

Topic #3 --- Quality Assurance for Alternatives Assessments

INTRODUCTION:

It is anticipated that, in many cases, AAs will be performed by the product manufacturer and that significant portions of the AA data and analysis will be subject to trade secret protection claims. It is also anticipated that DTSC will not have sufficient resources to conduct an in-depth of evaluation of each completed AA. In light of these circumstances, many stakeholders have called for the regulations to include provisions requiring review by an independent third-party or full transparency for public review). Subcommittee discussions focused on quality assurance of three different aspects of the AA:

- (1) Process (including logic flow, calculations, algorithms)
- (2) Data (including hazard information and other technical details)
- (3) Conclusions (judgment as to which alternative is preferred)

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List of Attachments

- 1 Statutory (AB 1879) Requirements for Alternatives Assessments (HSC section 25253)

NOTES:

- (1) Several of the options presented in this paper can be better informed by a more in-depth analysis of similar existing certification / validation programs (e.g., ISO Guide 65, ANSI, and CARB's GHG validation process).
- (2) As was suggested during the subcommittee discussions, DTSC plans to work with partners to provide AA guidance documents, which could include recommended qualifications to be considered for persons / entities performing or validating AAs, as well as for the validation process itself. However, it is important to keep in mind that standards contained in guidance documents are recommendations only, not mandates, and such standards cannot be enforced. Only standards specified in the regulations themselves can be enforced as binding requirements.
- (3) Some of the recommendations presented by one or more subcommittee members may not be viable given DTSC's resource limitations. Nonetheless, for completeness, these ideas have been captured in the conceptual options set forth in this paper. During the July 14-15 GRSP meeting, DTSC staff will identify those options that may fall into this category.

The options presented on the following pages are intended to present DTSC's understanding of the primary suggestions offered by one or more members of GRSP Subcommittee #3. Many of the options presented are not mutually-exclusive. Members of the subcommittees or the GRSP may wish to offer variations on these options. These options do not represent DTSC's proposals or perspective on these issues.

SECTION I: QUALIFICATION REQUIREMENTS FOR ASSESSORS & VALIDATORS

NOTE: Recommendations concerning certification or registration requirements generally assume that such certification or registration would be specific to a particular type of product and/or specific to a particular AA or LCA tool.

(1) Requirements for 3rd-Party Companies Offering Services to Perform AAs or to Provide Validation of AAs

OPTION I(1) A --- Specify requirements and minimum capabilities for such companies in the regulations. Review or approval by DTSC or an accrediting body is optional.

OPTION I(1) B --- Require such companies to “register” with DTSC by providing information demonstrating their applicable experience and capabilities.

OPTION I(1) C --- Require these companies to be “certified” by a certification body. This could be one or more existing entities (e.g., ANSI), or a newly formed entity(ies) accredited by DTSC (based on a process and criteria to specified in the regulations).

- If this option were selected --- the certification requirements for 3rd-party companies could be set by these certification bodies in lieu of being specified in the regulations.

(2) Requirements for Individuals Performing or Validating AAs

OPTION I(2) A --- Same as Option I(1) A above:

- Require all AA practitioners to be trained on tools and practices relevant to the AAs they will be performing.
- In the regulations, specify required qualifications for all 3rd-party AA practitioners: (i) relevant scientific and technical expertise and experience; and (ii) professional competencies (e.g., proof of ability to protect CBI materials, reputation recommendations, certification to ISO 65).
- Self-certification of these qualifications is sufficient.

OPTION I(2) B --- Same as Option I(1) B above.

OPTION I(2) C --- Same as Option I(1) C above.

OPTION I(2) D --- No DTSC-imposed requirements --- defer quality assurance to the company or 3rd-party employing the individual --- recognizing that public peer review will occur.

SECTION I: QUALIFICATION REQUIREMENTS FOR ASSESSORS & VALIDATORS (con't)

(3) Requirements for Maintaining Qualifications

OPTION I(3) A --- Continuing best practices education/training requirement as specified in the regulations OR as specified by the certification body (if there is one). Online continuing education program should be developed.

OPTION I(3) B --- Re-registration or re-certification requirement at an interval specified in the regulation OR as specified by the certification body (if there is one).

OPTION I(3) C --- Re-certification based on desk audit and/or onsite audit by certification body:

- Audit policies and procedures.
- Spot checks of completed AAs to ensure quality.

OPTION I(3) D --- No re-certification required.

SECTION II: Validation of Completed AAs

OPTION II A --- Require 3rd-party validation of all completed AAs, UNLESS the AA was performed by a 3rd-party entity.

OPTION II B --- If the AA (process, data and conclusion) is completely transparent (i.e., there are no trade secret claims), then no 3rd-party validation would be required as public peer review and comment is inevitable. If this is not the case, then 3rd-party validation would be required for those aspects of the AA that are subject to trade secret protections.

OPTION II C --- DTSC should establish a “Technical and Scientific Review Panel” (TSRP) (voluntary, non-paid membership) to review all AAs and *advise* DTSC on what action(s) should be taken. This process should allow for public participation. (It is not clear how CBI information would be handled under this process.)

OPTION II D --- DTSC should review all AAs, and a voluntary science review panel would only review DTSC AA determinations that are appealed. (Also see Section III: Conflict Resolution.)

OPTION II E --- Require a high-level corporate officer to sign the AA.

SECTION III: Conflict Resolution

NOTE: This issue, while not initially raised by DTSC, was of interest to several of the subcommittee members. Three different scenarios were identified:

- i. Manufacturer disagrees with validation findings.
- ii. Public, NGOs, academics, competitors, manufacturers of alternatives, or others wish to “appeal” an AA (based on AA process, data and/or conclusion).
- iii. Two AAs that address the same product type or the same chemical (in different products) may differ in one or more ways, for example: the process or algorithm used, the hazard traits identified for the chemical, or the conclusion of the AA.

OPTION III A --- In situations i and ii, the appeal would be made to the certification body that certified the validator of the AA.

OPTION III B --- Appeals would be made to the Technical and Scientific Review Panel (see Option II C above); or appeal first to DTSC, and the science panel would serve as a second level of appeal.

OPTION III C --- In the case of two or more “conflicting” AAs, sponsors of the AAs could nominate three registered 3rd-party validators for DTSC to choose from. The selected validator would be asked to determine which AA is more valid or that the AAs are equally valid. The review costs would be shared equally by the proponents of the AAs.

OPTION III D --- Limit appealable issues to process and data concerns (and not the AA conclusion).

NOTE: The suggestion was made that a system needs to be established to allow for sharing of hazard information for individual chemicals among AA practitioners, while at the same time maintaining the confidentiality of proprietary product formulations. Such a system would help to reduce the potential for conflicting chemical information in AAs.

SECTION IV: AA Work Plans

OPTION IV A --- No AA work plan required, or make submission of a work plan to DTSC optional.

OPTION IV B --- The AA work plan should be fairly simple, flexible to allow for adjustments as it is implemented, and set forth:

- Basic AA process to be followed
- Timelines
- Qualifications of those conducting and/or validating the AA

OPTION IV C --- The level of detail required in the work plan, as well as the rigor of DTSC's review, could be reduced if the AA will be performed by a certified assessor.

Statutory (AB 1879) Requirements for Alternatives Assessments

Health and Safety Code section 25253

25253. (a)(1) On or before January 1, 2011, the department shall adopt regulations pursuant to this section that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern, in accordance with the review process specified in Section 25252.5. The department shall adopt these regulations in consultation with all appropriate state agencies and after conducting one or more public workshops for which the department provides public notice and provides an opportunity for all interested parties to comment.

(2) The regulations adopted pursuant to this section shall establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. This process shall include life cycle assessment tools that take into consideration, but shall not be limited to, all of the following:

- (A) Product function or performance.
- (B) Useful life.
- (C) Materials and resource consumption.
- (D) Water conservation.
- (E) Water quality impacts.
- (F) Air emissions.
- (G) Production, in-use, and transportation energy inputs.
- (H) Energy efficiency.
- (I) Greenhouse gas emissions.
- (J) Waste and end-of-life disposal.
- (K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children.
- (L) Environmental impacts.
- (M) Economic impacts.

(b) The regulations adopted pursuant to this section shall specify the range of regulatory responses that the department may take following the completion of the alternatives analysis, including, but not limited to, any of the following actions:

- (1) Not requiring any action.
- (2) Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.
- (3) Imposing requirements on the labeling or other type of consumer product information.
- (4) Imposing a restriction on the use of the chemical of concern in the consumer product.
- (5) Prohibiting the use of the chemical of concern in the consumer product.
- (6) Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product.
- (7) Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.
- (8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.
- (9) Any other outcome the department determines accomplishes the requirements of this article.

(c) The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.