

Green Ribbon Science Panel

REPORT OUT

Subcommittee #1: Alternatives Assessments (as described in AB 1879) June 1 and 7, 2011 Teleconferences

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NOTE: In general, the notes set forth in this report out are presented in the sequence of the subcommittee's discussions rather than strictly by topic. Repeated comments that applied to multiple topics are generally only presented once in these notes.

Question #1A: WHAT BASIC REQUIREMENTS SHOULD BE SET OUT IN THE REGULATIONS TO ENSURE THAT AAS MEET THE REQUIREMENTS OF HSC SECTION 25253?

(i) Should there be minimum requirements for the content of an acceptable AA? If so, what should they be?

Minimum Requirement Responses:

- Applying the same level of rigor in performing an AA for the ingredient/chemical in use and the prospective alternative will be difficult.
- The 13 factors will not always be equal when comparing products, in terms of what you know and don't know.
- Suggest minimum requirements be specific to product groups or product functionality. Focus on factors that have the most control or influence on that particular product.
- Specify which of the 13 factors are critical for the priority products.
- Weighting the (A)-(M) factors (see page 8 for list of factors) to determine the most important criteria, and which issues would rise to the top, is a question that will need to be answered.
- Focus on factors that designers have the most influence over – this might be product or functionality group specific.

- Priority should be health and environmental impacts. Address factors which caused the chemical or product to be listed; e.g., a sensitive subpopulation or environment is impacted. May not be able to sequence, but should focus on what triggered the concern that caused the product to be a priority product.
- In a screening assessment of the (A)-(M) factors, the weighting in the abstract is only going to focus on the qualitative aspects of the data.
- There should be no weighting specified in regulations. Concern over “priority” weighting of the factors.
- Initially the information on the priority product must be complete at the onset or as close to it as possible.

(ii) Should there be minimum requirements for the process (the steps or procedures) for an AA evaluation? If so, what should they be?

AA Process/Procedure/Steps Responses:

- There should be a sequence of steps.
- Steps are important, but the sequence is not – should be flexible and iterative.
- Steps (suggestion #1):
 1. Identify the problem. Identify the concern that listed the product as a priority product.
 2. Determine whether the COC is necessary for the function of the product.
 3. Identify potential chemical alternatives to the COC in priority product.
 4. Screen first to see which potential alternatives will work for the product; and then screen out potential chemical alternatives based on the “priority” (A)-(M) factors.
 5. If the potential alternative has merit, conduct an AA on the COC and potential alternatives and report findings on all (A)-(M) factors.
- Steps (suggestion #2):
 1. First identify potential alternatives and screen out others -- based on some kind of minimum protectiveness. Screen out those that are obviously worse than the original based on human health and environmental concerns.
 2. Evaluate the functionality of the chemical in the product. Assume use on a broader scope just to see if another chemical has potential as an alternative. Use necessity of the chemical for the functional use in the product as a screen. Higher social utility items may be viewed differently from those of lower utility.
 3. Once a manageable number of alternatives have been identified using the above screens --- available data, relevant to the (A)-(M) factors, would be collected on those viewed as viable alternatives. After conducting a qualitative screening level consideration of all 13 factors, the entity performing the AA would determine which factors are relevant for a more rigorous comparative assessment.
 4. Identify the alternative’s viability and compare based first on human health impacts and then on functionality.
 5. These steps need to be iterative and do not consider trade-offs.

- Start out collecting information on all factors until a factor is ruled out as not relevant.
- Start by collecting data on priority product to form a baseline. Concentrate on the function of the COC in the priority product (and how the COC behaves), as well as other chemicals in the product and what role they play in the priority product.
- To start considering potential alternatives to the COC in a priority product consider:
 - The concerns that the COC is trying to address
 - The COC concentration and function of the chemical in the product
 - The potential chemicals necessary to achieve the intended function of the product.
 - The physical and chemical properties of the potential alternative chemical that can be used to start comparison.
 - Comparison of priority product against replacement products.
- Concern was expressed regarding weighting the (A)-(M) factors and how to consider trade-offs.
- Weighting factors will be qualitative assessment for many factors and weighting may be difficult if not done quantitatively.

(iii) What criteria should be used in pre-screening potential alternatives for inclusion in an AA? How should the term “availability of potential alternatives” be defined?

Availability of Potential Alternatives Responses:

- How broadly do we define “available” alternative?
- Scalability: is it readily available? Is there enough of the chemical / alternative to meet the need or demand?
- On a practical level --- at least in some industry sectors --- a thorough understanding of the existing product will be needed before screening for (A)-(M) factors, not focusing on human health necessarily, but focusing on understanding the product so as to understand viable alternatives and focusing on developing viable functional equivalents.
- To evaluate availability of and alternative, consideration must be given to market capacity to produce the alternative. This could in some cases be spurred by the imposition of regulatory responses. Feasibility evaluation needs to focus on the function of the product.
- Regulations need to be dynamic and create the scalability and availability of alternatives.

(iv) Should there be guidance or requirements for considering cost and performance factors in determining potential alternatives?

Cost/Performance Responses:

- There are many models for evaluation of performance and cost.

Miscellaneous Responses:

- Difficult to answer the question without knowing the scope of what DTSC will be requiring in the regulations.

- Design a system that is:
 - Consistent for all AAs.
 - Transparent in how the decisions are made and what process was used -- not so complicated that it's difficult to understand.
 - Rigorous to have meaning.
 - Proportional to the importance of any given factor to the comparison of the product and its potential alternatives.
- Look to techniques used in permitting programs (e.g., ARB new source review). The level of regulatory oversight is on a sliding scale based on the level of complexity.
- If DTSC engages in more oversight, then the regulations can be less “restrictive” (e.g., specify performance standards in the regulations), and there is more room for iterative AA discussions with the manufacturer. But with less DTSC oversight, or the more the process is removed from DTSC, then the regulations must be fairly directive (i.e., prescriptive standards).
- Need clear description of what data is being collected, how it will be used, and how decisions will be made.
- The stimulus for the regulations is to focus on better design of products.
- Need flexibility; there should be a balance between rigor and flexibility.

Question #1B: WHAT BASIC REQUIREMENTS (IF ANY) SHOULD BE SET OUT FOR MEETING THE LIFE CYCLE REQUIREMENTS OF HSC SECTION 25253? Should these requirements be satisfied by “life cycle thinking”, life cycle inventories, or more full blown life cycle analyses?

Life Cycle Thinking/Life Cycle Inventories Responses:

- The point in the life cycle that a product has the greatest impact should be identified and addressed in the AA.
- The regulations must address societal concerns – trade-offs.
- Criteria should be specified so that weighting is known and the reasons why DTSC made a particular decision.
- Look at this in different ways – e.g., qualitative versus quantitative. “Life cycle inventory” rather than trying to get to the specific criteria.
- “Life cycle thinking” is most appropriate. Think about each stage of the life cycle, which includes upstream use of materials and occupational exposure, as well as weighting mechanisms that could be used. Keep it a conceptual level, not specific like an ISO standard.
- There won't be a one size fits all tool -- AAs tend to be specific to a product class or functionality.
- Concern whether life cycle thinking or inventory will provide reliable or cost effective information. If not, a more qualitative approach like “ECHO” may be needed to assess impacts -- identify key environmental performance indicators then move to qualitative assessment of environmental impact of the product.
- Use a life cycle inventory/checklist.
- Need rational narrative on why an alternative is preferred or not preferred.

- Using a quantitative LCA will be resource intensive; keep regulations at the conceptual level rather than an ISO LCA.

Full Blown LCA Responses:

- The question must be answered as to whether a full blown LCA will provide the pathway to a safer product. In most cases, no – much of the information in an LCA does not really determine a safer alternative; many assumptions are made to decide whether a product or chemical is safe and what options are available (i.e., professional judgment).
- Some mathematical models will not provide transparency if not made publically available.
- Would not want to rule out tools even though they sound like plug-in (“black box”) models. Quantitative models improve over time and quantitative comparison is important. For example, in determining whether one chemical is better than another a quantitative discussion is entered into.
- Conducting a LCA on a chemical in the abstract (without other specific information) cannot be done – there are too many variables with infinite outcomes.
- Current models only address energy and performance although they are improving all the time, they don’t look at everything.
- There is a distinction between LCAs and AAs. Choosing a safer alternative may involve the use of information from mathematical models, but this alone may not yield an answer as to which alternative is the “safer” alternative. Professional judgment is important; looking at the trade-offs may lead to a different answer. In any case, transparency in decision making is needed.
- The LCA will inform a decision for a safer product; a full blown LCA does not necessarily lead to a safer product.

LCA Tools Responses:

- There are many tools for different AA’s (e.g., Green Screen, DfE, Swedish PRIO system, German Column system).
- Tools – specify in the regulations the criteria, not the tools.
- LCA could be an LCA segment; there are different levels of an “LCA”.
- Some tools are better at meeting some requirements. None meet all of the (A)-(M) requirements.
- Can’t have a regulatory program that cobbles together tools or allows entities to choose their own tools. The tools named so far were created for other purposes. This makes enforcement difficult.
- Identify performance standards for developing AA tools.
- There is a need for consistency and enforceability - by using tools that may not be designed for regulatory purposes, enforcement will be difficult.
- Identify performance standards and develop AA tools (using everything out there) either in regulation or guidance and establish a regimen that must be met. Include metrics that must be measured.
- None of the currently available LCA tools tell you how to identify the “safer” alternative.

- Not many alternatives tools are available. By definition LCA tools combine many characteristics and try to find or come up with a common factor/indicator.
- Need a decision making tool, decision analysis tool – need clear rationale for decisions being made on the AA.

Miscellaneous Responses:

- Do not want to be in the situation where DTSC must provide the oversight on the AA when conducted.
- First decide on what the role of DTSC will be and then draft the regulations to reflect that.
- There is discretion in how to implement the statute.
- AA must consider LCA - this is stated as a primary consideration in statute.
- Concern whether entities are capable and qualified to do an AA, if the range of options in the AA requires the use of a very sophisticated LCA.
- Not all chemicals in a product are necessary --- if necessary then a more rigorous approach should be used.
- The AA must support the regulatory response.

Question #1C: Should / how should the 13 elements specified in HSC section 25253 for AA evaluations be grouped and/or sequenced (or should this be left entirely to the discretion of the entity performing the AA)?

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| (i) For example, should the AA be staged so as to screen out alternatives as the AA progresses from one stage to the next? |
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AA Grouping/Staging/Sequencing Responses:

- Health and environmental impacts are the drivers for this whole effort --- legislation and regulations --- so it makes sense to first evaluate an alternative for hazard traits so as not to create a regrettable substitute.
- There needs to be flexibility in the tools that can be used.
- Reluctant to specify tools in regulation. There needs to be a resource list of tools, with identification of their strengths and weaknesses in different applications.
- No one tool covers all of the 13 factors. A qualitative assessment should be performed initially to determine relevant factors.
- Cannot trade off transparency and flexibility for objective decision.
- Prioritize the 13 factors based as follows:
 - E, F, I, J, K & L --- environmental and human health factors should be evaluated first.
 - C, D, G & H --- life cycle factors should be evaluated second.
 - A, B & M --- should be viewed as optional and evaluated last.
- Need iterative AA process with flexibility.
- Provide the tools and metrics for business to adopt. Then define the criteria by which AAs can move forward and in what order.
- Uncomfortable with how steps are laid out which does not allow for trade-offs between grouping factors across the life cycles.

- Lexigraphic approach may be useful. Start with most critical criterion then move to the next one and so on.
- Makes sense to group but not the sequencing.

(ii) Elements (A) and (B) are properties of an alternative, whereas, elements (C) through (M) are impacts of an alternative. Should the first two elements be used to screen out alternatives before, after or simultaneously with consideration of the other elements?

Screening Out Alternatives Responses:

- First look at why a COC is prioritized in the first place, and why it is present in the product.
- Identifying another COC to replace the original COC should not automatically be ruled out as an alternative chemical.
- A replacement chemical should not be used if it has a hazard trait.

Miscellaneous Responses:

- Facilitate collaboration among entities performing AAs.
- Think about the AA report as a way of justifying the approach taken in the AA.
- How information is presented in the AA report is, in fact, different from how the AA was developed. The process of doing an AA may be very iterative and exploratory; the presentation of information in the AA report should be well ordered.
- Don't want AA regulations to be overly prescriptive like risk assessments have.
- Producing AAs is different from knowing AA was conducted.

Question #1D: WHAT DATA OR OTHER INFORMATION SHOULD BE REQUIRED TO BE OBTAINED OR DEVELOPED AND EVALUATED TO SUPPORT THE AA ANALYSIS?

(i) Should there be minimum requirements for documentation data for each of the 13 factors? If so, what should those requirements be?

Data/Information Responses:

- Magnitude of the question is daunting.
- Data for evaluating toxicity ought to be clear. Consider the hazard trait that led to the chemical being identified as a COC.
- Need documentation regarding how data was generated. Concern with regard to data-poor chemicals and how to address them.
- Refer to OEHHA regulations with regard to quality of data. For baseline comparison, use the data which supported the listing of the chemical as a COC in the first place.
- Refer to OEHHA for hazard traits and LCA cluster for emerging consensus; but for (A) and (B) we may need to rely on industry to provide industry specific metrics.
- Some of the (A)-(M) criteria will have limited objective data.

- DTSC should specify minimum data requirements in regulations; if requirements are not specified there will be a vast array of approaches. Can't meet objective if you don't have criteria by which to measure them.
- The regulations need to work for both large and small companies.

Use of Proprietary Models Responses:

- This would not contribute to transparency, which is the one of the goals of the green chemistry initiative. Consider US EPA's approach to CBI for proprietary models.
- Black box approaches can be used by industry for internal decisions, but DTSC should have access to how it was done. But the public won't have access to the proprietary model – transparency is an issue.
- Black box approach will stand in the way of what DTSC is supposed to be able to do.
- "Transparency in a black box is an oxymoron." All will be stymied if we allow use of non-transparent methods.
- Prefer a less sophisticated method that is transparent over a black box approach.
- A black box approach for regulatory compliance should not be allowed; there are many publicly available tools.
- Not convinced proprietary tools are the only tools available.
- There are ways to get the necessary information without disclosing trade secrets (i.e., black box). Look at financial industry as useful model (disclose revenue, but not the details of the finances or suppliers).

Question #1E: WHAT IS A REASONABLE TIMEFRAME TO ALLOW FOR COMPLETION OF AN AA EVALUATION MEETING THE REQUIREMENTS OF HSC SECTION 25253?

Timeframe Responses:

- There is no one size fits all approach for completing an AA; the time frame should be based on the complexity of the product and AA.
- DTSC could specify time when selecting product as priority product that considers the complexity.
- Concern about time frames for individual products – there may be a tendency to put off the AA until the last minute and to extend time and delay the AA.
- Need clear deadlines – suggest deadline for initial data submittal and deadline for a final decision.

HSC Section 25253 Factors:

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

* Including impacts to sensitive subpopulations.