Introduction to Safer Consumer Products Alternatives Analysis (AA)

DTSC Alternatives Analysis Workshop on Life Cycle Impacts and Exposure Assessment

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Suzanne Davis, Senior Hazardous Substances Engineer

Safer Products and Workplaces Program

Introduction

Picture of Homer Simpson working on a complicated math problem. When we talk about Alternatives Analysis, it can be as daunting as the mathematical formula shown in this figure. However, the goal of alternatives analysis is not intended to paralyze you by analysis. It is a process to help answer two fundamental questions: 1) Is this chemical ingredient necessary? and 2) Is there a safer alternative?

Safer Consumer Products framework

Graphic shows the four key processes to identify safer alternatives under the Safer Consumer Products framework. Step 3, the Alternatives Analysis where the manufacturer evaluates alternatives, is circled.

Refer to Division 4.5, Title 22, California Code of Regulations, Chapter 55 Safer Consumer Products

Two Stage Alternatives Analysis

Graphic illustrating how a range of alternatives are evaluated. In general, the Alternatives Analysis process consists of two stages. In the 1st stage, potential alternatives are screened and a Preliminary AA report is submitted that contains the work plan and schedule for completing the 2nd stage AA report. The 2nd stage is where selected alternatives from the 1st stage are analyzed in more depth and a Final Alternatives Analysis report is submitted.

Alternatives Analysis – 1st Stage

Graphic showing the five steps to conduct the 1st stage screening analysis. Step 1 is to identify product requirements and function of Chemical of Concern. Step 2 is to identify alternatives. Step 3 is to identify factors relevant for comparing alternatives. Step 4 is the initial evaluation and screening of alternative replacement chemicals. Step 5 is to consider additional information. Step 6 is to generate the preliminary Alternatives Analysis report. Step 3 is highlighted since this step involves identifying relevant factors to screen and evaluate potential alternatives. One take away for this workshop is the ability to identify relevant factors by using tools and methods developed for analyzing life cycle and exposure assessment.

Alternatives Analysis – 2nd Stage

Graphic showing the five steps to conduct the 2nd stage screening analysis. Step 1 is to identify factors relevant for comparing alternatives. Step 2 is to compare the Priority Product and the alternatives. Step 3 is to consider additional information. Step 4 is consists of the alternative selection decision. Step 5 is to generate the final Alternatives Analysis report. Step 1 is highlighted since the selected alternatives from the first stage will be analyzed more in-depth during the second stage. You will be re-evaluating your relevant factors to incorporate multimedia life cycle impacts and economic impacts as part of your in-depth Alternatives Analysis.

Factors to be considered

Two graphics presented on this slide.

The right-hand graphic lists four types of information industry needs to consider during alternatives selection which are 1) the manufacturer's evaluation, 2) public comment, 3) confidential business information protections, and 4) life cycle thinking.

The left-hand graphic lists the factors to be considered which are: adverse environmental impacts, adverse public health impacts, adverse waste and end-of-life effects, environmental fate, materials and resource consumption impacts, physical chemical hazards, physiochemical properties, product function and performance, and economic impacts. Adverse environmental impacts is highlighted because it will be discussed in the next slide.

Refer to Division 4.5, Title 22, California Code of Regulations, Chapter 55 Safer Consumer Products

Adverse Air Quality Impact Definition

Graphic listing the chemicals associated with adverse air quality impacts which is a subset of adverse environmental impacts. Adverse air quality impacts include (1) greenhouse gases such as carbon dioxide, nitrous oxide, hydrofluorocarbons, perfluorocarbons, methane, sulfur hexafluoride, and nitrogen trifluoride; (2) nitrogen oxides; (3) particulate matter; (4) ozone depleting chemicals; (5) sulfur oxides; and (6) California toxic air contaminants.

Chemical Hazard Assessment

- Comprehensive list of hazard traits for evaluation
- Adverse public health impacts
    - 20 hazard traits

- Adverse ecological impacts
    - Aquatic, terrestrial, avian, plants, microbes
    - Environmental hazard traits
        - Growth, survival, reproductive and development
        - Phytotoxicity
        - Impairment of waste management organisms

Refer to Division 4.5, Title 22, California Code of Regulations, Chapter 54 Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data

Exposure Assessment Considerations

- **Chemical quantity**
- Exposures to the hazardous chemical in the product
- Household and workplace presence of the product
- Exposures during the product's life cycle
- **Bioaccumulation**[1]
- **Persistence**[1]

[1]Division 4.5, Title 22, California Code of Regulations Chapter 54 Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data

The factors are in bold on this slide: chemical quantity, bioaccumulation, and persistence. In an AA, the "Chemical Quantity" may serve as a surrogate for potential exposure when exposure data is not available. The SCP regulations require you to estimate the amount of the Chemical of Concern and any alternative chemicals needed to manufacture the product. This estimated volume or mass of the Chemical of Concern or alternative chemicals is based on the statewide sales of the Priority Product by volume or number of units.

"Bioaccumulation" and "Persistence" are not only considered as part of the environmental fate but are also considered as part of the potential exposure.

Comparative Exposure Assessment

The responsible entity **compares** the Priority Product and the alternatives under consideration using, at a minimum, the same relevant factors and, when applicable, associated **exposure pathways** and life cycle segments.

In the context of an AA, a comparative exposure assessment should be conducted for the Priority Product and the alternatives.

Methods to Evaluate Potential Exposure

- Data and Models for Exposure Assessment

- Conceptual Model
    - Graphical representation of exposure source and receptors
    - Identify exposure pathways
        - Fate and transport
        - Exposure routes
        - Potential receptors

There are numerous tools and models that are either publically available or can be purchased to assess the Chemical (s) of Concern and alternatives being considered. The regulations provide flexibility in the selection and use of methodologies, models, and tools. When selecting a model, you should consider the model's underlying assumptions and ensure the same model can be used for all alternatives being evaluated.

One tool highlighted on this slide is the conceptual model. The conceptual model is a graphical representation of the potential exposure pathways between people, wildlife, the environment, and the consumer product to which they may be exposed. With the conceptual model, you can visually identify various exposure pathways. Using fate and transport information, environmental media that may be impacted can be identified along with contaminated media and its associated exposure routes and impacted receptors.

Conceptual Model – Exposure Pathways

An example of a conceptual model for exposure pathways. The graphic shows the movement of the Chemical of Concern from the primary source (the consumer product) to secondary sources (affected soil and groundwater). The Chemical of Concern may expose receptors directly via use, be transported directly to food via affected soil, or transported from the consumer product to indoor dust. The Chemical of Concern may also travel to an exposure medium via a transport mechanism (e.g., airborne particulate matter, soil gas, wastewater treatment effluent, stormwater runoff, or leaching to groundwater). Exposure mediums are food soil, indoor ambient air, soil gas, surface water body, groundwater, and indoor dust. Exposure medium are linked to tables listing the exposure route and receptor type such as human (consumer and worker) and ecological (terrestrial and aquatic). For food and soil, the human (consumer and worker) and ecological (terrestrial and aquatic) receptors are exposed via the ingestion route while the human (consumer and worker) and terrestrial ecological receptors are also exposed via the inhalation and dermal routes. For indoor ambient air and soil gas, human (consumer and worker) and terrestrial ecological receptors are exposed via the inhalation route. For surface water body, human (consumer and worker) and ecological (terrestrial and aquatic) receptors are exposed via the dermal route while ecological (terrestrial and aquatic) receptors are also exposed via the inhalation and ingestion routes. For groundwater, human (consumers and workers) are exposed via the inhalation, ingestion, and dermal routes. For indoor air, human consumers are exposed via the inhalation, ingestion, and dermal routes. Using the consumer product exposes human (consumer and worker) and ecological (terrestrial and aquatic) receptors via the inhalation, ingestion, and dermal routes.

Conceptual Model - Life Cycle Impacts

An example of a conceptual model that is helpful for visualizing exposure pathways, and receptors associated with various life cycle segments. The figure shows the life cycle stages of a product from manufacturing to the end-of-life. At different stages of the product's life cycle, the product may be released to the environment in wastewater, trash, or runoff when used by the end user. Ecological receptors, such as fish or waterfowl, may be exposed to the product in the runoff from waste facilities, wastewater treatment plants, and the ground.

Addressing Information Challenges

- Unavailability of comprehensive data sets
    - Toxicological data, especially ecological hazards
    - Exposure data
    - Product ingredient and chemical quantity information
    - Life cycle inventory data
    - Public health and environmental costs
- Quality of data
- Temporal and spatial information
- Ways to address data gaps
- Reliability and robustness in regulatory context

As you perform the first and second stages of the Alternatives Analysis, you may come across several challenges due to incomplete data sets, variations in the data quality, etc. In the Alternatives Analysis reports generated, it is important to document these information gaps and your attempts at addressing these challenges.

Conclusion

Venn diagram showing Alternatives Analysis as the intersection of life cycle assessment, chemical hazard assessment, and exposure assessment.

Alternatives Analysis sits at the intersection of three disciplines: chemical hazard assessment, life cycle assessment, and exposure assessment. It uses data and tools from these disciplines to evaluate potential alternative(s) and identify safer ones.

Life cycle assessment and risk assessment (which is included in the exposure assessment toolbox) is not required under the SCP regulations. However, you are not precluded from using the tools or methods from the life cycle assessment or risk assessment toolbox. You must consider all factors, life cycle segments, and exposures outlined in the SCP regulations.

Thank you!

Questions or comments?

Suzanne.Davis@dtsc.ca.gov