

GREEN CHEMISTRY, DTSC, ALTERNATIVE ASSESSMENT

DTSC Releases Alternatives Analysis Guide with Few Changes from Earlier Draft

By ROGER PEARSON, June 30, 2017

The Department of Toxic Substances Control has released the **final version of its Alternatives Analysis Guide**¹⁾ (Guide) just in time for its possible use by manufacturers of the first product designated under the Department's Safer Consumer Products (SCP) program [see **DTSC Designates First Priority Product: Children's Foam-Padded Sleeping Products**²⁾, July 1, 2017]. **The new Guide, designated as Version 1.0**³⁾, is little changed from an earlier draft program, despite a number of concerns raised by potential users.

The new Guide is intended to assist those required to prepare an "alternatives analysis" (AA) of options to do away with suspect chemicals in products designated as "priority products" pursuant to the SCP. Responsible parties are not required to use this Guide in preparing an AA. However, in order to ensure that DTSC staff will approve a proposed AA a responsible party is likely to stick close to the format contemplated in the Guide.

DTSC began work on the Guide last September and released its first version of it last December. It fielded questions on the draft at a webinar held in January and separately in writing. Questioners were concerned primarily over what they viewed as a lack of specificity in the document [see **DTSC Emphasizes Flexibility in First Public Discussion of AA Guidance**⁴⁾, February 8, 2017]. DTSC staff pointed out during the webinar that this lack of specificity is deliberate with the Guide designed to be "highly flexible."

In releasing this final version of the Guide DTSC staff has continued to emphasize document's flexibility. Along with the release **DTSC provided its response**⁵⁾ to the various questions raised in writing and at the webinar.

- The Guide lacks sufficient clarity and details to complete a compliant AA. In response DTSC notes that it made no changes, because the SCP regulations allow flexibility for a responsible entity in preparing an AA. DTSC notes specifically that it did not prescribe arbitrary thresholds for AA decision-making processes. That burden lies with the responsible entity, which must document the basis for its decision making.
- The scope of the AA exceeds what was required in the SCP regulations. DTSC disagrees with this criticism arguing that it has been careful not to prescribe tasks beyond those contemplated by the regulations.

- The economic analysis is burdensome. Again DTSC disagrees claiming it is simply following the regulations. It emphasizes that responsible entities may use a more streamlined approach, so long as they adequately compare the priority product and its alternatives.
- AA estimates of public health costs using mortality and morbidity costs may be a roadmap for lawsuits. DTSC acknowledges this possibility but points out that the AA process emphasizes comparative analyses.
- Which non-profit organizations require cost estimates. This is one place where the Department responded to a comment by adding language limiting and clarifying the non-profits that must be considered.
- What constitutes a suitable data justification (e.g. when using read-across, structure-activity relationships, etc.). The Department incorporated detailed references and guidance documents into the Guide at the request of commenters, and added cautionary statements regarding the limits of data extrapolation. This topic, says DTSC, will continue to be an area of concern and development.
- How will the Department handle confidential business information (CBI). The Department has added language on CBI. It is also planning on developing policies and procedures specific to the SCP regulations and consistent with the requirements of other departments.
- Multiple commenters requested that DTSC conduct an example AA. While the Department has expanded its use of examples, it argues that preparation of a sample AA is beyond the scope of the Guide.
- Including sensitive subpopulations in exposure assessments is beyond the scope of the regulations. DTSC disagrees pointing out that the regulations require this.
- Mitigating factors should be considered in an exposure assessment. DTSC agrees that the regulations allow mitigating factors such as administrative and engineering controls to be considered when evaluating exposure pathways. However, the Department states that it will give preference to the inherent protection through redesign of a product or process rather than through administrative or engineering controls.

DTSC emphasizes that this first version of the Guide will be revised continuously to reflect new information and ideas. The Guide will also be discussed at the next meeting of the Department's green chemistry science advisory group—the Green Ribbon Science Panel—at its next meeting scheduled for two days starting Monday, July 17

Resources for this article

1. final version of its Alternatives Analysis Guide

<http://www.dtsc.ca.gov/SCP/AlternativesAnalysis.cfm>

2. DTSC Designates First Priority Product: Children's Foam-Padded Sleeping Products

<https://ceitoday.com/articles/13110>

3. The new Guide, designated as Version 1.0

<https://ceitoday.com/documents/21842>

4. DTSC Emphasizes Flexibility in First Public Discussion of AA Guidance
<https://ceitoday.com/articles/12696>

5. DTSC provided its response
<https://ceitoday.com/documents/21843>