

NRC Attributes, Potential Data Elements, Issues and Alternative

Attribute and NRC Definition	Potential Data Elements for this Attribute	Issue Identified for this Attribute	Alternatives
<p>Potency (page 95 NRC) <i>Indicates power or strength: amount of a contaminant required to cause an adverse health effect. How much (dose) of a contaminant does it take to cause illness (adverse effect)?</i></p> <p><i>Potency of a pathogen may refer to the # of organisms required to cause disease, while potency of a chemical refers to the dose required to cause disease.</i></p> <p><i>NRC recommended plotting as a percentile of the contaminant's potency relative to the potencies of all contaminants being considered. The percentile (0-100) scale should then be converted to a decile (1 through 10) scale.</i></p>	<p><u>Non-carcinogens</u></p> <ul style="list-style-type: none"> • RfD (chronic and/or acute) • TDI, ADI, MRL, etc • NOAEL (highest) • NOEL (highest) • LOAEL (lowest) and description of relevant endpoint • BMDL (lowest) • LD 50 oral (lowest) • RfC (if no oral) • LEL?? <p><u>Carcinogens</u></p> <ul style="list-style-type: none"> • Cancer slope factor <hr/> <ul style="list-style-type: none"> • Quantitative SARs • Uncertainty factors 	<ul style="list-style-type: none"> • Need to score non-carcinogens and carcinogens (NCAR and CAR) - for example data set - EPA used same definition as NAS and noted that the lower the critical dose/toxicity value the more toxic the contaminant. • Uncertainty factors would be applied to NOAEL, NOEL, LOAEL, BMDL, LD50 in order to make them comparable to risk-based value like the RfD. • Quality of the study should be considered • Need to determine how to select the program/programs for QSAR • Jamie noted that potency seems to run counter to scientific thinking - implies a level of exposure which is safe - while may apply to threshold chemicals - does not work for microbes and nonthreshold chemicals (genotypic carcinogens) - however, concept may be integrated with magnitude 	<p>For the example data set:</p> <ul style="list-style-type: none"> • EPA established a hierarchy for data elements with risk-based values having precedence over raw data and EPA assessment having a precedence over those of other agencies • EPA found that the decile distribution of potency values was not effective because the 92 percent of a test group of 171 chemicals would have received a score of 10 based on their RfD. Instead EPA/Cadmus used a logarithmic scale to assign the scores for potency. The logarithmic distribution for the test set of chemicals was close to normal • When cancer and noncancer effects could each be scored, EPA selected the higher potency score to represent the chemical. <p>NOTES: Inherent difference exist between using a "threshold" or a derived risk based value in comparison to a toxic effects concentration. Perhaps the threshold value, if available could be considered a toxic effect level for the purposes of scoring attributes.</p> <p>Units may be an issue, and if ADI's are compared with RfD's then some accounting for the derivation process may be warranted.</p>

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<p>Severity (page 94 NRC) <i>Degree to which a potential contaminant can cause an adverse health effect. (How bad is the effect?)</i></p> <p><i>Severity can be scored based on the anticipated clinical significance of the most sensitive health end point in affected individuals. NRC gave an example severity scale (page 96, Table 4.1)</i></p>	<ul style="list-style-type: none"> • Critical effect (associated with RfD or equivalent based on LOAEL) • Carcinogen classification <ul style="list-style-type: none"> • EPA • IARC • NTP 	<p>For example data set:</p> <ul style="list-style-type: none"> • During scoring, tendency to consider effects at doses above the critical effect caused some bias • Noted that scoring requires expert judgment and depends on nature of effect (cancer, repr, dev, etc). • Using EPA’s scoring scale, there were difficulties about how to score differences in organ and body weights. • If noncancer and cancer effect, used highest score to be conservative. • Need detailed description of critical effects. • Noted descriptions of critical effects data presented in IRIS were limited requiring assumptions or the desire to review IRIS files when scoring. • Need to develop an approach for chemicals that lack critical effect. • Need to expand descriptions and examples accompanying the scoring scale. • Note that raw data are qualitative/categorical, not numeric. • Inherent difference exists between severity of acute illness from pathogens and long term effects from chemicals. Temporal factors in severity will need to be discussed. 	<ul style="list-style-type: none"> • Definition used by EPA for the example data set - the degree of biological impact on survival and quality of life; Developed an EPA alternative severity scale to NRC’s. Deleted chemical name (identity) to remove bias. (Should re-evaluate chemicals with their identity known to ensure scoring was appropriate). • Jamie suggests objective and transparent metric such as morbidity/mortality and frequency of different outcomes. • Use log (\$ willingness to pay to avoid the health endpoint).

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<p>Prevalence (page 97 NRC) <i>How commonly does or would a contaminant occur in drinking water?"</i></p> <p><i>Two dimensions - temporal and spatial.</i></p> <p><i>Temporal is the fraction of time that a contaminant is found at a given locale (NRC, page 97)</i></p> <p><i>Spatial is the proportion at locales in which the contaminant is found (NRC, page 97)</i></p>	<ul style="list-style-type: none"> • Indicators of size of water system or geographical area sampled if available • # or % of PWSs with detects • # or % sites with detects • # or % samples with detects • Water type (finished water, ambient, etc.) • Population served/% of population served with detects • Production/release/use data (quantity/year) • # Facilities using (??) • Release Medium • Temporal (spring, summer, fall winter)? • Location of sampling sites; regional or state • Location of discharge sites; regional or state 	<ul style="list-style-type: none"> • Definition and meaning of prevalence needs to be discussed and agreed upon. • Spatial data limited; Temporal data even more limited; so may not be able to plot as NRC suggested. • Need to define temporal and spatial as far as amount of data necessary to make a temporal or spatial determination. • Type and amount of data for contaminants will vary. • Detection limit varies and changes over time so affects % prevalence • Need to define "level of concern" - appears that NRC meant for occurrence but Jamie said need to relate "level of concern" to health effects. Some folks at EPA may prefer not to - this approach may really be magnitude? • May/may not need population data • Raw data processing issues; data from various sources and data quality • Is geographical distribution of locales where the substance was found national or localized? • Inorganic contaminants have a much greater prevalence than most organic chemical contaminants, and may need a separate scale 	<p>Example data set was data rich and had no temporal data - had to only use spatial data.</p> <p>Most important elements may be:</p> <ul style="list-style-type: none"> • # or % of sites with detections • # or % of samples at a site with detects. • Production release/use/data are secondary to finished or ambient water. • Use log (fraction of samples with positive result * median detection or reporting limit / RfD), replacing RfD by the corresponding cancer dose if a carcinogen.

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<p>Magnitude (page 99 NRC) <i>The concentration or expected concentration (e.g., based on chemical production) of a contaminant relative to a level that causes a perceived health effect. In other words, is the level high enough to cause harm? Not absolute magnitude but magnitude relative to potency.</i></p> <p><i>NRC suggested using the median water concentration as the concentration parameter for the potency scoring.</i></p> <p><i>NRC suggested using the square root $\sqrt{\text{Potency score} \times 1-10 \text{ decile rank for median occurrence}}$</i></p>	<ul style="list-style-type: none"> • Median concentration detects • Mean concentration detects • Percentile concentration all data (25th, 50th, 75th, 90th, 95th, 99th) • Percentile concentration for all samples with detects (25th, 50th, 75th, 90th, 95th, 99th) • Median concentration all data • Maximum concentration all data • Mean concentration all data • Minimum concentration all data • Range of concentration • Amount released/year (to media) (TRI data) • Geographic distribution of releases • Potency score, if use NRC definition 	<ul style="list-style-type: none"> • Need to define meaning of magnitude since some are unclear about what NRC is suggesting that we use because the Square root $\sqrt{\text{Potency score} \times 1-10 \text{ decile rank for occurrence}}$ does not appear to be a measure of concentration relative to potency. It is a product of concentration and potency • Using potency data as part of magnitude score may create an interdependence of variables, which could affect model results. • Must redefine magnitude if potency is not to be used as an element in the scoring. • Minimum concentration is likely to be a “Not Detect” in almost all cases. • Should use the same measure for concentration in the scoring rather than a mixture of mean/median, 95% and minimum reporting levels. 	<ul style="list-style-type: none"> • Example data set only used concentration to establish the magnitude scores - If use this approach what is the best method to determine and score magnitude? • Should magnitude score be derived from the distribution of the ratio of the median concentration to potency as the definition implies? • Use log (mean or median concentration among detects)

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<p>Persistence/Mobility (page 100 NRC) <i>The likelihood that the contaminant would be found in the aquatic environment based solely on physical properties of the contaminant.</i></p> <p>NRC suggested scoring solubility and stability into high (3), medium (2) and low (1) depending on specified length of time for persistence and specified solubility in H₂O. Then average the two scores and multiply by 10/3 to obtain score from 1-10.</p>	<ul style="list-style-type: none"> • Stability (half-lives for hydrolysis, photolysis, biodegradation, aerobic soil, anaerobic soil) • Henry's Law constant • Kow, log Kow • Solubility product constant • Water solubility • Boiling point • log Koc • Melting point (?) • Vapor pressure • Transformation data - metabolites, degradation products of concern ?? 	<ul style="list-style-type: none"> • Some feel that pers/mob is really the lowest of the attributes (a default for lack of occurrence information). • Need a hierarchy for the selection and use of half life data. • When using temperature-related to physical property data, use the values for ambient temperatures. • Persistence/mobility could be important when using production/release data. Need to consider the stability of the contaminant in the environment and whether or not the contaminant moves from the site of release. • When persistence data indicate degradation of the contaminant, it is important to identify the degradates and insure that they are in the universe. 	<ul style="list-style-type: none"> • Use log (solubility, ug/L) + stability score + log (quantity manufactured * fraction released to environment) or something along this order.