

Article 5. Alternatives Analysis

§ 69505. Guidance Materials.

(a) Guidance Materials. Before finalizing the initial Priority Products list, the Department shall make available on its website guidance materials to assist persons in performing AAs under this article. The Department shall periodically revise and update the guidance materials.

(b) Sample Alternatives Analyses. The Department shall also post on its website examples of AAs that are available in the public domain at no cost. The posting must indicate, for each AA, the name of the person that prepared the AA.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code. Page **46** of **105**

§ 69505.1. Alternatives Analysis: General Provisions.

(a) Applicability. This article does not apply to a product for which the notification requirements of section 69505.2 or section 69505.3 have been fully and timely met.

(b) AA Requirements.

(1) Except as otherwise provided in subsection (a) above and subsections (b), (c) and (d) of section 69505.4, a responsible entity for a Priority Product shall conduct an AA for the Priority Product and shall comply with all applicable requirements of this article.

(2) A responsible entity subject to the requirements of paragraph (1) shall prepare, sign, and submit to the Department AA Reports as follows:

(A) Except as provided in subsection (c), a responsible entity shall submit the Preliminary AA Report to the Department no later than 180 days after the date the product is listed on the final Priority Products list posted on the Department's website, unless the Department specifies a different due date in the Priority Products list.

(B) Except as provided in subsection (c), a responsible entity shall submit the Final AA Report no later than twelve (12) months after the date the Department issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests and the Department approves an extended due date.

(C) For a product that is first placed into the stream of commerce in California after the date the product is listed on the Priority Products list, the due date for the Preliminary AA Report shall be 180 days after the product is first placed into the stream of commerce in California, unless the Department specifies a different due date in the Priority Products list.

(3) The requirements of this article applicable to a responsible entity may be fulfilled entirely or in part by the responsible entity, and/or entirely or in part by a person acting on behalf of or in the stead of the responsible entity. This paragraph does not apply to sections 69505.2 and 69505.3.

(c) AA Report Due Date Extension.

(1) A responsible entity may request, and the Department may grant, a one-time extension of up to ninety (90) days to the submission deadline for the AA Report or Alternate Process AA Work Plan if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. The extension request must be received at least sixty (60) days before the applicable due date.

(2) The extension request must include:

(A) The name of, and contact information for, the person filing the extension request;

(B) The name of, and contact information for, the responsible entity(ies) on whose behalf the AA Reports will be submitted; Page **47** of **105**

(C) If different from subparagraphs (A) and (B), the name of, and contact information for, the manufacturer(s) and importer(s) of the product;

(D) Information identifying and describing the responsible entity's Priority Product, and the brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California, and, if the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;

(E) The due date for the AA Report;

(F) The amount of additional time requested; and

(G) The reason the extension is needed, including an explanation as to why the circumstances necessitating the extension could not reasonably be anticipated or controlled by the responsible entity.

(3) The Department shall approve or deny the extension request in whole or in part and provide notice to the person submitting the extension request of the decision within thirty (30) days of receipt of the extension request. Failure by the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request.

(d) Consideration of Information. A responsible entity conducting an AA shall consider all relevant information made available on the Department's website, and any additional information or technical assistance the Department may provide regarding Alternatives Analysis. The responsible entity shall summarize these efforts in the Final AA Report or Abridged AA Report, whichever is applicable.

(e) Compliance Status. Notwithstanding any other provision of this chapter, failure of the Department to make a compliance determination for an AA Report or Alternate Process AA Work Plan within the applicable time frame specified in section 69505.9, or failure of the Director or the Department to respond to an appeal or Request for Review submitted under article 7 within sixty (60) days, shall not cause an AA Report or Alternate Process AA Work Plan to be deemed compliant with this article.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code. Page **48** of **105**

§ 69505.2. Removal/Replacement Notifications in Lieu of Alternatives Analysis.

(a) Applicability.

(1)

(A) The requirements of this article do not apply to a responsible entity's Priority Product if the manufacturer of the Priority Product submits one of the following notifications to the Department no later than the due date for submitting the Preliminary AA Report:

1. A Chemical Removal Intent and/or Confirmation Notification that complies with subsections (b) and (c);
2. A Product Removal Intent and/or Confirmation Notification that complies with subsections (b) and (d); or
3. A Product-Chemical Replacement Intent and/or Confirmation Notification that complies with subsections (b) and (e).

(B) If only a Chemical Removal, Product Removal, or Product-Chemical Replacement Intent Notification is submitted to the Department by the date specified in subparagraph (A), within ninety (90) days of the submission date, or by the due date for the Preliminary AA Report, whichever is later, the manufacturer shall submit one of the following to the Department:

1. A removal or replacement Confirmation Notification; or
2. A Preliminary AA Report, Abridged AA Report, or Alternate Process AA Work Plan.

(2)

(A) If a Preliminary AA Report or Alternate Process AA Work Plan has already been submitted to the Department, the requirements of this article pertaining to performance of a second stage AA and submission of a Final AA Report do not apply if one of the notifications specified in paragraph (1)(A) is submitted to the Department prior to the due date for submitting the Final AA Report.

(B) If only a Chemical Removal, Product Removal, or Product-Chemical Replacement Intent Notification is submitted to the Department by the date specified in subparagraph (A), the manufacturer shall submit a removal or replacement Confirmation Notification or a Final AA Report by the later of the following dates:

1. Ninety (90) days after the Intent Notification is submitted; or
2. The due date for the Final AA Report.

(3) A manufacturer is not in compliance with section 69505.1(b), if the manufacturer submits a notification under this section, in lieu of submitting the otherwise required AA Report(s), and that notification is not submitted by the applicable due date or does not fully meet the applicable content requirements specified in subsections (b) through (e).

(b) Content Requirements for Intent and Confirmation Notifications. Chemical Removal, Product Removal, and Product-Chemical Replacement Intent and Confirmation Notifications must include: Page **49** of **105**

- (1) The name of, and contact information for, the person submitting the notification.
- (2) The name of, and contact information for, any known responsible entity(ies).
- (3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and importer(s) of the product.
- (4) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer directly sold the Priority Product within the prior twelve (12) months.
- (5) Identification and location of the manufacturer's retail sales outlets where the manufacturer sold, supplied, or offered for sale the Priority Product in California, if applicable.
- (6) Information identifying and describing the Priority Product and the reformulated product, if applicable, and the brand name(s) and labeling information under which the Priority Product and the reformulated product, if applicable, are/were placed into the stream of commerce in California, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used.
- (7) The intended uses, and targeted customer base(s), for the Priority Product and the reformulated product, if applicable.
- (8) The measures the manufacturer will take, or has taken, to:
  - (A) If applicable, provide information regarding the reformulated product to persons selling or distributing the Priority Product in California; and
  - (B) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.
- (9) For Chemical Removal Notifications and/or Product-Chemical Replacement Notifications, the Chemical(s) of Concern that will be or have been removed from the product and, as applicable, the following information:
  - (A) Information explaining the rationale and the factors considered in deciding to reformulate the product;
  - (B) Laboratory analytical testing methodology and quality control and assurance protocols used or that will be used to confirm that the Chemical(s) of Concern has/have been removed, and identification of the testing laboratory;
  - (C) Information demonstrating that the Chemical(s) of Concern has/have been removed from the product that was a Priority Product;
  - (D) The name of the replacement chemical(s), the concentration of each replacement chemical in the reformulated product, and the hazard traits and/or environmental or toxicological endpoints known to be associated with the replacement chemical(s);
  - (E) Laboratory analytical testing methodology and quality control and assurance protocols used or that will be used to measure the

concentration of the replacement chemical(s) in the product, and identification of the testing laboratory; and

(F) Information demonstrating that the replacement chemical(s) meet one of the following criteria:

1. The replacement chemical(s) is/are not on the Candidate Chemicals list; or
2. The replacement chemical(s) is/are Candidate Chemical(s) that is/are already in use to manufacture the same product, in lieu of the Chemical(s) of Concern, by the same or a different manufacturer. For purposes of this subsection, "same product" means a product that has the same or similar product description as the Priority Product; has the same intended use(s) and targeted customer base(s) as the Priority Product; and fulfills the functional, performance, and legal requirements of the Priority Product.

(10) The certification statement specified in subsection (c), (d) or (e), as applicable.

(c) Chemical Removal Notification Certification Statements. Chemical Removal Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:

(1) Chemical Removal Intent Notifications must include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the notification is submitted to the Department:

(A) Remove the Chemical(s) of Concern from the Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product;

(B) Provide information regarding the reformulated product to persons selling or distributing the Priority Product in California;

(C) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and

(D) Submit a Chemical Removal Confirmation Notification to the Department for the Priority Product.

(2) Chemical Removal Confirmation Notifications must include a statement certifying that:

(A) The Chemical(s) of Concern has/have been removed from the product that was a Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product;

(B) Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California; and

(C) The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California. Page **51** of **105**

(d) Product Removal Notification Certification Statements. Product Removal Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:

(1) Product Removal Intent Notifications must include a statement certifying that the manufacturer intends to do both of the following within ninety (90) days of the date the notification is submitted to the Department:

(A) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and

(B) Submit a Product Removal Confirmation Notification to the Department for the product.

(2) Product Removal Confirmation Notifications must include a statement certifying that the manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.

(e) Product-Chemical Replacement Notification Certification Statements. Product-Chemical Replacement Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:

(1) Product-Chemical Replacement Intent Notifications must include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the notification is submitted to the Department:

(A) Remove the Chemical(s) of Concern from the Priority Product;

(B) Provide information regarding the reformulated product to persons selling or distributing the Priority Product in California;

(C) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and

(D) Submit a Product-Chemical Replacement Confirmation Notification to the Department for the Priority Product.

(2) Product-Chemical Replacement Confirmation Notifications must include a statement certifying that:

(A) The Chemical(s) of Concern has/have been removed from the product that was a Priority Product;

(B) The replacement chemical(s) meet the criteria specified in subparagraph 1. or subparagraph 2. of subsection (b)(9)(F);

(C) Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California; and

(D) The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code. Page **52** of **105**

§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis.

(a) Notification Requirements. This article does not apply to a responsible entity's Priority Product for which the manufacturer submits an Alternatives Analysis Threshold Notification to the Department concurrently with the Priority Product Notification, or by the due date for the Preliminary AA Report for the Priority Product. Each notification must include:

- (1) The name of, and contact information for, the person submitting the notification;
- (2) The name of, and contact information for, any known responsible entity(ies);
- (3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and importer(s) of the Priority Product;
- (4)

(A) A statement certifying that the Chemical(s) of Concern is/are present in the manufacturer's Priority Product only as contaminants and the concentration of each Chemical of Concern does not exceed the PQL for that chemical; or

(B) A statement certifying that the Chemical(s) of Concern does/do not exceed the Alternatives Analysis Threshold(s) specified by the Department under section 69503.5(c) for the Chemical(s) of Concern.

(5) If applicable, identification of the PQL for each Chemical of Concern in the Priority Product, and the information and method used to determine the PQL;

(6) The source of the Chemical(s) of Concern in the Priority Product;

(7) Information identifying and describing the Priority Product, the brand name(s) and labeling information under which the Priority Product is placed into the stream of commerce in California, and, if the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;

(8) Laboratory analytical testing methodology and quality control and assurance protocols used to measure each Chemical of Concern in the Priority Product, and identification of the testing laboratory; and

(9) A demonstration and certification that the manufacturer meets and will continue to meet the criteria and conditions that are the basis for the exemption in this section.

(b) Burden of Proof. The manufacturer bears the burden of proof to demonstrate that the concentration of the Chemical(s) of Concern in its Priority Product does not exceed the applicable Alternatives Analysis Threshold.

(c) Notification Revisions. If any of the information listed in subsection (a) changes significantly, the manufacturer shall submit to the Department a revised Alternatives Analysis Threshold Notification within thirty (30) days of the change.

(d) Change in Product's Exemption Status. If the Priority Product no longer meets the criteria for an Alternatives Analysis Threshold exemption, the manufacturer Page **53** of **105**



shall notify the Department of this change within thirty (30) days of the change, and shall submit to the Department a Preliminary AA Report or an applicable Intent and/or Confirmation Notification under section 69505.2 within 180 days of the change.

(e) Determination of Exemption Eligibility. The exemption in subsection (a) does not apply if the Department notifies the person who submitted the Alternatives Analysis Threshold Notification that the information contained in the notification is inaccurate or inadequate to support an Alternatives Analysis Threshold exemption.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code. Page **54** of **105**

§ 69505.4. Alternatives Analysis Process and Options.

(a) AA Stages.

(1) An AA must be conducted in two stages.

(2) The responsible entity shall initially complete the first stage of the AA in accordance with section 69505.5, and submit a Preliminary AA Report that complies with sections 69505.1(b)(2)(A) and 69505.7.

(3) The responsible entity shall next complete the second stage of the AA in accordance with section 69505.6, and submit a Final AA Report that complies with sections 69505.1(b)(2)(B) and 69505.7.

(b) Abridged AA Reports. After completing the first five (5) steps of the first stage of the AA under subsections (a) through (e) of section 69505.5, a responsible entity that determines a functionally acceptable and technically feasible alternative is not available may prepare and submit an Abridged AA Report, in lieu of the Preliminary and Final AA Reports, if:

(1) The responsible entity summarizes in the Abridged AA Report the first stage AA findings in compliance with the applicable requirements of section 69505.7;

(2) The responsible entity summarizes in the Abridged AA Report its findings with respect to section 69505.6(a) in compliance with the applicable requirements of section 69505.7;

(3) The responsible entity submits an Abridged AA Report to the Department by the due date specified in section 69505.1(b)(2)(A); and

(4) The responsible entity includes an implementation plan in the Abridged AA Report that specifies the milestones and dates for implementation of proposed regulatory responses, which shall, at a minimum, include the regulatory responses required under sections 69506.3 and 69506.8.

(c) Alternate Process AA.

(1) A responsible entity may use an AA process that differs from the process specified in sections 69505.5 and 69505.6, if:

(A) The responsible entity's alternate process provides the information needed to prepare a Final AA Report that substantially complies with section 69505.7.

(B) The responsible entity's alternate process 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 specified in sections 69505.5 and 69505.6.

(C) The responsible entity submits an Alternate Process AA Work Plan to the Department with sufficient information to demonstrate that the alternate process complies with subparagraphs (A) and (B), and sufficient information for the Department to specify an appropriate due date for submittal of the Final AA Report.

1. The Alternate Process AA Work Plan shall include the information specified in subsections (c), (d), and (e) of section 69505.7. Page **55** of **105**

2. If the Alternate Process AA Work Plan includes information for which trade secret protection is claimed, the responsible entity shall also submit a redacted copy of the work plan that excludes that information.

3. The Alternate Process AA Work Plan shall be accompanied by an executive summary organized in conformance with the organization of the work plan that is sufficient to convey to the public a general understanding of the work plan, and that excludes any information for which trade secret protection is claimed. If the Department subsequently rejects a trade secret claim, the responsible entity shall, at the Department's request, submit a revised executive summary within thirty (30) days of the request to add any information for which a trade secret claim is rejected and which the Department specifies must be included in the executive summary.

(D) The Alternate Process AA Work Plan is submitted to the Department no later than the due date for the Priority Product Notification for the product.

(E)

1. The responsible entity timely submits a Final AA Report to the Department that substantially complies with section 69505.7.

2. The due date for the Final AA Report is eighteen (18) months after the date the Department issues a notice of compliance for the Alternate Process AA Work Plan, unless the responsible entity requests and receives Department approval of an extended due date using the procedures specified for Preliminary AA Reports in section 69505.7(k)(1)(B), or the Department otherwise approves an extended due date under section 69505.9(b)(4). If the Department approves an extended due date, the responsible entity shall provide a yearly progress report until the Final AA Report is submitted. Each progress report must provide all of the information specified in subparagraphs 1. through 6. of section 69505.7(k)(1)(A).

(2) If the Alternate Process AA Work Plan is disapproved by the Department under section 69505.9(b)(3), the responsible entity shall submit a Preliminary AA Report to the Department within 180 days after the Department issues the notice of disapproval.

(d) Previously Completed AAs. A responsible entity may comply with section 69505.1(b) by submitting to the Department a report for a previously completed AA for the Priority Product, if the Department determines that the report is substantially equivalent to the Final AA Report requirements of section 69505.7 and contains sufficient information for the Department to determine any necessary regulatory response(s) under article 6. The previously completed AA Page **56** of **105**

may be either an AA conducted or obtained by the responsible entity or a publicly available AA.

(1) A responsible entity submitting a report under this subsection shall submit the report no later than the deadline for submitting a Preliminary AA Report, except that a one-time extension may be requested under section 69505.1(c).

(2) A responsible entity submitting an existing report under this subsection may supplement the report with additional information to render the report substantially equivalent to the Final AA Report requirements of section 69505.7.

(e) Revised Alternative Selection Decision.

(1) If after submitting the Final AA Report, the responsible entity selects one or more alternatives that differ from the alternative(s) identified as the selected alternative(s) in the Final AA Report, the responsible entity shall submit a revised Final AA Report to the Department at least sixty (60) days prior to placing the newly selected alternative product(s) into the stream of commerce in California. The revised Final AA Report must explain the differences from the original Final AA Report, identify the information used to support the revisions to the Final AA Report, and describe the rationale for selecting the different alternative(s). The Department shall review and make a compliance determination with respect to the revised Final AA Report in accordance with the procedures and criteria set forth in section 69505.9.

(2) Paragraph (1) also applies if:

(A) The selection decision in the original Final AA Report was to retain the Priority Product, and the responsible entity later decides to select an alternative to replace the Priority Product; or

(B) The responsible entity later decides to retain the Priority Product in lieu of a previously selected alternative product.

(3) The requirements of this subsection only apply for three (3) years after the date the original Final AA Report is approved by the Department.

(f) Reformulation. Except as provided in section 69505.2, if prior to submitting the Final AA Report for a Priority Product the responsible entity removes, or reduces the concentration of, the Chemical(s) of Concern and uses one or more replacement Candidate Chemicals, the Alternatives Analysis evaluation and comparison shall include consideration of both the Priority Product and the reformulated product.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code. Page **57** of **105**

§ 69505.5. Alternatives Analysis: First Stage.

The first stage of the AA shall include the six (6) steps described below:

(a) Step 1, Identification of Product Requirements and Function(s) of Chemical(s) of Concern.

(1) The responsible entity shall identify the functional, performance, and legal requirements of the Priority Product that must also be met by the alternatives under consideration.

(2) The responsible entity shall identify the role(s), if any, of the Chemical(s) of Concern in meeting the Priority Product's requirements identified under paragraph (1).

(3)

(A) The responsible entity shall determine if the Chemical(s) of Concern or alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements identified under paragraph (1).

(B) If the responsible entity determines that neither the Chemical(s) of Concern nor alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements identified under paragraph (1), the responsible entity shall evaluate removal of the Chemical(s) of Concern from the Priority Product without the use of any replacement chemical(s) as one of the alternatives to the Priority Product. Alternatively, the responsible entity may submit Chemical Removal Intent and/or Confirmation Notifications to the Department in lieu of completing the Alternatives Analysis and submitting the required AA Reports.

(b) Step 2, Identification of Alternatives.

(1)

(A) In addition to any alternative identified under subsection (a)(3)(B), the responsible entity shall identify and consider alternatives that meet the definition of "alternative" under section 69501.1 and meet the Priority Product's requirements identified under subsection (a)(1).

(B) The responsible entity shall research and evaluate available information that identifies existing possibly viable alternatives for consideration in the AA. This research and evaluation shall include, but is not limited to, information posted on the Department's website. The responsible entity shall consider any identified alternative in the AA, or explain in the AA Report why such an alternative is not viable for consideration.

(2) Alternatives that do not involve the use of one or more replacement chemicals, or otherwise adding chemicals to the product, do not require compliance with subsection (d).

(c) Step 3, Identification of Factors Relevant for Comparison of Alternatives. Page **58** of **105**

(1) A factor listed in paragraph (2), in conjunction with an associated exposure pathway and life cycle segment, if applicable, is relevant if:

(A) 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 resource consumption impacts associated with the Priority Product and/or one or more alternatives under consideration; and

(B) There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives.

(2) The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors listed below and the associated exposure pathways and life cycle segments, if applicable, that are relevant for the comparison of the Priority Product and the alternatives under consideration:

(A) Adverse environmental impacts;

(B) Adverse public health impacts;

(C) Adverse waste and end-of-life effects;

(D) Environmental fate;

(E) Materials and resource consumption impacts;

(F) Physical chemical hazards; and

(G) Physicochemical properties.

(3) The responsible entity's identification of relevant exposure pathways shall consider both of the following:

(A) Chemical quantity information:

1. Quantities of the Chemical(s) of Concern or alternative replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and

2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration.

(B) Exposure factors specified in section 69503.3(b).

(d) Step 4, Initial Evaluation and Screening of Alternative Replacement Chemicals.

(1) For those alternatives under consideration that involve removing or reducing the concentration of the Chemical(s) of Concern and using one or more alternative replacement chemicals, or otherwise adding chemicals to the product, the responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product with respect to each of the following factors to the extent relevant: Page **59** of **105**

- (A) Adverse environmental impacts;
- (B) Adverse public health impacts;
- (C) Environmental fate;
- (D) Physical chemical hazards; and
- (E) Physicochemical properties.

(2) The responsible entity may eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines has/have the potential to pose adverse impacts equal to or greater than those posed by the Chemical(s) of Concern.

(e) Step 5, Consideration of Additional Information.

In the first stage of the AA, the responsible entity may consider pertinent factors and information not specifically identified in this section. This may include, but is not limited to, consideration of the factors and information specified in section 69505.6. A responsible entity may eliminate an alternative from further consideration based on the additional factors and information as long as the reason for its elimination is explained in the Preliminary AA Report and there are alternatives remaining to be evaluated in the second AA stage.

(f) Step 6, Preliminary AA Report Preparation.

(1) The responsible entity shall prepare, for inclusion in the Preliminary AA Report, a work plan and proposed implementation schedule for completion of the second AA stage and preparation and submittal of the Final AA Report.

(2) The responsible entity shall prepare and submit to the Department a Preliminary AA Report as specified in section 69505.7.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code. Page **60** of **105**

§ 69505.6. Alternatives Analysis: Second Stage.

After receiving approval of the Preliminary AA Report from the Department, the responsible entity shall compare the Priority Product with the alternatives still under consideration. The second stage of the AA shall include the five (5) steps described below:

(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.

(1) Adverse Impacts and Multimedia Life Cycle Impacts. The responsible entity may use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to re-evaluate the identification of factors and the associated exposure pathways and life cycle segments, if applicable, determined to be relevant under section 69505.5(c) for the comparison of the Priority Product and the alternatives still under consideration after completion of the first AA stage. In addition to the factors determined to be relevant under this paragraph and/or section 69505.5(c), the factors specified in paragraphs (2) and (3) are relevant for all comparisons of the Priority Product and the alternatives.

(2) Product function and performance. The responsible entity shall identify the principal manufacturer-intended use(s) or application(s), the functional and performance attributes, and the applicable legal requirements for the Priority Product. The responsible entity shall, at a minimum, evaluate:

(A) The useful life of the Priority Product, and that of the alternatives under consideration;

(B) The function and performance of each alternative relative to the Priority Product and other alternatives under consideration; and

(C) Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.

(3) Economic impacts.

(A) The responsible entity shall evaluate, monetize, and compare for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives:

1. Public health and environmental costs; and

2. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.

(B) If the responsible entity's alternative selection decision is to retain the Priority Product based in whole or in part on internal cost impacts, this decision must be explained in the Final AA Report. The Final AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs.

(b) Step 2, Comparison of the Priority Product and Alternatives. Page **61** of **105**



The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare the Priority Product and each of the alternatives under consideration with respect to each relevant factor and associated exposure pathways and life cycle segments, if applicable, identified under subsection (a) above and section 69505.5(c). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives under consideration.

(c) Step 3, Consideration of Additional Information.

As part of the second stage of the AA, the responsible entity may also consider other pertinent information not specifically identified in this section. This may include, but is not limited to, reconsideration of the factors and information identified in section 69505.5.

(d) Step 4, Alternative Selection Decision.

The responsible entity shall select the alternative(s) that will replace the Priority Product, unless the decision is to retain the existing Priority Product. The selection of an alternative or the decision to retain the Priority Product shall be based on and supported by the comparative analysis conducted under subsections (b) and (c).

(e) Step 5, Final AA Report Preparation.

The responsible entity shall prepare and submit to the Department a Final AA Report as specified under section 69505.7.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code. Page **62** of **105**

§ 69505.7. Alternatives Analysis Reports.

(a) General Requirements.

(1) Preliminary and Final AA Reports and Abridged AA Reports must each include all of the applicable information specified in subsections (b) through (k).

(2) The responsible entity shall include in the AA Reports sufficient information for the Department to determine:

(A) Compliance with the substantive and administrative requirements of this article; and

(B) The appropriate due date for submission of the Final AA Report, and the appropriate due date for any regulatory response(s) required under article 6.

(3) The responsible entity shall identify and explain in the Final AA Report all differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report. The responsible entity must identify in the Final AA Report the information sources used to support changes from the Preliminary AA Report to the Final AA Report.

(4) The responsible entity shall maximize the scope of information in the AA Report that can be made available to the public, while maintaining protection of legitimate trade secrets.

(A) If the AA Report contains information claimed by the responsible entity to be a trade secret, a separate publicly available AA Report shall be submitted to the Department that excludes claimed trade secret information only to the extent necessary to protect its confidential nature.

(B) If the Department subsequently rejects a trade secret claim and/or the nature and/or extent of redaction, the responsible entity shall, at the Department's request, submit a revised publicly available AA Report and executive summary within thirty (30) days of the request to add any information for which a trade secret claim or redaction is rejected.

(b) Executive Summary. AA Reports must include a publicly available executive summary sufficient to convey a general understanding of the scope and results of the AA and the rationale for the AA selection decision. The executive summary must be organized in conformance with the organization of the AA Report and must include for each section of the AA Report a detailed summary of the information presented. Information for which trade secret protection is claimed must not be included in the executive summary.

(c) Preparer Information. This section of the AA Report must include:

(1) The name of, and contact information for, the person submitting the AA Report;

(2) If applicable, the name of, and contact information for, all responsible entities on whose behalf the AA Report is being submitted; and

(3) The names of the parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA. Page **63** of **105**

(d) Responsible Entity and Supply Chain Information. This section of the AA Report must include:

- (1) The name of, contact information for, and headquarters location of the manufacturer(s) and importer(s), if applicable, and, if the AA Report is prepared on behalf of a consortium of manufacturers or other persons in the Priority Product's supply chain, a list of the participants along with their contact information;
- (2) The name of, and contact information for, any person(s) identified on the Priority Product label as the manufacturer, importer, or distributor;
- (3) The name of, and contact information for, all persons in California other than the final purchaser or lessee to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months; and
- (4) Identification and location of the manufacturer's and/or importer's retail sales outlets where the manufacturer and/or importer sold, supplied, or offered for sale the Priority Product in California, if applicable.

(e) Priority Product Information. This section of the AA Report must include:

- (1) The brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California;
- (2) If the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
- (3) Identification of the Chemical(s) of Concern for the Priority Product;
- (4) Any Material Safety Data Sheets and/or Safety Data Sheets related to the Priority Product; and
- (5) The information specified in paragraphs (1) and (2) of section 69505.5(a).

(f) Scope of Relevant Comparison Factors. Each AA Report must identify which factors and, when applicable, associated exposure pathways and life cycle segments were determined to be relevant, under sections 69505.5(c) and 69505.6(a), for evaluation and comparison of the Priority Product and its alternatives. For each factor, and exposure pathway and life cycle segment, if applicable, determined not to be relevant, the AA Report must explain the rationale and identify, and explain the pertinent findings of, the supporting information for this determination.

(g) Scope and Comparison of Alternatives. The AA Reports must identify and describe the alternatives chosen to be evaluated and compared, and explain the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison process. For any alternative that is screened out because it is determined that its adverse impacts are equal to or greater than those of the Priority Product, the responsible entity shall describe in the AA Report the method used to determine equal or greater adverse impacts, including the method used to compare the multiple factors associated with the impacts, and the rationale for any trade-offs made among the factors.

(1) Each Preliminary AA Report and Abridged AA Report must include the information collected and the comparison conducted under section 69505.5 for the Chemical(s) of Concern and the alternative replacement chemical(s). This must include a matrix, or other summary format, that provides a clear visual comparison that summarizes the information

collected regarding the relevant adverse impacts, and their associated relevant exposure pathways and life cycle segments, for the Chemical(s) of Concern and each alternative replacement chemical being considered, and the comparative results of evaluating this information.

(2) The Final AA Report must include the information collected and the comparison conducted under sections 69505.5 and 69505.6 for the Priority Product and its alternatives, including:

(A) A matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant comparison factors, and their associated relevant exposure pathways and life cycle segments, for the Priority Product and each alternative considered, and the comparative results of evaluating this information; and

(B) Identification and description of how any relevant safeguards provided by other federal and California State regulatory programs were considered in the AA.

(3) The responsible entity shall demonstrate in the Final AA Report that all of the requirements of section 69505.6 have been met.

(h) Methodology. The AA Report shall identify and describe the analytical tools, models, and software used to conduct the AA, and discuss any of their limitations. The AA Report shall also identify any published methodologies and/or guidelines used, and any deviations from those methodologies and/or guidelines.

(i) Supporting Information.

(1) All information used as supporting information in performance of the AA and preparation of the AA Reports must be cited in the AA Reports and made available to the Department upon request. The AA Reports must include a brief summary of the information reviewed and considered under section 69505.1(d).

(2) The Final AA Report must identify information that is not currently available but, if it were available, could be used to:

(A) Validate information used for purposes of sections 69505.5 and 69505.6; and/or

(B) Address any uncertainties in the analyses conducted under sections 69505.5 and 69505.6.

(j) Selected Alternative(s).

(1) The Preliminary AA Report must identify and describe the alternatives selected for further evaluation in the second stage of the AA, and explain the rationale for the selection decision.

(2) The Final AA Report must identify and describe the alternative(s), if any, selected to replace the Priority Product. The description of the selection decision must include an analysis that evaluates and compares the selected alternative(s) against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product. The Final AA Report must also include: Page **65** of **105**

(A) The product function and performance information specified in section 69505.6(a)(2) for the selected alternative(s). If no alternative is selected, this information must be provided in the Final AA Report or Abridged AA Report, as applicable, for each alternative considered.

(B) An explanation of the rationale for retaining the Chemical(s) of Concern or using the alternative replacement chemical(s), if section 69505.5(a)(3)(B) applies, and one or more selected alternatives retains the Chemical(s) of Concern or uses one or more replacement chemicals.

(C) A list of all chemicals known, based on available information, to be in the selected alternative(s) that are Chemicals of Concern, that differ from the chemicals in the Priority Product, or that are present in the selected alternative(s) at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern. The following information, to the extent available, must be provided for those chemicals:

1. Environmental fate;
2. Hazard trait and environmental and toxicological endpoint information that has not already been provided to the Department under this chapter;
3. Information about the chemical purity, meaning the relative absence of extraneous matter, and identification of known impurities and additives in the chemical;
4. Physicochemical properties; and
5. Substance identification information, including all of the following that are applicable:
  - a. Chemical abstract services number;
  - b. Structural formula;
  - c. Molecular weight;
  - d. Synonyms;
  - e. International Union of Pure and Applied Chemistry name;
  - f. European Commission number;
  - g. Registry of Toxic Effects of Chemical Substances number;
  - h. International Union of Biochemistry and Molecular Biology number;
  - i. Japan Ministry of International Trade and Industry number;
  - j. Number assigned by the United Nations Experts on the Transport of Dangerous Goods;
  - k. North America Department of Transportation number;
  - l. European Inventory of Existing Commercial Chemical Substances number;

- m. European List of Notified Chemical Substances number;
- n. European Commission Directive 67/548/EEC No Longer Polymers number; and
- o. Other commonly recognized substance identification system numbers.

(k) Next Steps.

(1) Work plan. The Preliminary AA Report must include the work plan and proposed implementation schedule for completion of the second AA stage required to be prepared under section 69505.5(f)(1).

(A) The work plan and implementation schedule must specify the proposed submission date for the Final AA Report and must ensure that the Final AA Report or progress report, if applicable, will be submitted to the Department no later than twelve (12) months after the Department issues a notice of compliance for the Preliminary AA Report. If the Department approves an extended due date under section 69505.9(b)(4), the responsible entity shall provide a yearly progress report until the Final AA Report is submitted. The first yearly progress report shall be submitted no later than twelve (12) months after the Department issues a notice of compliance for the Preliminary AA Report. Each progress report must include:

1. Preparer information specified in subsection (c);
2. Priority Product information specified in subsection (e);
3. A summary of achievements since the last progress report;
4. A summary and discussion of issues that have arisen and their resolutions;
5. A summary of work that is pending; and
6. An assessment of whether the milestones in the schedule set forth in the Preliminary AA Report or Alternate Process AA Work Plan are anticipated to be completed on time and any contingency plans to ensure timely completion.

(B) The responsible entity may request an extended due date for submittal of the Final AA Report. Any requested extension shall not exceed twenty-four (24) months from the date the Department issues a notice of compliance for the Preliminary AA Report, unless additional time is needed to conduct regulatory safety and/or performance testing on multiple alternatives prior to making an AA selection decision, in which case the requested extension shall not exceed thirty-six (36) months. The extended due date request must include a detailed explanation of why additional time is needed.

(2) Implementation of selected alternatives. The Final AA Report must include a detailed plan for implementing any selected alternative(s).

(A) The implementation plan must include key milestones and dates for implementing the selected alternative(s), if applicable, and identify Page **67** of **105**

steps that will be taken to ensure compliance with applicable federal, state, and/or local laws.

(B) The implementation plan may also include the identification of and implementation plan(s) for any regulatory response(s) that the responsible entity wishes to propose that would best limit exposure to, or reduce the level of adverse impacts or adverse waste and end-of-life effects posed by, any Chemical(s) of Concern or replacement Candidate Chemical(s) that will be in the selected alternative(s) or the Chemical(s) of Concern that is/are in the Priority Product if the decision resulting from the AA is to retain the Priority Product.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code. Page **68** of **105**

§ 69505.8. Public Comments on AA Reports.

(a) Public Notice of Opportunity for Comment. Upon receipt of a Final AA Report or an Abridged AA Report, the Department shall post on its website, and send to persons on the electronic mailing list(s) that the Department establishes related to this chapter, a notice regarding the availability for public review and comment of the Final AA Report or Abridged AA Report. The notice shall include the last day for the public to submit written comments to the Department, the method(s) for submitting comments, and a link to the location on the Department's website where a copy of the Final AA Report or Abridged AA Report may be viewed. The last day for submission of public comments shall be no sooner than forty-five (45) days from the date the notice of availability of the Final AA Report or Abridged AA Report is posted on the Department's website or the date the notice is sent to persons on the electronic mailing list(s), whichever is the later date.

(b) Department Review of Public Comments. No later than thirty (30) days after the close of the public comment period established under subsection (a), the Department shall review the public comments received and notify the person that submitted the Final AA Report or Abridged AA Report of those issues that the Department determines must be addressed in an AA Report Addendum. The notice shall include the due date by which the person must submit an AA Report Addendum to the Department under subsection (c). In determining the due date for the AA Report Addendum, the Department shall take into consideration the scope and complexity of the issues the Department is requiring the person to address.

(c) AA Report Addendum. A person that receives a notice under subsection (b) shall prepare, and submit to the Department by the due date specified under subsection (b), an AA Report Addendum that addresses the issues identified by the Department as requiring further attention. The AA Report Addendum shall also include any revisions to the Final AA Report or Abridged AA Report determined necessary based on consideration of the issues identified by the Department.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code. Page **69** of **105**



§ 69505.9. Department Review and Determinations for AA Reports and Work Plans.

(a) Review Criteria. In reviewing AA Reports and Alternate Process AA Work Plans for compliance with the substantive and administrative requirements of this article, the Department shall consider:

- (1) Whether the AA Report or Alternate Process AA Work Plan was submitted timely;
- (2) Whether, and to what extent, the responsible entity considered and addressed all applicable provisions of this article pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable;
- (3) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable.

(b) Preliminary AA Reports and Alternate Process AA Work Plans.

(1) Within sixty (60) days of receiving a Preliminary AA Report or Alternate Process AA Work Plan, the Department shall review the report or work plan for compliance with this article, and issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review.

(2) Notice of Deficiency.

(A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information, which may not exceed sixty (60) days from the date the notice of deficiency is issued. The responsible entity shall submit a revised report or revised work plan, whichever is applicable, by the due date specified, and address the areas of deficiency.

(B) Within thirty (30) days of receipt of the additional information requested in the notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a notice of ongoing review for the revised report or revised work plan.

(3) Notice of Disapproval. If the revised report or revised work plan does not fully address the identified areas of deficiency, the Department shall issue a notice of disapproval. The Department shall also issue a notice of disapproval if a revised report or revised work plan is not submitted by the due date specified under paragraph (2)(A). If the revised report or revised work plan is disapproved, the Department shall explain the basis for the disapproval. A disapproved revised report or revised work plan is not in compliance with section 69505.1(b).

(4) Notice of Compliance. The Department shall specify in a notice of compliance for a Preliminary AA Report or Alternate Process AA Work Plan the due date for submitting the Final AA Report. The Department shall specify a due date twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify an extended due date for submission of the Final AA Report if it determines based on information in the Preliminary AA Report or Alternate Page **70 of 105**

Process AA Work Plan that more time is needed. The Department may also specify an extended due date for submission of the Final AA Report if the responsible entity submits a request under section 69505.7(k)(1)(B).

(c) Final AA Reports and Abridged AA Reports.

(1) Within sixty (60) days of receiving an AA Report Addendum, the Department shall review the Final AA Report or Abridged AA Report, including the AA Report Addendum, for compliance with this article, and shall issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review. If no AA Report Addendum is required under section 69505.8, the Department shall complete its review of the Final AA Report or Abridged AA Report within sixty (60) days of whichever of the following dates is applicable:

(A) The close of the public comment period, if no public comments are received; or

(B) Thirty (30) days after the close of the public comment period, if the Department determines after reviewing the public comments that there are no issues that need to be addressed in an AA Report Addendum.

(2) Notice of Deficiency.

(A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information to complete the Final AA Report or Abridged AA Report, which may not exceed sixty (60) days from the date of the notice of deficiency. The responsible entity shall submit a revised Final AA Report or revised Abridged AA Report by the due date specified, and address all areas of deficiency. The responsible entity may request and the Department may approve, under section 69505.1(c), a one-time extension of not more than ninety (90) days for submission of the revised Final AA Report or revised Abridged AA Report to correct the deficiencies.

(B) Within sixty (60) days of receipt of the requested additional information, the Department shall issue a notice of compliance, a second notice of deficiency, or a notice of ongoing review.

1. If the Department issues a second notice of deficiency, the Department may grant no more than thirty (30) days for submission of the requested information.

2. Within sixty (60) days of receipt of the additional information requested in the second notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a notice of ongoing review for the revised Final AA Report or revised Abridged AA Report.

(3) Notice of Disapproval. If the revised Final AA Report or revised Abridged AA Report does not fully address the areas of deficiency identified in the second notice of deficiency, the Department shall issue a notice of disapproval. The Department shall also issue a notice of disapproval if a Page **71** of **105**

revised Final AA Report or revised Abridged AA Report is not submitted by the due date specified under paragraph (2)(A) or paragraph (2)(B)1., whichever is applicable. If the revised Final AA Report or revised Abridged AA Report is disapproved, the Department shall explain the basis for the disapproval. A disapproved revised Final AA Report or revised Abridged AA Report is not in compliance with section 69505.1(b).

(d) Notice of Ongoing Review. The Department shall specify in a notice of ongoing review the estimated date by which the Department expects to issue a notice of compliance or notice of deficiency, which shall be based on its available resources and the complexity of the document under review.

(e) Issuance of Notices. All notices issued by the Department under this section shall be issued to the person who submitted the document, and a copy of the notice shall be sent by the Department to all persons identified in the document under subsections (c)(2) and (c)(3) of section 69505.7.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.