DRAFT RSET ISSUE PAPER #21 – Framework for Deriving Tissue Concentrations to be Protective of People Consuming Fish and Shellfish

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QUESTION/ISSUE: How should target tissue concentrations (TTCs) be derived to protect people who consume fish and shellfish?

DISCUSSION:

Background: The RSET bioaccumulation subcommittee was organized to propose methods to derive trigger concentrations for chemicals in sediments based on bioaccumulation into tissues. Current sediment guidelines and criteria are based on toxicity testing and do not directly address the potential for bioaccumulation into fish and shellfish and the resulting potential for risks to wildlife and human consumers, and to fish and shellfish themselves as receptors (Cite Teresa's Framework Paper here). This technical memorandum provides a proposed approach to deriving bioaccumulation trigger levels in tissues that would be protective of human health, which is a necessary step prior to developing bioaccumulation trigger levels in sediments. A separate paper discusses approaches for the back-calculation of sediment trigger levels from fish or shellfish tissue trigger levels. For the purposes of this assessment, only human health risks associated with consumption of bioaccumulative chemicals in fish or shellfish are considered. At some sediment sites, it may be necessary to also consider other potential pathways (e.g., direct human contact with sediments). However, where fish and shellfish consumption is one of the potential exposure pathways, the food-related pathway typically is a more substantial contributor to site risks than direct contact with sediments. Thus, initial focus on fish and shellfish consumption is appropriate.

The TTCs are intended to be tissue concentrations that would be applicable at all sites. The TTCs will be used to derive bioaccumulation trigger levels for sediments, which will be used in decision-making for: 1) screening at potential sediment cleanup sites; and 2) evaluating whether open-water disposal is acceptable for dredged material. In site screening, site-specific sediment data can be compared with bioaccumulation trigger levels or, if tissue data are available, tissue concentrations can be compared with TTCs. Because the intended uses for the sediment bioaccumulation trigger levels involve a wide variety of site-specific conditions, some flexibility is desirable in applying the TTCs to derive sediment bioaccumulation trigger levels. Specifically, the size and nature of the sediment source (i.e., the degree of contamination, the area and distribution of contamination) and the relative presence and abundance of fish and shellfish resources in the area with affected sediments may also be considered as part of regulatory risk management decision-making. In deriving the bioaccumulation trigger levels for sediments from the TTCs, it may be reasonable to apply a reduction factor to account for the degree to which sediments at a

specific site could contribute to fish and shellfish concentrations as considered in the TTC.

The first section of this paper provides an overview of the background and applicability of this methodology. Following this is a general algorithm for calculation of tissue levels to be protective of human health risks and a discussion of considerations in deriving such levels.

Proposed methodology for calculating target tissue concentrations to be protective of people consuming fish and shellfish: As described in the framework document, the initial list of bioaccumulative chemicals of concern (BCoCs) will be developed through consideration of numerous lines of evidence, including the potential for bioaccumulation and the presence of the chemical at concentrations greater than reference (or background) concentrations in sediments. It is proposed here that TTCs for fish and shellfish should not be lower than tissue concentrations observed at reference (or background) locations. This will serve to limit the amount of resources spent on addressing chemicals with widespread anthropogenic (or in some cases naturally occurring) sources where exposure within a relatively small area of contaminated sediments may have little or no influence on resulting tissue concentrations.

In order to accomplish this objective, it is proposed that TTCs first be calculated for all BCoCs and then compared with appropriate reference or background concentrations, taking into account the need to balance the objective of reducing overall environmental concentrations with the potentially limited benefit associated with reducing concentrations below those in adjacent sediments, particularly where ongoing sources are present. For example, in evaluating a cleanup site within an urban area, TTCs might best be compared with urban reference concentrations so that TTCs in these areas would not be set lower than urban reference conditions. In contrast, evaluation of TTCs for relatively pristine open-water dredged material disposal sites should not be set lower than background concentrations. This comparison will be most relevant for metals, particularly arsenic and mercury, but may also be relevant for ubiquitous organic compounds such as DDT, PCBs and PCDD/Fs. Identification of appropriate background (e.g., relatively pristine) and reference (e.g., urban sites with no known sources) is presently not well defined and will be a task to be addressed by the RSET bioaccumulation subcommittee through consideration of available regional data on tissue concentrations.

Toxicity values: TTCs will need to address both carcinogenic and non-carcinogenic effects of BCoCs through application of a carcinogenic slope factor (CSF) for carcinogenic effects and a reference dose (RfD) for non-carcinogenic effects. EPA-approved toxicity values are described on the EPA Integrated Risk Information System web site[1] and EPA's Provisional Peer Reviewed Toxicity Values for Superfund (PPRTV)[2]. Additional interim toxicity values

[1] http://www.epa.gov/iris/search.htm

[2] http://hhpprtv.ornl.gov/..

can be obtained by contacting EPA Region 10 or the EPA's National Center for Environmental Assessment (NCEA)[3].

Algorithm for calculating TTCs for carcinogenic effects of BCoCs: TTCs for carcinogenic effects of BCoCs can be calculated using the following general algorithm:

$$TTC\ (mg/kg) = \frac{TR \times AT_c \times BW}{EF \times ED \times FI \times CL \times IR \times 0.001\ kg/g \times CSF}$$

TTC = target tissue concentration in fish or shellfish tissue (mg/kg wet weight)
TR = target risk of 10^{-6} proposed for individual carcinogens
AT_c = averaging time (25,550 days)
BW = body weight (kg adult or child; varies with receptor population)
0.001 = conversion of grams fish to kg
EF = exposure frequency (365 days/year)
ED = exposure duration (years; varies with receptor population)
FI = fraction of intake assumed from site—(variable up to 100 percent; see text)
CL = cooking loss (none assumed; see text)
IR = ingestion rate for fish or shellfish (g/day; see text)
CSF = carcinogenic slope factor $(mg/kg\text{-}day)^{-1}$

Algorithm for calculating TTCs for non-carcinogenic effects of BCoCs: For non-carcinogenic effects, the following algorithm can be used to derive TTCs for fish and shellfish tissue:

$$TTC\ (mg/kg) = \frac{THQ \times BW \times AT_n \times RfD}{EF \times ED \times FI \times CL \times IR \times 0.001\ kg/g}$$

TTC = target tissue concentration in fish or shellfish tissue (mg/kg wet weight)
THQ = target hazard quotient (0.1)
AT_n = averaging time (exposure duration (years) × 365 days/year)
BW = body weight (kg adult or child; varies with receptor population)
0.001 = conversion of grams to kg
EF = exposure frequency (365 days/year)
ED = exposure duration (years; varies with receptor population)
FI = fraction of intake assumed from site (variable, up to 100 percent; see text)
CL = cooking loss (none assumed; see text)
IR = ingestion rate for fish or shellfish (see text)
RfD = reference dose for non-cancer effects (mg/kg-day)

[3] http://cfpub2.epa.gov/ncea/cfm/aboutncea.cfm?ActType=AboutNCEA

Selection of a target risk and hazard index: For carcinogenic effects of BCoCs, a total cumulative target risk level of 10^{-5} (upper-end) is proposed, which is consistent with regulatory requirements set out by the Oregon Department of Environmental Quality. This risk level represents the middle of the risk range (10^{-4} to 10^{-6}) typically identified as acceptable by EPA and allows for exposure to multiple carcinogenic BCoCs. In order to achieve this risk level, TTCs for individual BCoCs will be set at risk levels of 10^{-6}. Site managers may determine appropriate adjustments where fewer than 10 BCoCs are present at a site.

In deriving TTCs for non-cancer endpoints, a cumulative hazard index of 1 is proposed. In order to not exceed this cumulative level, initial TTCs for individual BCoCs will be derived through application of a hazard index of 0.1 for screening. Where multiple BCoCs are present at concentrations greater than the non-cancer TTC, site managers may consider additional evaluation to determine whether the BCoCs identified at the site could affect the same target organs at the concentrations present. If this is not the case, it may be appropriate to adjust the resulting sediment bioaccumulation target levels to result in a cumulative hazard index of 1.0.

Selection of receptor population and endpoint: It is desirable to have a single TTC to address all human health considerations. However, the TTC will need to be protective of both adults and children consuming fish and shellfish and protective of both the carcinogenic and non-carcinogenic effects of BCoCs. Where EPA has both a CSF and an RfD available for a BCoC, the carcinogenic effect will typically provide the lowest risk-based concentration for various reasons, including the assumption that there is no threshold for carcinogenic effects. However, in some contexts, there may be some BCoCs for which the TTC calculated based on non-cancer endpoints is lower (more health-protective) than that derived based on the CSF. In addition, depending on the consumption rates assumed for adults and children, the TTC for non-carcinogenic effects may be lower for children consuming fish than for adults, particularly at the 10^{-5} cancer risk level. Thus, once the target risk level and the consumption rates are selected for use in deriving TTCs, these considerations will need to be evaluated to derive a TTC protective of all receptors and endpoints.

Exposure assumptions – fish consumption, fractional intake, and cooking loss: As described above, the TTCs will be derived to be protective of all populations and endpoints. To meet this objective, fish consumption rates for various populations present in the region will need to be reviewed to determine the most representative rates for adults and children. Because consumption rates are highly variable among various populations, it may be beneficial to derive more than one set of rates (e.g., a recreational and a high-end or tribal rate) depending on the specific situation. Where site-specific consumption rate studies have been conducted, risk managers may determine whether they should be applied on a case-by-case basis.

Although studies of tribal consumption rates have estimated fish and shellfish consumption rates for children, most studies of recreational fish and shellfish consumption have focused on adults only, and therefore some rates may need to be developed based on adults, with

some consideration of their likely applicability to children. Because recreational rates are much lower than those identified for subsistence populations and because not all sites are locations for subsistence fishing, it may be appropriate to calculate separate TTCs for recreational and subsistence populations and determine on a site-by-site basis which is most appropriate as the basis for a TTC. An additional consideration is the fraction that the affected area represents of the overall subsistence or recreational fishing and gathering area (i.e. FI, or the fractional intake from the site). It is proposed that the TTCs be developed based on a default fractional intake of 100 percent, but then allow for consideration of site-specific characteristics as appropriate (e.g., limited resources within the site, small site size) in linking the TTCs to a given sediment evaluation.

Cooking reduces the concentrations of some organic BCoCs in fish and shellfish. However, given the variability in cooking methods applied by various populations in the region, cooking loss factors are not proposed for the generic TTCs. It may be appropriate to consider this factor on a case-by-case basis in more detailed evaluations at sites where warranted.

REFERENCES: None.

RECOMMENDATION: None.

PROPOSED LANGUAGE: None yet available.

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