



Safer Consumer Products
Alternatives Analysis Guidance Document Synopsis
Green Ribbon Science Panel

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Preface:

The Preface briefly describes the purpose of the guidance document (Guide) and tells readers what to expect from it. It describes the target audience, the level of knowledge expected of readers, and describes the limitations of the guide. The target audience for the Guide is alternatives analysis (AA) practitioners who have enough training and experience to evaluate the direct and lifecycle impacts associated with a priority product and its alternatives. Other readers may use the Guide as a reference, but the primary focus of the Guide is to provide various approaches and tools that could be useful to AA practitioners. Currently, the Guide is generic and not specific to any particular product.

1. Introduction

This chapter provides an overview of the Safer Consumer Products regulation framework and the Guide contents. It sets the stage for the succeeding chapters by describing the steps for conducting an alternatives analysis pursuant to the regulations. The guide identifies differences among the steps required by the CA SCP requirements and other tools and approaches in common practice. The chapter describes how the Guide is organized and provides brief descriptions of the chapters' contents. This chapter focuses on:

- Guide objectives
- An AA implementation overview
- Organization of the guide
- Guiding Principles for AA, which describe a core suite of principles when conducting an AA:
 1. Consider a wide range of alternatives (not just chemical substitution).
 2. Apply a life cycle perspective
 3. Capture the breadth of impacts – Consider environmental, economic, and social impacts. Consider impacts to workers, consumers and the environment across the life cycle and the supply chain.
 4. Support and document assessment assumptions and decisions. Address uncertainties.
 5. Be transparent. Disclose all information to provide support for decision-making. All assumptions, data sources, data quality determinations and decisions should be documented, justified and explained.

6. Use an iterative approach – Revisit assumptions and decisions when information is obtained, when choices are narrowed, and when additional detail is required by regulation.

2. Administrative Requirements for Alternative Analysis [§69505.4]

This chapter discusses the required notifications, due dates, and compliance options available to responsible entities. These include the steps to consider before beginning an AA process, as well as the four AA options.

2.1 Notifications

This section discusses the notifications that responsible entities can submit to DTSC in lieu of conducting an AA:

- Chemical Removal Intent and/or Confirmation Notification
- Product Removal Intent and/or Confirmation Notification
- Product-Chemical Replacement Intent and/or Confirmation Notification
- Alternatives Analysis Threshold Notification

2.2 AA Processes

This section describes the various AA options outlined in the regulations:

- Two-Stage AA: default two-stage AA process specified in the regulations, including a description of the required elements for both the preliminary AA and the final AA.
- Abridged AA: when the responsible entity determines that a functionally acceptable and technically feasible alternative is not available after completing the required steps.
- Alternate Process AA: when the responsible entity uses an alternate, but equivalent AA process.
- Previously Completed AA: for responsible entities with an existing completed AA that can be supplemented to meet the regulatory requirements.

The appendix to Chapter 2 presents an example of a format that lists all of the required contents of an AA report.

3. How to Implement the AA Steps

This chapter presents an iterative approach for applying various AA steps to fulfill the regulatory requirements. It also provides a brief discussion about how the AA outcomes correlate to different regulatory responses.

4. Identifying Product Requirements and Alternatives [§69505.5(a) and (b)]

This chapter focuses on describing the product under consideration and identifying its potential alternatives. It begins by describing the key ‘necessary’ questions:

- Is the Chemical of Concern necessary?
- Can the Chemical of Concern be removed?

- Is the Chemical of Concern a contaminant?

4.1 Identifying the product function, performance , and legal requirements

This section describes the importance of identifying the product requirements and the role of the Chemical of Concern (CoC) in the product, including the functional use of the CoC. It discusses and provides examples of a product's function, performance and applicable legal standards.

4.2 Identifying Alternatives

This section explains the regulatory definitions of an alternative and provides examples. It suggests probing questions that can help identify alternatives. The Appendix to this section lists some sources of information that may be helpful when identifying alternatives.

5. **Hazard Appraisal**

This chapter describes methods and approaches for collecting information about health, safety and environmental impacts for the analysis.

- Identifying hazard traits
- Description of data sources
- Description of models and tools

The appendix for this chapter lists sources of hazard trait data and links to models and tools.

6. **Initial Evaluation and Replacement Chemical Screening [§69505.5(d)]**

This chapter describes approaches a responsible entity may use, particularly during the first stage AA, to narrow the list of alternatives that will be thoroughly evaluated in the second stage, or final AA. It presents models and tools that can be used to compare the chemical of concern and its alternatives. This chapter addresses:

- Screening Approaches for Alternatives
- Tradeoffs: discusses the complexity of tradeoffs.

7. **Identifying Relevant Factors [§69505.5(c) and §69505.6(a)]**

This chapter explains the concept of relevant factors and the two conditions that make a factor relevant:

- The factor makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resources consumption; and
- There is a material difference in a factor's contribution to such impact(s) between the Priority Product and/or one or more alternatives.

This chapter includes a graphical representation of the interrelationship of life cycle segments, exposure pathways, and adverse impacts when identifying relevant factors. This chapter also addresses the following:

- **Data Needs:** describes an iterative process for collecting information to identify relevant factors and any associated exposure pathways and life cycle segments.
- **Relevant Factors for the First Stage AA:**
 - **Factors:** enumerates the seven categories specified in the regulations that must be evaluated to determine if they are relevant and offers suggestions that may help a responsible entity determine whether a factor is relevant or not. The appendix for this section contains an expanded list of all of the factors that may be considered when identifying relevance.
 - **Life Cycle Segments:** describes the life cycle segments of a product and provides a generalized life cycle flowchart. It also provides examples of methods to identify relevant life cycle segments. The appendix for this section relies on existing resources to present a life cycle thinking approach that may be helpful when identifying relevant factors.
 - **Exposure Pathways:** explains the exposure factors and data needs when identifying chemical quantity information and relevant exposure factors. It also gives an overview of approaches and resources that can be undertaken to estimate relevant potential exposure to sensitive subpopulations.
- **Relevant factors for the Second Stage AA:** describes the process to re-evaluate the factors and associated exposure pathways and life cycle segments identified to be relevant during the first stage AA. It also provides an overview of additional factors such as product function and performance, economic impacts that need to be considered during the second stage of AA.

The appendix in this chapter includes a set of non-exhaustive databases, tools and checklists that could be used to demonstrate which factors have been considered relevant, or not relevant, for comparison of alternatives. The appendix also presents an example of conceptual model approach to link the concepts of hazard, fate and transport, exposure, and life cycle thinking.

8. Exposure and Life Cycle Impact Assessment [§69505.6(a)(1)]

This chapter describes methods and approaches for collecting information about exposure estimates and life cycle impacts.

- **Exposure-related data sources and models:** to track a chemical's fate and transport through the environment, until it comes to a point of contact with exposed population, such as a sensitive subpopulation, and to describe anticipated exposure resulting from the priority product throughout its lifecycle
- **Life cycle impacts database and tools**

The appendix for this chapter lists sources of exposure-related data and links to models and tools; database and tools for life cycle impacts assessments.

9. Economic Analysis [§69505.6(a)(3)]

This chapter describes the economic analysis needed for the second phase of the AA. The economic analysis must address the impacts across the life cycle of the product or alternatives, and take into account the external costs associated with the impacts on public health and environment:

- **Public Health and Environmental Costs:** presents various approaches to determine public health and environmental costs, such as life cycle cost accounting (LCCA) and socio-economic analysis. It describes the quantification and valuation of impacts, as well as the concept of disability adjusted life year (DALY) and cost-benefits analysis (CBA). It presents a list of CBA and LCCA tools.
- **Costs to Governmental Agencies and Non-profit Organizations:** provides examples of average costs to governments for waste management costs and environmental cleanup and restoration costs.
- **Internal Costs:** describes the quantification and valuation of direct costs. It presents a list of tools & methods applicable to this type of analysis.

The appendices for this chapter include a summary of available cost/benefit analysis guidelines, and a list of reports about economic costs to public health and environment.

10. Information Needs and Transparency

This chapter presents a structured way to collect data and address data gaps. It also describes quality aspects of the information and the importance of transparency in the AA Reports.

10.1 Information Types in AA

- Data Types in AA
- Model Types in AA

10.2 Information Sources

This section describes a structured way to collect chemical-specific and process-specific information by using a hierarchy of sources based on information reliability and accessibility

10.3 Data Gaps and Approaches to Address Data Gaps

This section presents an overview on the best practices and approaches to address data gaps.

10.4 Uncertainty Analysis

This section describes ways to address uncertainties. It also presents a stepwise approach to carry out the AA process with sound decision-making in the presence of data gaps and uncertainties.

11. Comparison of the Product and Alternatives and the Alternative Selection Decision [§69505.6(b) and [§69505.7]

This chapter describes ways to compare the Priority Product containing the Chemical of Concern with the identified alternatives as part of the second stage AA. It describes the information that the responsible entity must present to evaluate and compare the product and alternatives and describes additional information that is not required, but may be used as part of the decision. This

chapter also summarizes different decision theories and approaches a responsible entity may find useful when making a selection decision:

- A stepwise, hierarchical decision approach that considers factors individually
- A weighted decision approach that considers factors simultaneously
- A combination of hierarchical decisions for some factors and simultaneous evaluation for others

The appendix to this chapter presents a sample format containing the required contents of the Final AA Report.

12. Review and Evaluation of AA Reports [§69505.9(a)]

This chapter presents a general evaluation approach for checking compliance with the substantive and administrative requirements of AA in the SCP regulations. It also presents a selection of indicators the responsible entity may use to assess the merit of the information and findings in the AA.

12.1 AA Evaluation Approach

This section presents a general evaluation approach for checking compliance with the substantive and administrative requirements of AA in the SCP regulations.

12.1.1 Completeness

The subsection, with appendix, contains an internal checklist and template that responsible entities can use to ensure all necessary documents are submitted and the AA Reports are consistent with the administrative elements required by the regulations.

12.1.2 Reliability, Validity, and Plausibility Considerations

This subsection presents a variety of indicators, including reliability, validity, and plausibility that the responsible entity can use to ensure the analysis is as rigorous as possible. It defines these indicators and provides examples to show how they may be used to assess the strength of both data and model results used in the AA. These considerations will help the responsible entity to demonstrate that the analysis meets the substantive requirements of the regulations and that the conclusions are well-founded.

13. List of Appendices

Appendix 2-1. Required Information on AA Reports

Appendix 4-1. Data Sources for Identification of Alternatives

Appendix 7-1. List of Factors Required for Determination of Relevance for AA Comparison

Appendix 7-1-1. Expanded List of Factors for Comparison of Alternatives

Appendix 7-2. How to Get Started – A Life Cycle Thinking Approach to Identify Relevant Factors.

Appendix 7-3. Tool Matrix for Identification of Relevant Life Cycle Segments

Appendix 7-4. Databases for Identification of Relevant Exposure Factors

Appendix 7-5. Checklists – Identification of Relevant Factors

Appendix 8-1 Resources for Exposure Assessment

Appendix 8-2 Resources for Life Cycle Assessment

Appendix 9-1. Summary of Existing Cost Benefits Analysis Guidelines

Appendix 9-2. Non-Exhaustive List of Reports on Economic Cost on Public Health and Environment