

Subgroup #2: Tiered alternatives assessments

Homework assignment

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General comments

The aim of tiering or otherwise streamlining AA's would be to quickly decide whether or in what contexts the availability of alternatives is a relevant and significant factor in deciding whether and how to regulate a chemical of concern in a product of concern

- Where it is found to be relevant, to focus a subsequent more in-depth AA on the most important elements.
- Where it is not relevant or needed – or is not relevant to informing *initial* or *interim* risk management steps that can or need to be taken – allow DTSC to move to appropriate regulatory responses expeditiously.

The statute requires that regulatory responses follow in a temporal sense the completion of the AA. However, none of the regulatory responses listed in the statute are explicitly linked to the outcome of the AA, i.e., dictate how the findings of an AA would determine or shape the regulatory response. Moreover, at least three of the regulatory responses (Section 25253(b), #s 3, 6 and 8) are not even implicitly dependent on the outcome of an AA. DTSC needs the ability to quickly impose these or other regulatory responses where needed, even as it may need the outcome of a fuller AA to inform other regulatory responses.

One way to approach streamlining of the AA is to invoke principles from alternatives assessment and lifecycle assessment frameworks:

- *Factors that are not significantly different*: Require a level of analysis sufficient but not more than needed to establish that a given factor does not significantly differ among alternatives being compared, and can be safely assumed not to be dispositive in selecting among them.
- *Avoid paralysis by analysis/Diminishing returns*: Similarly, limit the depth of analysis of a given factor to that needed to capture its differential contribution to the alternatives being compared, without forcing further quantitative analysis that would shed little additional light on the comparison (akin to a 90:10 rule).

The desired approach would then entail that each required factor be considered and a justification provided as to whether or not (and if not, why not) it would constitute both: a) a significant contribution to the impact of a given alternative, AND b) a significant differential among the alternatives being compared.

Question 2A:

I would favor an approach where:

- initially a Tier 1 (qualitative) approach to the AA would be required, with each of the listed factors considered as described above,

- followed by a determination of an initial/interim regulatory response that either is not dependent on the outcome of the AA, or does not require a full-blown AA,
- followed by a more in depth AA focused only on those listed elements that are: a) needed to inform a further possible regulatory response, and b) meet the significant contribution and significant differential tests described above.

I also think there is merit in bounding the type of alternatives to be compared, through tiering on that side as well as on the factors-to-be-considered side (as I believe was proposed last year):

- identify alternatives that are significantly better than the chemical of concern with respect to the parameter(s) that led it be identified as of concern in the first place;
- subject only those alternatives that meet the first requirement to subsequent more in – depth AA, in order to ensure that those alternatives do not present unacceptable trade-offs with respect to the other listed elements required to be considered.

Finally, among the alternatives to be compared should always be the alternative of *doing without* the chemical of concern in the product of concern, rather than replacing it with a chemical or non-chemical alternative. In this manner, the hypothesis can be tested and assessed as to the *essentiality* of the chemical in that application. For example, if a fragrance providing a 20th flavor in a line of air fresheners is found to be of concern, DTSC should be able to restrict use of that chemical without being concerned about whether or not an alternative is available. Including the do-without option is therefore critical to informing DTSC’s subsequent regulatory responses.

Question 2D:

I would reword this to read: “What should be the circumstances or conditions for *requiring* a manufacturer to conduct a *higher* tier AA?”

Using a multistep approach as outlined above, after completion of an initial qualitative or screening-level AA, DTSC would make a determination as to whether further analysis is needed or desired for it to determine the appropriate ultimate regulatory response (while allowing DTSC to take an interim regulatory response at this step). Only where DTSC so determined would a fuller AA be required, and DTSC could limit its scope according to what it determines is needed to inform its ultimate regulatory response.

Question 2E: This was really addressed in the general comments above, where I indicated that some regulatory responses do not depend on the outcome of the AA.