

Department of Ecology Alternatives Assessment Guidance

Washington State Department of Health Comments

September 11, 2011

**Question 1. What are your three main observations with the continuum process proposed by Ecology?**

a. Statement of problems and goals. The guidance document should discuss the importance of describing the problems and the goals. Prior to conducting an alternatives assessment, it is important to provide a detailed statement of the problems being addressed and the specific goals the alternatives are meant to achieve. These will help determine which components (or modules) of the assessment (e.g., human hazard/risk analysis, ecological assessment, contribution to global warming, cost, etc.) are most relevant to the goals. The assessment should focus on these modules, and the information gathered for these modules should be as complete as feasible and should be evaluated by rigorous and highly defensible processes. Other modules, which are less relevant to the goals, may be evaluated in a cursory manner or not be considered at all. For example, if the goal is to protect children's health by improving the chemical safety of children's products, the potential toxicity and exposure to children would be the focus of the alternatives assessment, while the effect of the chemicals and potential alternatives on climate change might be a minor consideration. A clear statement of the specific goals of the alternatives assessment will help determine what (and how much) information is needed and how the different types of information (i.e., modules) should be weighted to select appropriate alternatives.

b. Voluntary versus Regulatory Assessments. It would be useful for the guidance document to recognize the likely differences between alternatives assessments conducted voluntarily and those conducted due to regulatory requirements. Compared to voluntary activities, alternatives assessments in a regulatory context (i.e., with the intent to legally require that changes be made) have an increased burden to be scientifically defensible and to minimize errors in selection of chemicals. There is a public responsibility to choose wisely and avoid mistakes that can result in wasted resources, inappropriate regulation, and no benefit (or even a possible detriment) for human or environmental health. For voluntary assessments, speed and simplicity may be desirable despite the potential for error. For assessments leading to regulation, in-depth evaluations that include dose-response and exposure data from the start of the process will likely be needed to support the proposed changes and provide assurance that the alternative choices are among the most beneficial.

c. "Continuum of requirements?" The term "continuum" in this context is confusing. As noted in prior documents (Lowell Center "Alternatives Assessment Framework" and others), an alternatives assessment includes several distinct "modules" that are used to evaluate different, mostly unrelated issues associated with the potential alternatives. There might be a module for human health concerns, one for cost effectiveness, one for technical performance, one for environmental impact, and so on. It is

not clear why the term “continuum” is being used to describe an alternatives assessment process comprising numerous, generally unrelated modules. While some individual modules may have properties that can be described along a continuum (cost, flammability, toxicity, etc.), the process as a whole is discontinuous collection of diverse information that will be used in many different ways to solve many different problems. Goals may differ significantly from assessment to assessment. Since requirements and modules will be different for different goals, it is hard to see how these dissimilar combinations of requirements and modules could be considered a continuum.

#### **Question 4. Do you have any other concerns with the process?**

Set a high bar, not a low one, as a starting point in the guidance. Start from the top, encouraging robust and scientifically defensible assessments, but provide options for less rigorous evaluations when appropriate. For example, starting from the position that exposure assessment is a secondary tool suggests (incorrectly) that exposure is not particularly valuable in evaluating the potential harm from chemicals and in choosing safer alternatives. It is important that the guidance ensure that alternatives assessments are based on adequate data and appropriate criteria for the problems being addressed. Informed decisions cannot be made with inadequate data. Any ranking systems (e.g., QCAT or GreenScreen) and criteria that are recommended should be evaluated in a transparent manner to determine how well (and how consistently) they reflect our knowledge of the real world. Known problems and uncertainties should be clearly described so that users will be aware of the potential for errors.

First, do no harm. Speed and simplicity should not outweigh a high degree of confidence that mistakes have been minimized. A rushed, cursory alternatives assessment that contains mistakes may be worse than doing nothing because health benefits could be compromised and resources could be wasted for little or no gain. Guidance should encourage the use of readily available information, particularly dose-response and exposure data, in the earliest stages of the assessment in order to reduce uncertainty throughout the process. This is particularly true of alternatives assessments that focus on human health and will result in regulatory actions.

a. The importance of dose-response data. As a rule, it is important to consider dose-response information to avoid mistakes when evaluating potential harm to human health. Dose-response can vary more than 1,000,000-fold from chemical to chemical, adding a significant amount of uncertainty to a toxicity evaluation if it is disregarded. This information is available for many chemicals, and can often be incorporated into the assessment with little extra effort.

b. The importance of exposure data. As a rule, it is important to consider exposure to avoid mistakes when evaluating potential harm to human health. Some chemicals may be classified as carcinogens or developmental toxicants, but only when exposure is by certain routes of exposure and not others. If the exposure route associated with carcinogenicity is not relevant to the problem being addressed by the alternatives assessment, a chemical could be considered more dangerous than warranted. For example, some metals are carcinogenic when inhaled as

fumes or dust, an exposure route of little concern for children's products. In addition, the danger a chemical presents is a function of both toxicity and exposure (i.e., the dose makes the poison and exposure determines the dose). If the guidance document proposes to help users identify the safest alternatives, exposure cannot be ignored. For example, some chemicals may not be direct drop-in replacements; more may be needed to achieve the same level of functionality in a product. Further, in a particular material one alternative may off-gas significantly more than another, resulting in greater exposure.

**Question 5. Do you agree that the continuum approach is the best way to approach the various needs of an alternatives assessment?**

The Draft Scope does not contain sufficient detail to determine whether the approach being developed by Ecology is the "best" nor, as described in the answer to Question 1 above, whether the term "continuum" is an appropriate descriptor. However, the approach appears to advocate flexibility in order that specific information and evaluation criteria required are sufficient and appropriate for needs of the user and for the specific problem being addressed. Flexibility depends in large part on the goals of the assessment and the tolerance for poor choices. The specific goals will help determine which types of information (costs, human health, etc.) are most important so that greater weight can be given to those modules in the assessment. The goals and the tolerance for mistakes will influence the amounts and types of information needed for an adequate assessment. If the goals are modest and mistakes are OK, then a cursory evaluation of alternatives may be acceptable. If the results of the assessment will be used to regulate chemical use, where mistakes could be costly in terms of economics and health, a rigorous evaluation of significant amounts of data would likely be necessary.

**Question 6. Given the aggressive timeline, which of the components listed above are most important to be tackled first?**

Performance characteristics – are the alternatives suitable functional substitutes?

Human health toxicity and exposure potential.

**Question 7. Additional input.**

A discussion of uncertainty and how missing or inadequate information could be addressed should be included in the guidance document. Will there be standard methods, or will it depend on the situation?