

**Attachment 3****Green Ribbon Science Panel****April 9-10, 2014****Topic – Key Issues in Alternative Analysis Guidance**

While developing the Alternative Analysis (AA) guidance materials, numerous key issues have emerged. The brief statements below set the context for the questions for consideration by the Green Ribbon Science Panel. The questions are intended to begin a dialog, but additional questions may emerge from the conversation.

Throughout the conversation we ask that GRSP members consider concepts of importance to DTSC:

- Focusing on what is needed to support decision making for DTSC, Regulated Entities, and other AA stakeholders.
- Developing a flexible and adaptive structure that can accommodate imperfect information and understanding.
- Supporting a range of stakeholder and end user perspectives.

We will use this meeting as a first opportunity for the GRSP to inform DTSC's AA work. The topic is broad and complex so we limit our focus to two significant areas for this initial discussion.

**I. Guidance development approach and context**

The AA guidance document is one of a set of tools which will be made available to Regulated Entities to support the development of alternative analyses. The Guide will be structured so as to closely reflect the regulatory framework and requirements. It is intended to support an efficient and effective analysis workflow and to help Regulated Entities focus on those steps that are needed for a given study.

Conducting an AA is a systematic process, commonly involving iterations (within and between steps). The California regulations follow such a stepwise process and the AA guidance documents an approach that is both step by step and iterative. Throughout, practitioners are asked to make decisions about key processes and impacts. At the end of each step, practitioners will need to "ask the next right question" in order to begin the next step. With each iteration, assessments are expected to become increasingly quantitative. This helps to ensure that the main effort of data collection and acquisition is focused on the most relevant aspects.

The intention of the Guide is (wherever feasible) to identify existing available methods and provide several alternative approaches for a given step, that will support consistent, robust and reproducible AA studies.

The Guide's approach needs to be applicable for a wide range of situations, for different product types (e.g., formulated vs. assembled products), and for a wide variety of endpoints or impacts. It is being developed to help practitioners to conduct AA studies under diverse circumstances (company size, type of product, maturity of product, etc.).

Providing adequate guidance will be challenging due to the breadth of expertise of practitioners, breadth of products, differences between the California approach and other frameworks, anticipated uncertainties and data gaps.

*GRSP discussion topic: Guidance format*

What advice can you provide DTSC with regard to:

- Format for offering guidance about consideration of the exposure at each life cycle stage.
- Effective method for offering guidance about relevant factor selection: a series of questions, a data tool (e.g., green screen), a factor list for use in creating a comparison table, something else entirely.
- Type of tools that could be included into a toolkit to supplement the guidance document: web resources, example AAs, etc.

Currently, the guidance is primarily being aimed at technical experts who need to develop an AA study - for example engineers and environmental managers in companies and other institutions. However, we recognize that many others without expertise will refer to the guidance. How, on a practical basis, could DTSC structure its guidance to be useful to a diverse range of businesses with very different staff skill sets?

## II. Relevant Factors identification

The regulations require that responsible entities use available quantitative information and analytical tools, supplemented by available qualitative information to identify relevant factors for a given AA. The list of relevant factors has been included for reference (see Attachment 4).

In practice, identifying relevant factors often requires a combination of quantitative and qualitative approaches. A layered approach that begins with scoping, followed by screening and then quantitative analysis is a preferred framework. The AA preparer uses the information captured while determining relevance from each step to guide successive assessment. DTSC is interested in thoughts and suggestions for creating an approach for determining relevance that is both consistent with the requirements and practical to users.

*GRSP discussion topic: Relevant Factors selection*

- a) What is a practical means by which one can approach the identification of relevant factors within the seven areas specified by the regs? What are some key steps in a qualitative assessment to identify relevant factors?
- b) Discuss the general approach for relevant factor selection: big picture (e.g., adverse environmental impacts, adverse public health impacts, or materials and resource consumption impacts) or small picture (i.e., by specific commonly available hazard traits, such as what green screen does) or a mix.
- c) Some relevant factors identified in the regulations do not readily translate to standard scientific endpoints. In other cases, standard endpoints may be somewhat more detailed than called out in regulation. How might DTSC address any "translation" discrepancies between standard endpoints and the language of the regulations?
- d) Are there listed relevant factors for which there are unlikely to be data for most chemicals? What is an appropriate method of handling of data gaps at the relevant factor selection stage?