ECOLOGICAL RISK ASSESSMENT

FLORIDA POSITION PAPER

PRELIMINARY DRAFT
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Report to the Florida Department of Environmental Protection
Contaminated Soils Forum

by

The Ecological Risk Assessment Focus Group

ECOLOGICAL RISK ASSESSMENT FOCUS GROUP
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EXECUTIVE SUMMARY

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1. STATEMENT OF PURPOSE

The Ecological Risk Assessment (EcoRisk) Focus Group of the Florida Department of Environmental Protection (FDEP) Contaminated Soils Forum (CSF) was formed to evaluate whether the ecological environment is adequately protected from hazards associated with contaminated sites, and to advise the CSF if steps are necessary to ensure that ecological concerns are properly addressed.

The first report of the EcoRisk Focus Group determined that State-specific ecological risk assessment (ERA) guidance does not exist and recommended a process for the development of such guidance. The second report, in response to a request by FDEP staff during a CSF meeting, identified members of the Focus Group who would (1) be qualified to serve on a technical committee to develop such guidance, and (2) be willing to commit the necessary time such an effort would require. When recently asked what position the FDEP might be taking with respect to ERA, and specifically to EPA Region 4's issuance of draft soil screening values for ecological effects, FDEP staff replied that the Department is waiting for recommendations from the CSF. Therefore, in order to better inform the CSF's recommendation on ecological risk assessment, the EcoRisk Focus Group determined that this Position Paper should be developed with specific recommendations in order to assist the CSF in formulating their recommendation to the FDEP.

In order to provide an informed basis for recommendations, several questions need to be addressed. These include:

- What existing ERA guidelines are most suited for application to Florida environments?
- How should generic guidelines be modified to take into account unique elements of Florida environments?
- Would generic soil screening numbers be useful or would some other form of site-specific screening for ecological risks be necessary considering the diversity of Florida ecosystems?
- What is the need for expert resources to support ERA design and review?
- What critical lessons have we learned from past applications of ERA principles to Florida ecosystems?

Thus, the purpose of this Position Paper is to address these questions in order to provide the background from which reasoned, consensual recommendations can evolve. These recommendations, developed in the conclusions of each of the following sections and summarized at the end of the Position Paper, are intended to facilitate the process of assessing ecological concerns at contaminated or potentially contaminated sites. More specifically, they are intended to cull from multiple guidelines and screening approaches that which is most useful and scientifically sound, recognizing the uniqueness and diversity of Florida ecosystems, and to frame a scope of application that is both reasonable and cost effective.

2. SELECTION OF ECOLOGICAL RISK ASSESSMENT FRAMEWORK DOCUMENT

The development of methodologies and guidance for conducting ERAs is following a pattern that already occurred, in the 1980s and 1990s, for human health risk assessment. The pattern has been to go from general, less specific, guidelines at the EPA agency-wide level, to more "practical" guidance at the EPA programmatic level (e.g., Superfund), to even more specific, and in some instance codified requirements at the state level.

EPA published a series of agency-wide guidelines for human health risk assessment in the period 1986 through 1988. These guidelines remain in effect. In 1989, the Office of Emergency and Remedial Response (now Office of Solid Waste and Emergency Response) published Risk Assessment Guidance for Superfund (RAGS). Although entirely consistent with the agency-wide guidelines, RAGS provided more practical and specific guidance to risk assessors and Remedial Program Managers. Since 1989, several EPA Regions have "clarified" portions of RAGS, establishing Regional policies with respect to some areas of RAGS that were open to conflicting interpretations. In 1995, the American Society for Testing and Materials produced its "Standard Guide for Risk-Based Corrective Action (RBCA)" which provided more simplified instructions, intended to be consistent with RAGS, and many states found that the ASTM RBCA Guide provided a basis to incorporate RBCA into their contaminated site response programs and regulations. An important consideration in many states' decisions to implement RBCA was the specificity of the ASTM process. Now, modified versions of the RBCA process are codified in most states' contaminated site response regulations.

Although ecological risk assessment methods and guidance have not proceeded, yet, to the same level of specificity and regulatory acceptance, the development of ecological risk assessment guidance is at approximately the same status that existed for human health risk assessment in 1995. EPA published agency-wide guidelines, EPA's OSWER published Superfund guidance, ASTM's eco-RBCA is nearing finalization, and a few states published guidance or implemented regulatory requirements for ecological risk assessment. Further, the pattern of increasing specificity from Agency-wide guidelines to state regulatory requirements also is being repeated, and for the same reasons. There aren't enough experienced risk assessors for every state to have several on hand to review submittals that claim to follow sometimes vague and always flexible guidelines. States will require a step-by-step process with clear decision points that will apply to most (> 90 %) of the potentially contaminated sites. The regulated community also can benefit from clear-cut rules that will apply to most sites, so long as options are retained to use innovative assessment approaches at those few sites where the simple rules may not be reasonable.

Although few states have published guidance or codified ERA requirements, the contrast between the general (EPA guidelines) to the specific (state guidance or rules) can be illustrated by reviewing the requirements of several states. ASTM (1999) includes an Appendix that reviewed ERA guidance or rules published by EPA; the Department of Defense; the province of British Columbia, Canada; and seventeen states. That review summarized all the evaluated documents with respect to specificity and comprehensiveness. In our review, we will illustrate some of the identified issues by reference to specific state guidance or rules, limiting our review to states where the authors have submitted ERAs for state review or participated in the development of the state requirements.

Georgia Environmental Protection Division (GAEPD) – Georgia's "Guidance for Selecting Media Remediation Levels at RCRA Solid Waste Management Units" incorporates EPA Region IV's "Ecological Risk Assessment Bulletins" by reference and requires a Preliminary Risk Evaluation (PRE) as defined by EPA Region IV (1994). Region IV's Bulletin that defines a PRE has since been withdrawn, but Georgia retains the PRE requirement. GAEPD specifies the use of EPA Region IV Ecological Screening Values (ESVs), and states that ESVs should be proposed and submitted to GAEPD for approval. GAEPD requires summing HQs across chemicals if the chemicals exhibit consistent modes of toxicity and effect endpoints. GAEPD requires an Ecological Risk Assessment if the summed (as appropriate) HQs exceed 1. Remedial levels must be proposed for all chemicals that exceed and HQ of 1, and the facility must provide justification if the proposed remedial level would result in a HQ greater than 1.

New Jersey Department of Environmental Protection (NJDEP) – NJDEP promulgated a regulation (N.J.A.C 7:26E – Technical Requirements for Site Remediation) that includes ERA requirements. The regulation requires a Baseline Ecological Evaluation (BEE). The regulation specifies the sources of information to be used for ESVs. For soil these are:

- Contaminant Hazard Reviews, Fish and Wildlife Service, U.S. Department of the Interior, various dates, Eisler, R.;
- Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants: 1994 Revision, Oak Ridge National Laboratory, Oak Ridge, TN, Will, M.E. and G.W. Suter II;
- Other peer-reviewed published literature on the impact that specific contaminants have on non-human species.

Contaminants of Potential Ecological Concern (COPECs) include chemicals that biomagnify or bioaccumulate and any chemicals exceeding ESVs identified from the sources. The BEE also requires submittal of a map identifying adjacent environmentally sensitive areas identified in map files provided by NJDEP. Subsequent ecological investigations are required if COPECs exist at the site (i.e., exceeding the ESVs) and environmentally sensitive areas are affected (either contaminated or a pathway). Analogous to the state of Georgia, NJDEP requires that subsequent phases of the ecological investigations be conducted in accordance with EPA Guidelines, and that ecologically based site-specific remediation standards be developed.

Alaska Department of Environmental Conservation (ADEC) – In contrast to Georgia and New Jersey, Alaska provides detailed guidance for ecological risk assessment. Alaska divided the state into eight Ecoregions and identified default assessment endpoints and indicator species for each ecoregion. Responsible parties are encouraged to use these default endpoints, i.e., use of alternate endpoints require justification while use of default endpoints will not be challenged upon review. Alaska has constructed a three-tiered assessment flow chart with six Ecological Scientific/Management Decision Points. ADEC requires development of a Conceptual Site Model and provides an example. ADEC provides a list of sources for ecological benchmarks and recommends use of the most stringent benchmark found in those sources. ADEC provides a list of Uncertainty Factors that will be accepted for calculating Toxicity Reference Values. The Uncertainty Factors address both study/endpoint type (e.g., LD50) and interspecies extrapolation.

Pennsylvania Department of Environmental Protection (PADEP) – PADEP drafted a proposed rule (Pennsylvania Code; Title 25; Part I; Subpart D; Article VI; Chapter 250.311) to govern ecological risk assessments under the Land Recycling and Environmental Remediation Standards Act (commonly referred to as Act 2). The proposed rule identifies ecological receptors and habitats that are to be protected although the list is relatively vague in that it includes "Habitats of concern" and "Species of concern" which are not further defined. No additional ecological evaluation is required if any of the following conditions are met:

- Light refined petroleum products (listed in the rule) are the only constituents detected;
- The area of contaminated soil is less than 2 acres, and the area of contaminated sediment is less than 1,000 square feet;
- The site has features, such as parking lots, which eliminate soil exposure pathways; or
- Remediation will attain a level of $1/10^{th}$ the human health standards (promulgated by existing rule). This exemption does not apply for constituents of potential ecological concern (listed, these appear to be chemicals that biomagnify or bioaccumulate).

Subsequent actions required by the rule include ecological surveys of density and diversity of species compared with nearby reference areas. There is no reference in the rule to EPA Guidelines.

These four states are representative of state regulations or guidance for ecological risk assessment of contaminated sites. Each includes definitive decision criteria that are more specific than EPA Guidelines. Each identifies ESVs or benchmarks for surface soil, although they are incorporated by reference, rather than by listing numerical values. A potential problem in the states' method of presentation of benchmarks is the usual reference to the latest publication at the time the regulation or guidance was published. In fact, the referenced lists of benchmarks have been updated one or more times since state publication of the list of references. For example, Georgia references the EPA Region IV Ecological Risk Assessment Bulletins with a publication date of 1994. These Bulletins have been updated twice since then. PADEP's regulations are based in part on IRIS (1993) and EPA Region III Risk-Based Concentration Tables (1993) and do not require use of updated information. Oak Ridge benchmarks also have been updated at least twice since 1994. Referral to outdated benchmarks is often difficult because they are out of print, and is not standard risk assessment practice. The rules or guidance should reference instead the latest update of the source of benchmarks.

Alaska's guidance is expected to prove to be very helpful because of the substantial effort ADEC has undertaken to define default endpoints that are specific to the unique ecosystems of Alaska.

PADEP's exclusions are very specific and include an exclusion based on contaminated area that will limit the allocation of limited state resources to the review of numerous assessments. Although we agree that an exclusion based on contaminated area is a reasonable way to reduce the expenditure of limited risk assessment resources by both the regulators and the regulated community, some may consider the PADEP exclusion "generous." In particular, it does not address special cases that may occur for protected species or their unique and sometimes limited habitats. In such cases the rule may be found, ultimately, to be incompatible with the Endangered Species Act.

3. POINTS TO INCORPORATE TO MAKE FRAMEWORK DOCUMENT FLORIDA-SPECIFIC

This section is intended to identify those factors of particular concern in Florida environments that should be considered by the risk assessor developing a site-specific risk assessment of chemical-associated risks. The factors listed are intended to highlight unique aspects of the state and affect exposure characteristics and receptor species and community structure. These factors should be quantified to the extent possible during the Problem Formulation phase (USEPA, 1996) of the ecological risk assessment.

<u>Stressors</u>

Application of pesticides in Florida is enormous (e.g., agriculture, sod farms, mosquito control, golf courses), especially in south Florida. Data on background concentrations of pesticides are limited, with little to no correlation to potential biological effects. Because of the frequency and multitude of pesticides used, interactions of stressors may be prevalent. Consideration must also be given to background levels of chlorinated hydrocarbons and metals. In addition, the biological abundance and diversity of habitats in south Florida were once supported by complex hydrological patterns but human alterations beginning almost 100 years ago have greatly changed hydroperiods and hydropatterns. The relationship between hydrologic regime (as a stressor) and ecosystem structure and function has not been well studied.

<u>Receptors</u>

Ecological receptors in certain regions of Florida may be compromised because of prior exposure to chemical and non-chemical stressors (e.g., habitat changes resulting from non-indigenous, exotic species, and hydropattern). The stressors may have nothing to do with the activities at the site, but may come from non-point sources, such as atmospheric deposition of mercury, or point sources within the range of the receptor species but outside of the study area.

Soil/sediment characteristics

Florida exhibits extreme variability in the types of soil and sediments, from very sandy substrate found in the south, central, and coastal portions of the State, to mucks found in the Everglades and other wetland environments, to clay deposits found in the northern and panhandle regions. Sediment characteristics greatly influence chemical fate and transport, bioavailability, bioaccumulation, and habitat quality. Specific factors to consider include total organic carbon (TOC), cationic exchange capacity, sulfate/sulfide content, grain size, porosity, and buffering capacity (carbonate Levels).

Climatological/Seasonal Influences

The climatological conditions in Florida are 1) unique to the United States (e.g., subtropical in the south of the State); and 2) vary greatly across the state (e.g., temperate in the north and panhandle). As a consequence of the climatic influences, Florida has a distinct wet and dry season and differences in types of rain events (convection in summer versus frontal in winter). These differences and fluctuations in precipitation and temperature have profound influences on : erosion, deposition, translocation and other factors influencing chemical fate and transport, water levels, and temperature (and therefore dissolved oxygen levels), habitat quality (including flow, and sedimentation), and estuarine salinity gradients.

Introduced, Listed and Migratory Species

Related to some degree to the unique climatological and seasonal characteristics of the State is the ability of the environment to sustain a variety of non-indigenous species. These species inhabit various ecosystem niches either as a result of natural migration patterns or the result of intentional and non-intentional introduction. Some of these species may not be considered valued ecological components, but nonetheless may be characterized as potential receptors. Likewise, given the significant influx of different species during migratory seasons, species that may ultimately be considered important or sensitive receptors may not be obvious from a one-time, one-season species survey. The presence of introduced and migratory species also results in certain competitive pressures upon indigenous, resident species that must be considered when quantifying adverse effects and ecological stressors. Some of our listed species (threatened, endangered, and species of special concern) also may be unfamiliar outside of Florida (e.g., sea turtles, manatees, Florida panthers, snowy egrets). Since individual-level risk considerations may apply for such species, it is important that risk assessors consider their biology and potential susceptibility.

Unique Ecosystems and Food Chains

Florida contains ecosystems unique to the United States. Southern Florida, for example, is a heterogeneous environment dominated by the watersheds of the Kissimmee River, Lake Okeechobee, and the Everglades, as well as by a diverse coastal environment. Within this region there are wetlands, uplands, coastal and marine waters and islands, including Florida Bay, Biscayne Bay, and other estuaries, and the Florida Keys and reef tract to the Dry Tortugas. Associated with these unique environments are unique species structures, community assemblages, and energy dynamics (including food chains). Food chain characteristics in Florida result in unusual circumstances that must be considered, especially with regard to potential bioaccumulation. In Florida, a potentially important aquatic mammal receptor, the herbivorous manatee, has an unusually short food chain, and thus, is subject to fewer biomagnification steps than other aquatic mammals. Conversely, Florida has some long-lived top predators (e.g., alligators and snapping turtles), that are subject to multiple biomagnification steps. Dose-response data are currently limited for reptiles, so they are frequently omitted from the risk assessment process, even when they represent the top predators at a site. The fact that such data gaps exist for some of Florida's top predators highlights the need for region-specific risk assessment tools.

4. UTILITY OF SCREENING NUMBERS FOR ECOLOGICAL RISK ASSESSMENT

Background

Risk-based screening values for chemical contaminants have become an integral part of the human health risk assessment process under FDEP rules pertaining to petroleum, dry cleaning, and Brownfields sites. Screening values are chemical concentrations in environmental media (soil, water, or sediment) below which, there is negligible risk to receptors exposed to those media. As more prescribed ERA guidelines are proposed, the need and potential application of screening values for ecological effects will be discussed (e.g., Simon, 1998, ASTM, in preparation).

An initial task of any risk assessment is to identify concentrations of chemicals that could potentially adversely affect the human health or the environment so that they may be evaluated more thoroughly. This is typically accomplished by comparing concentrations in environmental media with defensible screening values or concentrations determined by appropriate regulations. Screening values for human health are developed using conservative assumptions about the exposure of individuals to environmental media combined with conservative toxicity factors based on toxicological data. Development of these values is relatively straightforward because only one species (humans) is considered. The development of a broadly applicable set of screening values for ecological effects, however, is much more problematic. The diverse array of organisms and ecosystems in the State of Florida, not to mention the entire United States, makes it extremely difficult to generate screening concentrations that represent conservative estimates of negligible risk levels for a wide array of sensitive species. In the process of examining the utility of Environmental Screening Values (ESVs), one of the goals of the EcoRisk Focus Group is to identify the sources of the various ESVs and present some information on their development in order to provide a basis for determining their applicability in Florida. Sources of surface water and sediment ESVs have been available for several years. These include Florida-specific sources including surface water criteria contained in Chapter 62-302 F.A.C., and the Florida Sediment Quality Assessment Guidelines (SQAGs) (MacDonald, 1994). The USEPA Region 4 has also recommended ESVs for marine surface water, fresh surface water, and sediment (EPA, 1996).

The development of ESVs for soil or Ecological Soil Screening Levels (hereinafter, Eco-SSLs) has lagged far behind the development of ERA guidelines. Such numbers that do exist, such as those assembled from a variety of sources by the Westinghouse Savannah River Company for use at the Savannah River Site (Friday, 1998), are of limited use. Many of the numbers recommended in the Friday report are based upon detection limits or background, or they acknowledge low confidence values based on single species testing. In short, most of the values that ultimately are recommended by the Friday study have little ecological relevance or questionable applicability for ecological screening purposes. Recently, these numbers have been given wider circulation by U.S. EPA Region 4 staff (e.g., Simon, 1998). However, as a group, these values should not be considered usable unless independently verified.

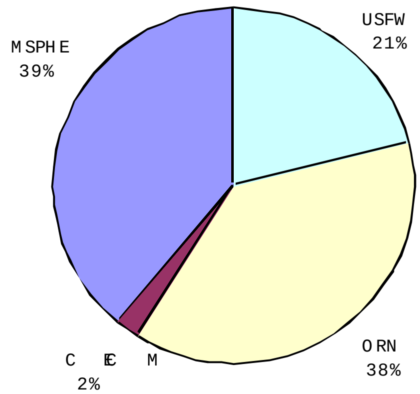
A creditable effort is currently underway to develop Eco-SSLs that has greater promise. A multi-stakeholder workgroup was organized by U.S. EPA's Office of Emergency and Remedial Response with members from EPA Headquarters and Regions 6 & 8, State regulatory agencies, industries, consulting firms, US Army, US Army Corps of Engineers, US Air Force, US Navy, DOE National Laboratories, U.S. and Canadian universities, and other international university and regulatory agency representatives. A discussion of Region IV screening values, including Draft Eco-SSLs (also referred to as "Recommended Ecological Screening Values for Soils" in the attachment to Simon, 1998), is provided below, followed by a discussion of EPA's Multi-stakeholder Workgroup process for the development of Eco-SSLs.

Draft EPA Region 4 Ecological Soil Screening Levels

The following information on the Region 4 Draft Eco-SSLs and their sources is taken largely from the Savannah River Site document (Friday, 1998).

As indicated above, the endorsement of Eco-SSLs by the USEPA has lagged behind that of ecological screening values for other environmental media. Existing Eco-SSLs are limited primarily to benchmarks issued by the US Fish and Wildlife Service (USFWS) (Beyer, 1990), Oak Ridge National Lab (ORNL) (Efroymson et al., 1997a,b), the Netherlands (MHSPE 1994, Crommentuijn et al., 1997), and Canada (CCME, 1997). The USFWS numbers (Beyer, 1990) are taken from the Dutch Ministry numbers issued in the 1980s (Richardson, 1987). From these various sources, Gary Friday of the Westinghouse Savannah River Company complied 132 "recommended" soil-screening values (Friday, 1998). The same 132 soil-screening values were then presented in draft form by Region 4 (EPA, 1998). These Eco-SSL values represent the lowest or most conservative value available from the sources cited above with three exceptions: (1) when a screening value was available from both the USFWS (Beyer, 1990) and Crommentuijn et al. (1997), the latter was used, (2) when target values (MHSPE, 1994) and maximum permissible concentrations (MPCs) (MHSPE, 1994) were available, the latter was used, and (3) if only an intervention value (MHSPE, 1994) was available, it was divided by a factor of 10 to derive the recommended Eco-SSL. The use of maximum permissible concentrations was restricted to metals, and is recommended because they are based on more recent data. Including the USFWS, Dutch values constituted 50% of the recommended values. ORNL benchmarks comprised 38% whereas the Canadian values comprised 2% (see figure below).

Distribution (%) of the Region IV Draft Eco-SSLs by source



Sources of the Draft Region 4 Eco-SSLs

U.S. Fish and Wildlife Service One of the earliest compilations of soil screening values was presented by Beyer (1990) of the USFWS. He listed over 200 contaminants from Japan, Netherlands, Canada, United States, and the former Soviet Union. Screening levels from the Netherlands were taken from the interim Dutch Soil Cleanup Act (Richardson, 1987) values issued in the 1980s. Three categories were identified by the Dutch: (1) category A refers to background concentrations in soil or detection limits, (2) category B refers to moderate soil contamination that requires additional study, and (3) category C refers to threshold values that require immediate cleanup.

Oak Ridge National Laboratory (ORNL) ORNL identified soil screening values specific to DOE sites for soil invertebrates and microbial processes (Efroymson et al., 1997a), and terrestrial plants (Efroymson et al., 1997b). The soil benchmarks for invertebrates were derived using NOAA's effects range-low (Long and Morgan, 1990) approach supported by information from field and laboratory studies, bibliographic databases, and the published literature. Assumptions, uncertainties, and how benchmarks were calculated are detailed in Efroymson et al. (1997a). Lowest Observed Adverse Effect Concentrations (LOAECs) were rank ordered and a value was selected that most closely approximated the 10th percentile of the distribution. If less than ten values were available, the lowest LOAEC was used. If ten or more values were available, the 10th percentile was used. Interpolation and the authors' expert judgement were used to derive some benchmarks (Efroymson et al., 1997 a,b). Because both natural soils and nutrient/mineral solutions have been used in toxicity testing, Efroymson et al. (1997b) presents screening benchmarks for terrestrial plants for both soil and soil solution. Values for plant benchmarks were derived in the same way that was used for invertebrates and microbial processes (Efroymson et al., 1997b).

Canadian Council of Ministers of the Environment (CCME) The Canadian protocol for deriving environmental soil quality guidelines (SQGs) takes into consideration levels of ecological protection, endpoints, availability of soil toxicity data, receptor arrays, and exposure pathways for four types of land use (CCME, 1996). In 1997, the CCME issued soil quality guidelines for 20 constituents (CCME, 1997). The guidelines were derived specifically for the protection of ecological receptors in the environment or for the protection of human health associated with agricultural, residential/parkland, commercial, and industrial land use types (CCME, 1997). The land use most closely associated with ecological resources was agricultural. Although the primary activity for this land use type is growing crops or livestock, it also includes agricultural lands that provide habitat for resident and transitory wildlife as well as native flora (CCME, 1997).

The 1997 SQGs were issued on a constituent-by-constituent basis after a comprehensive review of the physical/chemical characteristics, background levels in Canadian soils, toxicity and environmental fate, and behavior of each constituent were derived using toxicological data to determine the threshold level for key receptors. The derivation process for SQGs considers adverse effects from direct soil contact and from the ingestion of soil and food. Four approaches were used to evaluate contact with soil: (1) weight of evidence, (2) LOEC method, (3) median effects method, and (4) comparison with nutrient and energy cycling. The weight-of-evidence method, which is a modification of Long and Morgan (1990), estimates no adverse effects. For agricultural land use, the 25th percentile of the effects and no effects data distribution was chosen as the "no potential effects range" (NPER). An uncertainty factor was then applied to the NPER to give the "threshold effects concentration" (TEC). When the data were inadequate to perform a weight-of-evidence method, the TEC was derived by extrapolating from the lowest available LOAEC divided by an uncertainty factor. Thus, the TEC will lie somewhere below the lowest reported effect concentration. When LOEC values are unavailable, the TEC is derived using the median effects method. Here, the TEC is obtained by extrapolating from the lowest available EC_{50} or LC_{50} datum using an uncertainty factor ranging from five to ten. Thus, the TEC is estimated in the region of predominantly no effects in the data distribution. Once the TEC is calculated, it is compared to nutrient and energy cycling data for selected microbial processes. If the microbial value is less than the TEC, microbial nutrient and energy cycling processes may experience adverse effects at the TEC level. In this case, the geometric mean of the microbial and TEC values is selected as the SQG for soil contact. If the TEC is less than the microbial value, the TEC becomes the SQG. The procedure for deriving SQGs for ingestion of soil and food by grazing livestock and wildlife is only used for agricultural land use (CCME, 1997). This process is restricted to a herbivorous food chain, and considers the bioaccumulation of chemicals in plant tissue.

Several steps are required for the derivation of a SQG. First, species considered to be most at risk from ingesting soil and food are identified and a daily threshold effects dose is identified based on a minimum of three studies (e.g., two mammalian, one avian). Second, the daily threshold effects dose is calculated by dividing the lowest LOAEL by an uncertainty factor. Next, information is gathered including body weight, rate of soil ingestion, and rate of food ingestion for the most sensitive species as well as information on bioavailability and bioconcentration factor specific to the contaminant. This information is used to calculate the SQG in accordance with CCME (1996). Finally, the lower of the two values (soil contact versus ingestion) is used as the final SQG for agricultural (e.g. ecological) use.

Dutch Soil Quality Standards During the 1980s, the Dutch government issued three categories of soil quality values (i.e., A, B, and C). In 1994, the ABC benchmarks were replaced: (1) "A" values became "target values," (2) "B" values were replaced by the sum of the target value and intervention value divided by two, and (3) "C" values became "intervention values" (MHSPE, 1994). The target values indicate the soil quality required for sustainability or, expressed in terms of remedial policy, the soil quality required for the full restoration of the soil's functionality for human, animal, and plant life. Target values were based on standards for drinking water and surface waters. Values for heavy metals, arsenic and fluoride were derived from the analysis of field data from relatively pollution-free rural areas and aquatic sediments regarded as uncontaminated. The target values for soil were based on the target values for surface waters when scientifically possible. Intervention values, which apply to both terrestrial soil and to soil from the beds of rivers, lakes, etc. (i.e., sediments), indicate that the concentration levels of the contaminants in the soil above which the functionality of the soil for human, plant, and animal life is seriously impaired or threatened. Concentrations in excess of the intervention values correspond to serious contamination. These values are based on ecotoxicological effects that are quantified in terms of the concentrations in the soil at which 50% of the species actually (or potentially) occurring may undergo adverse effects. In 1997, the Dutch Ministry issued maximum permissible concentrations (MPCs) for 18 metals (Crommentuijn et al. 1997) using three methods. When NOAECs were available for at least four taxons, statistical extrapolation was used. When only LC_{50} or a few NOAECs were available, a modification of the EPA method was used. When no laboratory data were available, equilibrium partitioning was used to derive a benchmark value. The Dutch values are based on ecotoxicological effects that are quantified in terms of the concentrations at which 50% of the species and 50% of the microbial processes in the ecosystem are threatened or adversely affected.

Status of EPA's Multi-stakeholder Workgroup for the Development of Eco-SSLs
The Eco-SSL Workgroup was formed recognizing that there are no peer-reviewed values for Eco-SSLs, that costly literature searches are being repeated on a case-by-case basis, and that no national consistency exists. The mission and overall goals of the Eco-SSL Workgroup are presented below.

> Mission Statement: "Develop a set of generic, scientifically sound, ecologically based, soil screening levels that are protective of the terrestrial environment for up to 24 chemicals of concern; and methodologies and models that use site-specific exposure data to modify these screening levels. The screening levels and methodologies should be sufficiently specific and transparent to allow for consistent implementation by EPA and other Federal Agencies, States, and private parties at all Superfund sites."

Goals:

1. Include all interested stakeholders in developing the guidance.
2. Develop a list of national, generic, Eco-SSLs that are conservative, but balance protectiveness with reasonableness.
3. Provide a scientifically defensible process and exposure models that will use site-specific data to refine the list of chemicals of concern at individual sites.
4. Provide a process that can be implemented consistently at all sites by regulatory agencies and responsible parties.
5. Develop a mechanism for developing/funding new empirical exposure and toxicity data that can be used to modify the Eco-SSLs.

The Eco-SSL Workgroup, consisting of at least seven Task Groups, has made considerable progress in several areas including:

- development of literature search parameters and acceptance criteria;
- the incorporation of soil chemistry and chemical lability (availability, solubility, exchangeability) into a soil screening process;
- development of soil benchmark values for soil biota, plants & microorganisms;
- development/adaptation of soil ecotoxicity screening test methods;
- development of exposure models;
- selection of wildlife species representing 4 general trophic guilds (herbivore, omnivore, ground insectivore, carnivore);
- development of a method for derivation of wildlife toxicity reference values (TRVs) (including a scoring system to rank studies for a weight-of-evidence evaluation in deriving oral TRVs);
- development of a Wildlife Eco-SSL Model and application of the model in a tiered system.

Efforts of the Eco-SSL Workgroup will likely result in scientifically defensible Eco-SSLs. However, the usefulness of these numbers will be limited and not broadly applicable to all Florida Environments. Indeed, the success of their ambitious effort is in part dependent on keeping their scope very limited and focused. For example, under their working assumptions, the Eco-SSLs will be protective only of terrestrial species with risk derived from direct soil content. Florida is a water state. It is likely that most contaminated site ecological concerns will derive from transport along pathways leading to a water/wetlands environment.

It will take years to gather the toxicological data and develop benchmarks for the mammalian, avian, reptilian, invertebrate, plant and microbial Eco-SSLs envisioned to be protective of all terrestrial species. The approach taken by the EPA Multi-stakeholder Workgroup is commendable and should serve as a model for future attempts to develop Eco-SSLs for other types of environments. At this time or at any time in the near future, it is unlikely that useful Eco-SSLs will be available for application to Florida environments. To that end, however, we should begin to consider a strategy, based on the EPA Multi-stakeholder Workgroup model, to work toward the goal of developing Florida-specific Eco-SSLs.

Appropriate Use of Ecological Screening Values in the ERA Context

Frame of Reference An Ecological Risk Assessment (ERA) can be a costly and time-consuming exercise that requires the input from numerous professionals from a diverse range of vocations. Both the U.S. EPA and ASTM guidelines recommend that the ERA be conducted in a step-wise, or phased approach. Early in the ERA process (Phase 1) information is gathered to determine; the extent and type of contamination present, the types of media which are contaminated, possible exposure pathways which may exist, and likely receptor species.

Multiple lines of evidence are used to determine whether unacceptable ecological risk is predicted for the site to warrant the ERA continuing to the next phase. One of those lines of evidence is the comparison of water, soil, and sediment contaminant concentrations to screening values. These screening values have been derived by several methods, including compound specific toxicity tests, bioassays conducted with contaminated media collected from impacted areas, and full life-cycle assessments.

The utility of screening values becomes obvious when one considers the cost of conducting toxicity tests on a site-specific basis as part of the screening ERA process. While the bioavailability of a contaminant can change drastically with the qualities of the media in which they reside, it would be an unreasonable burden to expect each facility to conduct a suite of toxicity tests so early in the risk assessment process. Screening values, based on effects data developed by a qualified eco-toxicologist, provide a frame of reference in tiers 1 and 2 of the ERA. The Florida coastal sediment screening values (McDonald, 1994) were derived using the results of bioassays performed with numerous contaminated sediments. While it is likely that some of the sediments tested would have had considerably different physical and chemical makeup than the ERA site, some of them would probably have been similar, so that the screening values derived for each Contaminant of Possible Concern (COPC) would reflect an average for the range of conditions which were tested. The risk assessor can then compare the concentrations of COPC's detected in the sediment at the site to the screening values for a quick and inexpensive gauge of risk. If, for example, the on-site contamination is an order of magnitude higher than the screening values, this would indicate that there is a potential for possible risk and the risk assessment process may need to proceed to the next phase. On the other hand, if the on-site contamination is an order of magnitude lower than the screening values, the risk assessment process would not need to continue to the next phase, given that the other lines of evidence indicate no adverse affect.

Appropriate Use of Screening Values vs. Site-specific Cleanup Goals   Screening values should only be used in the first tier of an ERA to estimate risk associated with levels of contamination at a specific site (after visiting the site to determine the potential ecosystem(s) at risk, and to look for overt evidence of adverse effects). They should not be used as clean-up goals unless this action is elected by the owner/operator of the site in lieu of proceeding into higher tiers of the ERA. Should site-specific clean-up goals need to be derived in the second tier of the ERA, the ERA process will have, by design, proceeded far enough along to provide sufficient site data to establish these site-specific goals. If the ERA guidelines are followed, one cannot get to the management decision point that site-specific clean-up goals are needed, without having conducted enough site sampling and testing to provide adequate data to define those goals.

Because some screening values have been derived from bioassays using media that contained multiple contaminants and others were derived using single compound toxicity tests, there is a possibility that a screening value could be either under or over protective for a specific site if used as a clean-up goal. The cost of under protecting our environment is fairly obvious. What may be less obvious is the cost of over protection. The monetary cost of setting a clean-up goal too low can increase dramatically within only a few parts-per-billion.

In conclusion, generic soil screening numbers can be useful in the initial screening phase of an ERA. If the screening numbers are exceeded, or if other lines of evidence suggest that the environment is at risk, site data will be needed to develop site-specific cleanup goals that are adequate to ensure the environment is being adequately protected.

Relevance to Florida Ecosystems

The ecological status of the State of Florida is unique and complex, and therefore provides a significant challenge to developing a single set of Eco-SSLs that are applicable to the entire range of ecosystems. Florida bridges the tropics and temperate zone, its geological formations provide a mosaic of habitats that support a variety of organisms, the climate is humid, and as a peninsula contains both island and continental biogeographies (Meyers and Ewel, 1990). A wide variety of soils occur in the state, and generally range from loamy soils in the panhandle, to poorly drained sandy soils in the flatwoods, to excessively drained thick sands in the sandhill and scrub areas, to peat and muck soils around the Everglades, to limestone soils in southern Florida. The wide variety of natural habitats throughout the state includes coastal strand, dry prairies, pine flatwoods, sand pine scrub, longleaf pine forests, mixed hardwood-pine, hardwood hammocks, tropical hammocks, coastal marshes, freshwater marshes, and cypress, hardwood, and mangrove swamps. The common terrestrial and aquatic life associated with these and other habitats are also unique and diverse. Florida is host to a variety of threatened and endangered plant and animal species, including 470 State listed and 104 Federally listed species.

It would be difficult to maintain relevance of a standard set Eco-SSLs protective of all terrestrial wildlife in Florida given such a diversity of environmental conditions, natural habitats, and species. An ecologist must realize that soil and wildlife receptor characteristics play a large part in toxicity. For example, the various types of soils in the state have extreme ranges in saturation and organic carbon content, which can affect the bioavailability of some environmental contaminants. In addition, Eco-SSLs are typically based on total contaminant concentrations that are either rigorously extracted in the lab with a solvent or determined from nominal concentrations added to soil, resulting in concentrations that may not accurately represent concentrations exposed to the test organisms. There is a great deal of uncertainty regarding the relevance of Eco-SSLs since bioavailability is difficult to determine.

The test organism species used in developing Eco-SSLs should be considered relative to their actual occurrence within the state of Florida. This may not be practical at a screening level given the limited availability of soil toxicity data, however toxicity data will be more relevant to Florida environments if indigenous species are considered.

5. VALUE/FUNCTION OF EXPERT RESOURCES FOR ERA DESIGN/REVIEW

The establishment of a detailed protocol for conducting ERAs provides a standardized framework to assist regulators and managers in evaluating the application of ERA to a particular site. It should never be allowed to function as a simplification that circumvents professional judgement. In more complex ERAs, therefore, the adequacy of treatment through each step of the ERA protocol requires the review of a professional or professionals with the qualifications to make determinations of completeness as in the identification of contaminants or activities of potential concern, identification of ecosystems at risk, selection of surrogate species, and selection of assessment and measurement endpoints. Owing to the natural diversity of the Florida environment, an ERA addressing a single site often will require the attention of more than a single discipline. Although an ecologist or environmental toxicologist typically leads an ERA, experts used in the conduct of an ERA may include one or more additional discipline experts. The following list includes some of the more common of these disciplines:

- wetlands ecologist;
- uplands ecologist;
- aquatic ecologist;
- botanist;
- ornithologist;
- herpetologist;
- mammalogist;
- wildlife toxicologist;
- aquatic toxicologist;
- economist;
- environmental engineer;
- statistician.

The need for multi-disciplinary input and review for ERAs can be substantially reduced by the implementation of a Florida-specific, step-by-step, tiered ERA protocol. In a subset of ERAs, however, exceedance of ESVs or EcoSSLs, or the lack of applicable default values for certain stressors or populations, will result in decisions to conduct Tier 2 or Tier 3 assessments. It is at the Tier 3 level, where a plan of study is to be developed and implemented, that there will be the greatest need for expert advise and assistance in both design and review phases.

Although an experienced risk assessor performing an ERA under contract will typically recruit such experts as are needed, there may also be a need for appropriate regulatory and stakeholder oversight and review. The EcoRisk Focus Group recommends that DEP follow, in general, the guidelines on the selection of scientific and technical assistance set forth in Section 6 of the *Guidelines for Risk Analyses Undertaken in Conjunction with Rule-Making* submitted by the

Florida Risk-Based Priority Council in December 1996. This can be done in the context of a Science Advisory Board as the Council had envisioned, or independently by the Department, by establishing an ERA-specific list of experts. Such experts should be recruited from State and private sources across Florida, although expertise from outside of Florida should not be excluded. The latter may be necessary to avoid conflict of interests, particularly in cases of emotional local initiatives.

6. RECOMMENDATIONS

On 1 Oct 1998, the Ecological Risk (EcoRisk) Focus Group provided the following principal recommendation to the FDEP Contaminated Soils Forum (CSF):

1. **Develop Florida-specific ecological risk assessment guidelines for contaminated soils that use, as a framework or point of departure, the USEPA Guidelines for Ecological Risk Assessment.**

At the June 1999 CSF meeting, the EcoRisk Focus Group reported that it was preparing a Position Paper to support its principal recommendation to develop Florida-specific EcoRisk guidelines. At the February 2000 CSF meeting, a status report on the Position Paper added the following draft recommendations, all relating to Ecological Soil Screening Levels, or EcoSSLs:

2. **Before making a blanket endorsement of the Region IV Recommended Eco-SSLs, FDEP should carefully consider their applicability to the State of Florida.**

3. **Eco-SSLs in Florida should be based on ecological effects data for terrestrial species known to occur within the state. Critical data gaps, such as reptilian dose-response data, need to be filled in order to make the ERA guidelines more protective of Florida ecosystems.**

4. **Eco-SSLs should consider the issue of bioavailability associated with the variable soil characteristics throughout the state.**

5. **Eco-SSLs should not be adopted by Florida regulatory agencies prior to the adoption of a tiered ERA framework (i.e., an EcoRBCA).**

6. **Eco-SSLs should be used during the screening-level risk assessment process as one of several lines of evidence. They should not be used as clean-up goals unless elected to do so by the owner/operator of the site in lieu of proceeding into higher tiers of the ERA.**

7. REFERENCES

(TO BE ADDED LATER)

8. APPENDIX

Florida Ecosystem Specificity

The sensitivity of Florida's numerous ecosystems along with its dynamic population makes ecorisk management a site specific process. This situation is clearly demonstrated by the following description of the environmental conditions facing south Florida:

South Florida, in its natural state contains a large number of water bodies as well as an extensive coast line. The warm, humid climate (average yearly rainfall ranges from 53-60 inches) supports a wide variety of tropical vegetation, agricultural crops, wildlife and wetlands. The soils are for the most part low in organic content and are either silica or carbonate. The water table is high and there is constant interaction between the surface water and groundwater. The aquifer is relatively permeable and unconfined, leaving it especially vulnerable to pollution. South Florida is drained by a series of canals that empty into Florida Bay, part of the Everglades National Park and home to a variety of sport fish and shellfish.

The increasing human population, which has settled mostly along the east and southern coasts, adds a burden to the water resources and encroaches on the habitat of many of Florida's rare wildlife species. Agricultural practices and the growing entertainment and tourist industries consume resources while waste migrates into nearby water bodies and wetlands. International ports are gateways to additional ecosystem stressors in the forms of exotic species of plants, pests and diseases as well as petroleum leaks and fumes, metallic debris and human waste.

Pathway Analysis

The pathway analysis consists of the technical evaluation of available data on potential adverse effects caused by the concentration of stressors on the site. The analysis is a tier process to determine if further ecological evaluation is unnecessary or additional data should be obtained for site-specific conditions. Examples of ecological impacts of concern include: unacceptable reductions in the population of locally sensitive, threatened or endangered species; reduced lifespan, growth or reproductive capabilities; reduced diversity and habitat quality.

The Florida Department of Environmental Protection (FDEP) utilizes the process of pathway analysis on projects related to contaminated sites. Stressors of concern are the site specific contaminants. Pathway analysis should include the toxicity and physical-chemical characteristics of individual contaminants, their cumulative effects and interactions with the site-specific environmental conditions (soil type, hydrology, water chemistry, etc). Currently FDEP utilizes guidance from EPA's Region 4 Surface Water and Sediment Screening Values, the Florida Sediment Quality Assessment Guidelines and the soil screening values compiled by Westinghouse Savannah River Company. Because of the conservative nature of these values, only a few compounds pass the preliminary phase of the risk assessment. An example of the ERA process is the Port Everglades Oil Terminal Aquatic Toxicology and Ecological Studies (flowchart attached).

At this time, the Florida Department of Agriculture and Consumer Services (FDACS) does not have a procedure for consistent and comprehensive risk assessment; consequently, FDACS relies on the EPA OPP Ecological Risk Assessment. However, FDACS in accordance with the Florida Pesticide Registration Guidelines can obtain data regarding ecological effects on non-target species on a case-by-case basis. These effects data are compared to the environmental fate and potential exposure for pesticides under Florida conditions.

Surrogate Species

Limited data is available on sensitive species that represent wildlife at the national and state levels. For this reason, EPA recommends use of surrogate species in laboratory toxicity testing. Data obtained in these tests are extrapolated to evaluate potential effects to organisms present on the site. At the end, the hazard quotient (HQ) is calculated using a hypothetical dose which organisms at the site are exposed to, divided by a toxicological value (LC50, NOEC). If the HQ is higher than 1, it is assumed that adverse effects are possible. A number of ecological levels of concern (LOCs) have been established by EPA for different endpoints to facilitate the decision-making process. The problem is, all of the numbers used to get to this point are not measured values. The majority of the numbers are based upon data derived for other species, under different conditions.

Examples of Florida-Specific Ecorisk Assessments

An application of EPA's Ecological Risk Assessment Framework in Florida, was carried out by a group of national scientists under the leadership of Dr. Mark Harwell, University of Miami, Miami, Florida. The name of the project was COSAP (Comparative Oil/Orimulsion Spill Assessment Program). This project was developed to apply state of the art ERA methods to a prospective assessment of accidental fuel spills in the Tampa Bay ecosystems.

COSAP was designed to integrate toxicological studies, microcosm and field tests, fuel chemical characterization information, and environmental fate and transport modeling into a comparative ecological risk assessment. The organizing principles of this ERA were consistent with EPA's published framework. The results of this study were intended to provide a more complete scientific foundation for agency review and public response concerning potential environmental effects of transporting fuels in the Tampa Bay system. The ERA results were used to provide input to management options in order to minimize the probability of spill occurrence, the size of the spill, and the potential for ecological damage of an accidental fuel spill. In the unlikely event of an actual major spill, the ERA provided a scientific basis for prioritizing habitat protection and spill response. Although the geographic focus of COSAP was on Tampa Bay, this ERA approach is applicable to other coastal estuarine areas.

The results of this ERA have been presented at the Society of Environmental Toxicology and Chemistry (SETAC) and were successfully used as the scientific basis during Administrative Hearings in Florida.

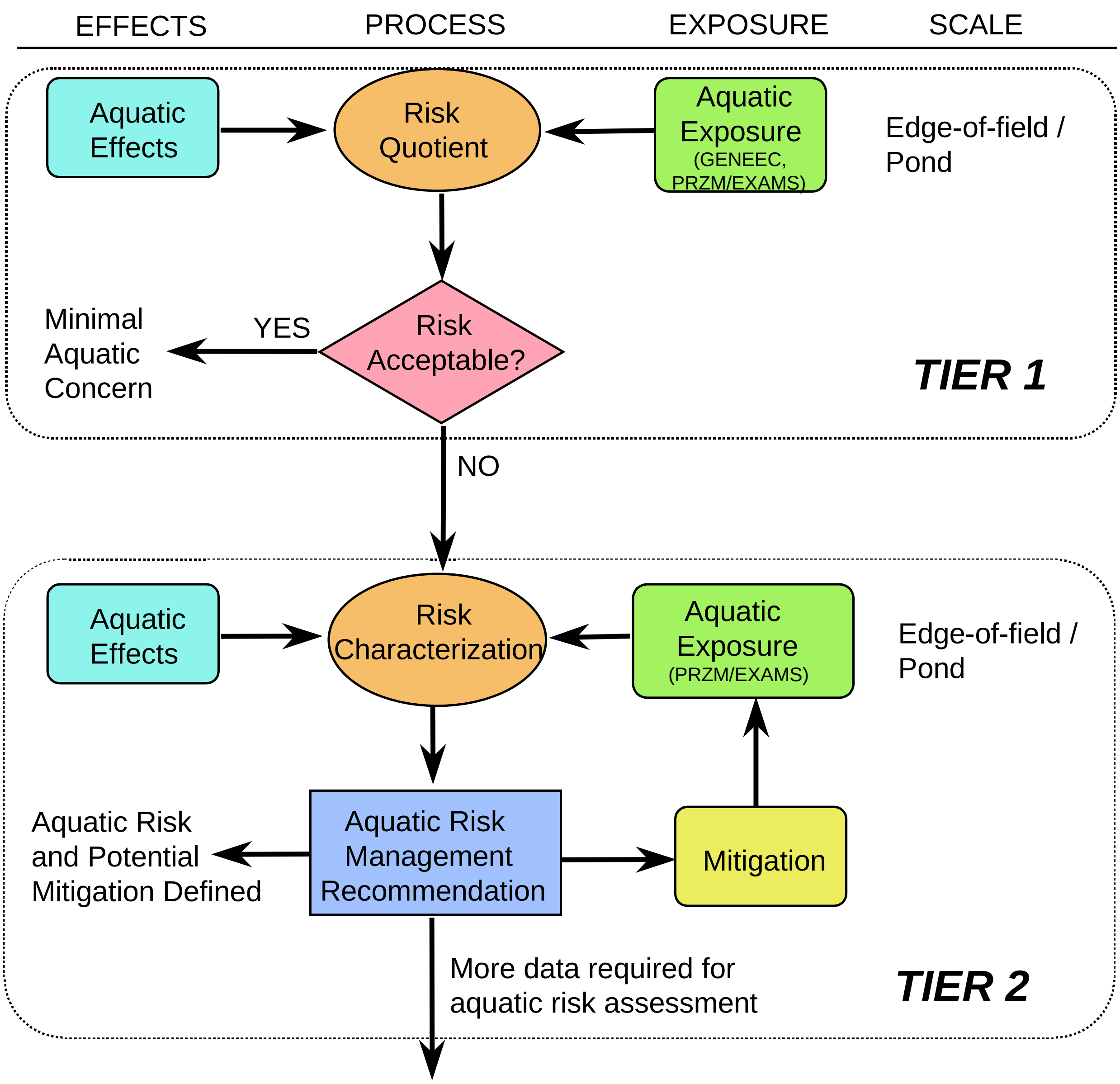
A streamlined, site-specific process for ERA is being applied at Eglin Air Force Base. Some components of the ERA process that are being considered for some level of standardization include: assessment and measurement endpoints, development of toxicity reference values, exposure models (exposure point concentrations, bioaccumulation models, etc.) and biological assessment tests (toxicity tests, bioaccumulation assays, community evaluations, etc.).

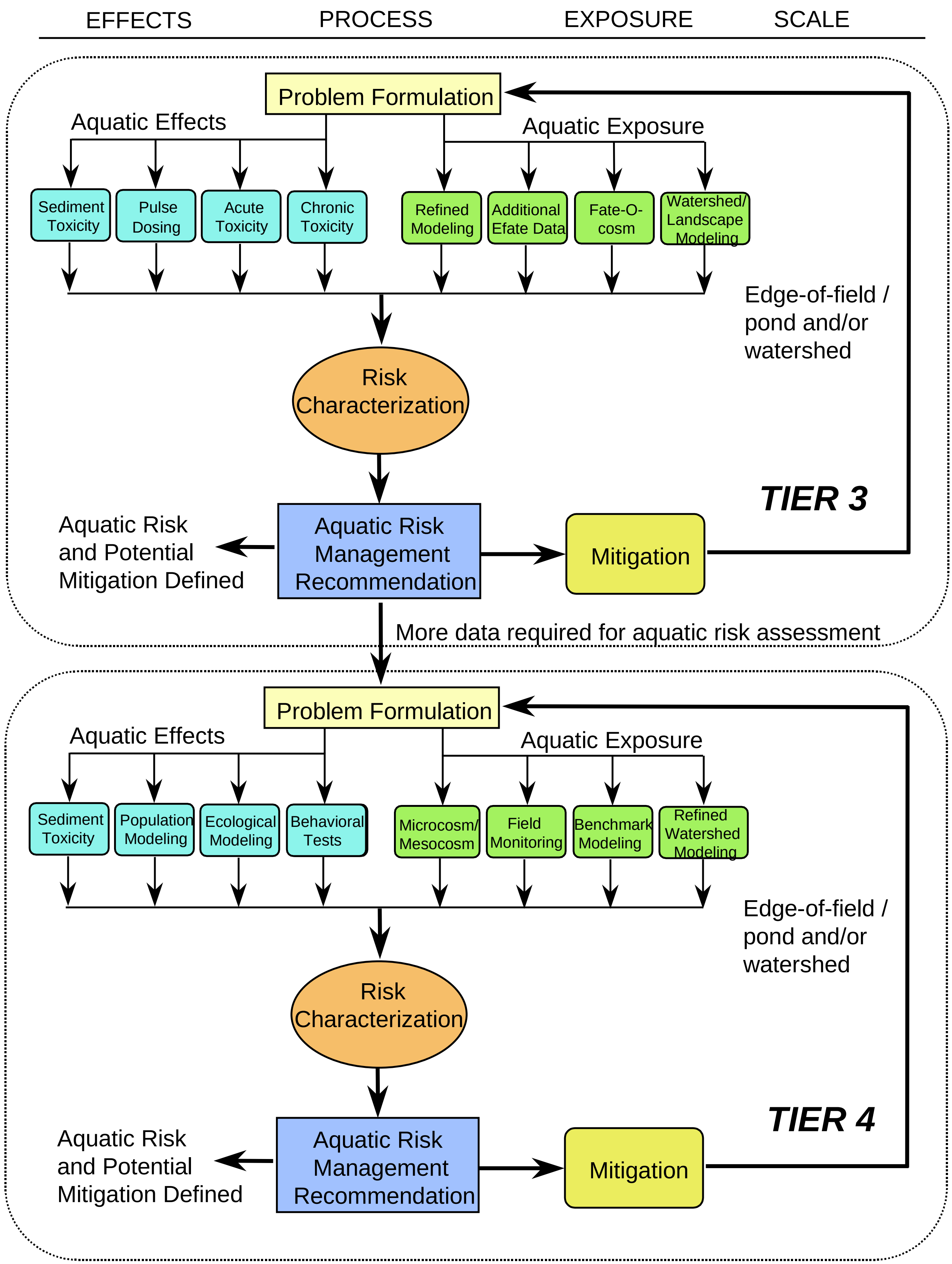
FDEP has reviewed several ERAs developed for hazardous waste and petroleum contaminated sites. Examples include the Port Everglades Oil Terminal (see Attachment 1), Sapp Battery Superfund site, United Technologies Corp/Pratt & Whitney Facility and Kaiser Aluminum and Chemical Corp. A major goal of the review process for these ERAs was to ensure that the ecological risks identified during the assessment were pertinent to each individual site and were being evaluated in an appropriate manner.

The Florida Department of Agriculture and Consumer Services (FDACS) has also reviewed a number of ecological risk assessments for pesticides registration conducted by EPA-OPP, pesticide industry, and consultants. FDACS has participated in the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) recommended by the Scientific Advisor Committee of EPA. The Ecological Committee was charged with conducting a primary review of the current assessment process, and developing new tools and methodologies (see Attachment 2). In addition, the Committee identified additional methods as well as developmental and validation needs to ensure that the assessment process provides a sound scientific basis to support environmental decisions. Their conclusions, recommendations and peer review comments were summarized in the following homepage: http://www.epa.gov/oppefed1/ecorisk/ In addition, EPA has developed a plan for the implementation of probabilistic risk assessment for the evaluation of the potential risk to the environment from pesticide exposure. This information has been posted at http://www.epa.gov.scipoly/sap/0405agen.htm.

ATTACHMENT 1

Aquatic Risk Assessment Process




EFFECTS
PROCESS
EXPOSURE
SCALE
Problem Formulation
Aquatic Effects
Aquatic Exposure
Sediment Toxicity
Pulse Dosing
Acute Toxicity
Chronic Toxicity
Refined Modeling
Additional Efate Data
Fate-O-cosm
Watershed/ Landscape Modeling
Edge-of-field / pond and/or watershed
Risk Characterization
TIER 3
Aquatic Risk and Potential Mitigation Defined
Aquatic Risk Management Recommendation
Mitigation
More data required for aquatic risk assessment
Problem Formulation
Aquatic Effects
Aquatic Exposure
Sediment Toxicity
Population Modeling
Ecological Modeling
Behavioral Tests
Microcosm/ Mesocosm
Field Monitoring
Benchmark Modeling
Refined Watershed Modeling
Edge-of-field / pond and/or watershed
Risk Characterization
TIER 4
Aquatic Risk and Potential Mitigation Defined
Aquatic Risk Management Recommendation
Mitigation