DRAFT STAGE 1 ALTERNATIVES ANALYSIS GUIDE COMMENTS DUE NOVEMBER 16TH

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The comment period for the Draft Stage 1 Alternatives Analysis Guide (AA Guide) has been extended until November 16, 2015. The Guide is considered guidance only, as an advisory resource. It is not a regulatory document or legal standard. The Guide is intended for broad use and is not specific to a particular geographic location, company size, or product type and not all of the content will be applicable to all users. In other words, it provides a menu of options, not a checklist of required actions. The responsible entity will decide which approaches, assumptions, tools, methodologies, data, and decision frameworks will best suit its particular situation.

California's Safer Consumer Products (SCP) program requires manufacturers to identify, evaluate, and adopt better alternatives to certain chemicals in products, while avoiding regrettable substitutions. SCP requires an Alternatives Analysis (AA) to consider impacts of the chemicals and the alternatives throughout the product's life cycle. When performing an AA, a responsible entity must ensure that the elements of the analysis comply with the regulatory requirements and are scientifically robust and complete. To demonstrate the scientific validity of the AA, the responsible entity must document data quality, assumptions, and decision methods in their AA Reports.

The Draft Stage 1 AA Guide is now available for review on the CalSAFER website. The AA Guide provides examples of how to fulfill SCP's regulatory requirements for the first stage AA. It also provides approaches, methods, resources, and tools for compliance with the AA requirements. For example, the Guide lists generic "tenets" to follow:

- **Completeness:** Comply with all regulatory requirements of the AA process.
- **Applicability:** All methods used and data collected for the AA should be appropriate and sufficient for the product, chemicals, and processes involved. The responsible entity should disclose all relevant information used for its evaluations and decision-making, and the information needed for the Department and stakeholders to assess the robustness and reliability of the analysis and conclusions.
- **Consistency:** Observe strict conformity within all steps of the AA to support internal consistency and comparability with similar analysis.
- **Accuracy:** Use an iterative approach to reduce uncertainties in all calculations, data management, and models used in the AA and in reporting of results. Revisit assumptions.

In addition to these tenets for conducting SCP AAs, other practitioners have developed more general guiding principles for alternatives assessment.

- **Reduce Hazard:** Reduce hazard by replacing a chemical of concern with a less hazardous alternative. This approach provides an effective means to reduce risk associated with a product or process if the potential for exposure remains the same or lower. Consider reformulation to avoid use of the chemical of concern altogether.
- **Minimize Exposure:** Assess use patterns and exposure pathways to limit exposure to alternatives that may also present risks.
- **Use Best Available Information:** Obtain access to and use information that assists in distinguishing between possible

choices. Before selecting preferred options, characterize the product and process sufficiently to avoid choosing alternatives that may result in unintended adverse consequences.

- **Require Disclosure And Transparency:** Require disclosure across the supply chain regarding key chemical and technical information. Engage stakeholders throughout the assessment process to promote transparency in regard to alternatives assessment methodologies employed, data used to characterize alternatives, assumptions made and decision making rules applied.
- **Resolve Trade-Offs:** Use information about the product life cycle to better understand potential benefits, impacts, and mitigation options associated with different alternatives. When substitution options do not provide a clearly preferable solution, consider organizational goals and values to determine appropriate weighting of decision criteria and identify acceptable trade-offs.
- **Take Action:** Take action to eliminate or substitute potentially hazardous chemicals. Choose safer alternatives that are commercially available, technically and economically feasible, and satisfy the performance requirements of the process/product. Collaborate with supply chain partners to drive innovation in the development and adoption of safer substitutes. Review new information to ensure that the option selected remains a safer choice.

In addition, the appendices to the Guide provide lists of tools and other resources. The methods and tools identified include:

- European Union REACH: REACH requires that firms wishing to use Substances of Very High Concern (SVHC -Annex XIII) that cannot be adequately controlled must assess suitable alternatives and, if suitable alternatives are available, may prepare a substitution plan. The European Chemicals Agency published Guidance on Alternatives Assessment for Restrictions (Annex XV). REACH regulation calls for comparison of risks, in addition to other attributes including economic feasibility and technical feasibility. http://echa.europa.eu/support/guidance;jsessionid=7486850544608729C37A20774C935623.liv e2
- U.S. EPA Design for the Environment (DfE) Program Alternatives Assessment Criteria for Hazard Evaluation: The DfE program has developed a methodology for chemicals alternative assessment (CAA) to identify safer alternatives to toxic chemicals. The DfE tool uses existing primary data and predictive computerized modeling to determine human health and environmental hazards of chemical of concern. Life cycle thinking is used to consider chemical hazards throughout manufacture, use and disposal. DfE alternative assessment hazard evaluation criteria use hazard thresholds to classify hazards as high, moderate, or low. In assigning a designation of high, moderate, or low hazard, DfE uses the best available experimental data (data generated from U.S. EPA Data Adequacy Guidelines) and modeled information. The GHS criteria and data evaluation approach, and EPA risk assessment guidance are applied in the review of dose descriptors (NOAEL/NOAEC and LOAEL/LOAEC).
- DfE chemical alternative hazard assessments combine information from five sources, in the following order of preference: (1) publicly available empirical/measured data on the chemical being evaluated; (2) confidential empirical data received at EPA under TSCA regulations; (3) structure–activity relationship (SAR)-based estimations from EPA Pollution Prevention Framework and Sustainable Futures predictive methods; (4) professional judgment of EPA staff, often predicated on experimental data for chemical analogues; and (5) confidential empirical data on experimental studies supplied by the chemical manufacturers for the alternatives assessment. CAA is an analytic methodology that requires expertise in toxicology and chemistry to interpret the scientific data. http://www.epa.gov/dfe/alternative_assessments.html
- Massachusetts Toxics Use Reduction Institute: *Five Chemicals Alternatives Assessment Study.* The Toxic Use Reduction Institute of University of Massachusetts Lowell (TURI) Pollution Prevention Options Analysis System (P2OASys): The TUR Institute developed this systematic tool that assists companies in identifying potential hazards associated with chemicals and processes and helping to choose the alternative that is most protective of worker health and environment. The P2OASys tool provides numerical hazard scores for a company's current process and identified options, which can then be combined with other information sources and professional expertise to make decisions on adoption of alternatives. Users of this tool must have expertise in occupational and environmental health and in researching chemical databases including toxicological and

chemical hazard databases. http://www.turi.org/Our_Work/Research/Alternatives_Assessment/Chemical_Hazard_Comparison_Tools/P2OASys_Tool_to_Compare_Materials

- Interstate Chemicals Clearinghouse (IC2): The Guidance was developed through the State's designated Technical Alternatives Assessment Guidance Team, which includes representatives from the seven states who are members of the Interstate Chemicals Clearinghouse. The Guidance is based on the Environmental Protection Agency's (EPA) Design for the Environment (DfE) principles. The IC2 guidance is quite detailed and structured using a modular approach. The guidance document also includes a Decision Module that pulls together all of the individual modules and provides a range of recommended approaches designed to address a variety of needs, from a minimum approach to a preferred assessment with greater requirements. http://www.newmoa.org/prevention/ic2/aaguidance.cfm.
- Stockholm Convention on Persistent Organic Pollutants: The guidance provides a general description of the issues to be considered in identifying and evaluating alternatives to listed persistent organic pollutants and candidate chemicals included in the Stockholm Convention on Persistent Organic Pollutants. http://www.subsport.eu/substitution-tools/stockholm-convention-alternatives- guidance.
- Clean Production Action GreenScreen for Safer Chemicals (GreenScreen): The GreenScreen is a comparative chemical hazard assessment tool that uses the DfE criteria with a scoring system. Like the DfE CAA method, the GreenScreen tool includes threshold values to determine a hazard level for each hazard trait or toxicological endpoint. The GreenScreen method aggregates criteria and related thresholds into four benchmarks. By benchmarking the alternatives, the GreenScreen tool provides a decision framework to identify and screen out the chemicals (and their metabolites/predicted breakdown products) with the least safety, human health, and environmental concern. http://www.cleanproduction.org/Greenscreen.php.
- German Guide on Sustainable Chemicals and Substitution Support Portal (SubsPort): The German Ferderal Environment Agency has developed criteria for the selection of sustainable chemicals to make it easier for chemical producers, developers and final users to opt for sustainable chemicals. The guide provides a tool for assessing the risks posed by substances step by step and for distinguishing non-sustainable chemicals from sustainable ones. The goal of the SUBSPORT project is to develop an internet portal that constitutes a state-of-the-art resource on safer alternatives to the use of hazardous chemicals. http://www.subsport.eu/guide-on-sustainable-chemicals and http://www.subsport.eu/about- the-project.
- Quick Chemical Assessment Tool (QCAT): The State of Washington Department of Ecology has developed QCAT, a simplified version of the GreenScreen hazard assessment methodology. It is not intended as a replacement for the GreenScreen, it can be useful to small and medium size companies that find the GreenScreen too complicated and expensive to implement. The QCAT includes detailed information on where to find data and how to interpret what is found. The primary goal of the QCAT is to assign an appropriate grade to a chemical using both a refined group of high priority hazard endpoints identified in the EPA Design for the Environment (DfE) Program and fewer data sources.
- U.S. EPA Screening-Level Tools: The U.S. EPA has developed a series of screening-levels models and tools for evaluating the safety of existing and new chemicals. These tools are developed as part of EPA Sustainable Futures Initiative to assist chemical developers to evaluate toxicity of the chemicals in the design phase and find safer substances if hazards are identifies. Most of these tools require knowledge of toxicology and chemistry http://www.epa.gov/opptintr/sf/tools/methods.htm. These tools include:
- Analog Identification Methodology (AIM): An on-line tool to identify publicly available experimental data on structurally related chemicals to help users determine the potential hazards of untested chemicals.
- EPI Suite: A software program that provides screening-level estimates of physical/chemical properties and environmental fate properties.
- PBT Profiler: An online tool that screens chemicals for their potential to persist, bioaccumulate and be toxic to aquatic life
- Oncologic: A software program designed to predict the potential cancer causing effects of a chemical by applying Structure Activity Relationship (SAR) analysis

- Non-Cancer Screening Protocol: A five step process for screening chemicals for non-cancer health effects in the absence of data.
- ECOSAR: A software program that predicts toxicity of industrial chemicals released into water to aquatic life. The model estimated acute and chronic toxicity by using SAR analysis.

DTSC notes in the Guide that it is a resource not only for responsible entities, but also for the Department when it evaluates submitted AA Reports and supporting documentation. For this reason, comments pertaining to the AA Guide, which may assist DTSC in a fair and reasonable application of the AA requirements, should be a priority for manufacturers, trade groups and other responsible entities. DTSC specifically requested input regarding the names of tools, methods, approaches, and data sources not already mentioned. In addition, DTSC encourages responsible entities to provide examples of products so that DTSC can add steps and approaches to complete an AA for a specific product within the AA Guide for the first stage.

The two stages of the AA process are:

- **First Stage AA:** During the first stage the responsible entity identifies the goal, scope, legal, functional, and performance requirements of the Priority Product and the Chemical of Concern, and uses this information to identify and screen an array of alternatives to consider. The responsible entity documents the analysis findings in a Preliminary AA Report and submits that report along with a Work Plan for completing the AA to DTSC.

- **Second Stage AA:** During the second stage AA, the responsible entity follows the approved work plan from the first stage AA to compare the Priority Product with the alternatives being considered. The second AA stage contains an in-depth analysis and expands the analysis to consider additional impacts, including life cycle and economic impacts. A draft AA Guide for the second stage AA is anticipated in the first quarter of 2016.

The Department's 2008 California Green Chemistry Initiative outlined policy goals that expand the focus of impact evaluation to include additional stages like product design, product manufacturing, and the product's end-of-life management. By considering effects from a life cycle perspective, manufacturers can create products that are benign by design and that avoid unintended consequences from the outset. The Department affirmed this shift in focus when it adopted SCP regulations that require manufacturers to evaluate product ingredients systematically and to answer two fundamental questions: (1) Is this ingredient necessary? and (2) is there a safer alternative? The AA Guide assists with the analysis required by the SCP regulations to answer these two questions.

The AA Guide can be found at: http://www.dtsc.ca.gov/SCP/upload/Draft-Stage1-AA-Guide.pdf.

Comments may be sent to DTSC via: https://calsafer.dtsc.ca.gov/Comments/PackageDetail.aspx?PID=11741