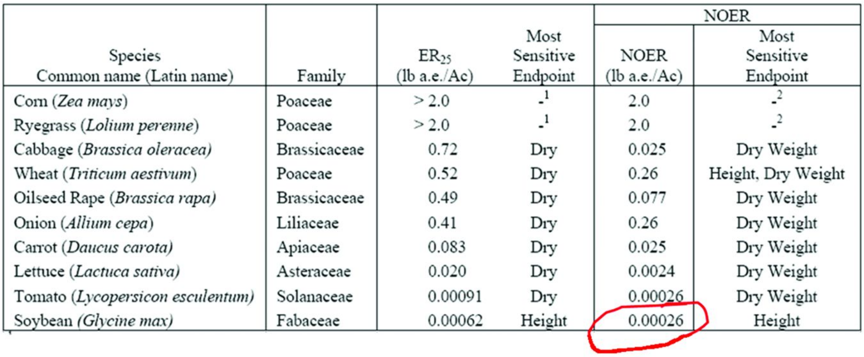


Figure 3. An illustration of the iterative process used for determining risk-based buffer distances. (see color insert)

Figure 4. Plants at about the proper treatment size and growth stage for a vegetative vigor study.



Species Common name (Latin name)	Family	ER_{25} (lb a.e./Ac)	Most Sensitive Endpoint	NOER NOER (lb a.e./Ac)	NOER Most Sensitive Endpoint
Corn (*Zea mays*)	Poaceae	> 2.0	-[1]	2.0	-[2]
Ryegrass (*Lolium perenne*)	Poaceae	> 2.0	-[1]	2.0	-[2]
Cabbage (*Brassica oleracea)*	Brassicaceae	0.72	Dry	0.025	Dry Weight
Wheat (*Triticum aestivum*)	Poaceae	0.52	Dry	0.26	Height, Dry Weight
Oilseed Rape (*Brassica rapa)*	Brassicaceae	0.49	Dry	0.077	Dry Weight
Onion (*Allium cepa*)	Liliaceae	0.41	Dry	0.26	Dry Weight
Carrot (*Daucus carota)*	Apiaceae	0.083	Dry	0.025	Dry Weight
Lettuce (*Lactuca sativa)*	Asteraceae	0.020	Dry	0.0024	Dry Weight
Tomato (*Lycopersicon esculentum*)	Solanaceae	0.00091	Dry	0.00026	Dry Weight
Soybean *(Glycine max)*	Fabaceae	0.00062	Height	0.00026	Height

Figure 5. Image of a report table from a vegetative vigor study.

Appropriateness of Model Selection

The output of the three models used by North American regulatory agencies, AgDRIFT, AGDISP, and the PMRA tool, are compared in Figure 6, which illustrates how conservative the estimates of the two former models are. Both AgDRIFT and AGDISP deposition curves are for the same spray quality or VMD_{50} (or nozzle). Both the AgDRIFT and AGDISP deposition curves should be close to the AAFC (Agriculture and Agri-Food Canada) flat fan data, which is consistent with the Spray Drift Task Force Data (*7*, *8*) that the AgDrift model is based on. However, at 400 feet both models greatly over predict deposition. The

PMRA model provides a good approximation of the AAFC field data assuming use of modern air induction nozzle technology. We can see from this evaluation that both AgDRIFT and AGDISP do not match the field data they are meant to predict, while the PMRA tool provides a much better fit.

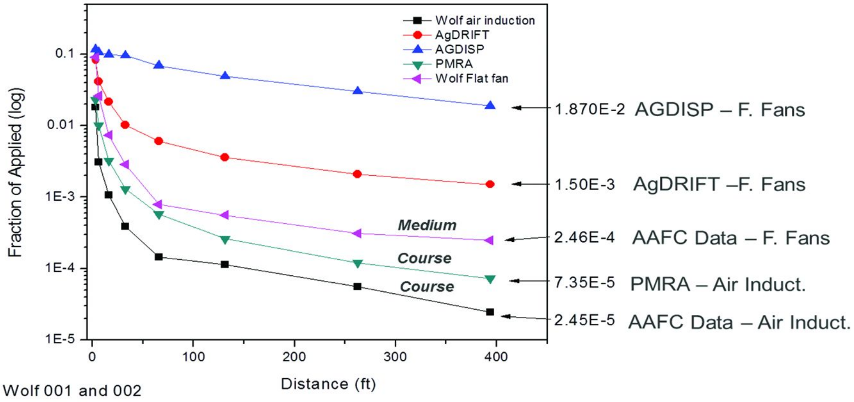


Figure 6. Deposition curves from models and field data.

Table I. Comparison of data used for AgDrift ground and the PMRA model

	2000 AAFC Datasets	*SDTF Datasets*
Wind	Variable function (3-16 MPH)	No - 1 speed assumed
Sample intervals (edge of field)	3 – 394 ft	26 – 1200 ft
Number of trials	29 usable studies	10 not all usable
Number of years/locations	1 location/2 year	1 location/2 year
Boom heights	2	2
Nozzles types	5 (air induction included)	4 (older types only)
Year Data generated	2000, 2004	1992, 1993

A comparison of data generated by AAFC and the SDTF are summarized in Table I. While there are still significant differences in the two underlying datasets, the results obtained are very comparable for trials in which the technology used was analogous. Many of the differences in model predictions and the field data they were derived from can be attributed to data analysis and summarization (especially in the case of AgDRIFT).

Determining Buffer Distances

The model estimate is compared to the endpoint chosen as a level of concern. Using the study illustrated in Figure 5, the level of concern could be 0.00026 lb/acre based on soybean plant height effects ((no observed effects rate). This would mean for the purposes of setting a risk based buffer, the spray parameters would need to be adjusted until exposure was less than or equal to 0.00026 lb/acre. If a buffer of 200 feet was deemed to be agronomically viable, the allowable droplet size, maximum wind speed, and boom height could be adjusted until exposure was 0.00026 lb/acre at 200 feet and restrictions would be placed on the label accordingly. Figure 7 is an illustration of attempting to reach a particular goal using AgDRIFT. Using a high boom setting in the model, and the averaged spray quality categories fine to medium/course, the ER_{25} protection goal was met with a 900 foot buffer. It was not possible to meet the NOER protection goal with the same parameterization. In order to meet the NOER protection goal, spray quality, boom height and wind speed would need to be altered.

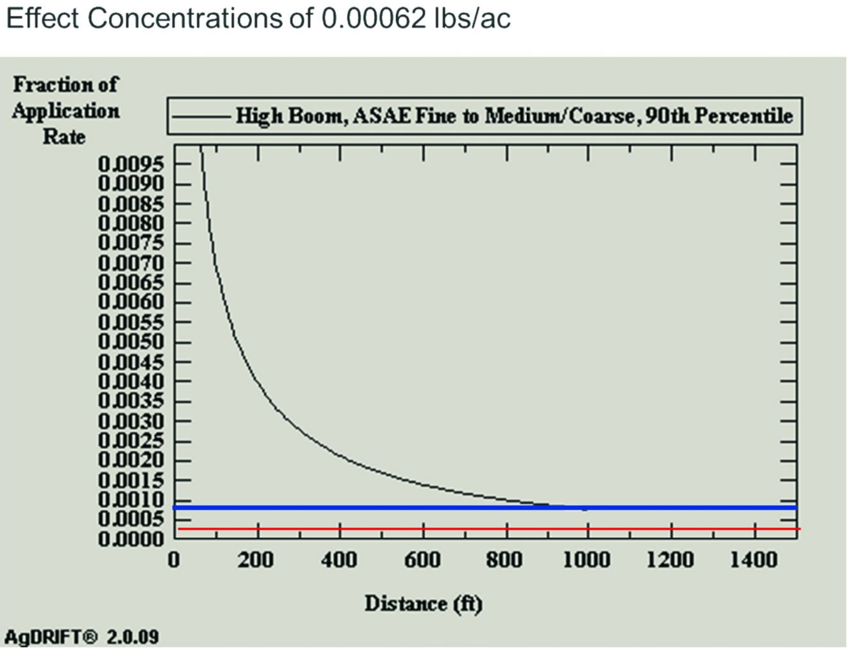
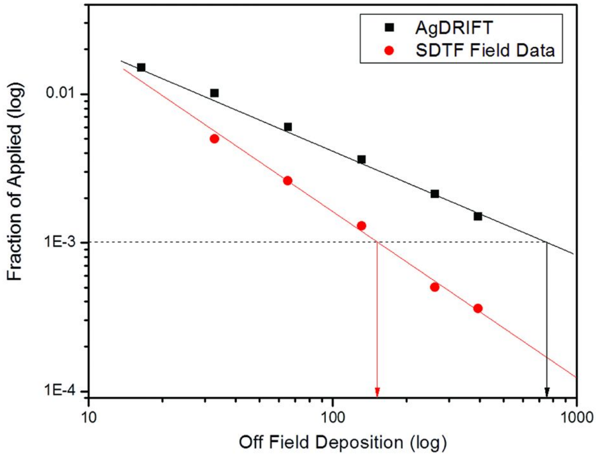


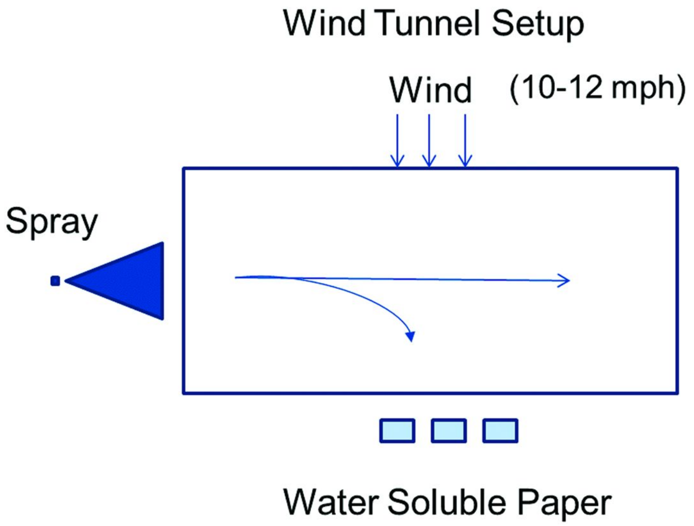
Figure 7. Example deposition curve from AgDrift. The blue line is the ER_{25}, while the red line is the NOER. (see color insert)

Figure 8 is another comparison of AgDRIFT to field data. This comparison is of model prediction to the SDTF (Spray Drift Task Force) data upon which model development was based. In this comparison, the buffer required for the 0.001 fraction of applied rate would require a distance of 755 feet based on the model, or 150 feet based on the actual deposition data.



Source	Buffer Distance (ft)
AgDRIFT	755
SDTF Data	150

Figure 8. A comparison of Ag DRIFT to Spray Drift Task Force data.



Courtesy of Dr. Bob Wolf, KSU and Wolf Consulting and Research

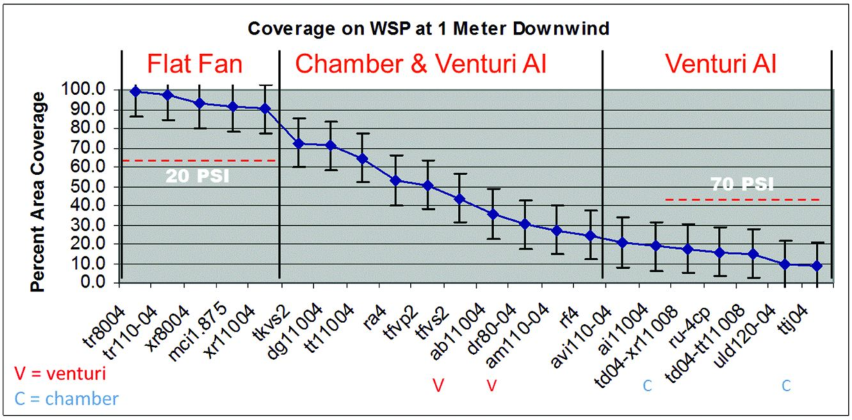
Figure 9. Schematic illustration of the wind tunnel setup used in the Kansas State University study.

Factors Mitigating Drift and their Consideration in Risk Assessment and Regulation

Nozzle Selection

While many factors can affect off-target movement of spray, the factor that has the greatest impact on off-target movement is nozzle selection or droplet size (VMD_{50}). An example of this has been well illustrated by the Kansas State University wind tunnel experiments. A schematic of the wind tunnel setup can be found in Figure 9. The spray was atomized and moved down the chamber. A cross-wind was placed on the spray as it moved down the tunnel, and there was water soluble paper directly across from the source of the cross wind. The percent spray coverage on the water soluble paper is a measure of drift, relatively speaking, that could be expected from each nozzle.

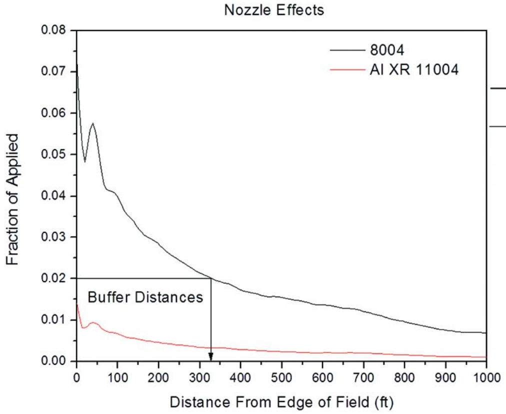
The results presented in Figure 10 reflect the percent coverage from the atomized spray that was deflected onto the water soluble paper for the various nozzle types. The flat fan TR8004 (tr8004) nozzle provided 100% coverage on the water soluble paper, while the AI11004 (ttj04) nozzle provided about 10% coverage on the paper. This work indicates how the large differences in nozzles can be used to inhibit or induce spray droplet off-target movement.



Chamber AI nozzles are 1st gen, Venturi nozzles are 2nd gen

Figure 10. Off-target deposition results by nozzle from the Kansas State University study.

As a further illustration of the effect of nozzles in mitigating off target movement, two nozzles were modeled using AGDISP. The results from that modeling can be found in Figure 11.



Nozzle	VMD_{50}	Buffer Distance (ft)
8004 FF	273	326
11004 AI	525	0

Protection: NOER = 0.02

Figure 11. Comparison of two nozzles for controlling off-target drift and resulting buffer distances.

The results presented in Figure 11 indicate that by proper nozzle selection, spray buffers to protected areas can be minimal or not required at all if nozzle use is considered in risk assessment and stipulated on the label.

Canadian Approach to Buffer Management

EPA and the PMRA are analogous regulatory agencies. However, the product use restrictions for a wheat grower in Montana and a wheat grower in Saskatchewan may be very different due to the different way that buffer distances are calculated. The Canadian regulators have developed an online tool (*9*) that allows users to determine the appropriate level of buffer mitigation given the field conditions and drift-reducing technologies, for example nozzle selection, used at the time of application. This enables Canadian growers to reduce the buffer from the label 'base case' distance which is based on worst-case estimates. This approach fosters use of drift-reducing technologies by farmers. It is facilitated by inclusion of air induction and chamber drift-reducing nozzles as mitigation options based on underlying AAFC data that is the most current and best available science. The use of the tool might be extended to including the influence of near-field windbreaks, and other habitat-inducing enhancements in near-field regions, in mitigating drift.

Real Impact of Buffers

We have outlined a process for the use of risk-based buffers. One question remaining is whether the implementation of buffers has any real impact on production agriculture. Figures 12 and 13 are GIS images indicating how far into a field a 150 foot buffer and a 250 buffer, respectively, would encroach onto agricultural land from the riparian area they are meant to protect. The buffer area could not be sprayed if winds were moving toward the sensitive areas. The use of this buffer area approach would require that land in the buffer area not be sprayed if wind was moving toward the sensitive area, or it would have to be sprayed when the prevailing wind direction was away from the riparian area.

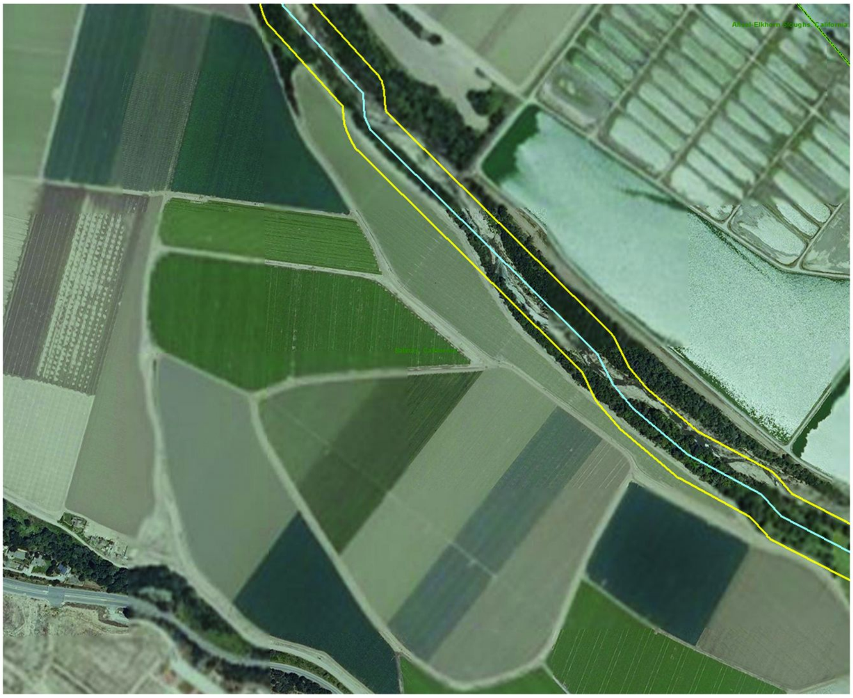


Figure 12. A 150' buffer to a riparian area. The yellow line is the 150 foot buffer boundary. (see color insert)

One consideration of the use of buffers is the potential disincentive for growers to improve or create habitat in riparian areas resulting in new regions that warrant protection and require additional buffers. The USDA Natural Resource Conservation Service (NRCS) and private conservation groups work diligently to provide incentives to farmers to place marginal lands and near-stream areas under conservation. The most realistic estimates of exposure should be applied in order to minimize the impact of no-spray buffers on production agriculture and ensure that riparian and near-field habitat improvement is fostered.

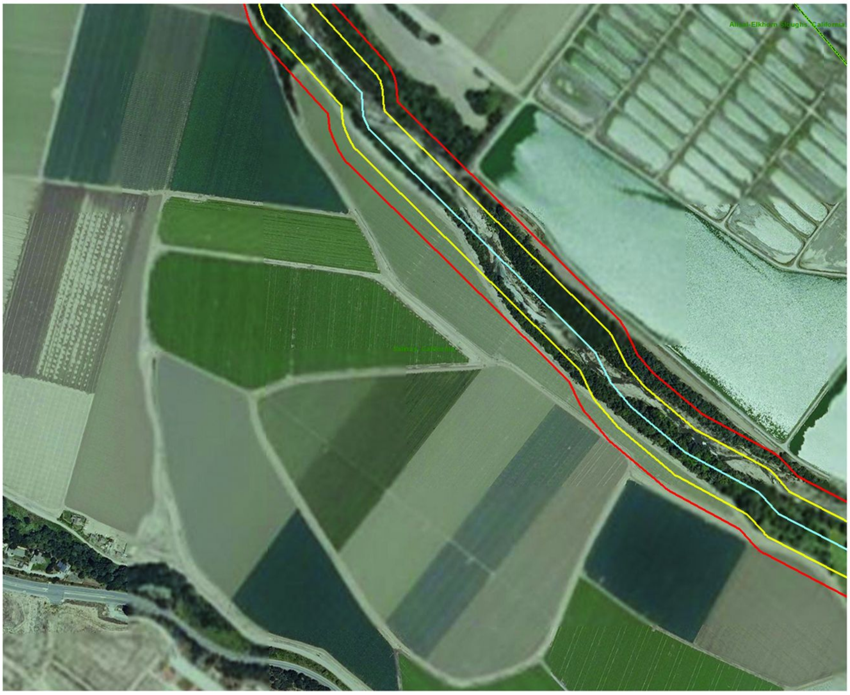


Figure 13. A 250' buffer to a riparian area. The red line is the 250 foot buffer boundary. (see color insert)

Conclusion

Protection of threatened and endangered species can be achieved through the use of risk-based buffers. Spray buffers to grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas, and shrub lands not only protect current habitat and species, but they may also protect future habitat. However, the risk-based buffer approach requires the use of best available science tools. Currently AgDRIFT is "old science"; a static tool fixed by the technology that described it in the early 1990's. We need tools that are flexible, and able to accommodate changes in technology (e.g., newer types of spray nozzles). The Canadian approach for calculating buffers is a much more pragmatic process than we currently have with FIFRA (or ESA). However, a software tool framework should be implemented so that as new technology emerges, it can be evaluated, and if deemed appropriate, incorporated into the tool.

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Chapter 24

Recommendations for Improvements to Pesticide Regulation in Compliance with the Endangered Species Act

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It is clear, from the wealth of information and diverse methods discussed by the contributors of chapters in this book, that good science abounds with respect to endangered species assessment. However, definition of whose scientific approach is the "right one" and how a regulatory process should incorporate that science is only now emerging after more than 30 years of uneven and incomplete policy development. This final chapter explores ways in which the "nexus that perplexes" – the complicated intersection of the Federal Insecticide, Fungicide and Rodenticide Act and the Endangered Species Act – might be best improved within the processes that define the current framework of consultation under the Endangered Species Act. Ideas presented by the chapter authors for this volume relate to many lessons learned and this collective wisdom can be applied to clarify a common vision for what successful consultation may look like in the future. A first step toward practical improvement may be for all parties to step back from differences in perspectives, favored methods, and intensity of scientific scrutiny and ask the simple question, "Just what is it we really need to do to cooperatively develop and successfully advance this vision?" This chapter looks back on the contributions made by all authors and distills that wealth of thought to a platform of recommendations for process improvement. Recommendations are made for three main initiatives: (1) establish trust and a cooperative process between agencies; (2) provide resources, or leverage existing resources, to establish priorities for accomplishing the task at hand; and (3) improve communication with and early involvement of stakeholders.

Introduction

Help, master, help! here's a fish hangs in the net, like a poor man's right in the law (1).

Much of the current attention that is focused on pesticide consultation, in fact this book itself, grew from the rising profile that litigation has given to the regulatory intersection of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA) and its impact on the U.S. Environmental Protection Agency's (EPA's) Office of Pesticide Programs and the Federal "Services" (U.S. Fish and Wildlife Service [USFWS] and National Marine Fisheries Service [NMFS]). The Northwest's iconic salmon has figuratively become that fish that "hangs in the net" while law and policy eek their way through iterative development of process and application. Likewise, early products entering the EPA's Registration Review program are also the fish hung in the net, awaiting clear policy to define their way forward. Listed species, regulators, registrants, pesticide users and other stakeholders are the poor men with rights to the law but devoid of a ready mechanism to act on their desire to make the process work and "just get on with it!"

As pointed out in the introductory chapter of this book, "*Although there has been sporadic cooperation, a significant gap remains between EPA's nationalized and chemical-specific, risk/benefit focus and the Services localized and species-specific, precautionary emphasis*" (*2*). It is clear from Table II of the introductory chapter (which traces a chronology of key events for pesticide regulation and ESA) that EPA and the Services have been striving for more than 30 years with how best to address ESA obligations with respect to national pesticide registration decision-making. The timeline of responses and consequences is a statement of the difficult challenges that must be overcome, from a policy and scientific – and even political – perspective. Even our cultural differences come into play, as much as we would like to insist we deal in a world of "pure science and fact." There is no question that world view and personal value systems all exercise influence. Bosso notes, "*Value conflict is accompanied by disputes over means and methods. Whose scientific data are more 'correct?' Which analytical techniques do we accept as valid? Who decides? Values intrude mightily into every facet of science and technology" (3).*

Dealing with the ESA-pesticide regulation challenges we all face, as pointed out in the introductory (*2*) and in succeeding chapters by McGaughey *et al* (*4*), Somma *et al* (*5*), and Li (*6*), may involve approaches couched slightly differently by each author, but which are upon reflection parallel in many ways. These may be summarized as having to:

- Establish trust and a cooperative process between agencies
- Provide resources, or leverage existing resources, to establish priorities for accomplishing the task at hand
- Improve communication with and early involvement of stakeholders
- Provide a stable scientific platform defining data use and assessment methods
- Devise a mechanism to deal with complexity and scale especially when considering nationwide assessment

One additional overarching challenge is the value conflict mentioned above, that causes some of the varied impressions that chapter contributors have of the current state of affairs. A few of these divergent perspectives are summarized below in Table I. Whether the value system is driven by what the implementing agency perceives as Congressional intent or by closely held personal beliefs, it is still "there" like the proverbial elephant in the room. Having said that, however, nearly all parties agree that resolving matters through administrative action is the most straightforward path for improvement and preferable to grinding through legislative action or enduring perpetual litigation. Reporting on a conference sponsored by the Minor Crop Farmer's Alliance, attended by registrants, EPA, the Services, and affected stakeholders, Botts noted that *"The consensus among all participants is that it would be in everyone's best interest to develop a comprehensive and transparent process during registration review rather than having the consultation process continue to be litigation-driven" (7).* Certainly, evolving or unclear policy and unpredictable outcomes exacerbate value-driven differences (*4*) and promote distrust, not to mention the drain of litigation on agency resources. The incentives are high for a resolution, but the battle of values raises the bar for achieving resolution. Li notes, "*If the Services and EPA can resolve their differences through administrative action* [as opposed to legislative], *they are more likely to retain control over the fate of the pesticide consultation program and defuse volatile controversies (6).*

Perhaps the fact that fundamental scientific education focuses on environmental effects in the context of pollutants and pre-technology driven pesticide invention has done us a disservice. The generalities of instruction which use molecules like DDT or sodium arsenate as historical examples do not alert us to distinguish between the pest killing chemical byproducts of the Industrial Revolution that were used as "pesticides" and the modern and intentional development of diverse technologies for the intervention of disease, invasive species and crop pests. Bosso notes, "*Pesticides are not "externalities" of the market system, like air and water pollution, nor are they unfortunate byproducts of urban industrial society. We intentionally apply these chemicals for important agricultural and public health reasons. Pesticides are in many respects the key to*

America's agricultural abundance, and have proved instrumental in eradicating such diseases as typhoid and malaria. Pesticides, as we shall see, might be characterized simply as "good things that can cause harm," or, "bad things that can do good," depending upon your perspective" (3). Keeping this difference and the impact of values in mind, this chapter will summarize recommendations for improvements to pesticide regulation in compliance with the ESA, based on the wealth of information and wisdom shared by this book's authors.

Table I. Illustration of Divergent Viewpoints Regarding Pesticide Assessment and Endangered Species

FIFRA Pesticide Risk Assessment	
Opinion 1	*Opinion 2*
The conventional wisdom associated with EPA's assessment approach has been that, based on the conservative nature of the assessment design, restrictions identified for protection of species groups in general will also provide significant protections for endemic endangered species, any edge of doubt (or "uncertainty") would be further removed by the extra [safety] *factor applied specifically to the endangered species level of concern (2).*	*FIFRA, as implemented over the past 65 years, does not safeguard ESA-listed species, because EPA has not properly considered impacts to these species (6).*
ESA Ecological Risk Assessment	
Opinion 1	Opinion 2
. . . ecological risk assessments typically have not accounted for the spatial and temporal distribution of Pacific salmon in freshwater. Instead, they have been based on the simplifying worst-case assumption that 100% of a salmon population is exposed to an environmental stressor of interest (e.g., agricultural pesticides at a given concentration)...by assuming the worst-case, they do not provide decision-makers with information about the range of exposure that could occur (8).	*This approach to error* [concluding an effect when there is no effect] *may lead to a different conclusion than scientists who take a more traditional approach to avoiding error, but is more consistent with the purposes of the ESA and direction from Congress (5).*

Seeking a Regulatory Balance

The law hath not been dead, though it has slept (9)

Since the time of EPA's first requests for consultations in the late 1970's, the wheels of administrative procedural change slowly rotated through one attempt after another at finding a way to manage how scientists operating as experts within the FIFRA regulatory environment could effectively interact with scientists operating as experts within the ESA regulatory environment. Through much of that period, even though both groups of agencies (EPA and the Services) recognized that the consultation process as procedurally described by the ESA and implementing regulation was close to impossible to apply to a national level exercise, various approaches were promoted. And yes, the law "slept" through many of these attempts until the mid-to-late 1980's. In absence of stakeholder pressure and over time, the cultural differences between agencies built walls preventing the development of a comprehensive process agreed upon by all. By the early 1990's, the remnant of a process in place might best be described as "bring me a rock; no, bring me a different rock." What had evolved was a give-and-take that attempted to address the process but never adopted it fully, stuck in a "do-loop" wherein EPA would attempt to deliver a consultation package and the Services would either attempt to gather additional information or reject EPA's request along with a request for further data.

The Consultation Handbook (*10*) and its general processes are discussed thoroughly by Somma (NMFS), Sayers (USFWS) and Brady (EPA) (*5*), but even within the Handbook there is recognition that national-level pesticide consultation requires a special process. The Handbook's section 5.2 devotes discussion to national consultations, such as those often necessary for the USDA's Animal and Plant Health Inspection Service (APHIS) and the EPA's pesticide registration program, noting *"Successful conduct of these consultations requires the Regions to provide strong support to the development of these opinions, including funding and staff time to complete assigned portions of the work, and the Washington Office to designate a liaison to facilitate the consultation" (10).* The Handbook goes on to describe a program-specific protocol for pesticide consultations, the only national program specifically addressed. Keeping in mind the 90 and 135 day limitations placed on the duration of consultation and reading through this section of the Handbook can lead one to conclude that the level of analysis, depth of communication, and number of players described by the protocol is laudable but potentially unmanageable given expected resources. It is interesting that this section of the Handbook has not been cited in any chapters of this book – which could leave one with the impression that the described approach was simply not a practical alternative once the Services and EPA attempted to implement it.

We do see one recent example of this approach, however, which resulted in the second set of county bulletins now populating EPA's *Bulletins Live* (*11*), EPA's system of species- and pesticide-specific bulletins to map out geographically specific restrictions. During early 2012, USFWS produced a biological opinion on the use of Rozol® Prairie Dog Bait regarding its potential effects on listed species when used as a control agent for Black-tailed prairie dogs (*12*). Black-tailed prairie dogs negatively impact rangelands, destroying grasses and leaving soil vulnerable to erosion and invasive plant species (*13*). The animals also can host vectors that carry diseases threatening to humans and other mammals. This is the most recent USFWS Biological Opinion issued on a national registration action, although this particular registration action affects a limited geography (10 Western States), a single use (prairie dog control), one formulation having one product label (Rozol® Prairie Dog Bait, 0.005% chlorophacinone) and few listed species (18 from various taxa). Of note are several items; (a) the registrant, affected stakeholders, EPA and USFWS worked very closely together to address the issues and science, particularly during the last 4 years before the final opinion; (b) the assessment was carried out between headquarters EPA and a regional office of USFWS which made available much more local knowledge of the needs, conditions, and circumstances of the use and potential risks than is available to the USFWS headquarters office; (c) the process was affected by litigation from 2009 forward; (d) the time necessary for resolution (if in fact time proves out that issues are resolved) spanned 21 years, from February 1991 to April 9, 2012, with mitigations in the form of county bulletins in six states being implemented immediately, on April 10, 2012 (*11*, *12*).

The latest listed salmon Biological Opinion required by settlement to litigation followed the Handbook protocol design (*10*) in action, if not by formal organization. This opinion, on the herbicide thiobencarb, circumstantially ended up having to deal with only one product, having only one use in one state (*14*). Litigation that elicited this opinion was initiated in 2001, EPA produced an effects determination and request for consultation in 2002 and, in response to further litigation, NMFS responded to EPA's effects determination in 2012, the entire process spanning more than 10 years (*14*). In preparing for this opinion, NMFS was able to make site visits, meet with the regional U.S. Geological Survey (USGS) water monitoring staff, regional EPA staff, California Department of Water Resources (CDWR), California Department of Fish and Game (CDFG), California Rice Commission (CRC), rice farmers, and the California Department of Pesticide Regulation (CDPR), including a meeting with the CDPR Endangered Species Division to learn more about California's County Bulletins. NMFS also obtained examples of state, regional, and county permit requirements for thiobencarb use in California. This was the first of the series of Biological Opinions driven by the Pacific salmonid ESA litigation to have an entirely "not likely to jeopardize" conclusion for the uses reviewed. The biological opinion clearly demonstrated the value and importance of knowing local conditions, state requirements and best management practices, and how critical it is to have such information to establish valid assumptions for the assessment process.

Having had direct experience with the logistics of the "nexus that perplexes," and recognizing that ESA consultations on pesticide registrations are among the most challenging of all consultations, Somma, Sayers and Brady (*5*) reach process improvement recommendations that are intended to facilitate the capture of the kind of data used in the two opinions just discussed. These recommendations are (a) earlier involvement of stakeholders in the Registration Review Process; (b) consideration of pesticide use and usage data; and (c) increased use of the informal consultation process. EPA proposes an integration tool to bring efficiency to the risk assessment process, consistency to data application, and transparency to the stakeholders, noting that "*Performing such an information and modeling intensive assessment with a high degree of spatial and biological specificity and simultaneously accessing the best available information from a variety of sources is beyond the manual calculation capabilities of a risk assessor for any but the most limited pesticide suites of formulations and sites of use" (15)..* While these recommendations are "spot on," additional wisdom, which we see from other contributing authors, can hone these recommendations and craft a vision for success. As Li notes, "*A key component to realizing this vision* [equal distribution of workload] *is to craft a risk-tolerance framework with a clearly articulated and constrained decision-making process, such that capable agency biologists—whether sitting at EPA or the Services—can easily agree on and draft a biological effects determination that is transparent and defensible" (6).* As the vision coalesces, added participants, new tools and integration of those tools will be necessary. States and growers also propose greater involvement in data contribution, an aspect we will discuss later in this chapter.

Applying Lessons Learned: Case Studies

Many of the diverse viewpoints expressed by chapter authors justify their approach to error avoidance, whether it is by applying rigorous analysis, collecting multiple lines of evidence, or through giving all benefit of the doubt to the listed species. These are often debated in the framework of "Type I" (concluding no effect when there is an effect) and "Type II" (concluding an effect when there is not one) error avoidance. Rightfully or not, the "Type I" avoidance is pinned to a risk assessment under FIFRA, where the statute requires a "risk/benefit" standard. It is important to understand, however, that the risk assessment conducted for pesticides does not, in and of itself, consider the *benefits* of use. It is an entirely different scientific group that conducts a separate benefits assessment, with the results of both processes incorporated into risk management-driven regulatory decision-making. There is no equivalent process under ESA, and the "benefit of the doubt" given to species biases the risk equation for "Type II" error avoidance. However, when we examine the Rozol® and thiobencarb Biological Opinions, we see that given a data-rich environment and the wisdom of many participants, FIFRA and ESA scientists can reach a mutually-agreed endpoint. If we continue with this perception of "FIFRA equals Type I" and "ESA equals Type II" we will have two parallel lines that never meet. Celestial navigation requires that two parallel lines *do* meet, but (setting the complicated mathematic aside) to do that they have to bend.

Ruhl, a professor of law from Florida State University, participated in the Klamath National Academy of Sciences panel evaluating the science behind water restrictions proposed to protect listed salmon (*16*). These initial actions for mitigation posed potentially devastating effects to agriculture and thus were highly controversial. In an article reflecting on that and other experiences, Ruhl notes, *"The capacity to disprove conclusively the possibility of Type II error events is not within reach of even rigorous scientific methods. Indeed, by discounting the value of science, these strong versions of the precautionary principle would reward ignorance. . . Precaution is a well-understood instinct, but in regulatory contexts such as ESA it lacks the structural decision-making framework that science supplies to the Scientific Method" (17).* Thinking on this observation and the error avoidance behaviors that may exist, it is useful to examine the lessons learned in three applications reported by authors in separate chapters here: two products that are the first to go through a Registration Review endangered species analysis (*18*, *19*) and a separate process that resulted in the production of the first EPA county bulletins introduced to the public through "Bulletins Live" (*20*)!

Conducting Effects Determinations under Registration Review: Fomesafen Case Study

Campbell *et al* (*18*) present a roadmap for the evaluation of direct and indirect effects of the herbicide fomesafen on listed species potentially of concern with respect to current product labeling and its evaluation under Registration Review. By employing a series of refinements, Campbell *et al* demonstrate the changes these bring to EPA's screening level process as reported in their initial effects determination (*21*). The recommended refinements are those for determining:

- Exposure from runoff
- Exposure from drift
- Spatial extent and proximity
- Biological characteristics influencing likelihood of exposure or risk
- Mitigation measures already in place through other programs
- Subcounty circumstances influencing likelihood of exposure or risk
- Taxonomic considerations influencing likely susceptibility

Each refinement was applied in the case study using higher tiered risk assessment methods and data produced by the FIFRA Endangered Species Task Force (FESTF). Being the first of two products to undergo EPA's screening level assessment, the initial process envisioned for work flow did not offer the capacity for generating the expected results. EPA predicted it would take approximately three years for the fomesafen Registration Review to be completed, concluding in March 2010. At the time of the writing of this chapter [October, 2012], EPA has not issued a revised assessment or Registration Review decision for fomesafen. Additionally, NMFS rejected EPA's consultation request, stating it was premature and incomplete (*18*).

It is unclear when pesticide Section 7 consultations should occur in the Registration Review process, but the logical options suggested by Campbell *et al* are when (a) the preliminary endangered species assessment document is issued, as was attempted with fomesafen; (b) the interim decision is issued; (c) after EPA has issued the final decision for the Registration Review process on a given active ingredient; or (d) informal engagement of the agencies and stakeholders during the early phases of Registration Review, followed by formal consultation, if necessary, upon issuance of either an interim or final Registration Review decision (*18*). Based on the recent USFWS and NMFS opinions on Rozol® (*12*) and thiobencarb (*14*), the fourth option (d, above) seems the most productive approach. This would allow initial concerns, and additional data to address them, to be fully embraced in the EPA effects determination, with little left to reinvent when formal consultation is required. Under the first option (a, above), the efforts by the registrant to provide additional data that reduces the number of species potentially requiring consultation were provided to EPA but have not yet been reviewed or adopted into EPA's conclusions about potential risk (*18*). Campbell *et al* note, "*The appropriate timing and approach for consultation with the Services by EPA needs to be addressed to help streamline the process* *for efficiently completing these assessments. Refinements, as described in this chapter, should be implemented into the assessments prior to consultation such that the most accurate depiction of risk for listed species is determined" (18).*

Conducting Effects Determinations under Registration Review: Clomazone Case Study

Frank *et al* (*19*) present a summary of the results produced by the application of data and techniques developed by FESTF. While EPA, in their introduction to the effects determination for the herbicide clomazone, characterized the differences between the clomazone and fomesafen exercises as one that "utilized proximity analysis" (clomazone) and one that "utilized to a large degree, biological characteristics" (*22*), agency time constraints limited the assessment process to consideration of only readily available, limited proximity and biological data in either case study. Essentially, the difference between the refinements not yet employed by EPA as discussed by Campbell *et al* (*18*) and Frank *et al* (*19*) could be characterized as a process driven by risk refinement for fomesafen (*18*) and one driven by species refinement for clomazone (*19*). As was the case for fomesafen, the registrant data submitted to support species evaluation for clomazone has not yet been reviewed, and the scheduled next steps for consultation and Registration Review have not occurred.

About 73% of the species occurring in the action area for clomazone required further evaluation or potential risk management using EPA's method in absence of having reviewed the extensive data submitted by the registrant. The authors note that *"Based on the EPA screening level approach to date, and without further refinement, further evaluation or risk management related to all of these species will draw heavily on resources from either the EPA's Office of Pesticide Programs or the Services. . . Reliance by the EPA and the Services on registrant-submitted proximity and potential exposure data transfers a large portion of the national assessment burden to the registrant without relinquishing the EPA's responsibilities to complete the risk determination and reach risk management decisions" (19).* Data sources used in the registrant's analysis included general data sources for species locations, locations of critical habitat, locations of use, and land cover, as well as specific data gathered from USFWS species accounts, Federal Register documents, county bulletins, federal and state level inventories and departments, consultations with species and site experts, and the NatureServe database (*19*). Analysis of this information was managed by FESTF's Information Management System. When the supportive data submitted by the registrant is considered and relied upon, something neither EPA nor the Services have yet done, the number of species for which EPA chooses to assign a MA/LAA ("may affect" or "likely to adversely affect") may be reduced by as much as 74% (*19*). For example, EPA's assessment for non-rice uses began with 1,358 species requiring further assessment and EPA completed a screening level assessment that left 685 species for potential consultation. Using the registrant's additional, more detailed assessment data removed all but 177 species. This is an astonishing workload reduction for formal consultation, but still a heavy one. The number of species requiring consultation might be reduced further by incorporating local knowledge from growers or states, an undertaking that was not done in the registrant's assessment on clomazone.

EPA's quandary in utilizing the registrant's additional data is knowing that it is useful but not having the allotted time in the Registration Review process to review and embrace it. Not having that time or making that effort to review the data shifts undue burden to the Services, potentially to address about 75% of the species that enter the Registration Review process. In the clomazone case study, where the registrant's data were applied to EPA's potential effects determination, fewer than 20% of the species entering the Registration Review process are left for potential consultation. The authors point out that the logical place to further fill such data gaps for the remaining 20% might be at the implementation of any required mitigation, as described by EPA's Endangered Species Protection Program (*23*). This introduces a potentially workable pattern, but it would require a different operational paradigm between the Services and EPA, perhaps one best supported by informal engagement of the agencies and stakeholders during the early phases of Registration Review, followed by formal consultation, if necessary, upon issuance of either an interim or final Registration Review decision (Campbell's "option d" (*18*)). It is also useful to envision how the more detailed data provided by the registrant might contribute to interactions between EPA and state and local entities if county bulletins are needed, and how the state/s might participate in closing knowledge gaps for the remaining 20% of the species (*19*).

In the clomazone registrant assessment, the lessons learned were similar to those learned by the parallel exercise on fomesafen, and include:

- There is a wealth of data available to support and enhance the effects determination
- Early communication with the registrant will support current uses and available or expected data
- To benefit from resources and knowledge available, the applicant should be fully engaged in pre-consultation communications and at critical points in the Services and EPA interactions

Applying Mitigations Following Consultation: Methoxyfenozide Case Study

The registration of methoxyfenozide (Intrepid* 2F) in cranberries for the control of insect pests is the first new use registration to move through consultation and produce a resolution that provided workable mitigations. The insecticide was approved for this use in 2003, but that approval was based on applying a 1-mile buffer for protection of the Karner Blue butterfly (KBB), which rendered the product unusable by cranberry growers. Through a series of local agency, grower and EPA headquarters interactions, a workable protection program was established in 2009 (6 years after initial registration) and, through EPA's "Bulletins Live!," the federal product label effectively incorporated those mitigations (*20*). Interestingly, at the time of EPA's 2003 risk assessment for the purpose of evaluating the addition of a new use in cranberries (and other uses), there was already an approved Wisconsin state Habitat Conservation Plan (HCP) in place for the KBB. This award winning plan was established in 1999 (*24*). Contributing to its success was the innovation in its approach: "*An innovative aspect of the HCP is the voluntary participation (and automatic inclusion) of private landowners and land users, including the agricultural community, in the KBB conservation program (and ITP* [Incidental Take Permit]*). Although the HCP recognized that 'Most agricultural operations do not appear to support habitat for the Karner blue butterfly or present a threat to the continued existence or recovery of the Karner blue butterfly in Wisconsin,' the take (per the ESA) of the KBB from agricultural activities, including agricultural use of pesticides, is covered by the ITP issued for the HCP, and supported by the membership of the state pesticide regulatory lead agency, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP)" (20).*

The Wisconsin HCP proved to be the basis for EPA county bulletins in Wisconsin, but it was an arduous 6 year project to reach the point of having a program whereby cranberry growers could use methoxyfenozide, a "reduced risk" alternative and organophosphate replacement product. At initial registration, EPA was concerned about the potential exposure of the KBB to methoxyfenozide in six states (New Hampshire, New York, Minnesota, Wisconsin, Illinois and Indiana, but not Michigan because it already had a protection plan in place), but for various reasons could eliminate those concerns in all but Michigan and Wisconsin, thus the 1-mile buffer for cranberries (*20*). "*Although by the spring of 2004 both EPA and state regulatory agency approval (DATCP) of Intrepid* 2F for use on cranberries had been received, Wisconsin growers were largely unable to use the product. . . A shared interest for the* [local consultation] *effort developed among cranberry growers, the DNR, the statewide KBB HCP Coordinator, DATCP and USFWS. Based on this statewide consensus, USFWS submitted a proposal to EPA in March of 2007. The USFWS noted that use of Intrepid* 2F by growers included in the HCP was not expected to result in jeopardy to the KBB and any incidental take was already covered by the ITP associated with the HCP. The USFWS recognized that, although the 1-mile buffer established by EPA would certainly offer protection, 'it unnecessarily, in our opinion, restricts the pesticide's use and forces operators to use more broad spectrum insecticides'" (20).*

The end result of having mitigations in "Bulletins Live!" was to simply retain the 1 mile buffer for Michigan, where there was no HCP, and in Wisconsin counties where the statewide KBB HCP was implemented, to establish a set of relaxed restrictions (in place of the 1-mile buffer) for use of Intrepid* 2F in affected areas (*20*). It took six years of effort to incorporate agriculturally practical and species-protective practices onto labeling for the cranberry growers in Wisconsin, but the process itself – consultation on a registration action – was fulfilled. So, the case study here points again to the importance of local input, existing mitigation efforts and "*the immense future task whereby EPA will consider potential impacts of more than 700 pesticide active ingredients for nearly 2,000 threatened and endangered species across some 3,143 U.S. counties" (20).* Multiply that out and you find 4,400,200,000 permutations. But there is hope: we have learned additional lessons from this case study:

- The ESA Section 7 consultation process for a pesticide can result in protection of both endangered species and agricultural interests if the appropriate stakeholders are involved
- Consultation efforts will be greatly facilitated by the availability or federal-level recognition of any Species Recovery Plan (SRP) or Habitat Conservation Plans (HCP) already in place.
- The EPA Endangered Species Protection Program (ESPP) county bulletin system can be an effective way of communicating geographic-specific restrictions to pesticide users.
- There is a need for a new paradigm to handle the massive number of permutations EPA and the Services will face through the continuum of Registration Review.
- For endangered species to truly benefit from pesticide regulation, the ESA consultation process must incorporate consideration of the benefit of an action [in this case registering a new, reduced risk product to replace an organophosphate]

Exploring Data Sources and Stakeholder Input

Above all, in contemplating the life of this unique bird, we realize not only what we have lost. We are reminded again of the strangeness and complexity of the universe that surrounds us, and of how much more there is to know (25).

The above quote is from *A Feathered Tempest*, a fascinating reflection on the fate of the passenger pigeon. The author, Steven Bodio, encourages us to look with greater encompassment at conditions around an ecological event like the extinction of the passenger pigeon. Perhaps that is what is also needed with respect to working on the vision for successful consultation. In this section, we examine the wealth of factual resources available at the state and grower level. In the next section, we will examine many advancing scientific methods as applied to endangered species assessment. This is our tool bag. Considering the magnitude of the challenge before us, the regulatory process of consultation must provide a construction blueprint that makes best use of the tools at hand, combining them so that the knowledge of all relevant resources is sufficiently and efficiently tapped.

States have assisted in the consultation process in some instances, but have voiced concerns about their ability to play a meaningful role in the Registration Review process, particularly in light of the complications often connected to the Services and EPA's responses to litigation. EPA and the Services, as pointed out in the above case studies, are forced under the current paradigm to deal with only those facts immediately available to them, except in those cases where the complexity of consultation is distilled to a simple equation. We also saw in the case studies above, that when local or informed knowledge is added to the more readily available data, consultation proceeds to a more amenable conclusion. Consequently, *"while the biophysical and socioeconomic concepts . . . offer some scientific guidance, local knowledge also can clarify the appropriate direction and governance approaches" (26).* The three chapters discussed below, one by a grower group (*7*) and two by states having extensive relevant data (*27*, *28*), give insight to how these resources might be tapped for the tool bag, and the chapter on NatureServe's multi-jurisdictional dataset (*29*) provides a template for the aggregation of a national-level dataset as well as the manner in which it may be used. We will wrap up this section of review by consideration of various aspects of data quality (*30*), all-important to the appropriate use of any data resource.

Grower Group Contributions to Data

Dialogue begun at a Minor Crop Farmer Alliance workshop held in Denver in May, 2011 included representatives from EPA, USFWS, NMFS, USDA, and the agrochemical industry, with each group having the opportunity to present their thoughts, scientific approaches and role (*7*). Minor uses are particularly impacted by restrictions put on pesticide use via buffers or other actions that remove cultivated acreage from the treatable category. As we saw with the cranberry case study (*20*), often minor use crops only have access to older-generation crop protection products because the bar to obtaining a registration for small acreages is quite high and often not pursued commercially for newer products that are very expensive to develop. Ironically, many high value, minor use crops like cranberries, blueberries, mint and others are grown in areas where there is also a higher number of listed species – perhaps because the diversity of the microecosystems of these areas is also higher. Given this background, growers of minor use crops are anxious to provide any help they can to support a well-informed, efficient FIFRA/ESA process.

The three discussion questions presented to attendees at the workshop were:

- *"Is there grower information that may be valuable in the ESA Section 7 consultation process the risk assessment and risk mitigation consultation process among the Agencies?*
- *If grower information is useful, what information is most valuable, and how should it be collected and entered into the process?*
- *What is the appropriate entry point for growers in the evaluation process" (7)?*

Two case studies, not examined in this book, were reviewed at the workshop: phosmet, very important to pest control in minor use crops and one of the few remaining organophosphate insecticides, and prometryn, a triazine herbicide used more broadly, largely across cotton growing regions. Included in the presentation on phosmet was a trend analysis of the future use of phosmet products, which *"triggered a lengthy discussion of the various use and usage databases and non-reported data retention requirements at the farm level. The use of monitoring data for risk assessments was also highlighted with the actual data suggesting a much reduced potential exposure than indicated in the models based on maximum use rates" (7).* The presentation and discussion on prometryn included an approach to conduct more refined geospatial analysis and stimulated much interest in the use of such tools, and the need to develop a verifiable database on cropping locations and usage information. In response to the detailed discussions that followed as reported by Botts (*7*), EPA noted the importance of grower involvement during development of risk mitigation steps in the endangered species consultation process. They concluded that there is clearly a need for better pesticide usage information at the species-interface level to support a robust Registration Review process. A list of detailed inputs was collaboratively compiled, forming the basis for further discussion and evaluation as the dialogue of stakeholders continues.

Many stakeholders have sought use information as a tool that would support pesticide analysis. While there is no nationally compiled dataset at this time other than statistical extrapolations, this does not mean it cannot somehow be assembled. Perhaps the NatureServe data discussed below (*29*) provides an example of how sensitive data can be assembled and protected, while also being made available for scientific analysis. It is useful to note that we are moving more toward precision in farming and should do the same for precision related to the evaluation of its impact. Contrary to some beliefs, the movement to precision agriculture is not about maximizing yields; it is about minimizing costs: *"The thing that has influenced the propagation of precision services more than anything is not the growing gross revenue of producers but the ballooning input costs on the fertilizer and seed sides" (31).* This movement has produced a data-rich resource that has not yet been explored for its potential use in pesticide assessment.

State Agency Contributions to Data

Under EPA's Endangered Species Protection Program (ESPP) (*23*), states can propose their own specific plans ("state initiated plans" or SIPs) for involvement in the protection of species with respect to pesticide use (*23*). Such plans are submitted to EPA and, if approved, serve as an extension of the ESPP, thus bolstering the resources available to federal agencies. Feken *et al* note that only three states currently have approved state-initiated plans (California, Washington and Oregon) (*27*). The Washington and North Dakota plans, fairly similar to one another, help to *"ensure that EPA has access to accurate and relevant pesticide use data, cropping information, and accurate information on the occurrence and distribution of listed species in their state. Input from the state may also include state-specific risk assessments based on local soil types, weather conditions, or pesticide use patterns" (27).* Unfortunately, however, to date neither EPA nor the Services have fully developed use of these SIPs resources in Registration Review or in effects determinations conducted in response to litigation. It is very interesting to note that when North Dakota applied their statewide SIPs data to EPA's effects determination on clomazone, their conclusions (*32*) were substantially similar to those reached by the registrant in its detailed effects determination (*19*), and both were drastically different from EPA's.

In contemplating what states can do with endangered species and crop data to assist in the "nexus that perplexes," Feken *et al* conclude *"The simplest approach, initially, would be to link the crop data by county to the endangered species data by county to determine what species may be exposed to a pesticide used on a specific crop. A simple relational database can be set up using linked tables containing endangered species by county, crops by county and pesticide by crop data" (27).* Actually, this exercise has already been undertaken by the FIFRA Endangered

Species Task Force, and EPA is beginning to use these data in their assessment process (*18*, *19*). Perhaps it could serve as a launching pad for building state involvement and resources supportive to the process and allow states the role they desire in having input into the entire ESA process.

California has what Feken *et al* call the "gold standard" of pesticide use data (*27*). Wilhoit (*28*) devotes a chapter to describing how these data are collected, quality-checked, assembled and delivered, noting that *"The California Department of Pesticide Regulation's (DPR) Pesticide Use Report (PUR) is probably the largest and most complete database on pesticide use in the world."* For example, looking back to the minor use workshop phosmet discussions above, about labeled use rates (*7*), it is the PUR data that support use trends evaluated for phosmet. Consequently, in addition to reflecting use of pesticides, data in the PUR system can be used in trend analysis that is helpful to understanding potential future use or changes in use.

Multijurisdictional Species Data

In the consultation process, the Services are the species experts. But with nearly 2000 species to understand and manage across more than 50 states and U.S. territories, no single individual or office can provide or analyze all of the data needed in risk assessment. While the Services have high quality and specific species location and characteristics data, it is not currently compiled in a way that makes it readily accessible. At this point in the Registration Review process, and in some of the litigation effects determinations, it has been more efficient to access species data derived from NatureServe and its natural heritage network. These data are described by Howie and Honey in an earlier chapter, who note that currently *"over 1,000 biologists, data managers, and other professionals constitute the NatureServe network. Through decades of careful research, analysis and on-going inventories, these scientists have identified the species and places that are most important to conservation. . . Unique expertise and a steadfast commitment developed in pursuit of these fundamental questions have created the most comprehensive and authoritative database on the locations and status of species in the Northern Hemisphere" (29)...* In response to proximity data requests from EPA, registrants turned to NatureServe as the most comprehensive, reliable and readily accessible source for a nationally-aggregated listed species location and characteristics database (*19*). In Figures 6 (traditional regulatory datasets) and 7 (NatureServe's data and modeling expertise) of their chapter, Howie and Honey vividly demonstrate how the use of NatureServe data and predictive distribution modeling focuses on the actual areas of concern (*29*). EPA is in the early stages of adopting such focus, but this adoption is inhibited by the Services reluctance to rely nationally on such a data set. Ironically, the Services in some USFWS or NMFS regions rely on NatureServe's heritage program data providers for their own species distribution information (*33*).

Building confidence in use of NatureServe data, in absence of any other national data set of this quality, will be important to supporting improved efficiency in the national-level pesticide risk assessment screening process. Such a valuable collection of data, provided in a way that protects its confidentiality yet allows detailed analysis, cannot be ignored. In fact, *"Courts that have considered the "best data available" language have held that an agency is not obliged to conduct studies to obtain missing data, but cannot ignore available biological information, especially if the ignored information is the most current"* (*34*) and in this case, most comprehensive and accessible.

Data Quality

Feken *et al* (*27*), Wilhoit (*28*) and Howie *et al* (*29*) discuss the importance of addressing data quality in the building of complex data systems. Another dimension to data quality is the manner in which data are applied to an assessment: *"The agencies that administer pesticide regulation and species protection have processes to address data quality, but not necessarily agreement on a standard approach to qualifying data used in an assessment with respect to its "reliability," and "relevance." Data of the best methodology and quality performance standards may serve well in one assessment role but poorly in another. A robust ecological risk assessment must assemble and depend upon data that is reliable and relevant in order to address its protection goals" (30).* In other words, the context of a risk assessment and the studies used to support it must match. For example, well conducted studies on a tropical species of fish may not support a risk assessment on Pacific Northwest salmon. Likewise, startle-response studies on caged birds that may have learned to suppress their natural responses may not be relevant to predicting the response of wild birds of the same species. Hall *et al* suggest a weight-of-the-evidence approach not only for reaching scientific conclusions, but also for establishing what data are of the quality and relevance to support that conclusion (*30*). Li notes that *"Sharp criticism from the pesticide industry has saddled every recent pesticide biological opinion issued by NMFS" (6),* and in many cases this criticism is based on omission of important data or inappropriate use of data that is not relevant to the risk assessment framework. When pesticides are assessed, data should be examined in light of its relevancy or reliability to the assessment goals at hand in order to reduce polarization between parties having differing value systems. However, since no clear and specific instructional guidelines exist for this purpose, *"It is therefore imperative to apply relevance and reliability standards to the data examined" (30).* Even with the response expected soon from the National Academy of Sciences as guidance (*35*), the development of programmatic, clear relevance and reliability standards may be an additional mechanism to provide consistency when an assessment passes from one set of circumstances (FIFRA) to another (ESA). Data quality is tied to uncertainty and variability in risk assessment and management. Sensitivity analysis can be used to determine which input variables are important to model predictions. Data quality and accuracy are critically important for those input variables that have a major influence on model predictions. Managing data quality though specific standards will help reduce uncertainty, and focus the outcome to produce optimal risk management options. Most certainly, "*Uncertainty and variability analysis should be planned and managed to reflect the needs for comparative evaluation of the risk management options" (36).*

Advancing Scientific Methods

By default, a national level risk assessment on an endangered species must rely heavily on consolidated data sources such as those discussed above. Additionally, it must rely on predictive modeling applied in such a way as to bring the least amount of uncertainty and variability possible, while still portraying a valid characterization of the exposure and risk scenario. USFWS notes, *"The results of a quantitative or qualitative model are only "true" for the tiny world of the model itself. Applying model results to the real world requires careful assessment of how the model reality matches actual reality, how the model takes variance into account, and whether the model answers the question posed (37).* NMFS further elaborates on this, when addressing salmon issues: *"Because salmon ESUs typically consist of groups of populations that inhabit geographic areas ranging in size from less than ten to several thousand square miles (depending on the species), the analysis must be applied at a spatial resolution wherein the actual effects of the action upon the species can be determined" (38).* Determining the actual effects is central to the contributions from all authors for this book. In this section, we turn to the abundance of science that is being applied to consolidated data and modeling and in turn being evaluated for its match to reality. Contributions to the science of the matter come from all authors, but here we will focus on applied spatial and temporal modeling, product-specific risk characterization, qualitative assessment and mitigation development.

Spatial, Temporal, and Qualitative Assessment

Bodio (*25*) notes how much we don't know, and have to learn, about the world around us. Teply *et al* (*8*) captures what we *do* know by demonstrating *"which accounts for the spatial and temporal variability of salmon exposure to agricultural pesticides in freshwater...such models can provide information about the range of pesticide exposures and how this information can be used to better represent population effects (8).* In testing the consequences of ignoring data, particularly spatial and temporal data, a spatially- and temporally-explicit exposure model was developed for Pacific salmon. Employing these factors in the predictive model changed the assumption of 100% exposure to juveniles that NMFS used in their non-specific model to 13% when more of the factors known about salmon were built into the model. In the Willamette Basin example presented by Teply *et al, we find that*: "*Because the amount of backwater habitat is limited in the Willamette Basin, the proportion of the population rearing in backwaters is, therefore, limited. Overall, such detail about patterns of fish and pesticide use in the Willamette Basin provides the regulatory decision-maker with more information relevant to risk assessment than when assuming 100% exposure" (8).* Additional lines of evidence are then important to build into the model once the model is focused on the areas of exposure concern. For example, indirect effects due to the loss of food items are assessed in this exercise by addressing the carrying capacity of the backwater, off-channel habitat (*8*) that Somma *et al* noted was of particular concern to the Services (*5*). In this application, *"Overall, we found that the basin-wide reduction in carrying capacity* *was about 5%. We posited that this lost capacity is probably compensated elsewhere via increased occupancy (emigration to other habitats) not accounted for in the model" (8).*

There are process and scientific benefits to be gained by improving models to reflect more realistic exposure scenarios and meet the Services concern about their application (*37*, *38*) However, there is also a reluctance to adopt new models among scientists and policy-makers. It is not enough to say these models are "more ecologically realistic" without asking what gains such realism provides to the decision-maker. So, the authors and their scientific team tested whether such benefit might be realized, by applying refinements to the approaches taken in recent biological opinions (*39*, *40*) and they found that *"By applying well-understood aspects about the spatial and temporal distribution of juvenile salmon, more ecologically realistic exposure estimates are possible. These improvements can lead to improved regulatory decision-making. In some instances, they can affect risk determinations."* Immediate adoption of a new method like this into the regulatory application arena, even though it appears to move the modeling exercise closer to reality, is not likely, due to the Services concerns about uncertainty (which the authors point out can be overcome by sensitivity analysis) and increased Type II error rate (which the authors note can be a perception related to a mathematical artifact). Reaching a balance between the refinements added to the model and unnecessary complexity is also important to the eventual use of that model in a regulatory setting (*8*). Here again, however, cultural values and fixed mindsets enter into the picture and need to be set aside as the denominator that determines "acceptability" so that advances in modeling can contribute to improved risk assessment and mitigation.

For salmon, population modeling is likely to continue to be refined in the future, but *"to pursue salmon management based solely on trying to improve the theoretical basis for standard spawner/recruit models and/or the accuracy and quality of data used in the models would be imprudent . . . Because of significant uncertainty about factors influencing run sizes, even the best models simply will not perform to the degree that we can totally depend upon them" (41).* This means that the data we have examined above, and additional approaches to quantifying risk, will also provide the multiple lines of evidence needed to move toward a uniform and reliable FIFRA/ESA assessment process. Moving from what happens in the water with refined population modeling to what happens around the water, Winchell *et al* present a refined approach to using spatial information about crops and land cover to determine the proximity of potential pesticide use to water bodies identified as supporting salmon habitat (*42*). One argument against reliance on spatial data is the possibility that it does not inclusively represent all spatial areas that may contribute to exposure to a given pesticide. Winchell illustrates that the available data sets, as selected and applied in this proximity analysis, likely overstate spatial areas of concern rather than understate them (*42*). Spatial crop distribution can then be combined with hydrology and salmon habitat data sets, again using those most relevant, representational and robust for the exercise at hand.

Winchell *et al* note that it is also important to improve the precision of the datasets as they are layered one upon another. They also suggest balancing these refinements with the use of a resolution that allows practical analysis at a multi-state level. The methods and datasets utilized here demonstrated that, in the Willamette Chinook salmon ESU *"over 65% of the use sites are beyond 8,200 ft., with over 86% of the potential use site area beyond 1,000 ft" (42).* The authors noted, via a cumulative distribution analysis, that there is a trend for pesticide use sites to be a relatively small proportion of the area within proximity to salmon habitat. Pairing this with lessons learned from the refined population modeling exercise (*8*) brings an additional perspective to evaluate or predict pesticide concentrations that may reach water. Teply *et al* depended upon monitoring data, in part, to test the reality of his refined model (*8*). Another reality test can be provided by using spatial data, as proposed by Winchell *et al* (*42*), to predict the potential runoff and drift loading of pesticide to salmon-bearing waters. The refinements that can be brought by using this method in the risk assessment process were demonstrated earlier by the fomesafen case study (*18*). Through different methods from those presented by Teply *et al* (*8*), Winchell (*42*) found that by considering use site proximity for migrating, spawning, and rearing habitat classifications, pesticide use site intensity within the spawning habitat was a fraction of that for migrating and rearing habitats, thus validating similar conclusions reached by Teply *et al* (*8*).

Having thus demonstrated the importance of such data to making a national level assessment relevant and reliable, we now examine how these data have been made more robust by examining the efforts of the Washington State Department of Agriculture (WSDA) to refine national datasets (*43*). This exercise was undertaken in direct response to protection of listed salmon species and was also linked to the design of water monitoring for pesticide contamination. An analogous program, driven by differing agricultural concerns, has also been produced by a program that began in Indiana. Driftwatch™ is *"a tool to help protect pesticide-sensitive crops and habitats from the drift that sometimes occurs during spray operations"* and is now available for 6 Midwestern states (Minnesota, Wisconsin, Michigan, Illinois, Indiana and Nebraska) and may soon be available for 2 Western states (Montana and possibly Colorado) (*44*). A third iteration, chemically specific and national in scope – directed specifically at endangered species protection – has been developed by Monsanto for users of the herbicide glyphosate (*45*).

Ultimately, the data produced by Washington (*43*) was included in the SIP approved by EPA for Washington. Cowles *et al* note that in a minor crop state like Washington, over 200 types of crops, each with unique registered pesticide uses and pest pressures, are represented by the National Land Cover Database by only 2 land cover categories (*43*). Seeing the impact this circumstance can have on Washington agriculture (*46*), WSDA *"instituted a program to collect state-specific pesticide use data and compile a high resolution land cover dataset of agricultural land for use in ecological risk assessment for pesticide registration" (43).* Using National Agricultural Imagery Program (NAIP) color mosaics and individual field surveys, field boundaries were mapped along with crops grown in each field and documentation of land that has been taken *out* of agricultural production, largely due to the encroachment of urbanization. Using these data and the herbicide oryzalin as an example, WSDA demonstrated how their data can be used by NMFS and EPA in salmon assessment. EPA through the

Registration Review program is in the early stages of turning to these data, and the Services have addressed them but to-date have not completely embraced their use (*47*) The Washington program further demonstrates how states and federal agencies can work together to validate and/or refine data that in turn will be used for national level risk assessment. Not only were these data wrapped into EPA's ESPP SIP process, WSDA *"has also developed a cooperative agreement with NASS to augment their Fruit and Vegetable Chemical Use surveys to include application timing windows for data collected in Washington State" (43).*

Taking the Washington approach one step further, an independent effort to help guide decision-making, research and monitoring priorities, and best management practices (BMPs) in the California Central Valley area is reported by Hoogeweg *et al* (*48*). This work takes the spatial proximity and co-occurrence analysis, as undertaken by Winchell *et al* (*42*) and Cowles *et al* (*43*), one step further by using multiple spatial data and pesticide monitoring data to develop an indexing method. The resulting index can then be applied to the question of whether or not pesticides are playing a role in the decline of pelagic species (*48*). For this study, co-occurrence was determined by partitioning the landscape into discreet segments based on the likelihood that at least one pesticide provides a potential risk and the possibility that one or more species are present during the same period. Thus the higher the count of each, the higher the resultant index. Through a highly complex combination and application of datasets (soil, water, species and land cover) and modeling (including use of the Pesticide Root Zone Model, the Rice water quality model, and spray drift modeling) cast in light of temporal assessment, the analysis was conducted. The authors note, however, that results were both positive and negative: *"Given sufficient data, a co-occurrence assessment is certainly possible and the information it yields can be valuable on a variety of levels….However, there are limitations and assumptions that lead to uncertainty in predictions of co-occurrence. Degradation products, chronic toxicity, and indirect effects were not addressed. There are gaps in the data, particularly in the estimation of water volumes and channel routing that compromise the ability to estimate exposure concentrations" (48).* This study is instructional in how larger regional planning and species protection efforts can be prioritized to focus on manageable subsections of the geography examined and how relative risk can be ranked. However, risk ranking differs from the mission of national level risk assessment. Perhaps Hoogeweg *et al* give us a look into the future, where a complex process like this will not exceed the current capacity of the Registration Review and ESA regulatory settings. The Hoogeweg *et al* exercise (*48*) integrates data, spatial analysis and modeling in a way that is envisioned by Odenkirchen (*15*) in his integration tool concept.

Given this wealth of data and techniques to incorporate them into models, we now turn to the area where cultural value differences are probably the most entrenched: the interpretation of toxicological endpoints. Stark (*49*) and Golden *et al* (*50*) address the potential necessity of moving beyond traditional FIFRA methods by means of using a different collection of specific endpoints to characterize hazard. Stark (*49*) suggests a new approach *"involving population-level estimates of effect followed by population modeling,"* and points out concerns with multiple toxic effects, measurement of individuals rather than populations, use of surrogate species, sensitivity of life stages, variability of susceptibility shown in closely related species, and use of the risk quotient method. Certainly, these concerns are at the heart of the impasse between EPA and the Services, as expressed in their commissioning letter (*51*) to the NAS panel on Ecological Risk Assessment under FIFRA and ESA (*35*). These questions are under consideration by the panel as this book approaches publication. Stark proposes to address such questions by utilizing demographic toxicity studies followed by matrix and population modeling, and through a hypothetical example demonstrates the benefit of such an approach (*49*). Unfortunately, such data are not currently available and the uncertainties related to them must be resolved through future validation trials. Stark's research continues and is likely to contribute to our future thinking, but for now the body of information that scientists do have available must be relied upon.

Golden *et al* (*50*) plots increasing sensitivity as moving from behavioral responses, through sublethal responses and ultimately to lethal responses, giving linear relatively to these endpoints. Not all scientists agree with this approach. But, like Somma *et al* (*5*), Golden points out that the Congressional intent for the Services implementation of ESA was to give the species the "benefit of the doubt" with respect to assuming or concluding a possible effect. Golden notes, *"The types of responses that can be elicited from contaminant exposure are too numerous to list and are constantly growing as researchers evaluate new chemistries and measure novel endpoints" (50),* and concludes that FIFRA-required laboratory toxicity tests lose their conservatism when extrapolated to the environment. Further discussion contemplates reliance on mesocosms and other tests directed at behavioral and sublethal responses (*50*), some of which in fact were popular FIFRA toxicological refinement methods in the 1980's and still are a type of study that EPA relies upon as a higher-tiered evaluation tool. Under FIFRA, when such studies are conducted they often support reduction of the concentration of concern rather than adding more precaution. That fact and the unavoidable variability that occurs in large-scale mesocosm studies and field testing were factors in EPA's "new paradigm" announcement in the early 1990's, a decision that placed greater emphasis on use of laboratory data and innovative modeling approaches to support rapid identification of risk mitigation needs (*52*). New testing endpoints or use of them in risk assessment may be valid, but careful interpretation of them in context is necessary. For example, in the way Rachel Carson's *Silent Spring* (*53*) raised public concern about pesticides, Theo Colburn's *Our Stolen Future* (*54*) spawned concern that ultimately resulted in new FIFRA requirements for endocrine effects testing. Now well into that program, the potential for test results to yield data not detected by tests using traditional endpoints is debatable and in fact has stalled the proposed testing schedule. And while most of the FIFRA-regulated world has forgotten, one author of this section (McGaughey) recalls reviewing FIFRA-required "fish potentiation studies" that were generated in the 1960's and 1970's for the purposes of determining whether aquatic mixtures of chemicals increased potential toxicity of products to fish. The practice was dropped in part due to no positive findings that potentiation ever occurred and in part due to the growing ability of science to selectively predict the selected circumstances under which it might occur.

As Golden *et al* point out, *"To determine potential effects from sublethal responses, logical, science-based causal linkages are sought to support the extrapolation to effects at the individual level. Identification of linkages is based on the available information on a toxicant (exposure and toxicity) and on the species/taxa assessed. If appropriate data are available, sub-organismal effects may be linked quantitatively to whole organism responses (e.g., % decline in reproduction or survival). However, for the majority of pesticides, toxicity studies have not been conducted at multiple levels of biological organization (i.e., suborganismal-organism-population), and thus quantitative analyses will often not be possible. In such cases, the expertise of scientists is required to qualitatively evaluate the linkages and weigh the lines of evidence based on the best available scientific data" (50).* And herein the debate continues: how do we bring consensus when there are two (or more) differing qualitative opinions? Borrowing from scientific discussions and debate in the European regulatory community about evaluating chemical mixtures, for example, we have this suggested resolution: *"Where there is no obvious cause of environmental impacts, causal analysis needs to be employed to identify probable cause as these are many, ranging from habitat, including a number of natural perturbances, to anthropogenic stressors of which toxic chemicals are one" (55).*

Product-Specific Risk Assessment

Reiss, assessing malathion (*56*), and Ma *et al*, assessing dimethoate (*57*), demonstrated two risk assessment methods for higher-tiered risk quantification. Malathion was addressed in the first NMFS pesticide biological opinion (*39*) and dimethoate was addressed in the third (*58*). Reiss applied the AgDRIFT model's Stream Assessment Tool that allows the user to estimate stream dilution after a pesticide plume first enters the water, noting that this tool was not used in the NMFS opinion but allows results to be characterized mathematically (*56*). While we previously discussed temporal differences as adopted in modeling regimes, we did not address the dramatic differences in toxicity based on exposure duration. If the expected hazard is not tied to the toxicity value reflecting a relevant duration of exposure, Reiss' results suggest that risk may be overstated by as much as 4-fold, demonstrating how important it is to account for the duration of exposure (*56*). Ma *et al* note that *"one of the primary goals of aquatic ecological risk assessment, whether it is at the screening-level or at higher levels, is to prioritize the potential risks at different locations and to eliminate from further considerations those species and locations that are unlikely to be at risk" (57).* The value of this with respect to a national level risk assessment was demonstrated in the fomesafen (*18*) and clomazone (*19*) case studies, where sequential applications of risk screening techniques greatly reduced the potential number of species that may be handed off to the Services for consultation. For salmon, Ma *et al* show that using species sensitivity distributions (SSDs), EPA exposure scenarios, and the probability distribution of exposures in a joint probability distribution analysis could either have resulted in dimethoate not being subject to consultation or in the consultation process not finding jeopardy (*57*).

Deriving Mitigations

Another consideration driving the differences between the Services and EPA is the derivation and application of mitigations. In the methoxyfenozide case study (*20*), we saw that local input about existing protections and conditions reduced EPA's restrictions on a registered use in cranberries. Jackson *et al* propose that a programmatic approach to developing mitigation might be realized through adoption of *risk-based* spray drift buffers (*59*). Such an approach may be an alternative to identifying the specific area and mechanism for protection in a given crop-species intersection. Jackson *et al* note, however, that *"While agreement on a near zero exposure estimate may be easier to attain than agreement on data requirements for risk assessment, such an approach may cause undue impacts on the grower" (59).* Nevertheless, the work presented by this author presents an alternative to highly detailed species assessments, but still depends upon an agreement on approaches, between EPA and the Services, to the use of spray drift deposition models and selection of non-target organism effects data. One of many important points made is the impact of new technologies for low-drift nozzle design on the potential for drift. Spray drift models currently in use were not validated with field trials using such technology and thus must be manipulated to properly portray it. This highlights a conundrum pointed out by Bosso: *". . . federal regulation in almost any area of national life is today's governmental response to yesterday's conditions. Such unplanned policy obsolescence creates gaps that become painfully apparent when yesterday's policy no longer addresses today's realities. This observation applies particularly to any policy area of great scientific or technological complexity" (3).* This circumstance is not the government's fault: it is their dilemma.

Recommendations for Scientific and Process Improvements

"What we have here, contrary to appearances, is an amazing opportunity" (60)!

Careful study of the chapters of this book and continued "solutions-focused" dialogue among all stakeholders *will* yield fruit. EPA and the Services are obligated to interact with one another in the endangered species protection process, and necessity is the mother of invention. Rather than bobbing up and down like a yoyo, going through a pedantic process that isn't working, it is time for a new vision. What if our existing USDA Cooperative Extension Service (representing agricultural interests), state and regional offices of EPA and the Services, and state lead agencies all had a window of view and constructive role in the consultation process? The fact is they do, but efforts are not organized or coordinated in a way to allow the vast resources of all involved parties to collectively function in advancing improvements. Our opportunity is to break free of the string that binds the yoyo and become instead the wheel that bears the load. To do this, we might:

- *Establish trust and a cooperative process between agencies*
    - Form independent, expert panels as needed to address unresolved aspects of ESA pesticide assessment and adopt their recommendations (e.g., forthcoming scientific recommendations expected from the NAS panel on FIFRA and the ESA).
    - Work together at the state and federal level to gather, validate and refine data to be used in risk assessment, possibly through an interagency, web-based communication and data management tool.
    - Promote open discussion among agencies around existing case studies so that lessons learned, both positive and negative, can be captured in support of a spirit of continuous improvement.

- *Provide resources, or leverage existing resources, to establish priorities for accomplishing the task at hand*
    - Based on the Registration Review schedule, develop a prioritized, multi-year interagency work plan and resource estimate for completing ESA-related assessments and as appropriate, informal or formal consultations. Seek Congressional inputs on balancing legislative-mandated scheduling requirements with supported agency budget resources.
    - Find a way to more effectively mobilize regional resources, including the EPA and Services regional offices and state agencies.
    - Formally accept, as mitigation, any existing Species Recovery Plan, Habitat Conservation Plan, Environmental Impact Statement, or State Implemented Program that has already dealt with the use of pesticides.
    - Rely on and leverage all available resources to accomplish the task, including those available to registrants and academic institutions.
    - Find a way to redirect wasteful, litigation-driven assessment efforts towards work for improving scientific assessment methods and addressing established species priorities in an orderly fashion.

- *Improve communication with and early involvement of stakeholders*
    - Form a standing work team to build upon the detailed inputs identified by the MCFA workshop for incorporating grower data and comments.
    - Form an “Endangered Species/Pesticide Registration Dialogue Group” as a Federal Advisory Committee Act entity
    - Provide a mechanism for considering alternative mitigation options, as contributed by local participants or programs.
    - Enlist informal engagement of the agencies and stakeholders during the early phases of Registration Review, followed by formal consultation, if necessary, upon issuance of either an interim or final Registration Review decision
    - Ensure that agronomic and related application technology and precision agriculture are understood and considered by agency risk assessors and risk managers.

- *Provide a stable scientific platform defining data use and assessment methods*
    - Create a roadmap for evaluation of direct and indirect effects.
    - Formally establish relevance and reliability attributes desirable for data used to support risk and risk management decisions.
    - Refine assessment methods and data collection to give an as accurate as possible depiction of risk.
    - Reach conclusions by employing multiple lines of evidence in a process that is clear and transparent.

- *Devise a mechanism to deal with complexity and scale*
    - Consider programmatic analysis of species potentially affected by pesticides and identify use conditions not of concern to reduce wasted effort.
    - Adopt a spatial resolution that gives the best representational accuracy for the scale of the evaluation.
    - Study the FESTF platform for information management and continue to work with industry, states and growers to render a fully effective and transparent information management resource.
    - Create an open climate for the development of models that account for spatial and temporal distribution and ecologically realistic exposure estimates.

We trust that the spirit of constructive dialogue experienced at the symposium upon which this book was based, as well as the thoughtful and innovative proposals captured in the chapters of this book, will the support significant progress that is so urgently required. Only by doing this will the unique opportunity presented to this generation of policymakers, regulators, scientists and industry leaders to safeguard the interests of *both* endangered species *and* our agricultural heritage be preserved.

Concluding Remarks

Perhaps the single most important lesson to be learned by direct experience is that the natural world, with all its elements and interconnections, represents a complex system and therefore we cannot understand it and we cannot predict its behavior. It is delusional to behave as if we can, as it would be delusional to behave as if we could predict the stock market, another complex system . . . Human beings interact with complex systems very successfully. We do it all the time. But we do it by managing them, not by claiming to understand them. Managers interact with the system: they do something, watch for the response, and then do something else in an effort to get the result they want. There is an endless iterative interaction that acknowledges we don't know for sure what the system will do-we have to wait and see. We may have a hunch we know what will happen. We may be right much of the time. But we are never certain. Interacting with the natural world, we are denied certainty. And we always will be (61).

Science recognizes the dynamic of uncertainty, but science doesn't *manage* the uncertainty inherent in our complex world. In dealing with endangered species in a regulatory environment as complex as that created by the FIFRA/ESA "nexus that perplexes," perhaps we need to accept the fact that we indeed do have an "*endless iterative interaction that acknowledges we don't know for sure what the system will do-we have to wait and see*" *(61).* In physics we know that for each action there is an equal and opposite reaction – but in the living world, *"It's what we learn after we think we know it all that counts" (62).*

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Subject Index