Julia Quint, Ph.D.
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SC1 Meeting 2 –AA Case Study
Responses to Case Study Questions

Question #1A: What basic requirements should a compliant AA for a window cleaner contain that should be set out in the regulations?

(i) At a minimum, what should the AA for a window cleaner contain that will meet HSC 25253? Should a basic requirement in the window cleaner AA include consideration or evaluation of whether the chemical of concern (CoC) is necessary in the product? If not, what? Or are there other basic requirements?

Minimum AA Requirements

(a) Priority window cleaner information:
- υBrand name
- υCoCs (chemical name, concentration, CAS #, hazard traits, physical/chemical properties, function)
- υOther chemicals in window cleaner (chemical name, concentration, CAS #s, function, hazard traits)
- υPerformance, functionality, and other technical requirements
- υFunction of CoCs in product and in meeting window cleaner technical and other requirements
- υIntended use/targeted customers (e.g., households, institutions, etc.)
- υCritical exposure pathways (human and environment)
- υWaste disposal and other end-of-live methods /costs
- υOther environmental compliance requirements/costs

(b) Alternative chemical information in reformulated window cleaner:
- υChemical name/synonyms, CAS#, physical/chemical properties, concentration in product, function, hazard traits
- υCoC that alternative chemical is replacing
- υFunction in meeting product's performance, functionality and other technical requirements

(c) Other chemicals in the alternative product (chemical name, CAS#, concentrations, hazard traits), if different than priority window cleaner

(d) Screening results, which provide evidence demonstrating that the alternative chemical is not a CoC (that will be above de minimis concentrations, if applicable)

(e) Comparative assessment of the health and environmental impacts of the priority window cleaner and alternatives, addressing K, L, F, I, J, & E in HSC 25253, and assessing worker safety as specified in section 25252.5. The assessment should be based on the prioritized hazard traits defined in Chapter 54, Green Chemistry Hazard Traits, Division 4.5 of the California Code of Regulations that were used to identify CoCs, using well conducted scientific studies that are consistent with the strong and suggestive evidence criteria for the prioritized traits.

(f) Identification of the critical exposure pathways (human and the environment)

(g) Comparative assessment of the exposure potential of the chemicals with hazard traits in the priority window cleaner and the alternative window cleaners

(h) Comparative assessment of factors C, D, G, H in section HSC 25253 for the priority window cleaner and alternative window cleaners, based on criteria specified by the Department.

(i) Comparative assessment of the function or performance product (A and B in HSC 25253) of the priority window cleaner and the alternative based on criteria specified by the Department.

(j) Comparative assessment of the economic impacts of the priority product and the alternative product (M in section 25253) based on criteria specified by the Department.

Should include consideration or evaluation of whether the COC is necessary in the product? If not, what? Or are there other basic requirements?

Include evaluation of whether the CoC is necessary in AA?

Yes—function of CoCs in meeting performance, functionality, and other technical requirements for the window cleaner should be included in AAs

Other basic requirements:

(a) Chemical name and synonyms, CAS#, concentration, and function in the priority and alternative window cleaners

(b) Alternative chemical should not be a CoC (that will be present above de minimis concentrations, if applicable). A reformulated window cleaner with a CoC, would by definition, be a "priority" product, not an "alternative" window cleaner

(c) Must have sufficient hazard information on the alternative chemical (based on strong evidence criteria in Chapter 54, Green Chemistry Hazard Traits, Division 4.5 of the California Code of Regulations) to determine that it is not a CoC.
(d) Critical exposure pathways (human and environmental) for alternative chemical
(e) Comparative assessment of the exposure potential of the priority window cleaner and the alternatives if chemical have hazard traits

(ii) What are the minimum steps or procedures (i.e., process) needed in the AA evaluation of the window cleaner that the mfg must follow?
(a) Screen alternative window cleaners to determine that chemical/chemicals are not CoCs (that will be present above de minimis concentrations, if applicable)
(b) Assess health and environmental impacts of the CoC in the priority window cleaner and the alternative chemical as described in (i) (e) above. Assessment must address potential chemical or physical hazard traits (as defined in Chapter 54, Green Chemistry Hazard Traits, Division 4.5 of the California Code of Regulations) that may result from interaction with or presence of other chemicals in alternative product
(c) Conduct comparative assessment of the exposure potential of priority and alternative cleaners if chemicals have hazard traits
(d) Conduct comparative assessment of alternative and priority window cleaners, addressing C, D, H, & G of HSC 25253 based on criteria specified by the Department.
(e) Conduct a comparative evaluation of the alternative and priority window cleaners, addressing A, B, HSC 25253, based on criteria specified by the Department.
(f) Conduct a comparative evaluation of the alternative and priority products, addressing M, section 25253, based on criteria specified by the Department.

(iii) What pre-screen criteria should be used to decide whether the potential alternatives for the window cleaner should be addressed in the AA?
<u>All alternatives for the CoC in the window cleaner should be addressed in the AA unless</u>:
(a) A Chemical Removal Notice for the priority window cleaner is submitted
(b) An existing AA for the potential alternative window cleaner that meets the regulatory requirements is submitted
(c) Other submitted evidence consistent with the criteria specified by the Department indicates that potential alternatives for the window cleaner satisfy the requirements in HSC section 25253
(d) There is insufficient information available from "well-conducted scientific studies" based on a search of the strong and suggestive evidence criteria for the prioritized hazard traits (Chapter 54, Green Chemistry Hazard Traits, Division 4.5 of the California Code of Regulations) to assess whether the alternative chemical is a CoC (that will be present above de minimis concentrations, if applicable)
<u>The responding entity may decide not to proceed with the AA for the potential alternatives under the following circumstances</u>:
(a) Alternative chemical has strong or suggestive evidence of a prioritized hazard trait as defined in Chapter 54, Green Chemistry Hazard Traits, Division 4.5, of the California Code of Regulations that was used to identify CoCs
(b) Limited availability and/or supply of the alternative chemical or chemicals would result in substantial impacts (the Department would have to decide what constitutes "substantial", e.g. 2-3-fold increase?) on material resources (energy requirements, water usage) and costs on production of the alternative window cleaner
(c) Alternative chemical will result in the alternative window cleaner not meeting the required performance, functionality, and other technical criteria of the priority product

<u>Definition of "availability of potential alternatives"</u>
Window cleaners, commercially available in CA, that do not have CoCs (above de minimis concentrations, if applicable) in the formulations.

(iv) What kind of guidance requirements should be used to determine the potential alternatives for the window cleaner when evaluating the economic impacts (cost) and performance (product function) factors?
The Department should specify criteria (as opposed to non-mandatory guidance) for evaluating these factors. The following could be used to develop criteria. The requirements of HSC 25253 (c) should guide development of the criteria.

Economic impacts
Costs to produce the alternative window cleaner compared to the priority product of:
υraw materials
υequipment & maintenance
υlabor
υelectricity
υgas
υwater
υtransportation
υwaste and other end-of-life disposal methods
υother environmental compliance

Product function
Comparative function or performance evaluations of the priority and alternative window cleaners should be based on the required performance, functionality, and other technical criteria for the priority window cleaner, such as:
υability to remove diverse contaminants from a specified number of substrates
υcleaning efficiency (how much window cleaner is needed, time required to clean)
υpotential residues left on surfaces after cleaning
υodor
υrequired packaging
υshelf life / expiration date

Question #1B: What are the basic requirements (if any) that would meet the life cycle requirements of HSC section 25253 for the window cleaner? Are the requirements for a window cleaner life cycle assessment satisfied by "life cycle thinking", life cycle inventories, or more full blown life cycle analyses?

(i) For example, the potential alternatives identified for a window cleaner are: (1) glacial acetic acid and water, (2) household vinegar and water and (3) household ammonia and water. Should each potential alternative undergo a complete full blown life cycle analysis for each of the 13 factors? Or can "life cycle thinking" be used to satisfy all or some of the 13 factors instead of a more full blown life cycle analysis?

Basic requirements that would comply with HSC section 25253
(1) Hazard evaluations (as described above in (i) e) to determine whether glacial acetic acid, household vinegar, and household ammonia (at the concentrations used in the window cleaner) have adverse impacts on health and the environment; (2) identification of critical exposure pathways for the alternative window cleaners and the priority product; (3) comparative assessment of the exposure potential of the priority and alternative window cleaners if chemicals have hazard traits as defined in Chapter 54, Green Chemistry Hazard Traits, Division 4.5, of the California Code of Regulations (4) comparative assessments, that comply with criteria specified by the Department, to determine impacts on C, D, G, and H of each alternative window cleaner and the priority window cleaner; (5) comparative function or performance (A and B) evaluations of the priority and alternative window cleaners based on criteria specified by the Department and linked to the performance, functionality, and other technical requirements of the priority window cleaner (see #1A iv); and (6) comparative evaluations of the economic impacts (M) of manufacturing the alternative window cleaners and the priority window cleaner, that comply with criteria specified by the Department, as described above in #1A (iv).

Complete full blown life cycle analysis for each of the 13 factors for the alternatives? Or can "life cycle thinking" be used to satisfy all or some of the 13 factors instead?
The objective or desired outcome of the information in HSC section 25253, including the 13 factors, appears to be to ensure that alternatives to CoC-containing products do not have adverse impacts on health or the environment throughout their life cycle (production to disposal), and that they perform adequately and are cost-effective compared to the priority product. Assessments that meet this overall objective should be compliant regardless of whether "life cycle thinking" or a full-blown life cycle analysis is used, especially since these terms are subjective and are open to interpretation.

Minimum criteria for AAs should be specified in the regulation

To ensure that the AAs are "transparent", "consistent", "rigorous", and "proportional", the regulations should specify criteria for compliant AAs as specified in HSC section 25252 (b) (1). Section 25252 (b) (1) mandates that the criteria include, but not be limited to, the hazard traits as described in Chapter 54, Green Chemistry Hazard Traits, Division 4.5 of the California Code of Regulations. The hazard traits therefore provide the minimum criteria for assessing the factors related to health and environmental impacts in section 25253 (E, F, I, J, K, L). This is consistent with the fact that the hazard traits (or, in the initial implementation phase, a prioritized subset), along with an assessment of exposure potential, provide the scientific basis for identifying priority products. Criteria that meet the remaining requirements of HSC section 25253 life cycle-related factors, C, D, G, H; product function or performance factors, A, B; economic impacts, M; and which identify, evaluate, and compare critical exposure pathways for the priority and alternative window cleaners should be specified in the regulation.

Question # 1C: Should/how should the window cleaner AA evaluation group the 13 elements specified in HSC section 25253? Should the 13 elements be sequenced or be left entirely to the discretion of the entity performing the AA on the window cleaner?

The grouping or sequencing of the 13 elements can be discretionary and does not have to be specified in the regulation. It is more important and critical to ensure that the primary focus or purpose of evaluating chemicals of concern in consumer products and their potential alternatives is made clear in the regulation. HSC section 25253 (a) (1) states that the purpose of this evaluation is: *"to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern."* The AA "process" to be developed by the Department, a further requirement that must include the 13 elements, is a part of the evaluation of the CoCs in consumer products and their alternatives. As a result, the purpose of the AA process is also *"to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern."* Stating this purpose in the regulation would help to ensure that it is understood and given highest priority in evaluating alternatives to CoCs in the window cleaner. Specifying criteria [including the hazard traits, characteristics, and endpoints as mandated in HSC section 25253 (b) (1)] that must be addressed to ensure that the purpose of the AA and the requirements of HSC section 25253 (a) (1) and (2) are met, is more useful and important than grouping or sequencing the 13 elements.

(i) Should the window cleaner AA be staged to screen out alternatives as the AA progresses from one stage to the next?

Staging the AA to screen out alternatives to the CoC in the window cleaner will help to ensure that the purpose of the AA (see above response) is met. However, this information should be presented as non-mandatory guidance in the regulation since many entities may place equal or more importance on first ensuring that potential alternatives meet the required performance and other technical criteria for the window cleaner (i.e., does the alternative window cleaner function properly so that it will be marketable?).

Is this the most effective sequence and is it considered "proportional"?

The sequence is effective in helping to ensure limited exposure and reduction of the hazards associated with the CoCs and alternatives to the CoCs in the window cleaners. The criteria developed by the Department as specified in HSC section 25252 (b) (1) will determine whether the AA is "proportional" since availability of information or resources needed to comply with the criteria may vary by the size of the affected manufacturer or business. For example, the criteria to evaluate elements C, D, G, and H of section 25253 could require conducting a full-blown LCA instead of simply providing evidence of the comparative amounts of water, electricity and other energy sources that were used to produce the alternative window washer and the priority window washer. Conducting a full-blown LCA would probably be more difficult for small businesses compared to large businesses.

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

This decision should be left to the discretion of the responding entity and should not be specified in the regulation. Responding to the criteria developed by the Department for a compliant AA should be mandatory.

Question #1D: What data or other information should be required or developed and evaluated to support the window cleaner AA analysis?

(i) What would be the minimum documentation and data requirements to address each of the 13 elements specified in HSC section for the window cleaner AA? Would trade secret data that has been peer reviewed be acceptable (i.e., transparent, rigorous, and consistent)?

Minimum documentation and data requirements for 13 elements of section 25253 (a) (2)

- υA, B: Performance and other technical criteria for priority window cleaner and alternative window cleaner. See examples in response to #1A (iv).
- υC: raw materials, equipment and maintenance, and personnel or labor that are required to produce the priority and alternative window cleaners.
- υD: average volumes of water used to produce the priority and alternative window cleaners
- υE: acute aquatic toxicity [LC50 or EC50 (mg/L)]; chronic aquatic toxicity [LOEC (mg/L]
- υF: (a) ambient ozone formation- VOC content of the priority and alternative cleaners and measurements of reactivity of the CoC and the alternative to the CoC, such as the Maximal Reactivity Scale adopted by CARB; (b) stratospheric ozone depletion potential –whether any of the chemicals in the priority and alternative window cleaners are listed in the Montreal Protocol or U.S. EPA pursuant to Section 612(a) of the Clean Air Act as a substance that depletes stratospheric ozone
- υG: Electricity usage (e.g., heating, cooling, water heating, equipment usage, lighting, electronics, etc.); fuel consumption; miles traveled; other measures of energy usage required to produce, use, and transport the priority window cleaner and alternative window cleaner
- υH: Reduction (or not) of energy usage (producing, using, and transporting) for the alternative window cleaner compared to priority cleaner
- υI: Identification of greenhouse gases emitted for the priority and alternative window cleaners and measures of the global warming potential which meet the criteria of the International Panel on Climate Change
- υJ: Evidence, including manifests if applicable, of the types and amount of waste and waste byproducts generated (from production through use), and/or other end-of-life disposal procedures of the priority and alternative cleaners and their chemical ingredients
- υK: (**a**) Information and/or data (e.g., test results, citations of published research studies and authoritative organizations' reports, authoritative organizations' chemical evaluation status, literature search results, etc.) from "well-conducted scientific studies" (as defined in Division 4.5, Title 22, CCR Chapter 54. Green Chemistry Hazard Traits) that pertain to the strong and suggestive evidence criteria for the prioritized hazard traits that were used by the Department to identify CoCs. The prioritized hazard traits may include: carcinogenicity, reproductive toxicity, developmental toxicity, endocrine toxicity, epigenetic toxicity, genotoxicity, respiratory toxicity (asthma), bioaccumulation, environmental persistence, global warming potential, and lactational or transplacental transfer; (**b**) intended users and marketed use; (**c**) identification and comparative evaluation of critical exposure pathways; (**d**) potential exposure of sensitive populations, including fetuses, infants, children, immune compromised, elderly, pregnant women
- υL: (**a**) Experimental or estimated data on persistence in air, water, soil, or sediment for CoCs and CoC alternatives, consistent with EPA DfE proceedure to determine environmental persistence; (**b**) bioaccumulation factor (BAF) / bioconcentration factor (BCF) or octanol:water (Kow) and octanol:air (Koa) for CoCs and CoC alternatives, consistent with EPA DfE procedure to determine bioaccumulation.
- υM: Data on the costs of producing the priority window cleaner and the alternative window cleaners. See response to question #1A (iv) for types of costs for which data would be required.

(ii) Should the window cleaner AA analysis use tools or instruments that are commonly available, but are proprietary (e.g., fill in the information and the tools/instrument (e.g., model) provides an answer to use for comparison with potential alternatives to the window cleaner)? Would the proprietary model satisfy the following criteria: transparent, rigorous, and consistency?

The window cleaner AA analysis should not use proprietary tools since, by their very definition, they would not meet the requirement for "transparency of application" as specified in HSC 25253 (c). Such tools also may not meet the "ease of use" requirement of this section and the requirement that the department "make every feasible effort to devise simplified

and accessible tools" (emphasis added) that consumers, product retailers, and others can use. If "black box" proprietary tools are available but not understood, their use will not be "consistent" among responding entities. The degree of rigor the proprietary tools provide is subject to interpretation, and may not be needed to satisfy the primary purpose of the AA analysis as specified in HSC 25253.

Question #1E: What is a reasonable timeframe to allow for completion of the window cleaner AA evaluation to address and meet the requirements of HSC section 25253?
Three months may be a reasonable timeframe to complete the window cleaner AA evaluation. Extensions to the required timeframe should be allowed on a case-by-case basis only when it is documented that a reasonable effort has been made and the evaluation could not be completed. Conditions that may require a longer time period for AA analyses include: consumer products that contain multiple CoCs; evaluation of newly developed or conflicting hazard trait data on potential alternative chemicals; in-progress tests with projected completion dates that will provide critical information for conducting the AA; awaiting information regarding the availability (in sufficient quantities) of a potential alternative that has passed the adverse health and environmental and exposure potential impact screens.

Question #1F: Other related ideas?

Set guidelines for what constitutes minimum documentation that "no potential safer alternatives" exist for a priority product, and under what circumstances the priority product can continue to be used.

Determine under what circumstances the factors in HSC 25253 that are not related to "limiting exposure or reduce level of harm by the chemical of concern" (i.e., factors A, B, C, D, G, H, and M) will result in an alternative product not being acceptable if the alternative product does not have adverse impacts on health or the environment and does not present an exposure problem compared to the priority product.

Use case studies in the guidance materials to illustrate how to conduct an AA for formulated products and assembled products.