**ATTACHMENT 1-4: Process for Determining Effects Thresholds:**

1. **Effects Thresholds for the Action Area (Step 1):**
	1. **Mortality (Acute) and Sublethal Thresholds**:

An action area is defined as “all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action” [50 CFR §402.02]. Due to the unique nature of this consultation, we are using a quantitative approach to delineate the action area. The action area is determined by using the lowest toxicity value for the most sensitive species (*i.e*., not limited to ESA-listed species) that results in the farthest distance from the use site(s) based on the effects thresholds described below. The aquatic portions of the action area incorporate downstream transport. All effects/endpoints considered relevant to the ‘No Effect’ – ‘May Affect’ determination, irrespective of whether or not they are associated with a listed taxon, are included in Step 1. The effects/endpoints that are used to establish the off-site portion of the action area, may include, but are not limited to the following (see **Table A 1-4.1**):

* For direct effects to animals - acute lethality endpoints (LC50 or LD50):
	+ For animals with robust data sets, exposure that results in a one-in-a-million chance of mortality based on the 5th percentile (HC05) species from a species sensitivity distribution (SSD) (see **ATTACHMENT 1-5**).
	+ If there are not enough data for a SSD, exposure that results in a one in a million chance of mortality based on the most sensitive species tested for each taxon *(e.g.,* most sensitive LD50 or LC50 extrapolated to 1 in million chance of mortality based on representative slope).

The calculation of the dose (LCk) associated with a defined response for a probit dose curve is as follows:

 logLCk = logLC50 + (probit k-probit5)/b

 Where: LC50 equals probit 5 and b equals slope

This can also be expressed as:

 LCk = (LC50)(10z/b)

 logLCk = logLC50 + (z/b)

 where: z is the standard normal deviate and b equals the slope.

The empirical slope associated with the lowest LD50/LC50 value is used when an SSD cannot be derived. When an SSD can be derived, the slope associated with an LD50/LC50 value close to the 5th percentile value on the SSD is used. If a slope is not available, a default slope of 4.5 is used (see USEPA, 2004 – the overview Document[[1]](#footnote-1))”.

* For direct effects to all taxa - sublethal endpoints (NOAEC, NOAEL, or ECx):
	+ For plants, the level corresponding to a reproduction/growth no observed adverse effect concentration or level (*i.e*., NOAEC or NOAEL) for the most sensitive species is used.
	+ For animals, the lowest available NOAEC or NOAEL or other scientifically defensible effect threshold (ECx) is used.

Endpoints generally are: a) from *in vivo* studies that are conducted with whole organisms; b) representative of environmentally relevant exposure~~s~~ routes, and C) able to be quantitatively or qualitatively linked to effects on survival, growth or reproduction.

Decisions on the use of effects levels other than NOAEC or NOAEL values (*i.e*., ECx) involve a consideration of the statistical power of the concurrent NOAEC or NOAEL from that study and whether there is sufficient information regarding dose response to establish a different threshold with a reasonable degree of confidence. Only NOAECs or NOAELs from studies containing a corresponding LOAEC or LOAEL for the measured endpoint are considered for threshold values.

Establishing “may affect” thresholds for given ESA-listed taxa may alsobe based on toxicity studies that are conducted at the suborganismal level (*e.g*., on organs or cells), provided data are consistent with other criteria for use.

**TABLE A 1-4.1. Endpoints and associated threshold selection strategies that will be used to delineate the boundary of the action area in Step 1.**

| **Taxon** | **Mortality** | **Sublethal Effects** |
| --- | --- | --- |
| Birds1 | Concentration (or dose) that would result in a chance of 1 in a million of causing mortality to an individual. This is calculated by using HC05 of SSD of LC50, LD50, or EC50 values for taxa and representative slope. If SSD cannot be derived, most sensitive LC50, LD50, or EC50 for taxa will be used and most representative slope.  | The lowest available NOAEC, NOAEL or other scientifically defensible effect threshold (ECx). Endpoints are generally from *in vivo* studies that are conducted with whole organisms; are representative of environmentally relevant exposure~~s~~ routes; and are able to be quantitatively or qualitatively linked to effects on survival, growth or reproduction. |
| Mammals1 |
| Reptiles |
| Terrestrial-phase amphibians |
| Aquatic-phase amphibians |
| Fish |
| Aquatic invertebrates |
| Terrestrial invertebrates |
| Aquatic plants | Not Applicable | Aquatic plants: *Non-vascular* - Concentration equal to the lowest value among the available NOAEC and EC05 values for non-vascular aquatic plants*Vascular* - Concentration equal to the lowest value among the available NOAEC and EC05 values for vascular aquatic plantsTerrestrial and wetland plants: *Monocots* - Concentration equal to the lowest value among the monocot NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies*Dicots* - Concentration equal to the lowest of the dicot NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies*Non-angiosperm* - Concentration equal to the lowest of the NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies |
| Terrestrial plants |
| Wetland plants |

1Lowest LD50 or NOAEL/LOAEL for birds and mammals determined by normalizing results to 100 g body weight for birds and 15 g body weight for mammals prior to establishing threshold values.

Once the action area has been delineated, species ranges will be overlayed onto the action are to determine where any overlap occurs.For species/critical habitats that do not overlap with the action area (as determined by the process described above), the call will be ‘No Effect’ and no further analyses will be required (*i.e*., there is no need for Steps 2 and 3). For species and/or critical habitats that do overlap with the action area, the call for that species and/or its critical habitat will be “May Affect,” and the analysis will proceed with Step 2, to determine whether adverse effects would be anticipated. This process is iterative [*i.e*., if additional information becomes available during the course of conducting Step 2 that indicates that the action area is not adequate for the action(s) being assessed, the action area can be revisited].

1. **Effects Thresholds for Effects Determinations (Step 2):**

In Step 2, toxicity values and other data for direct and indirect effects to listed species are analyzed using a weight of evidence approach. These data are organized into lines of evidence that inform risk hypotheses and ultimately the effect determinations (NLAA or LAA) for listed species. Effects thresholds represent just one line of evidence in the overall weight of evidence. The overall effects determination for each species and critical habitat being assessed will be based on the weight-of-evidence approach described in **Section 1.4.2.2** and **ATTACHMENT 1-9**.

* 1. **Direct and Indirect Effect Thresholds Based on Mortality:**

For mortality, either the one-in-a-million chance of mortality as established in Step 1 (derived from consideration of all species in the environment, as described above) or from data for a more appropriate surrogate, when available, is used as a threshold. Use of data from surrogate species is based on an assessment of the quantity and quality of the surrogate data available for the listed species. For example, if a listed species’ range overlaps with the action area, where there is an estimated chance of at least one individual in one million dying from that exposure, this would result in a ‘LAA’ call. If enough data from appropriate surrogates are available to create a SSD for the surrogates (*e.g*., data for several salmonid species are available to assess risks to listed salmonids), the 5th percentile of the SSD or a surrogate LD50, LC50, or ECx from the subset of data may be used to make this determination. For listed species which lack more appropriate surrogate data (*e.g*., only data from trout and sunfish are available to assess risks to a listed sturgeon), the taxon-specific threshold derived in Step 1 is carried over for this analysis.

The potential for indirect effects (*e.g.,* effects on diet, habitat) is based on chlorpyrifos toxicity to the taxa that are relevant to the specific species being assessed. For example, for potential indirect effects based on prey lethality for those species without obligate relationships, the exposure that results in a 10% effect for the 5th percentile species on an SSD for the prey species is used. If not enough data are available for a SSD, the 10% effect for the most sensitive prey species tested in that taxon is used. The 10% effect is determined using the most sensitive LD50 and the corresponding slope, if available (if not available a default slope of 4.5 will be used) (see **Table A 1-4.2**, below).

* 1. **Direct and Indirect Effect Thresholds Based on Sublethal Endpoints:**

For sublethal effects to plants, the level that corresponds to the reproduction or growth NOAEC, NOAEL, or EC05 for the most appropriate surrogate species is used to derive the threshold. If data on a specific surrogate are not available, the most sensitive species tested in a taxon is used (as described above). For indirect effects related to terrestrial and wetland plants (*e.g*., impacts to the diet or habitat of listed species based on potential effects to plants), the lowest available LOAEC or EC25 from the available terrestrial plant studies is used. The lowest LOAEC or EC25 from the available aquatic plant studies is used to assess indirect effects associated with potential impacts to aquatic plants. For species with obligate relationships, the threshold for potential indirect effects to the obligate species is based on the effects endpoints identified for assessing the threshold for potential direct effects to a species as described above (see **Table A 1-4.2**).

For deriving a threshold based on sublethal direct effects to listed animals, the lowest available NOAEC or NOAEL or other scientifically defensible effect threshold (ECx) that can be quantitatively or qualitatively linked to survival or reproduction of a listed individual is used. For deriving a threshold for indirect effects, the LOAEC or LOAEL or other scientifically defensible effect threshold (ECx) for growth or reproduction is used.

* NOAEC or NOAEL and LOAEC or LOAEL values from sublethal tests will be used.
* ECx values may be used when reported in studies.
* Threshold concentrations from sublethal endpoints will stem from studies that are representative of environmentally relevant exposure routes.

**TABLE A 1-4.2. Step 2 Thresholds [these values are used to derive thresholds for use, along with other data, in the weight-of-evidence approach for making NLAA and LAA determinations for listed species and critical habitats].**

| **Taxon (Direct Effects) (Indirect Effects) or Taxa on which a listed species depends** | **Mortality**  | **Sublethal Effects** |
| --- | --- | --- |
| Birds1 | Direct Effects: Same as those identified in **Table 1** unless species surrogate data can be used.Indirect Effects: Concentration (or dose) that would result in a decrease of 10% of individuals (i.e. the EC10). This is calculated by using HC05 of SSD of LC50/LD50 or EC50 values and representative slope. If SSD cannot be derived, most sensitive LC50/LD50 or EC50 will be used. | Direct effects: Lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (ECx) that can be linked to survival or reproduction of a listed individual will be used. Indirect Effects: LOAEC/LOAEL for growth or reproduction will be used (see text for details). |
| Mammals1 |
| Reptiles |
| Terrestrial-phase amphibians |
| Aquatic-phase amphibians |
| Fish |
| Aquatic invertebrates |
| Terrestrial invertebrates |
| Aquatic plants | None | Direct Effects: Same as those identified in **Table 1**.Indirect Effects: *Aquatic plants*: Concentration equal to the lowest available LOAEC and EC25 value for aquatic plants*Terrestrial and wetland plants*: Concentration equal to the lowest LOAEC and EC25 value from the available seedling emergence and vegetative vigor studies |
| Terrestrial plants |
| Wetland plants |

1Lowest LD50 or NOAEL/LOAEL for birds and mammals determined by normalizing results to 100 g body weight for birds and 15 g body weight for mammals prior to establishing threshold value.

1. USEPA (2004). *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*. U.S. Environmental Protection Agency. Office of Pesticide Programs. Washington, DC. January 23, 2004. [↑](#footnote-ref-1)