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Generic Assessment Endpoints for Ecological Risk Assessments

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PREFACE

Ecological risk assessment is a process for evaluating the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. A critical early step in conducting an ecological risk assessment is deciding which aspects of the environment will be selected for evaluation. This step is often challenging because of the remarkable diversity of species, ecological communities, and ecological functions from which those involved in risk assessment can choose and because of statutory ambiguity regarding what is to be protected. The purpose of this document is to build on existing EPA guidance and experience to assist those who are involved in ecological risk assessments in carrying out this step, which is termed "selecting assessment endpoints" in the parlance of ecological risk assessment. The document describes a set of endpoints, known as Generic Ecological Assessment Endpoints, that can be considered and adapted for specific ecological risk assessments.

This document was prepared by a Technical Panel under the auspices of EPA's Risk Assessment Forum. The Risk Assessment Forum was established to promote scientific consensus on risk assessment issues and to incorporate this consensus into appropriate risk assessment guidance. To accomplish this, the Forum assembles experts from throughout EPA in a formal process to study and report on these issues from an Agency-wide perspective. The document reflects the Forum's long-standing commitment to advancing ecological risk assessment and is intended to supplement the use of the Forum's *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a). Following the publication of the *Guidelines*, the Forum surveyed ecological risk assessors from across the Agency to prioritize and select risk assessment topics for further development. Additional guidance on assessment endpoints emerged as one of the highest priority topics. A subsequent EPA colloquium sponsored by the Forum to consider high priorities from the survey identified a need for Agency-wide generic ecological assessment endpoints and directly led to the development of this document.

A goal of this document is to enhance the application of ecological risk assessment at EPA, thereby improving the scientific basis for ecological risk management decisions. However, the document is not a regulation nor is it intended to substitute for federal regulations. It

describes general principles and is not prescriptive. Rather, it is intended to be a useful starting point that is flexible enough to be applied to many different types of ecological risk assessments. Risk assessors and risk managers at EPA are the primary audience; the document also may be useful to others outside the Agency.

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1. INTRODUCTION: PURPOSE OF THIS DOCUMENT

Assessment endpoints are used in the process of ecological risk assessment (U.S. EPA, 1998a). They represent valued attributes of ecological entities upon which risk-management actions are focused. Since not all organisms or ecosystem features can be studied, regulatory agencies and other risk managers must choose from among many candidates. A recommendation for improving ecological risk assessment and management within EPA has been to develop a set of generic assessment endpoints that are based on environmental legislation, EPA's policies and precedents, and which cover EPA's range of concerns for the protection of ecological resources and functions.

The Guidelines for Ecological Risk Assessment provide three selection criteria for assessment endpoints – ecological relevance, susceptibility (exposure plus sensitivity), and relevance to management goals. Assessment endpoints are developed during the Problem Formulation phase of ecological risk assessment, based on input from the Planning process (U.S. EPA, 1998a). This document presents a set of Generic Ecological Assessment Endpoints (GEAEs) to provide examples of endpoints applicable to a wide variety of assessment scenarios and guidance for using these GEAEs to develop robust, assessment-specific endpoints.

1.1. Definitions

An assessment endpoint is defined as "an explicit expression of the environmental value to be protected, operationally defined as an ecological entity and its attributes" (U.S. EPA, 1998a). For example, an ecological entity might be an important fish species (e.g., coho salmon), with its attributes being fecundity and recruitment. GEAEs are endpoints that are applicable to a wide range of ecological risk assessments (ERAs) because they reflect the programmatic goals of the Agency, are applicable to addressing a wide array of environmental issues, and may be estimated using existing assessment tools. Selecting appropriate assessment endpoints is a critical step in ensuring that an assessment will be useful to risk managers in making informed and scientifically defensible environmental decisions.

Published generic endpoints are available for regional assessments (Suter, 1990), population assessments (Suter and Donker, 1993), assessments of hazardous waste combustors (U.S. EPA, 1999a) and contaminated sites in Alaska (Alaska Department of Environmental

Conservation, 2000). In addition, examples of ecological assessment endpoints evaluated within certain EPA programs have been highlighted in prior EPA documents (U.S. EPA, 1994, 1997a, 1997c, and 1998a). These examples are presented, as appropriate, in Appendix A.

GEAEs are not a complete list of what EPA protects, or by exclusion, what it does not protect. They are not specifically defined for every conceivable case, and some ad hoc elaboration by users is expected (Section 3.3). Furthermore, they are not goals or objectives, but should be related to them, when known. For example, a generic endpoint could be created for endangered species, but the specific species of concern would be defined during problem formulation and attributes of the species may be selected to fulfill the regulatory mandates under the Endangered Species Act.

Text Box 1-1. Overlap of GEAEs.

GEAEs are not necessarily discrete, mutually exclusive concepts. As such, there may be some redundancy in a set of GEAEs. For example, the condition of an ecological entity at one level of biological organization (e.g., organism) may influence the condition of that and interdependent entities at higher levels of biological organization (e.g., population or community). Also, a large change in one attribute may overlap with another attribute as in the case of abundance and extirpation. Furthermore, GEAEs may relate to more than one environmental value (Appendix B), which may be reflected in multiple statutes, regulations, public policies, or public perceptions (Appendix A).

1.2. Potential Uses for a Set of Generic Endpoints

The initial set of generic endpoints proposed in Section 2 of this document should be useful for risk assessors and managers involved in planning and performing ecological risk assessments within various EPA programs and offices. In particular, this document can be consulted during the problem formulation stage of ecological risk assessments to assist in developing assessment endpoints that are useful in EPA's decision making process, practical to measure and well defined. In addition, the specific environmental laws, precedents and other polices that provide the supporting information for this initial set of generic endpoints in Appendix A of this document should be equally useful in supporting assessment-specific

endpoints.

Individual programs may have specific uses for these generic endpoints beyond ecological risk assessments. For example, the water quality management program could find this information useful for refining designated aquatic life uses in State and Tribal water quality standards, developing guidance for consistent and environmentally relevant monitoring programs, and in interpreting and implementing narrative water quality standards. For example, this initial set of generic endpoints could be used to establish an appropriate target for a Total Maximum Daily Load for a waterbody that has been listed for non-support of aquatic life, but where there are no numeric biocriteria in the state's water quality standard. This initial set of generic endpoints could be used to assist in the selection of water quality indicators or to target attributes for those ecological entities.

Ultimately, generic assessment endpoints could have several other uses within the Agency. Briefly, those uses, described more fully by Suter (2000), are:

- To give risk managers a basis for action similar to commonly employed human health endpoints.
- To provide a threshold for prevention of environmental degradation, by ensuring that certain values are at least considered for assessment.
- To comply with legal requirements.
- To improve the consistency of ecological risk assessment and management.
- As models for site-, action-, or region-specific endpoints.
- For screening-level ecological risk assessments, which may need to rapidly develop endpoints with little input.
- To provide clear direction for the development of methods and models.
 - To facilitate communication with stakeholders, by creating a set of familiar and clear generic endpoints.
 - To reduce the time and effort required to conduct assessments.

It is important to emphasize that the generic assessment endpoints are not mandatory or applicable to all assessments. This particular set of generic endpoints will be used only when and where they are relevant. It is likely that in most ecological risk assessments, generic assessment endpoints will be supplemented by more specific endpoints relevant to the stressor or ecosystem being assessed. Over time, EPA anticipates that this initial set of generic ecological assessment

endpoints will be periodically reviewed, modified, and supplemented as experience is gained in how to apply and interpret them in a variety of natural conditions and regulatory contexts (Section 4).

1.3. Criteria for GEAEs

EPA has provided criteria for developing assessment-specific assessment endpoints (U.S. EPA, 1998a, Section 3.3.2). They are: ecological relevance, susceptibility, and relevance to management goals. Ecological relevance pertains to the role of the endpoint entity in the ecosystem and therefore depends on the ecological context. Susceptibility pertains to the sensitivity of the endpoint to the stressor relative to its potential exposure and therefore depends on the identity of the stressor and the mode of exposure. Relevance to management goals pertains to the goals set by the risk manager and therefore depends on the societal, legal and regulatory context of the risk management decision as well as the preferences of the individual risk manager and of influential stakeholders. Hence, these situation-specific criteria are applied whenever GEAEs are implemented in individual assessments (Section 3). They are not, however, useful for evaluating the broad applicability of potential GEAEs. Rather, the GEAEs presented in this report were evaluated against the following criteria, which are independent of specific assessment situations:

- 1. Generally useful in EPA's decision making process. This utility may be indicated by the language found in statutes, treaties, and regulations that the Agency implements or with which it must comply. Judicial decisions also indicate how the values defined by statutes may be translated into generically useful endpoints. In addition, Agency guidance, guidelines, protocols and official memoranda indicate potentially useful endpoints. Finally, various actions of the Agency that were based on ecological protection (i.e., Agency precedents) provide evidence of general utility for GEAEs. These various sources of environmental policy are summarized in U.S. EPA (1994, 1997a). Additional sources have been identified by the authors of this document (Appendix A). Note that the reliance on available policy and precedent in this document should not suggest a similar restraint on risk assessors and managers in practice. EPA has a broad mandate to protect the environment which can support the use of novel endpoints in individual assessments (Section 3, 4).
- 2. Practical. Methods used to estimate risks to the endpoint entity and attribute should be

- available and reasonably practicable in various assessment contexts. This requires methods to directly measure or observe the endpoint's attributes or methods to estimate them using a combination of measurements and models. However, this does not require that a GEAE be useful for all situations. Some GEAEs will not be implementable for some taxa or ecosystems, but they should be practical in many situations.
 - **3. Well defined.** At a minimum, GEAEs must include an entity and an attribute of that entity (U.S. EPA, 1998a). The entity and attribute should be clearly explained, so that they are understandable to the public and decision makers without being ambiguous to environmental scientists. A definition should be supported by a clear explanation of the endpoint's relationship to the Agency's management goals and programmatic applications.

Support for the first two criteria (usefulness and practicality) is presented in Appendix A and summarized in Table 2.2. The third criterion (that GEAEs be well defined) is supported by the definitions in Section 2.1, supplemented by the background in Appendix A.

2. EPA'S INITIAL SET OF GENERIC ECOLOGICAL ASSESSMENT ENDPOINTS

This chapter presents EPA's initial set of Generic Ecological Assessment Endpoints to be considered for the uses described in Section 1.2. As stated before, these GEAEs are not exhaustive or mandatory, but are provided to assist EPA programs, researchers and decision makers involved in protecting the Nation's ecological resources as described in Section 3. The entities and properties comprising the initial set of GEAEs is presented in Table 2.1. They are defined in Section 2.1, and the basis for the terms assessment community and assessment population, which are used in the definitions, is explained in Section 2.2. Information concerning laws, regulations and precedents, which support the selection and use of these GEAEs is summarized in Table 2.2 and presented in Appendix A. A general discussion of the values that are related to these GEAEs is presented in Appendix B. Other potential GEAEs that were promising, but did not fully meet the criteria in Section 1.3, are discussed in Section 4.

Table 2.1. Generic Ecological Assessment Endpoints

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3	Entity	Attribute	
4	Organisms	kills (mass mortality, conspicuous mortality)	
5 6	(in an assessment population or community)	gross anomalies	
		survival, fecundity, growth (This endpoint applies particularly to threatened and endangered species, marine mammals, bald and golden eagles, and migratory birds.)	
		avoidance	
7	Assessment population	extirpation	
		abundance	
		production	
8	Assessment community or assemblage	species richness	
		abundance	
9	Plant assemblage	production	
10	Wetlands	area	
		function	
11	Coral reefs	area	
		species richness	
12	Critical habitat for threatened or	area	
13	endangered species	quality	
14	Endangered/Rare ecosystem types	area of the type (direct destruction or change to another type)	
15	Aquatic ecosystems	physical structure	
16	Special places	ecological properties that make them special and legally protected properties	

2 3 in pragmatic terms. For example, the generic endpoint "population extirpation" is an extreme 4 case of the generic endpoint "population abundance." However, the extirpation of a population 5 is qualitatively different from a simple percentage loss of abundance. The implications of 6 reductions in fish abundance mean a loss of fishing income, but extirpation means an end to the 7 fishery. In addition, it is typically much easier to establish that extirpation has occurred (e.g., the 8 fish are no longer caught) or will occur (e.g., the trout stream will be drowned in a reservoir, or 9 the pH will be far beyond the lethal level), than to establish that some percentage reduction in 10 abundance has occurred or will occur. This difference in implications for the assessment and 11 decision making processes justify treating extirpation and abundance as different endpoints. 12 Similarly, kills of organisms have short-term effects on population abundance, but do not 13 necessarily have a significant or long-term effect on abundance. The methods for determining 14 that a kill has occurred are much simpler than determining that the abundance of a population has 15 changed. In addition, the effect of a kill on the public (such as concerns over odor and disease) is 16 not necessarily related to effects on the populations involved. For example, public response to a 17 fish kill may not be related to the ability of the fish populations involved to recover rapidly.

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2.1. Definitions of the GEAEs

assessment approaches and management implications.

Organisms – Organisms are the most distinct units of ecology, and attributes of organisms have been the focus of the U.S. EPA's efforts to protect the environment. However, the use of organisms as endpoints does not necessarily imply that each individual is protected. Rather, organisms are a level of biological organization with certain attributes which may be the basis of management decisions.

Therefore, kills are distinct from both population abundance and extirpation in terms of

These GEAEs are not always biologically distinct, but the apparent overlaps are justified

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1. Kills – An event or multiple events involving numerous mortalities of organisms within an assessment population or community. Kills may also be referred to as mass mortality or conspicuous mortality. These events may be repeated and widespread, as in bird kills due to pesticide applications; repeated at a location, as in fish kills due to repeated treatment failures; or a single event, as in a seabird kill due to an oil spill. They

1 may involve one or more species. 2 **2. Gross Anomalies** – Deformities, lesions, or tumors in animals; death or necrosis of 3 plant leaves; or other overt physical injuries of organisms within an assessment population or community. The occurrence of these injuries may involve one or more 4 5 species. 6 3. Survival, Fecundity, or Growth – Survival (which may be reduced by direct lethality 7 or by sublethal effects that diminish survival probabilities), fecundity (the production of viable young), and growth (increased mass or length) of some proportion of the animals 8 9 or plants in an assessment population or community are the basic attributes of concern for 10 nonhuman organisms. Species that are protected at the organism level by statute include: 11 a) Endangered and threatened species (i.e., those listed by the U.S. Fish and Wildlife 12 Service or the National Marine Fisheries Service as in danger of extinction under the 13 Endangered Species Act), b) Marine mammals (i.e., whales and porpoises, seals, sea 14 lions, and walruses, polar bears, sea otters, and manatees) which are protected by the 15 Marine Mammal Protection Act, c) Bald eagles and golden eagles, which are protected by 16 the Bald Eagle Protection Act, and d) nearly all birds in the U.S., including their eggs and 17 nests, which are protected by the Migratory Bird Treaty Act. 18 **4. Avoidance** – Withdrawal of members of an assessment population from an area. 19 **Assessment Population** – A group of conspecific organisms occupying an area that has been 20 defined as relevant to an ecological risk assessment. 21 **5. Extirpation** – Depletion of an assessment population to the point that it is no longer a 22 viable resource or may not fulfill its function in the ecosystem. 23 **6. Abundance** – Numbers or density of individuals in an assessment population. Total 24 abundance or abundances by age or size classes may be used. 25 7. **Production** – The generation of biomass or individuals in an assessment population

Assessment Community or Assemblage – A multispecies group of organisms occupying an area that has been defined as relevant to an ecological risk assessment. The group may include all organisms in the area, in a taxon (a plant community or bird community), or in certain samples (macroinvertebrates in Hester-Dendy samples).

due to survival, fecundity, or growth.

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8. Species Richness – The number of species or of native species in an assessment

1	community or assemblage.
2	9. Abundance – The number of individuals in an assessment community or assemblage.
3	Total abundance or relative abundances of individual species or other taxa may be used.
4	10. Plant Production – The generation of biomass or individuals in an assessment
5	assemblage of plants. The assemblage may include all plants in an area or water body, in
6	a taxon (e.g., flowering plants), or other definition (e.g., phytoplankton or aboveground
7	herbs).
8	Wetlands - Ecosystems transitional between terrestrial and aquatic systems where the water
9	table is usually at or near the surface or the land is covered by shallow water. Wetlands generally
10	include swamps, marshes, bogs, and similar areas. (This definition is derived from the more
11	comprehensive definitions of wetlands provided in National Research Council, 1995; U.S. Fish
12	and Wildlife Service, 1979; and U.S. Army Corps of Engineers, 1984.)
13	11. Area of Wetlands – The area may be defined simply as surface extent of wetlands of
14	any type, but more often is defined as extent of a particular type (e.g., Atlantic white
15	cedar bog) or a particular category (e.g., palustrine).
16	12. Function of Wetlands – Processes performed by wetlands that are services to
17	humans or other ecological entities. Specific functional attributes may include: water
18	storage, maintenance of high water tables, nutrient retention and cycling, sediment
19	retention, accumulation of organic matter, and maintenance of habitats for wetland
20	dependent plants and animals.
21	Coral Reefs - Marine ecosystems characterized by hydrozoan corals and associated flora and
22	fauna.
23	13. Area of Coral Reefs - Depending on the goals of the assessment, area may be
24	defined as the total spatial extent of the reef, the extent of living reef, the extent of
25	unbleached reef, or some other definition.
26	14. Species Richness of Coral Reefs – The number of coral species or of species of
27	other assemblages in a reef.
28	Critical Habitat for Threatened and Endangered Species - The specific area within the
29	geographical area occupied by an endangered or threatened species on which are found physical
30	or biological features essential to the conservation of the species and which may require special
31	management considerations and protections (16 U.S.C. 1532(5)). Critical habitats, legally

- defined and specified by the Secretary of Interior, are listed in 50 CFR Ch. 1 Section 17.94-76.

 However, habitats which are critical to a threatened or endangered species should be protected when identified even if they are not listed.
 - **15.** Area of Critical Habitat for Threatened and Endangered Species The land coverage or equivalent aquatic extent (e.g., stream kilometers) that potentially supports the endangered or threatened species.
 - **16.** Quality of Critical Habitat for Threatened and Endangered Species The suitability of the habitat to support the endangered or threatened species.
 - 17. Area of Endangered or Rare Ecosystem Types Endangered or rare ecosystems are ecosystems that are at high risk of extinction because they are rare or significantly declining due to destruction or transformation to another type. They may be generic (e.g., old growth or virgin forests in the conterminous U.S.) or geographically specific (e.g., Hempstead Plains grasslands on Long Island, NY). The National Biological Survey (Noss et al., 1995) and the Association for Biodiversity Information, for example, have compiled information on rare and endangered ecosystem types.
 - **18. Physical Structure of Aquatic Ecosystems** The physical attributes or characteristics of water bodies, including hydrological characteristics; bathymetry; bank form; sinuosity; pool and riffle structure; bank and channel vegetation; and substrate type and composition. This endpoint encompasses the aesthetic and other values of aquatic ecosystem structure, and not simply habitat quality for aquatic organisms.
- 19. Properties of Special Places – Special places are public and private areas of ecological or cultural significance that are not necessarily endangered or threatened, but are important, as revealed by laws or other actions that set them aside to sustain their unique character or natural heritage. Examples include: World Heritage Sites; National Parks and Natural Landmarks; Wilderness Areas; National Wildlife Refuges; National Conservation Areas; Wild and Scenic Rivers; Estuarine and Marine Sanctuaries; private nature preserves (e.g., Nature Conservancy Preserves and National Audubon Society Sanctuaries); and state and local parks. For a more comprehensive list, see U.S. EPA (1991a). The ecological properties to be protected are those that make the place special including those that are an important part of the historical or cultural heritage of a place (e.g., shortgrass prairie at Little Bighorn National Monument). Hence, this GEAE is relevant only to special places with ecological properties that are important to their

designation. We would not, for example, apply this GEAE to a renovation of Grant's Tomb.

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2.2. Assessment Populations and Communities

Because the conventional ecological terminology of "populations" and "communities" presents problems in practice, this document introduces the terms "assessment population" and "assessment community" (defined above). While ecological assessment endpoints inevitably include population properties such as abundance and production and community properties such as species richness, it is difficult to delineate populations and communities in the field. Classically defined populations are discrete and interbreeding. Classically defined communities are discrete and their constituent species are relatively consistent and interact in predictable ways. While these classical definitions have been important to the development of genetics, evolution, and ecology (e.g., Hardy-Weinberg equilibrium and the competitive exclusion principle), they have always had manifest limitations in practice. More recently, ecology has become more focused on temporal dynamics, spatial patterns and processes, and stochasticity that belie the notion of static, independent populations. One example of this is metapopulation analysis, which reveals that population dynamics are significantly determined by exchange of individuals among habitat patches or differential movement across a landscape that continuously varies in suitability (Hanski, 1999). Communities are subject to the same dynamics. For example, the species diversity of Pacific coral reefs is apparently determined by the availability of recruits from other reefs within 600 km (Bellwood and Hughes, 2001). If the composition of coral reefs, which would appear to be classic discrete communities, is in fact determined by regional dynamics, there is little chance of delimiting discrete communities in general.

Populations may be readily delimited if they are physically isolated within a broader species range (e.g., a sunfish population in a farm pond) or if the species consists of only one spatially discrete population (e.g., the endangered Florida panther, whose current range is restricted almost exclusively to southwest Florida). Otherwise, population boundaries are difficult to define because they are typically structured on multiple scales. Genetic analyses, which are needed to define discontinuities in interbreeding frequencies and thus to delimit populations, are not a practical option for most ecological risk assessments.

The practical problems are even greater for communities. While the members of a population consist of a single species, it is not always clear whether a particular group of

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organisms constitutes an instance of a particular community type. This is because the species composition of communities varies over space and time.

To protect properties such as population production or community species richness, it is necessary to develop a pragmatic solution to these problems. An example of such a pragmatic solution is the approach taken to inventorying and mapping biodiversity by the Nature Conservancy and NatureServe (formerly the Association for Biodiversity Information) (Stein et al., 2000). Since it is not feasible to define discrete populations or communities, they inventory and map occurrences of conservation elements. These may be defined at various scales, depending on the elements and circumstances. For example, a plant community occurrence may be "a stand or patch, or a cluster of stands or patches." However, an occurrence of a bird species would be defined quite differently.

We propose a similar approach for GEAEs. For individual assessments, the population or community entities to be protected must be defined during the problem formulation stage of risk assessment. These assessment populations and assessment communities should be defined in a way that is biologically reasonable and supportive of the decision. For example, it would not be reasonable to define the belted kingfishers occurring in a 20 m steam reach as an assessment population if that reach cannot fully support one belted kingfisher pair. On the other hand, even though its range is effectively continuous, it would not be reasonable to define the entire species as the assessment population given that it ranges across nearly all of North America. Rather, it may be reasonable to define the kingfishers on a watershed or a lake as an assessment population. Assessment populations may be defined by nonbiological considerations as well. For example, for Superfund ecological risk assessments on the Department of Energy's Oak Ridge Reservation, populations of large terrestrial vertebrates were delimited by the borders of the reservation (Suter et al., 1994). This definition was reasonable not only because the Superfund site was defined as the entire reservation, but also because the reservation was large enough to sustain viable populations of deer, wild turkey, bobcat, etc. Although the reservation is more forested than surrounding agricultural and residential lands, the borders of the reservation are not impenetrable and are not ecologically distinct at all points. However, the pragmatic definition proved useful and acceptable to the parties. For similarly practical reasons, one might define an assessment community of benthic invertebrates in the mixing zone of an effluent plume or in the first fully mixed reach.

The selection of a scale to define an assessment population or community involves a tradeoff. If the area is large relative to the extent of the stressor, the effects of that stressor will be diluted. However, if the area is small, the assessment population or community may be significantly affected but may seem too insignificant to concern stakeholders or prompt action by the decision maker. Hence, appropriate spatial scales should be determined during the problem formulation stage for individual risk assessments, taking into consideration both the ecological and policy aspects of the problem.

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Table 2.2. Generic Ecological Assessment Endpoints: summary of the policy support for their use and their practicality.

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Entity: Attribute(s)	Policy Support	Practicality
Organism-Level Endpoints		
Organisms (in an assessment population or community): kills (mass mortality, conspicuous mortality)	Supported by many EPA programs. For example, EPA has restricted pesticide use (e.g., diazinon and carbofuran) due to incidents of bird mortality.	Likelihood of kills from chemical pollutants can be estimated from toxicity testing. Incidents may be easy or difficult to observe, but when seen suggest a common mechanism or stressor exerting a strong effect.
Organisms (in an assessment population or community): gross anomalies	Gross anomalies in birds, fish, shellfish, and other organisms are a cause for public concern and have been the basis for EPA regulatory action and guidance (e.g., assessed at Superfund sites, incorporated into biocriteria for water programs).	External gross anomalies are readily observed and are commonly included in survey protocols for fish and forests. They are also reported in toxicity tests of fish, birds, mammals, and plants.
Organisms (in an assessment population or community): survival, fecundity, growth (particularly endangered species, marine mammals, eagles, and migratory birds)	Many EPA programs rely on organism-level attributes of survival, fecundity, and growth in assessing ecological risks (e.g., water quality criteria, pesticide and toxic chemical reviews, Superfund sites). Organism-level species protection is mandated by the Endangered Species Act, Marine Mammal Protection Act, Bald Eagle Protection Act, and Migratory Bird Treaty Act.	Results of toxicity tests of the survival, fecundity, and growth of organisms are abundant and often can be extrapolated to endangered species and other species of concern. Information on the ranges of listed endangered species is available through state and federal governments.
Organisms (in an assessment population or community): avoidance	EPA water quality guidance (such as for mixing zones) indicates that effluents should not prevent or interfere with passage of migrating fish and other organisms.	Avoidance can be observed, but it is not readily predicted. Laboratory tests exist for avoidance but have not been required by EPA.

	Entity: Attribute(s)	Policy Support	Practicality
1	Population-Level Endpoints		
2 3	Assessment population: extirpation	EPA has taken action or provided guidance to prevent extirpation of local populations (e.g., assessment of likelihood of extirpation of fish populations due to acid rain). See also description for assessment population: abundance.	Extirpation can be predicted using population viability analysis. Demonstrating extirpation may be easy or difficult, depending on the conspicuousness of a species. See also description for assessment population: abundance.
4 5	Assessment population: abundance	Major environmental statutes mandate protection of animals, plants, aquatic life, and living things generally, which can be inferred to entail protection of populations. EPA policies for pesticides, toxic chemicals, hazardous wastes, and air and water pollutants are intended to protect assessment populations of organisms. Mammals, birds, fish, aquatic invertebrates, and plants are typically assessed.	Changes in abundance may be predicted using conventional toxicity data (the most common approach), statistical extrapolation models, and population models. An example of population modeling at EPA was an assessment of the risks from chloroparaffins to trout populations under the Toxic Substances Control Act. Measurement of abundance in the field may be easy or difficult, depending on the species.
6 7	Assessment population: production	See description for assessment population: abundance. Additionally, a number of laws are intended to maintain production of various economically valuable species. EPA water (e.g., National Estuary Program) and air programs (e.g., criteria pollutant standards) have involved protecting production of resource species populations.	Changes in production may be predicted using conventional toxicity data as well as from population-based approaches. For resource species such as tree or fish species, production changes may be measurable in the field but may require long periods of observation time.

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Entity : Attribute(s)	Policy Support	Practicality
Assessment community or assemblage: species richness or abundance	EPA water quality biocriteria frequently incorporate measures of community species richness and abundance, such as part of an Index of Biotic Integrity (IBI). Additionally, EPA testing for pesticides, toxic chemicals, and water pollutants is intended to assess impacts to communities as well as populations and kills of organisms. Fish, aquatic invertebrates, and aquatic plants are often assessed.	Changes in communities can be inferred or modeled from conventional toxicity data. Measuring species richness and abundance of aquatic communities, at least for fish and macroinvertebrate communities, is practical and wellestablished. Ecosystem models that assess effects of toxicants on community properties are available, and can use data acquired from organism-level laboratory testing, but are not routinely applied to date.
Assessment community or assemblage: plant production	EPA water quality policies address overproduction of aquatic plants (and concomitant eutrophication) due to excess input of nutrients. EPA policies for pesticides, toxic chemicals, water pollutants, and air pollutants (as in the case of ozone and acid rain) also target decreases in production of forests or other plant communities.	Methods for measuring plant production are well developed for both terrestrial and aquatic communities. Methods for predicting effects of nutrient addition are relatively well-developed. Protocols for testing plant toxicity are available and include production metrics.

	Entity: Attribute(s)	Policy Support	Practicality
1		Ecosystem-Level Endpoints	
2	Wetlands: area or function	Management and protection of wetlands by EPA is supported by a variety of federal laws, regulations, and directives. These include the Clean Water Act (Section 404, dredge and fill permit program, and several other sections), the National Environmental Policy Act, the Coastal Zone Management Act, Executive Order 11990 – Protection of Wetlands, and the federal Wetland Delineation Manual.	Methods for delineating wetlands are well-established (although criteria used by EPA and other agencies are under revision). Changes in wetland area are therefore relatively easy to measure. Losses of wetland function independent of area loss generally are not readily observable or predictable.
3 4	<u>Coral reef</u> : area or species richness	An Executive Order (13089) establishes policies for protection of coral reefs. Additional support may be found in the Coastal Zone Management Act and the Marine Protection, Research, and Sanctuaries Act. Many U.S. coral reefs are protected by state or federal government.	The area of a coral reef is relatively easy to determine. The species richness of corals and some other assemblages (e.g., fish) is also practical to determine. Prediction of effects of pollutants on coral reefs is difficult due to limited toxicology information.
5 6 7 8	Critical habitat for threatened and endangered species: area or quality	The Endangered Species Act specifically mandates the protection of critical habitat for endangered species, in addition to the species themselves.	Information on habitat used by listed species is available from state and federal agencies, although critical habitat has not been officially designated for most listed species. Generally it is practical to determine effects on habitat area and quality.
9 10 11 12	Endangered/rare ecosystem types: area of the type (direct destruction or change to another type)	Fewer EPA precedents exist for this endpoint than many others, but a variety of EPA programs have considered rare ecosystems. Superfund guidance, for example, calls for consideration of sensitive ecosystems, and NEPA guidance recommends mitigation measures to reduce adverse impacts on imperiled ecosystems.	NatureServe (www.natureserve.org) is a ready data source for endangered and rare ecosystem types. Drawing from state natural heritage programs, it maintains data on all known ecological communities in the United States, ranked from critically imperiled to secure. Area loss is relatively straightforward to measure, but prediction of change to another type could be difficult.

	Entity: Attribute(s)	Policy Support	Practicality
1 2	Aquatic ecosystems: physical structure	Restoring and maintaining the physical integrity (along with the chemical and biological integrity) of the nation's waters is the primary goal of the Clean Water Act. EPA policies and monitoring guidance under the Act include measures of physical structure.	Protocols exist for measuring many of the physical characteristics of aquatic ecosystems. The impacts of many actions (e.g., channelization, dam construction) on the physical structure of water bodies can be readily predicted. Other effects (such as hydrology changes due to land use changes) are more difficult, but still possible, to model.
3 4 5 6	Special places: ecological properties that make them special and legally protected properties	The Clean Air Act, National Environmental Policy Act, and other statutes require protection of special places such as national parks, wilderness areas, and wildlife refuges, and this is reflected in EPA policies. The Clean Water Act gives EPA a role in designating National Estuaries and Outstanding National Resource Waters, which receive additional protection.	Special places and their important ecological properties usually can be defined readily. Ability to predict or detect impacts to these properties will depend on the nature of the properties and whether impacts are direct or indirect.

3. HOW TO USE THE GEAES

When these GEAEs are used in a risk assessment for a specific site, effluent, stressor, etc., it will be necessary to determine whether any of them are applicable to the assessment and, if so, how they can be made specific to the case, and whether they are sufficient for the case. These activities are performed as part of the problem formulation phase of risk assessment (U.S. EPA, 1998a).

3.1. Choosing From the Set

The set of GEAEs is intended to be a helpful starting point for identifying and specifically defining assessment endpoints. During problem formulation, assessment scientists, risk managers, and any stakeholders involved may select from the set those GEAEs that are relevant to the assessment and are of sufficient importance to potentially influence the decision. This process should be informed by any goals that may have been set prior to the problem formulation (U.S. EPA, 1998a). The assessment-specific criteria for selecting assessment endpoints from the guidelines for ERA (ecological relevance, susceptibility to known or potential stressors, and relevance to the management goals) can be used to arrive at a final list of endpoints for that particular assessment (U.S. EPA, 1998a).

The most obvious approach to using the GEAEs is to simply review the list to determine which GEAEs are susceptible, relevant and important to the assessment. For example, one might consider whether any aspect of the project or stressor might result in kills (i.e., susceptibility) and whether the occurrence of those kills meets the criteria of ecological relevance or relevance to management goals. Similarly, the two GEAEs for wetlands would require consideration of whether any wetlands are potentially exposed and whether the exposure could result in loss of area or changes in function that are potentially relevant.

Alternatively, assessment endpoints may have been suggested by stakeholders or others by an independent process. In that case, those assessment-specific endpoints may be compared to the set of GEAEs. If a proposed assessment endpoint corresponds to one of the GEAEs, then the policies and precedents that support the GEAE (Appendix A) also support that proposed assessment endpoint. For example, if stakeholders propose to protect a wetland adjoining a

contaminated site, then the regulations and precedents that support the two GEAEs for wetlands lend support to those stakeholder concerns as a basis for defining an assessment endpoint. If there is no correspondence to a GEAE, then the proposed assessment endpoint may still be used, but it must be supported for that case (Section 3.3).

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3.2. Making the Generic Endpoints Specific

To convert a GEAE into an assessment endpoint for a specific assessment, it is necessary to define the specific entity and attribute and the spatial and temporal context of the entity. This specificity is necessary to make the endpoint relevant to the assessment and to determine what measurements and models are needed to estimate it.

Consider the first GEAE, kills of organisms, as an example. The generic entity is organisms. For a specific assessment endpoint, we must specify whether the endpoint entity corresponds to members of a specific taxon such as fish or birds, an assemblage such as macroinvertebrates, or a specific species such as sea otters. The generic attribute is kills, which should be defined more specifically and in terms that are appropriate to the assessment. For example, the definition of a "kill" would differ in a well-monitored experimental use of a pesticide versus public reports of mortalities, for oil spills versus lawn treatments, and for modeling studies versus observational studies. Possible definitions could include the number of organisms that must die during an episode to be considered a kill, the proportion of organisms visiting a site that would be expected to die, or the frequency of public reports of dead organisms associated with the stressor. Finally, the spatial and temporal context should be defined. For an effluent, the spatial context may be the downstream reach within which mixing occurs, and the time period may be the period of a permit. For a pesticide, the spatial context may be the region within which the pesticide is used on a particular crop and the temporal scale may refer to the number of applications per year over the period of use. For an oil spill, the context may refer to the area encompassed by the plume and the time until the plume is dispersed or degraded to the point that it no longer oils marine birds or mammals. Hence, an assessment endpoint derived from this GEAE might be: episodic mortality of several fish of any species occurring in the one kilometer reach downstream of the effluent release point.

Note that more than one assessment endpoint may be derived from a GEAE for a particular assessment. For example, the GEAE population abundance, may be used to generate

assessment endpoints for each of several populations of concern and the change in abundance and spatial context may be different for each. On the other hand, a site-specific concern may relate to more than one GEAE. In the example of the wetland discussed in the previous section, the site specific problem formulation must determine whether the management concern and the evidence of wetland susceptibility are related to the area of the wetland, some functional attribute of the wetland, or both.

3.3. Adding Other Ecological Assessment Endpoints

The set of GEAEs presented in this document contains those that are thought to be currently generically useful in EPA, and does not preclude the use of other endpoints. Other endpoints may be chosen because they reflect some particular environmental value associated with a site or held by a particular stakeholder. In addition, some endpoints that are not generically practical may be practical in a particular case because of peculiarities of the stressor or receptor, data availability, availability of a model of the receiving system, or because time and resources are available to assess a difficult endpoint. Finally, the mode of exposure or mode of action of a stressor may imply susceptibility of certain endpoints that have not been commonly considered.

3.4. Completing the List of Assessment Endpoints

When a list of potential assessment endpoints has been developed, it may be necessary to review the list and reduce it to the set that is important to the decision. Because of the limitations of time and resources, it is often advisable to limit the list of assessment endpoints to those that are most relevant and susceptible. There is likely to be some redundancy in the endpoints. Kills of organisms imply immediate changes in population abundance which may influence community abundances. If population or community properties are important to the decision maker, they should be retained. However, if kills are sufficient to warrant action, the extrapolations to higher levels of biological organization may be unnecessary and those endpoints may be dropped as unnecessarily redundant.

4. RECOMMENDATIONS FOR FURTHER PROGRESS

The main purpose of this report has been to improve ecological considerations within EPA by developing an initial set of generically useful ecological assessment endpoints. These assessment endpoints are based on existing policy and practice rather than an evaluation of all the potentially useful ecological assessment endpoints that may exist. In looking toward the future, readers of this report are encouraged to develop and maintain a continual, open process for reviewing and amending these GEAEs, and to establish a means of keeping track of the many rationales and precedents used for making ecological risk-based decisions throughout EPA. The remainder of this chapter provides a discussion about these two recommendations and presents potential GEAEs for future consideration.

4.1. Developing a Continual, Open Process for Reviewing and Amending GEAEs

The initial GEAEs presented in this report include important ecological attributes to consider when conducting ecological assessments throughout EPA. However, the Agency should not remain static nor constrain itself to the past. EPA should institute an adaptive, ongoing, and open process of reviewing and amending this initial set of generic endpoints over time as Agency experience and science evolve. The mechanism and frequency of these reviews must be established by Agency management, but the members of this panel believe that five year intervals would be appropriate and that broad participation is vital. Members of the reviewing panel should represent as many programmatic, regional, and support offices of EPA as possible and this process should be open to stakeholder input.

4.2. Keeping Track of New Rationales and Precedents Used in Ecological Risk Assessment and Management Decisions

A more efficient means of recording and referencing how EPA is breaking new ground in ecological protection needs to be established. As such, the Agency should formally document assessment endpoints used in ecological risk assessments on an ongoing basis. Where a program or regional office finds scientific and societal justification for an assessment endpoint, the office should consider it again in future assessments, and share this knowledge with other offices throughout the Agency. We suggest that a central, web-based database would greatly facilitate

this process.

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4.3. Potential GEAEs for Future Consideration

An important question the technical panel preparing this report considered was whether to restrict the list of GEAEs to assessment endpoints for which Agency precedent existed, or if new endpoints (without EPA precedent) should be considered as well. Because the technical panel was primarily scientific in nature and lacked authority to establish new Agency policy, the panel decided that all the initial generic endpoints should have some existing legal or regulatory basis or other precedent within EPA. Such precedents, as presented in Appendix A, include treaties, statutes, regulations, judicial decisions, official memoranda, guidance or procedures, and others precedents. Nevertheless, the technical panel was concerned that otherwise valid and important ecological endpoints were excluded and felt it important to encourage Agency progress and innovation in this area. In that light, potential GEAEs meriting consideration by EPA include the following:

- Nutrient cycling in ecosystems other than wetlands.
- Soil productivity.
- Other soil functions (e.g., nutrient retention, organic matter decomposition).
- Physical structure of terrestrial ecosystems.
- Landscape characteristics (e.g., extent, pattern, and diversity).
- Attributes of wetlands besides area or functional capacity (e.g., stability, resilience, diversity).
- Behavior other than avoidance, such as courtship behavior or migratory behavior (e.g., in birds and salmonids), or lapses in nurturing and rearing (e.g., nest abandonment).
- Riparian system area or function.
 - Ecosystem attributes that influence public health.

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We encourage EPA's program and regional offices to regularly consider these and other relevant assessment endpoints for EPA's evolving ecological mission. One suggested method for deriving other potential endpoints is to consider the many dimensions associated with ecological systems (Table 4.1). The initial GEAEs presented in this report incorporate or touch upon many of these dimensions, but many other endpoints could be derived by increasing the range, or

1 integrating two or more of these dimensions in a new way.
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Table 4.1. Example scales to consider in developing assessment endpoints.

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- 1) Levels of biological organization (e.g., ranging from DNA to ecosystems, landscapes and beyond).
- 2) Spatial scale (e.g., ranging from local to global).
- 3) Temporal scale (e.g., considerations of the timing, duration and/or frequency of biological activities or events).
- 4) Magnitude (e.g., the total number of ecological entities present, impacted or remaining).
- 5) Less often considered taxonomic groups (i.e., beyond mammals, fish and birds to other taxa such as amphibians, reptiles, invertebrates, fungi, flowering and nonflowering plants, etc.).
- 6) Conceptually broader range of ecological properties of concern (e.g., resiliency in ecosystems).

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5. CONCLUSION

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While the legislative mandates to protect public health and the environment are equal in their lack of specificity, the development of endpoints for human health risk assessment has proceeded more expeditiously. Health risk assessments began with cancer risks and evolved to include a range of noncancer endpoints such as birth defects, kidney function, intellectual development, and infertility. This is due in large part to the fact that the public and Agency scientists and managers can readily understand and personally relate to those health endpoints. In contrast, many ecological endpoints are not as well understood by non-ecologists and lack the same emotional immediacy. As a result, ecological endpoints have been slower to develop and have often not been as clearly or consistently defined as are health endpoints (U.S. EPA, 1994, 1997a, 1998a). This set of GEAEs should help to remedy that situation by defining ecological endpoints that have broad utility in the Agency and may be used by risk assessors and risk managers with confidence that they are supported by regulations and precedents.

APPENDIX A. SUPPORTING INFORMATION

This appendix serves as a reference for those who need to know the basis for a particular GEAE defined in Section 2. The GEAEs have been divided into four categories of biological organization: organism, population, community, and ecosystem. Each category is introduced by general information about how the GEAEs in that category have been used by the Agency. Additional supporting information is then provided for each GEAE, divided into two sections. The first is Laws, Regulations, and Precedents, which discusses the authorities that support use of each GEAE by EPA and gives examples of Agency actions that provide a further basis for their use. The second section is Practicality, which discusses the availability of methods to estimate risks to the endpoint and their applicability in various risk assessment contexts. Because assessment endpoints are defined as valued properties of the environment (U.S. EPA, 1998a), public values associated with the GEAEs are discussed in broad terms in Appendix B.

It should be noted that the specific laws and other policies cited below are not the only support for ecological endpoints. The many federal environmental laws and their implementing regulations provide a general mandate for environmental protection that goes far beyond the specific instances presented in this Appendix. In particular, the National Environmental Policy Act of 1970 creates a broad mandate for federal agencies to protect and prevent degradation of the environment. While nearly all environmental statutes refer to the environment as an entity to be protected, and many refer to more specific ecological entities such as fish, wildlife, and estuaries, few indicate an attribute to be protected or even the nature of the entity. In addition, terms are not necessarily used in a technical way. For example, the Clean Water Act refers repeatedly to "a balanced indigenous population of fish, shellfish and invertebrates." Clearly, the phrase does not refer to a biological population, which is formed of members of one species. Further, when referring to fish, does the act mean fish at the level of organism, population, assemblage, or as a taxon? Given these ambiguities, the wording of the statutes must be interpreted to define endpoints. The primary source of support for the following interpretations is precedent.

The precedents and other expressions of policy discussed below are a sample of those that have been used in assessments, guidance, protocols, and other Agency actions over the years.

Although they are derived from particular laws and regulatory contexts, they may be interpreted

as examples of what Congress and the Agency have meant by protecting the environment. For 2 example, the Clean Air Act calls for specific protection of "national parks, national wilderness 3 areas, national monuments, national seashores, and other areas of special national or regional 4 natural, recreational, scenic, or historic value." This requirement can be interpreted as a mandate 5 to the Agency to protect those special areas from pollution, not just the threats from air pollution 6 that were brought to the attention of Congress.

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- 8 Abbreviations and Acronyms Used in this Appendix:
- CAA 9 Clean Air Act
- **CERCLA** 10 Comprehensive Environmental Response, Compensation, and Liability Act
- 11 CFR Code of Federal Regulations
- 12 **CWA** Clean Water Act
- 13 **ESA Endangered Species Act**
- 14 FR Federal Register
- 15 NCP National Contingency Plan
- 16 NEPA National Environmental Policy Act
- 17 PCB Polychlorinated Biphenyl
- 18 **FIFRA** Federal Insecticide, Fungicide, and Rodenticide Act
- 19 **RCRA** Resource Conservation and Recovery Act
- 20 TSCA Toxic Substances Control Act

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A.1. Organism-Level Endpoints

Major EPA statutes such as the Clean Air Act, Clean Water Act, CERCLA, FIFRA, TSCA, and RCRA require EPA to consider and protect organism-level attributes or various taxa of organisms including fish, birds, and plants and, more generally, animals, wildlife, aquatic life, and living things. The toxicity information that is available to EPA in administering these statutes is dominated by organism-level attributes such as mortality. Organism-level attributes tend to be more practical to measure or predict than attributes at higher levels of organization for most EPA assessments. Consequently, EPA's ecological assessments historically have focused on organism-level endpoints.

Note that these endpoints do not normally imply protection of each individual organism, but rather the protection of these critical attributes of organisms within assessment populations or communities. EPA's principles for ecological risk assessment and risk management at Superfund sites (U.S. EPA, 1999b) illustrate a common usage of organism-level endpoints at EPA: "Except at a few very large sites, Superfund ERAs [ecological risk assessments] typically do not address effects on entire ecosystems, but rather normally gather effects data on individuals in order to predict or postulate potential effects on local wildlife, fish, invertebrate, and plant populations and communities that occur or that could occur in specific habitats at sites Levels [of chemicals] that are expected to protect local populations and communities can be estimated by extrapolating from effects on individuals and groups of individuals using a lines-of-evidence approach." That is, we assess risks to attributes of organisms and assume that populations and communities will be protected if they are protected. As will be described, however, certain special categories of organisms such as endangered species and marine mammals have been afforded protection on an individual basis.

In ecological assessments, EPA considers organism-level effects in a variety of taxa. For example, tests required for pesticide regulation can include effects on survival, growth, and reproduction of aquatic invertebrates, fish, birds, mammals, and both terrestrial and aquatic plants. Effects to a similar range of taxa are considered under TSCA (Lynch et al., 1994; Zeeman et al., 1999) and in deriving water quality criteria under the CWA. Less commonly, other taxa are considered such as earthworms (e.g., at certain Superfund sites), honeybees (e.g., for certain pesticides), and reptiles and amphibians.

A.1.1. GEAE #1: Kills of Organisms

A.1.1.1. Laws, Regulations, and Precedents

The regulation of chemicals to prevent kills of organisms, in the absence of effects on populations or communities, has been sustained by federal courts. For example, use of the pesticide diazinon on golf courses and sod farms was prohibited after documentation of widespread and repeated kills of birds (U.S. EPA, 1988a). Subsequently, EPA cited continuing bird kills as a factor in the agreement with pesticide manufacturers to phase out all outdoor residential uses of diazinon (U.S. EPA, 2001a). Bird kills were also the basis for phasing out

most uses of another pesticide, granular carbofuran (U.S. EPA, 1991b; Houseknecht, 1993). Kills of birds and other wildlife in oil pits are considered evidence of "imminent and substantial endangerment to the environment" under RCRA §7003 (U.S. EPA, 2001b). Fish kills have also been considered a concern by EPA; for example, Region 5 considers fish kills and other excess mortality to be obvious impacts under RCRA (U.S. EPA, 1994).

Under FIFRA reporting requirements for adverse effects of pesticides (40 CFR Part 159), EPA categorizes kills (and other adverse incidents) involving multiple organisms as more severe events than single organism incidents and imposes additional reporting requirements on pesticide registrants for such events. More severe wildlife incidents are defined as those involving at least 1,000 individuals of a schooling fish species or 50 individuals of a non-schooling species; 200 individuals of a flocking bird species, 50 individuals of a songbird species, or five individuals of a predatory species; or, for mammals, reptiles, and amphibians, 50 individuals of a relatively common or herding species or five individuals of a rare or solitary species. (Note that incidents involving numbers of organisms below these thresholds still must be reported, but the requirements are different than for more severe incidents. Also note that these criteria do not apply outside FIFRA.)

A.1.1.2. *Practicality*

The likelihood of kills is relatively readily estimated using the common acute lethality tests which generate LC50s and LD50s. The number of species involved in kills may be estimated from species sensitivity distributions (SSDs) of LC50s or LD50s, as in the calculation of the acute National Ambient Water Quality Criteria (U.S. EPA, 1985; Posthuma et al., 2001). The occurrence of kills in the field may be readily observed in the cases of conspicuous organisms and open habitats, but in other cases, such as small birds in crops or fence rows, kills may be unobserved and difficult to document. Recently, a model has been developed to predict the probability of bird kills for a particular use of a cholinesterase-inhibiting pesticide using SSDs of LD50s and field studies (Mineau, 2002).

A.1.2. GEAE #2: Gross Anomalies of Organisms

A.1.2.1. Laws, Regulations, and Precedents

Gross anomalies in birds, fish, shellfish, and other organisms are a cause for public concern and have been the basis for EPA regulatory action and guidance. For example, crossed bills and other deformities in piscivorous birds are a basis for the proposed remediation of the PCB-contaminated sediments at the Fox River/Green Bay Superfund site (Wisconsin Department of Natural Resources, 2001; U.S. EPA, 1998b), and were a basis for the designation of the system as an Area of Concern by the Great Lakes National Program Office (U.S. EPA, 2001c). EPA actions to restrict the use of tributyltin as an antifoulant on boats (U.S. EPA, 1988b), as well as the restrictions imposed by the Organotin Antifouling Paint Control Act of 1988, were triggered by the observed induction of gross deformities in molluscs which threatened the marketability of oysters, reduced the fecundity of the deformed organisms, and suggested the potential for other effects. Natural resource damage regulations for CERCLA, the CWA, and the Oil Pollution Act include gross anomalies among the designated injuries (43 CFR §11.62(f)), and Deformities, Erosion, Lesions and Tumors in fish (DELT anomalies) are used in the biocriteria of many state water quality standards and in Agency guidance (Yoder and Rankin, 1995; U.S. EPA, 1996). Changes in development, which can be manifested in physical anomalies, have been identified as an environmental effect of regulatory concern under TSCA (U.S. EPA, 1983).

Anomalies in plants and plant injuries have also been the basis for EPA action. For example, EPA established a secondary ambient air quality standard for ground-level ozone based in part on visible foliar injury to commercial crops and natural vegetation, stating that "foliar injury is occurring on native vegetation in national parks, forests, and wilderness areas, and may be degrading the aesthetic quality of the natural landscape, a resource important to public welfare" (U.S. EPA, 1997b). EPA has also used visible injury of plants as a basis for regulating air emissions of aluminum reduction plants and sulfuric acid production units (U.S. EPA, 1994).

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A.1.2.2. Practicality

External gross anomalies are readily observed, as are some internal anomalies with external manifestations such as severe scoliosis or large tumors. They are commonly included in biological survey protocols for fish and in forest health surveys. Gross anomalies are also included as endpoint responses in some chronic tests of fish and birds.

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A.1.3. GEAE #3: Survival, Fecundity, and Growth of Organisms

As discussed in Section A.1., EPA's ecological assessments have considered effects on survival, fecundity, and growth in a variety of taxa. While actions based on survival may be most common, EPA has also made regulatory decisions based on effects on fecundity and growth of organisms identified in ecological risk assessments. For example, the pesticide chlorofenapyr was not approved by EPA based on Agency concerns over reproductive risks to birds. Additionally, federal statutes and other precedents confer special status on particular kinds of organisms: endangered and threatened species, marine mammals, bald and golden eagles, and migratory birds. The remainder of this section will concentrate on the basis for the special status of these organisms within the organism-level endpoints.

A.1.3.1. Laws, Regulations, and Precedents

Endangered and Threatened Species

The Endangered Species Act prohibits taking of threatened or endangered species which is defined as to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 US Code, §1532 and 50 CFR Parts 14, 17, and 23). Under the Act, the term "species " includes "any subspecies of fish or wildlife or plants and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature." The ESA states that it is "to be the policy of Congress that all Federal departments and agencies shall seek to conserve endangered species and threatened species" and that "Federal agencies shall cooperate with State and local agencies to resolve water resource issues in concert with conservation of endangered species" (16 US Code, §1531).

Hence, the provisions of the ESA are applicable to EPA actions, and both the prohibition against harming individual members of threatened or endangered species and the affirmative obligation to conserve those species would seem to preclude toxic effects. Additionally, the Clean Air Act (§112) specifically requires EPA to prevent adverse effects to endangered species in regulating hazardous air pollutants. Like other federal agencies, EPA has published regulations and taken actions to protect endangered species. For example, EPA has consulted with the U.S. Fish and Wildlife Service and National Marine Fisheries Service to prevent jeopardy to endangered species, as required by the ESA, for actions such as setting water quality standards and regulating pesticides. In these consultations, the attributes of concern have generally been

survival, fecundity, and growth, although other attributes may be important in specific cases. The National Contingency Plan specifies that the ESA is a federal "applicable or relevant and appropriate requirement" (ARAR) with which Superfund remedial actions must comply under CERCLA §121(d)(2)(A), and examples of Superfund ecological risk assessments that used endangered species as endpoints include the Asarco Tacoma site (chinook salmon and bull trout) (Hillman and Rochlin, 2001), the Metal Bank of America site (shortnose sturgeon) (Wentsel et al., 1999), and the Montrose, Iron Mountain Mine, Fort Ord and Monterey Marine Sanctuary,

Camp Pendelton-Santa Margarita River, and Pearl Harbor sites (U.S. EPA, 1994).

Marine Mammals

The Marine Mammal Protection Act protects marine mammals from taking, which is defined as "to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal....The term 'harassment' means any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering" (US Code, §1362). While the Act does not specifically address toxic effects on marine mammals, the special protection afforded these species by the act implies a particular concern for their well-being. Also, the law clearly protects properties of marine mammals at the organism level.

As in the case of threatened and endangered species, the NCP specifies that the Marine Mammal Protection Act is a federal "applicable or relevant and appropriate requirement" (ARAR) with which Superfund remedial actions must comply under CERCLA §121(d)(2)(A), and it cites marine mammals as examples of specific natural resources to be protected under CERCLA Part 101, §16.

Bald and Golden Eagles

Prohibited actions under the Bald and Golden Eagle Protection Act include to "take, possess, sell, purchase, barter, offer to sell, purchase or barter, transport, export or import, at any time or in any manner any bald eagle commonly known as the American eagle or any golden eagle, alive or dead, or any part, nest, or egg thereof of the foregoing eagles ..." (16 US Code,

§668). To take is defined by regulation to include: "to pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to pursue, hunt, shoot, wound, kill, trap, capture, or collect" bald eagles or golden eagles, including any "part, nest, or egg of such bird[s]" (50 CFR §10.12).

Deaths of bald eagles due to secondary poisoning were an endpoint in EPA's assessment of granular carbofuran (U.S. EPA, 1991b), which led to the phaseout of most uses of this pesticide. Also, EPA's ecological risk assessment for PCBs in the Hudson River included survival, growth, and reproduction of piscivorous birds as an assessment endpoint, with the bald eagle selected as one of the representative species of piscivorous birds (U.S. EPA, 2000a).

Birds

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The Migratory Bird Treaty Act of 1918 prohibits or regulates a number of activities. including pursuing, taking, hunting, capturing, killing, possessing, selling, transporting, or purchasing migratory birds, including their eggs and nests (16 US Code, §703). This Act, based originally on a treaty between the United States and Great Britain (including Canada), has since been extended by migratory bird conventions with Mexico, Japan, and the Soviet Union. Since nearly all species of birds native to the United. States are protected by the Act (U.S. Fish and Wildlife Service, 2001), the endpoint may be assumed to apply to birds in general. While the Migratory Bird Treaty Act does not specifically address toxic effects on birds, the special protection afforded these species by the Act implies a particular concern for their well-being. Also, the law clearly protects birds at the organism level. Furthermore, by Executive Order 13186, all federal agencies are required to "support the conservation intent of the migratory birds conventions by integrating bird conservation principles, measures, and practices into agency activities and by avoiding or minimizing, to the extent practicable, adverse impacts on migratory bird resources when conducting agency actions" and "prevent or abate the pollution or detrimental alteration of the environment for the benefit of migratory birds, as practicable" (Clinton, 2001).

EPA policies and precedents affirm the use of survival, growth, and reproduction of birds in ecological assessments. The NCP specifies that the Migratory Bird Treaty Act is a federal "applicable or relevant and appropriate requirement" (ARAR) with which Superfund remedial actions must comply under CERCLA §121(d)(2)(A), and examples of Superfund ecological risk assessments that used birds as endpoints include the Baird and McGuire site (survival and

reproduction of songbirds) (Menzie et al., 1992) and the United Heckathorn site (reproductive effects on birds) (Wentsel et al., 1999). EPA's ecological risk assessment for PCBs in the Hudson River included survival, growth, and reproduction of insectivorous birds, waterfowl, and piscivorous birds as assessment endpoints (U.S. EPA, 2000a). EPA regulations authorize the Agency to require pesticide registrants to submit tests on avian mortality and impaired avian reproduction caused by pesticides. Results from these tests are used by EPA, in conjunction with other available information, in making pesticide registration decisions. Also, EPA's involvement in bird conservation initiatives such as Partners in Flight and the North American Bird Conservation Initiative provides further support for using birds in assessment endpoints (U.S. EPA, 2002).

A.1.3.2. Practicality

Since the vast majority of standard toxicity tests determine effects on the survival, fecundity and growth of organisms, direct toxic effects on this endpoint are readily predicted. In addition, extrapolation models are available that can estimate effects on this endpoint for particular organisms and exposure routes of concern based on tests conducted on other species, life stages or exposure durations or routes.

It is rarely possible to obtain toxicity data for threatened and endangered species, but species sensitivity distributions, intertaxa regressions, or other interspecies extrapolation models should serve to estimate effects of these species. EPA research has confirmed that endangered species are not inherently more sensitive to toxic effects than other species (Sappington et al., 2001), although, from a population standpoint, they may be at greater risk due to their low abundance.

Effects on marine mammals are relatively difficult to observe in the field. However, dieoffs of pinnipeds and cetaceans are readily observed when their conspicuous carcasses appear on beaches. The toxicology of marine mammals is poorly known, and, for obvious reasons, they are not included in routine toxicity testing. However, effects on all mammals are routinely estimated from tests performed with rodents. Exposure of marine mammals is also poorly known and is not routinely estimated even though they can accumulate high levels of persistent pollutants.

Eagles are highly conspicuous, and dead or debilitated eagles are more likely to be reported by the public than most birds. In addition, federal, state, and private organizations

monitor eagles at various scales. Toxic effects on eagles may be predicted from standard avian toxicity tests or, more confidently, from tests with kestrels, with avian allometric models used to extrapolate toxicity results to eagles.

In the case of birds generally, their biology is well known and well-developed methods exist for surveying bird populations and communities. Both acute and chronic test protocols for birds are available and avian toxicity data are available for most pesticides and many other chemicals. However, because birds are highly mobile, often migratory, and often territorial, it is usually difficult to demonstrate chronic effects on these organisms in the field.

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A.1.4. GEAE #4: Avoidance by Organisms in an Assessment Population

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A.1.4.1. Laws, Regulations, and Precedents

Fish are the class of organisms for which EPA has most frequently considered avoidance as an endpoint. Avoidance of a noxious effluent is one of the effects which may be considered in determining whether to allow a mixing zone around a point source discharge, and if allowable, its location and dimensions. The Clean Water Act allows mixing zones at the discretion of States, and therefore policies regarding them vary widely from state to state. EPA guidance (e.g., Water Quality Standards Handbook; Technical Support Document for Water Quality-based Toxics Control) requires that, where allowable, mixing zones must not prevent the designated uses of the receiving waterbody from being attained. This would mean, for instance, that a mixing zone around the effluent discharge could not be so large and noxious as to prevent passage of migrating fish due to their avoidance of the plume. In general, avoidance by fish is not monitored by permittees or permitting agencies around discharges or mixing zones. Rather, the dimensions of the mixing zone are determined either by use of simulation models (which predict the chemical concentrations or temperature at different points within the proposed mixing zone) or by default values (e.g., 25% of 7Q10 flow). However, where there are important migratory species (e.g., salmonids), observance of avoidance behavior can be an important factor in determining mixing zone dimensions.

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A.1.4.2. Practicality

Avoidance of an effluent plume by fish, particularly large migratory species, may be

observed by divers or observers in boats or by telemetric tagging. Laboratory tests exist for avoidance of chemicals or materials in water or food, but have not been required by the Agency. Although EPA's use of this endpoint has emphasized vertebrates, methods are available for invertebrates as well (Slimak, 1997).

A.2. Population-Level Endpoints

As described in Section A.1., most environmental statutes authorizing EPA activities call for protection of a diverse array of organisms. These statutes generally can be inferred to protect population-level endpoints in addition to organism-level endpoints, even if populations are not specifically cited by law. EPA's principles for ecological risk assessment and risk management at Superfund sites exemplify EPA concern about population-level endpoints, stating that "Superfund's goal is to reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota" (U.S. EPA, 1999b).

Predicting population-level impacts generally is not as straightforward as estimating organism-level effects and, as a result, explicit estimates of population effects are less common in EPA ecological assessments. Adverse effects to organisms are often inferred to indicate risk to populations and hence a cause for concern under certain EPA programs, however, such as at Superfund sites. Similar inferences are made for chemical reviews under TSCA. In examining environmental effects of concern under TSCA, an EPA position paper reviewed a number of statutes spanning the period of 1785 to 1978 to determine what society values in the environment (U.S. EPA, 1983). EPA concluded that such laws were passed to prevent any reduction, degradation, or loss in the quality, quantity or utility of a resource that is valued by the public. It also concluded that chemicals could adversely affect these resources by causing an undesirable change in the population structure of a species by affecting rates of mortality, reproduction, or growth and development. Thus, organism-level attributes such as mortality can be inferred to affect population-level attributes valued by society. Less commonly, EPA prepares quantitative estimates of population effects based on organism-level effects or other information.

A.2.1. GEAE #5: Extirpation of An Assessment Population

Extirpation can be viewed as an extreme case of a change in abundance or production of an assessment population, and thus its selection is supported by the factors cited in Section A.2.2.

as well as this section. Additionally, extirpation of an assessment population may have qualitatively more significant impacts on ecological function and environmental values than reduction in size of an assessment population. This significance is reflected in an alternative term for this population attribute, functional extinction.

A.2.1.1. Laws, Regulations, and Precedents

Several EPA precedents exist for assessing population extirpation. For example, EPA examined the likelihood of extirpation of fish populations in northeastern lakes under the acid deposition program, and vetoed a permit for a dam and reservoir project under Section 404 of the CWA based in part on projected extirpation of populations of birds of special interest (U.S. EPA, 1994). Absence of a species normally occurring in the habitat has been used as evidence of ecological risk at Superfund sites. Where designated aquatic life uses have been specified in state water quality standards, extirpation of a naturally occurring species may be considered as evidence that the waterbody is not attaining its designated uses.

A.2.1.2. Practicality

Field observations to determine whether a species is present usually are not difficult to conduct, but ease of observation depends upon the species and care must be taken in interpreting results. Failure to observe a species that is expected to occur in low numbers even in the absence of stressors, is subject to substantial natural fluctuations in abundance, or is inconspicuous may not be indicative of extirpation. Demonstrating extirpation at a site also requires evidence that the species was formerly present.

In some cases, risk of extirpation can be inferred from toxicity data. Very high exposure in the field in comparison to exposures where toxic effects have been observed in laboratory tests suggests a high likelihood of extirpation, and conversely very low exposure levels implies that extirpation is unlikely. Population modeling (such as population viability analysis) or ecosystem modeling may be required to estimate the likelihood of extirpation in cases where exposure is lethal to only a portion of individuals, where effects on reproduction are expected but limited, or effects are indirect. Population modeling typically requires species-specific data on parameters not routinely available in ecological risk assessment, such as age-specific reproduction rates.

See also Section A.2.2.2.

A.2.2. GEAE #6: Abundance of An Assessment Population

A.2.2.1. Laws, Regulations, and Precedents

Abundance is the most common population-level endpoint considered by EPA. On occasion, EPA has used population models to assess effects on abundance by chemicals regulated under TSCA. For example, EPA evaluated the risks of chloroparaffins to a rainbow trout population using a projection matrix model (U.S. EPA, 1993a). Maintenance of populations of piscivorous birds and mammals was the ecological assessment endpoint for the Mercury Report to Congress (U.S. EPA, 1995).

Additionally, more than 25 estuaries have been selected as National Estuaries by EPA as authorized by the CWA. Restoring or protecting populations and production of fish and shellfish for commercial and recreational use typically are among the goals of individual National Estuary programs. Similarly, a goal of the Chesapeake Bay Program (a partnership among EPA and the states adjoining the Bay) is restoring, protecting, and enhancing fish and shellfish, with measures including populations of oysters and priority migratory fish species such as striped bass.

A.2.2.2. Practicality

Changes in population abundance may be predicted using conventional toxicity data, statistical extrapolation models, and population models. This approach can produce reasonable results, at least in controlled conditions. For example, Kuhn et al. (2001) recently compared mysid shrimp population prediction from a stage-based projection matrix model with a 55 day laboratory population study involving shrimp exposed to p-nonylphenol. The population model was able to project within a few micrograms per liter the concentration where population-level effects would begin to occur (projected $16~\mu g/L$ from the model vs. measured $19~\mu g/L$ from the assay). Population abundance may also be estimated using individual-based population models or, as discussed in Section A.3., ecosystem models. Measurement of changes in population abundance in the field may be easy (e.g., flowering plants) or difficult (e.g., pelagic cetaceans).

A.2.3. GEAE #7: Production of An Assessment Population

A.2.3.1. Laws, Regulations, and Precedents

Much of the support for GEAE #6, abundance of an assessment population, also applies to this endpoint. For example, the Clean Water Act sets a national goal of "protection and propagation of fish, shellfish, and wildlife," which implies both abundance and production, and efforts under the National Estuary and Chesapeake Bay Programs to protect resource species involve both abundance and production. Additionally, numerous federal laws and treaties have the purpose of maintaining or increasing the production of game birds and mammals, commercial fish, and timber species. Examples include the Migratory Bird Hunting Stamp Act (48 Stat. 451), Wildlife Restoration Act (50 Stat. 917), Fish Restoration and Management Act (64 Stat. 430), Convention on Great Lakes Fisheries (6 UST 2836), and Fish and Wildlife Act of 1956 (70 Stat. 1119). Relevant provisions include requirements to "develop measures for maximum sustainable production of fish" (70 Stat. 1119) and "make possible the maximum sustained productivity of Great Lakes fisheries" (6 UST 2836).

Prevention of adverse effects to public welfare is mandated under Section 108 of the CAA (National Ambient Air Quality Standards), including (but not limited to) effects on soils, water, crops, vegetation, animals, and wildlife (§109). EPA has included production of an assessment population, among other endpoints, as an indicator of public welfare. For example, EPA revised the secondary ozone standard to provide increased protection against ozone-induced effects on vegetation, such as agricultural crop loss and damage to forests (U.S. EPA, 1997b). Also, EPA regulations authorize the Agency to require pesticide registrants to submit tests on pesticide effects on plant mortality and plant growth inhibition. Results from these tests are used by EPA, in conjunction with other available information, in making pesticide registration decisions. Changes in production of specific legume species were endpoints in a TSCA assessment of release of recombinant rhizobia (McClung and Sayer, 1994; Orr et al., 1999).

A.2.3.2. Practicality

Plant production is relatively easily and commonly measured in the field. Production of animals is more difficult to measure in the field, but well developed techniques exist and are commonly employed for fisheries, game species, and pest insects. Toxic effects on production may be estimated from chronic tests that include survival, fecundity and growth. The combined effects on population production of these organismal responses may be estimated using population or ecosystem models.

A.3. Community-Level Endpoints

To date, the most common application at EPA of direct assessment of community-level endpoints has been in the context of aquatic communities, particularly fish and macroinvertebrate communities. Section 101(a)(2) of the Clean Water Act calls for an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife. Section 304(a) of the Water Quality Act of 1987 directs EPA to develop and publish water quality criteria and information on methods, including biological monitoring and assessment methods, that assess the effects of pollutants on the aquatic community. Aquatic community components and attributes addressed include "biological community diversity" and "productivity." Species richness and abundance of fish and macroinvertebrate communities are used in the biocriteria of many states and in Agency guidance (Yoder and Rankin, 1995; U.S. EPA, 1996).

In addition, potential community-level impacts have been inferred and considered a basis of concern by EPA programs based on organism-level responses. The U.S. Ambient Water Quality Criteria for Protection of Aquatic Life are based on Species Sensitivity Distributions (SSDs), with the criteria set at the fifth percentile (U.S. EPA, 1985). Hence, they can be interpreted as protecting at least 95% of species in a community. The assessment community is also commonly used in EPA programs under TSCA. The Quotient Method is typically applied to the most sensitive organismal response, as well as uncertainty factors, to infer effects on a community. Organisms are chosen to represent a variety of taxonomic groups.

EPA's principles for ecological risk assessment and risk management at Superfund sites state that "Superfund's goal is to reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota," with community effects either measured directly (e.g., benthic species diversity) or estimated indirectly (e.g., from toxicity tests on individual species) (U.S. EPA, 1999b). Ecosystem models are particularly useful for assessing secondary (indirect) effects of toxicants on community properties (Bartell et al., 1992). EPA has occasionally used ecosystem models to estimate community-level effects, as in case of evaluating the primary and secondary effects of chloroparaffins to top predator fish (Bartell, 1990; U.S. EPA, 1993a).

A.3.1. GEAE #8: Species Richness of An Assessment Community

A.3.1.1. Laws, Regulations, and Precedents

In addition to the applications cited in Section A.3., aquatic community composition is presented as an example of an assessment endpoint in Superfund ecological risk assessment guidance (U.S. EPA, 1997c) and community diversity or species richness is a generic endpoint for ecological risk assessments of hazardous waste combustors (U.S. EPA, 1999a). EPA regional offices have considered effects of federal projects on species diversity in decisions under NEPA, such as in an assessment of the impacts of the loss of bottomland hardwood forest on species composition of the wildlife community due to levee construction (U.S. EPA, 1994).

A.3.1.2. Practicality

Species richness is the simplest, least controversial, and most easily interpreted expression of community diversity. Changes in species richness are readily observed in standard biological surveys. If it is assumed that significant toxic effects are likely to result in local extirpation of a species, changes in species richness may be predicted using species sensitivity distributions or regression models that relate all species of a community or assemblage to a test species. If indirect effects are expected to result in the loss of species, ecosystem models may be used to predict species losses.

A.3.2. GEAE #9: Abundance of An Assessment Community

A.3.2.1. Laws, Regulations, and Precedents

As described in Section A.3, this GEAE has most often been applied to aquatic communities. Abundance of fish and macroinvertebrate communities is used in the water quality biocriteria of many states and in Agency guidance, and community abundance can be inferred to be an element of ambient water quality standards and of chemical evaluations under TSCA. Aquatic community composition (including a metric describing abundance) is presented as an example of an assessment endpoint in Superfund ecological risk assessment guidance (U.S. EPA, 1997c).

A.3.2.2. Practicality

Abundance of communities or assemblages, either as a whole or by species, are available

from most routine biological surveys. While one can readily infer from standard toxicity tests that some changes in abundance are likely to occur, they are difficult to predict quantitatively. As discussed in Section A.3., community properties may be estimated from standard toxicity test data using ecosystem models.

A.3.3. GEAE #10: Production of A Plant Assemblage

A.3.3.1. Laws, Regulations, and Precedents

This endpoint shares a basis in laws, regulations, and precedents with production of plant populations described in GEAE #7, such as under FIFRA, TSCA, and CAA programs. For example, the secondary ambient air quality standard established by EPA to protect public welfare for ground-level ozone (U.S. EPA, 1997b) cited growth and yield reductions in tree seedlings and mature trees, and impacts on forest stands and community structure due to these reductions.

Superfund directives and guidance identify plant production, such as productivity of wetlands vegetation, as candidate assessment endpoints (Environmental Response Team, 1994a, b, c, d). Community productivity and, in particular, herbaceous plant productivity, is a generic endpoint for ecological risk assessments of hazardous waste combustors (U.S. EPA, 1999a). EPA actions to control acid rain and its precursors have been based on concerns over damage to high elevation forests, among other effects, attributed to acid rain.

As stated in Section A.3., the Clean Water Act (§101(a)(2)) calls for an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife. Section 304(a) of the Act also lists effects of pollutants on plant life and on rates of eutrophication as factors to consider in establishing pollutant limits. Excessive plant production and its sequelae (e.g., fish kills from low dissolved oxygen) due to nutrient pollution (eutrophication) has been the basis for many federal and state regulatory actions and voluntary control programs. These include establishing Total Maximum Daily Loads (TMDLs) for nutrients (U.S. EPA, 1999c), controls on nutrient discharges from sources such as publicly owned treatment works (POTWs) and confined animal feeding operations, and restrictions on phosphorus in detergents.

A.3.3.2. Practicality

Eutrophication has long been a major concern of environmental managers, particularly with respect to sewage outfalls, so the models for predicting effects of nutrient additions are relatively well developed. Similarly, studies of fertilizer addition to crops, pastures and commercial forests are numerous and provide a good basis for predicting effects of terrestrial nutrient additions on plant production. In addition, methods for measuring plant production are well developed for both terrestrial and aquatic communities. Protocols for testing toxic effects on terrestrial and aquatic plants focus on various measures of production. However, toxicity data for plants are less abundant than for animals.

A.4. Ecosystem and Location-Specific Endpoints

From an ecological perspective, attributes that characterize ecosystems include primary production, energy flow, total biomass, and nutrient cycling. The authors of this report found little precedent for using such endpoints at EPA (with the exception of functional properties of wetlands), perhaps because these concepts are somewhat abstract and not as directly linked to management values of concern as other endpoints. Nevertheless, abundant statutory and regulatory support exists for environmental protection at levels above the organism, population, and even community level. This is both due to the recognition that to maintain particular organisms of concern their surrounding environment must be preserved (e.g., in the case of endangered species) and due to appreciation for the ecosystem as a whole (e.g., National Parks, coral reefs). Endpoints based on these concerns tend to be location-specific and defined by the area they encompass and sometimes by particular properties they exhibit within the area. While arguably some of the following endpoints could be regarded as community-level endpoints, they are collected in this section on the basis of their shared association with particular geographical locations and their broadly-defined attributes that are not restricted to a particular level of biological organization.

A.4.1 GEAEs #11 & 12: Area and Function of Wetlands

A.4.1.1. Laws, Regulations, and Precedents

The Clean Water Act forms the primary statutory basis for this endpoint. In meeting the Clean Water Act's objective of restoring and maintaining the integrity of the Nation's waters,

under Section 404 of this Act wetlands are considered "waters of the United States" and are protected from discharge of dredged and fill material through a permit program jointly administered by the U.S. Army Corps of Engineers and EPA. Wetlands are defined for regulatory purposes as areas that are inundated or saturated by surface or ground water at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas (33 CFR §328.3(b); 1984). The Clean Water Act provides authority for the Corps to require permit applications to avoid and minimize wetlands impacts and requires EPA to develop, in coordination with the Corps, the criteria used for Section 404 permit decisions. When damages to wetlands are unavoidable, the Corps can require permitees to provide compensatory mitigation. Compensatory mitigation activities may include enhancement, restoration, creation or preservation efforts associated with the impacted wetlands or other wetlands preferably within the same watershed.

Additionally, Executive Order 11990, Protection of Wetlands, requires that "Each agency shall provide leadership and shall take action to prevent the destruction, loss or degradation of wetlands and to preserve and enhance natural and beneficial values of wetlands in carrying out the agency's responsibilities" (Carter, 1977). As an extension of this order, President George Bush in 1989 and succeeding Presidents have adopted a national policy of no net loss of wetlands in recognition of the significance of wetland areas and their ecological functions. The 1972 Coastal Zone Management Act also calls for the protection of coastal wetlands.

EPA has prepared various regulations and guidance documents supporting the wetlands protection goals of the CWA and Executive Order. For example, the Guidelines for Specification of Disposal Sites for Dredged or Fill Material (40 CFR Part 230, Subpart E) require consideration of potential impacts on special aquatic sites, including wetlands, referencing changes that result in loss of wetland status due to permanent flooding or conversion to dry land as well as loss of functions of water purification, water storage, and provision of wetland habitat.

Due to the large number of Superfund sites in or adjacent to wetlands, EPA's policy and emphasis has lead to a greater concern regarding the impact of contamination from Superfund sites on the extent and ecological functions of wetlands. EPA's Office of Solid Waste and Emergency Response (OSWER) highlights the importance of wetlands protection in their directive, "Policy on Floodplain and Wetland Assessment for CERCLA Action" (U.S. EPA,

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1985). Under this policy, Superfund action must meet the substantive requirements of the Floodplain Management Executive Order (E.O. 11988) and the Protection of Wetlands Executive Order 11990.

Throughout the Superfund process, site managers should address the potential ecological impacts from response actions to both on-site and adjacent wetland resources. Prior to the national listing of a site, information regarding the presence of wetlands is factored into the Hazard Ranking System (U.S. EPA, 1990a and 1992b). During any removal actions, the Superfund Removal Process Guidance (U.S. EPA, 1992a) requires the On-Scene Coordinator to undertake special considerations for actions that include wetlands. From the initiation of the onsite investigation during the Remedial Investigation/Feasibility Study to evaluating the effectiveness of remedial alternatives, requirements set forth in E.O. 11990 and Section 404 of the Clean Water Act should be considered and any unavoidable impacts to wetlands must be mitigated (U.S. EPA, 1984). Section 404 of the Clean Water Act is also considered a federal "applicable or relevant and appropriate requirement" (ARAR) with which Superfund remedial actions must comply under CERCLA Section 121(d)(2)(A). Types and levels of mitigation necessary to demonstrate compliance with Section 404 are discussed in a Memorandum of Agreement (MOA) between the U.S. EPA and the Department of Army (U.S. EPA, 1990b). In general, the MOA indicates that any enhancement, restoration, creation, or replacement of wetlands should be based on functional equivalence to include the minimum of a one to one ratio. The prevention of secondary wetland impacts due to activities in or adjacent to a wetland as part of the Superfund response action are addressed in the OSWER Directive, Controlling the Impacts of Remediation Activities In or Around Wetlands (U.S. EPA, 1993c).

EPA's "Procedures for Implementing the Requirements of the Council on Environmental Quality on the National Environmental Policy Act" (40 CFR §6.108) singles out wetlands in stating that "if the proposed action may have significant adverse effects on wetlands" an Environmental Impact Statement is required. EPA's regulations for State and Local Assistance (40 CFR Part 35, Appendix A to Subpart H) require that project proposals demonstrate compliance with Executive Order 11990.

The Wetlands Loans Act (75 Stat. 813) established financing for acquisition and restoration of wetlands. While this Act places no obligations on EPA, it further demonstrates Congressional intent to protect and enhance wetlands.

Ecological risk assessment case studies sponsored by EPA have used attributes of wetlands as assessment endpoints. A case study of physical disturbance of wetlands used water purification with respect to specific pollutants as the assessment endpoints (Detenbeck, 1994).

A.4.1.2. Practicality

Wetlands are classified and mapped by the National Wetlands Inventory of the U.S. Fish and Wildlife Service, but determination of wetland boundaries at a given site may be difficult, particularly in areas of low topographic relief. The 1987 Corps of Engineers Wetlands

Delineation Manual (Environmental Laboratory, 1987) is the current federal delineation manual used in the Clean Water Act Section 404 regulatory program for the identification and delineation of wetlands. Most effects on wetland area are readily predicted or observed, because they occur due to processes such as dredging, filling, draining, or inundation. Losses of wetland functions are less readily observed or predicted except when they result from the loss of wetland area. The Corps and Natural Resources Conservation Services (NRSC) have agreed to formally adopt the Hydrogeomorphic Method (Brinson, 1993) for assessing wetland function under the Clean Water Act Section 404 Program. Toxic effects on wetland functions or on the type of wetland community are difficult to predict.

Within the Superfund program, unavoidable impacts to on-site and adjacent wetland resources from current or potential exposure to hazardous substances and from implementation of selected response actions are addressed within the Record of Decision for that site. Records of Decision for the New London Submarine base in New London, Connecticut (U.S. EPA, 1998c), Loring Air Force Base in Limestone, Maine (U.S. EPA, 1997d) and Pease Air Force Base in Portsmouth/Newington, New Hampshire (U.S. EPA, 1997e) include remedies involving compensatory wetland mitigation. Mitigation actions are monitored through the development of long-term monitoring plans and an annual and five year review process to ensure the success of the wetlands restoration efforts.

A.4.2. GEAEs #13 & 14: Area and Species Richness of Coral Reefs

A.4.2.1. Laws, Regulations, and Precedents

At present, coral reefs have not attained the same legal and regulatory stature under EPA programs as wetlands, but the basis for their protection has been increasing. Executive Order 13089 on Coral Reef Protection establishes special protection for coral reefs (Clinton, 1998). In particular, "All Federal agencies...shall...utilize their programs and authorities to protect and enhance the conditions of such ecosystems." This Executive Order names the EPA Administrator as a member of the Coral Reef Task Force, which is responsible for implementing the Order. An EPA memorandum to the field specifically applies EO 13089 to EPA's responsibilities under Section 404 of the Clean Water Act, Section 102 and 103 of the Marine Protection and Sanctuaries Act, and Section 307 of the Coastal Zone Management Act (Fox and Westphal, 1999). The order is also considered a federal "applicable or relevant and appropriate requirement" (ARAR) with which Superfund remedial actions must comply under CERCLA Section 121(d)(2)(A). The Guidelines for Specification of Disposal Sites for Dredged or Fill Material (40 CFR Part 230, Subpart E) require consideration of potential impacts on special aquatic sites, including coral reefs. The Guidelines refer to loss of productive colonies and subsequent loss of coral-dependent species.

Diversity is the only ecological attribute defined as a value of coral reefs in the National Action Plan to Conserve Coral Reefs (U.S. Coral Reef Task Force, 2000). A practical operational definition of that attribute is species richness. This document also mentions "shoreline protection, areas of natural beauty, recreation and tourism, and sources of food, pharmaceuticals, jobs, and revenues" as services of coral reefs. These services could be protected by preserving the area and species richness of coral reefs.

The Convention on International Trade in Endangered Species (CITES), to which the U.S. is a party, restricts international trade in corals and other reef organisms. All coral reefs in Florida are protected by either the U.S. or State government. Other specifically protected reef communities are found in Puerto Rico, Hawaii, the U.S. Virgin Islands, Guam, Northern Marianas, American Samoa, and several small outlying islands.

Despite the regulatory and other policy support for protecting coral reefs, there is little precedent for use of this endpoint at EPA to date, perhaps because EO 13089 is new and few EPA actions involve coral reefs.

A.4.2.2. Practicality

The area of coral reef and the species richness of corals are relatively easily determined. The species richness of some other assemblages (e.g., fishes and sessile noncoral invertebrates) is practical to determine. Methods for assessing the condition of coral reefs are discussed by Jameson et al. (1998). Prediction of effects of pollutants on coral reefs is difficult due to the paucity of toxicological information for corals.

A.4.3. GEAEs #15 & 16: Area and Quality of Habitat for Threatened or Endangered Species

A.4.3.1. Laws, Regulations, and Precedents

The obligation to protect endangered and threatened species under the ESA includes protection of the critical habitats on which they depend. Thus the legal and regulatory basis for protecting endangered species described under GEAE #3 generally also applies to this endpoint. For example, the Superfund NCP specifies that, "evaluations shall be performed to assess threats to the environment, especially sensitive habitats and *critical habitats of species protected under the Endangered Species Act*" (emphasis added) (U.S. EPA, 1989). EPA's regulations for "State and Local Assistance" (40 CFR Part 35, Appendix A to Subpart H) require that project proposals determine whether there would be significant adverse effects on critical habitat of endangered species.

A.4.3.2. Practicality

Designated critical habitat is readily identified, and it should be practical to determine whether it will be destroyed (reduced area) or adversely modified (reduced quality). However, critical habitat has not been officially designated for many endangered or threatened species. Critical habitat that has not been officially designated must be identified based on the distribution of the species and its ecological requirements. Toxic effects may be predicted if species or taxa that are components of critical habitat are identified and their response to pollutants can be evaluated.

A.4.4. GEAE #17: Area of an Endangered or Rare Ecosystem Type

A.4.4.1. Laws, Regulations, and Precedents

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Support for this endpoint at EPA is less extensive and more indirect than for many of the other GEAEs, but can be identified in a variety of programs. In particular, several lines of support are apparent in Superfund programs. The NCP specifies that, "evaluations shall be performed to assess threats to the environment, *especially sensitive habitats*" (emphasis added) (U.S. EPA, 1989). The Hazard Ranking System for Superfund (U.S. EPA, 1990a) gives as an example of 'sensitive environments': 'particular areas, relatively small in size, important to maintenance of unique biotic communities.' The Superfund Removal Process Guidance (U.S. EPA, 1992a) requires the On-Scene Coordinator to undertake special considerations for actions that include sensitive ecosystems, which may be interpreted as calling for protection of endangered or rare ecosystem types.

Other EPA programs also consider endangered ecosystems. For example, the protocol for screening-level ecological risk assessment for hazardous waste combustion facilities calls for special consideration of areas having unique and/or rare ecological receptors and natural resources (U.S. EPA, 1999a). EPA Regions 4, 5, 6 and the Great Lakes Program Office are developing approaches for identifying high quality area (critical ecosystems) for enhanced environmental protection and restoration. EPA Region 4 has been involved in the development of the Southeastern Ecological Framework (SEF) as a decision support tool useful in integrating program resources for protecting and sustaining ecological processes. EPA Region 5 also developing an approach for prioritizing and targeting high-quality areas in the Midwest (Mysz et al., 2000). Two of the criteria for identifying these areas, also called "critical ecosystems," share features with this GEAE: 1) presence of an indigenous ecosystem and biological community types (used as an indicator of relative ecological diversity), and 2) numbers and rarity of native species and natural features (used as indicators of surviving relict native ecosystems). In addition, the EPA Great Lakes program in collaboration with Environment Canada have developed Biodiversity Investment Areas (BIAs) as natural areas along the Great Lakes shoreline with high ecological value that warrant exceptional attention to protect them from degradation. EPA Region 6 is using a GIS screening tool to assist in prioritizing ecological areas of concern for programs like NEPA (Osowski et al., 2001).

In carrying out its responsibilities for reviewing Environmental Impact Statements under

- NEPA, EPA has developed guidance that calls for paying special attention to human activities in imperiled ecosystems and identifies mitigation measures to reduce adverse impacts (U.S. EPA, 1993b). Approximately a dozen "principal habitats of concern" were identified within each of six major U.S. habitat types. Ecological concerns raised by EPA to other federal agencies in review of NEPA documents have included impacts to endangered or rare ecosystems (U.S. EPA, 1994).
- State Natural Heritage programs identify rare ecosystem types and their locations and, depending on the state, provide for protection or special consideration of those areas.

A.4.4.2. Practicality

An endangered or rare ecosystem type might be diminished by physical destruction, which is readily observed and quantified, or by physical conversion to another type (e.g., due to selective logging or grazing), which can also be readily observed and quantified if the type is clearly defined. The prediction of loss of an ecosystem type due to extirpation of many or most of the constituent organisms (e.g., due to an herbicide application or oil spill) is practical since it would involve severe toxicity. However, loss of a type due to more subtle effects, such as changes in species composition due to differential susceptibility to a stressor, could be difficult to predict. Information useful in identifying rare and endangered ecosystem types is available from NatureServe (www.natureserve.org), a nonprofit organization that works with natural heritage programs throughout the United States and elsewhere in the Western Hemisphere. NatureServe maintains databases on all known ecological communities in the United States, ranked from critically imperiled to secure. According to NatureServe, the completeness of inventory and classification work varies widely among states, provinces and regions.

A.4.5. GEAE #18: Physical Structure of an Aquatic Ecosystem

A.4.5.1. Laws, Regulations, and Precedents

The Clean Water Act [§101(a)] states that, "The objective of this Act is to restore and maintain the chemical, *physical*, and biological integrity of the Nation's waters" (emphasis added). The importance of physical structure is reflected by EPA regulations implementing the CWA that note the following conditions of a water body that may preclude attainment of desired

- beneficial uses (40 CFR §131.10 (g)):
 - "natural, ephemeral, intermittent or low flow conditions of water levels"
- "dams, diversions or other types of hydrologic modifications"
 - "physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality"

The *Protocol for Developing Sediment TMDLs* lists channel modification, pool filling, filling of substrate with fine sediments and other effects on physical structure as sediment issues that can result in loss of designated uses (U.S. EPA, 1999d). These changes in stream ecosystems are themselves changes in the ecosystem attributes that result in the lost recreational/aesthetic or other uses, and not simply stressors that affect biological endpoints.

Physical structure has been a factor used in setting the designated use of streams in state water quality standards. For example, in Ohio, a designated use of Modified Warmwater Habitat applies to streams with extensive and irretrievable physical habitat modifications.

A.4.5.2. Practicality

Physical characteristics often are readily observed or measured at sites being assessed and are usually recorded in biological surveys. Protocols exist for measuring many aquatic habitat attributes. In addition, most of the actions that modify the physical structure of water bodies (e.g., channelization, dam construction and operation, water withdrawals, and culvert installation), have obvious effects on structure which are readily predicted. Other effects, such as changes in hydrology resulting from changes in land use, are more difficult, but still possible, to model.

A.4.6. GEAE #19: Ecological Properties of Special Places

A.4.6.1. Laws, Regulations, and Precedents

The legislative acts establishing the National Parks and Monuments, Wildlife Refuges, Wilderness Areas, Wild and Scenic Rivers, Recreation Areas, Marine Sanctuaries, and other special places establish their status and indicate the properties for which they were provided with

protected status. Several statutes either give EPA a role in designating special places or direct EPA to consider environmental impacts to such places in administering Agency programs. The CWA directs EPA to administer the National Estuary Program, and permits states to designate waterbodies as Outstanding National Resource Waters, which then receive increased protection in their water quality standards. The Clean Air Act also has several provisions for special places. Section 160 of the CAA establishes that a purpose of the Act is "to preserve protect, and enhance the air quality in national parks, national wilderness areas, national monuments, national seashores, and other areas of special national or regional natural, recreational, scenic, or historic value." Section 162 designates national (and international) parks, wilderness areas, and memorial parks of a certain size as "class I" areas that merit the highest level of protection from air pollution. Other special places cited in both the CAA and CWA include the Great Lakes, Chesapeake Bay, and Lake Champlain.

In the area of EPA regulations and guidance, the NCP cites special places such as National Marine Sanctuaries and Estuarine Research Reserves as natural resources to be protected under CERCLA. The Superfund Removal Process Guidance (U.S. EPA, 1992a) requires the On-Scene Coordinator to undertake special considerations for actions that include wild and scenic rivers. EPA procedures for implementing NEPA (40 CFR §6.108) require an environmental impact statement to be prepared if "the proposed action may have significant adverse effects on parklands, preserves, or areas of recognized scenic, recreational, archeological, or historic value." The Guidelines for Specification of Disposal Sites for Dredged or Fill Material (40 CFR, Part 230, Subpart E) requires consideration of potential impacts on special aquatic sites, including sanctuaries and refuges. The protocol for screening-level ecological risk assessment for hazardous waste combustion facilities calls for special consideration of areas having legislatively-conferred protection (U.S. EPA, 1999a).

A.4.6.2. Practicality

Special places and their important ecological properties usually can be defined readily. Given the diverse set ecological of properties at different places, it is not possible to make overall statements about the practicality of this endpoint. Potentially, all of the surveying, testing, and modeling methods discussed in prior sections could be applicable.

APPENDIX B. TYPES OF VALUES ASSOCIATED WITH ASSESSMENT ENDPOINTS

EPA's Ecological Risk Assessment Guidelines define an assessment endpoint as "an explicit expression of the *environmental value* that is to be protected, operationally defined by an ecological entity and its attributes" [emphasis added] (U.S. EPA, 1998a). In the context of the Guidelines, an *environmental value* refers to a component of the environment (or an ecological entity) that society values, with some examples being endangered species, and commercially or recreationally important species. Literature on environmental valuation covers a wide range of ecological systems and components; for example, bays (Kahn, 1985), wetlands (Barbier, 1993), riparian corridors (Lant and Tobin, 1989), deserts (Richer, 1995), recreation areas (Adamowicz et al., 1994), and wilderness or "un-spoiled" natural areas (Hanink, 1995; Kopp and Smith, 1993; and Randall and Peterson, 1984). In many of these studies, ecosystems are conceptualized as having assets or structural components such as energy resources, minerals or timber; services or natural functions benefitting society (e.g., groundwater recharge, flood control, or the absorption or assimilation of pollutants) and/or other attributes provided by the whole ecosystem such as biological diversity, cultural uniqueness, or natural heritage (Westman, 1977; Daily et al., 1997).

Table B.1 presents one way of organizing environmental values, drawing on Blomquist and Whitehead (1995), Daily (2000), Ehrlich and Ehrlich (1981), MacLean (1995), Primack (1993) and Freeman (1984, 1993). Table B.1 is not intended to represent a definitive or comprehensive list of environmental values, but rather is intended to illustrate the breadth of values that may be cited in support of a GEAE. Another common approach in the literature is to distinguish between <u>use values</u> (e.g., natural resources consumed or used in economic markets) and <u>non-use values</u> (ecological attributes with social values beyond mere economic considerations). In this context, "consumptive" and "information" values in Table B.1 could typically be considered as use values, and "educational" and "preservation" values as non-use values. "Functional," "option" and "recreational" values in Table B.1 could be considered as use or non-use values depending on the context in which they are used. Non-use values are also sometimes characterized as "existence," "intrinsic," "preservation," or "passive use" values. Nevertheless, when quantified in cost-benefit analyses, non-use values may, in some cases, be more significant than use values (Ehrenfield, 1976; Randall, 1984; Smith, 1993; and Kahn,

1 1995).

Each of the GEAEs presented in this document relate to one or more of these environmental values. For example, an "assessment population" and its attributes may be used to represent a commercially and recreationally valuable fish or wildlife population (consumptive and recreational values). Such an assessment population could also represent a species population that is valued as a learning tool (educational value) and protected for cultural and aesthetic reasons (preservation value). Table B.1 provides further examples of how each of the GEAEs may correspond with these values.

Table B.1. Some Categories of Environmental Values.

12	Value	Definition and examples
13 14	Consumptive value	Definition: the value of commodities produced by the environment such as food, energy, timber, fiber, and pharmaceutical and industrial products.
		Examples of corresponding GEAEs: • Assessment population and coral reefs: commercially valuable fisheries • Plant production: timber and fuel production by trees • Organisms (in an assessment population): commercially valuable furbearers
15 16	Information value	Definition: the value of natural structures, chemicals or processes as models for anthropogenic structures, chemicals or processes (e.g., pharmaceuticals, synthetic commodities and engineering designs). Also see Option value.
		 Examples of corresponding GEAEs: Endangered/rare ecosystem types: as examples of process integration Species richness of communities: as sources of bioactive chemicals as models for pharmaceuticals Organisms (threatened and endangered species): as sources of model adaptations to extreme environments
17 18	Functional value	Definition: the value of ecological functions benefitting public health and welfare, such as pollen and seed dispersal, water retention and purification, detoxification of wastes, and moderation of weather extremes. In some cases, ecosystems are reestablished to make use of their functional value for remediation.
		Examples of corresponding GEAEs: • Wetlands: water retention and purification • Assessment community or assemblage: water and soil retention by forests • Assessment population: pollination by insects

	Value	Definition and examples
1 2	Recreational value	Definition: the value of recreational opportunities such as fishing, birding, boating, and hiking. In some cases, this is a passive use of a resource, but in others (e.g., tourism) it is an economic activity.
		Examples of corresponding GEAEs: • Wetlands, coral reefs, and aquatic ecosystems: boating, fishing • Organisms (migratory birds): birding, hunting • Special places: camping, hiking, boating
3 4	Educational value	Definition: the value of academic and nonacademic educational opportunities, including nature and scientific study.
		Examples of corresponding GEAEs: • Special places: parks and wildlife refuges for nature study and research • Wetlands and aquatic ecosystems: environmental education sites
5 6	Option value	Definition: the value to future generations of preserving the option of using the environment at some future time. Option value also includes human welfare gains or net benefits associated with delaying a decision when there is uncertainty about the payoffs of certain alternatives, or when one of the choices involves an irreversible commitment of resources.
		Examples of corresponding GEAEs: • Wetlands and aquatic ecosystems • Special places • Endangered/rare ecosystem types
7 8	Existence value	Definition: value ascribed to the existence of ecological systems independent of any direct services or functions. Aesthetic, moral, cultural, religious, or spiritual grounds may be cited in support of this type of non-use value.
		Examples of corresponding GEAEs: Organisms—endangered species and their critical habitat Organisms—marine mammals Endangered/rare ecosystem types Special places

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