SAFER CONSUMER PRODUCTS
SUMMARY OF REVISED PROPOSED REGULATIONS

NOTE: *This is an informational summary only. For a more precise understanding of the provisions of the proposed regulations, please refer to the regulations themselves.*

Table of Contents

Page

I. Summary of the Regulations 2
A. Four-Step Process 2
B. Applicability 2
C. Responsibility for Compliance 3
D. Consequences of Non-Compliance 4
E. Chemical and Product Information 4
F. Information on DTSC's Website 4
G. Disputes 4
H. Trade Secret Protection 4

II. Chemical and Product Prioritization 5
A. Candidate Chemicals (CC) Identification 5
B. Candidate Chemicals and Product Prioritization 6
C. Products Listing Process 7
D. Initial Priority Products List 8
E. Petition Process 8

III. Alternatives Analyses (AAs) 8
A. Guidance Materials 8
B. Alternatives Analyses --- General Provisions 8
C. Chemical/Product Removal/Replacement Notifications 9
D. Alternatives Analysis Threshold Exemption 9
E. Alternatives Analysis Process and Options 10
F. First Stage of the AA 11
G. Second Stage of the AA 12
H. Alternatives Analysis Reports 13
I. DTSC Review and Determinations for AA Reports 14

IV. Regulatory Responses 15
A. Regulatory Response Selection Principles 15
B. Applicability 16
C. Regulatory Response Process 16
D. Regulatory Responses 17
E. Regulatory Response Exemptions 19

V. Key Implementation Milestones 20

I. Summary of the Regulations

A. Four-Step Process *[Section 69501(a)]*
The regulations provide for a four-step continuous, science-based, iterative process to identify safer consumer product alternatives:

- *DTSC* --- The regulations establish an immediate list of Candidate Chemicals (~1,200) based on the work already done by other authoritative organizations, and specify a process for DTSC to identify additional chemicals as Candidate Chemicals (CCs).***** *[Article 2, see section II for further details.]*

- *DTSC* --- The regulations require DTSC to evaluate and prioritize product/Candidate Chemical combinations to develop a list of "Priority Products" for which alternatives analyses must be conducted.* A Candidate Chemical that is the basis for a product being listed as a Priority Product is designated as a Chemical of Concern (COC) for that product. *[Article 3, see section II for further details.]*

- *Product Manufacturers* --- The regulations require responsible entities (manufacturers, importers, assemblers, and retailers) to notify DTSC when their product is listed as a Priority Product. DTSC will post this information on its website. Manufacturers (or other responsible entities) of a product listed as a Priority Product must perform an alternatives analysis (AA) for the product and the COCs in the product to determine how best to limit exposures to, or the level of adverse public health and environmental impacts posed by, the COCs in the product. *[Article 5, see section III for further details.]*

- *DTSC* --- The regulations require DTSC to identify and require implementation of regulatory responses designed to protect public health and/or the environment, and maximize the use of acceptable and feasible alternatives of least concern. DTSC may require regulatory responses for a Priority Product (if the manufacturer decides to retain the Priority Product), or for an alternative product selected to replace the Priority Product. *[Article 6, see section IV for further details.]*

***** The regulations provide a process for any individual or organization (including federal and other California State agencies) to petition DTSC to add/remove a chemical to/from the Candidate Chemicals list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to or removed from the list of Candidate Chemicals. *[Article 4]*

B. Applicability *[Section 69501(b)]*
Except as noted below, the regulations apply to all consumer products that contain a Candidate Chemical, and are sold, offered for sale, distributed, supplied, or manufactured in California. The regulations do not apply to the following products:

(1) Products exempted by law (Health and Safety Code section 25251): dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials, and medical devices; food; and pesticides.

(2) A product that DTSC determines is regulated by other federal or California State regulatory programs, or treaties or international trade agreements, for the same adverse

public health and/or environmental impacts, exposure pathways, and waste and end-of-life effects that would otherwise be the basis for listing the product as a Priority Product. This exemption only applies if DTSC determines that these other program(s) provide a level of public health and environmental protection equivalent to or greater than the protection that would potentially be provided if the product were listed as a Priority Product.

C. Responsibility for Compliance

(1) The regulations *[Section 69501.1(a)(60)]* define "responsible entity" to include:
   (i) The manufacturer (i.e., the person who makes or produces a product that is subject to the regulations, or any person that controls the manufacturing process for, or has the capacity to specify the use of chemicals in, such a product).
   (ii) The US importer of a product that is subject to the regulations.
   (iii) Assemblers (i.e., persons who assemble a product containing a component that is a product subject to the regulations).
   (iv) Retailers (i.e., persons to whom a product that is subject to the regulations is delivered or sold for purposes of sale or distribution by that person to a consumer).

However, the principal duty to comply with the requirements of the regulations that apply to responsible entities lies with the manufacturer. If the manufacturer does not comply, the importer, if any, then has the duty to comply. A retailer or assembler is required to comply with the regulations only if the manufacturer and importers (if any) fail to comply, and only after this information is posted on the Failure to Comply List on DTSC's website. *[Section 69501.2(a)(1)]*

(2) The regulations *[Section 69501.2(a)]* require a responsible entity for a product to ensure compliance with the requirements pertaining to:

   (i) Notifying DTSC that its product is a Priority Product;
   (ii) Performing an AA, and submitting AA Reports to DTSC, for its product; and
   (iii) Complying with regulatory responses applicable to its product.

(3) Under specified conditions, a manufacturer may opt out of complying with the AA and regulatory response requirements by submitting a chemical removal, product removal, product-chemical replacement, or alternatives analysis threshold exemption notification to DTSC. *[Sections 69505.2, 69505.3, and 69506.1(b) – see section III.C. and D. for further details.]*

(4) A retailer or assembler who becomes responsible for complying with the above requirements, due to non-compliance by the manufacturer/importer, may opt out by ceasing to order the product and providing a notification to DTSC. *[Section 69501.2 (b)]*

(5) The regulatory requirements applicable to responsible entities may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in the stead of, one or more responsible entity(ies). (This does not apply to Priority Product Notifications, Chemical Removal Notifications, Product Removal Notifications, Product-Chemical Replacement Notifications, or Alternatives Analysis Threshold Exemption Notifications.) *[Section 69501.2(a)(2)]*

D. Consequences of Non-Compliance

(1) When DTSC determines a requirement has not been fulfilled for a product, DTSC will issue a notice of non-compliance to the manufacturer and importers. *[Section 69501.2(c)]*

(2) If the non-compliance is not remedied, the product and information concerning the product will be placed on a Failure to Comply List maintained on DTSC's website. The regulations specify the conditions under which a product will be removed from the Failure to Comply List. *[Section 69501.2(c)]*

(3) DTSC may conduct audits to determine compliance with the requirements of the regulations pertaining to alternatives analyses, regulatory responses, and various notifications and information submittals. *[Article 8, Section 69508]*

(4) In accordance with *article 8 of chapter 6.5 of division 20 of the Health and Safety Code*, DTSC may also initiate enforcement actions, including imposition of fines and penalties, against responsible entities for failure to comply with the regulations.

E. Chemical and Product Information *[Section 69501.4]*

DTSC's implementation of the regulations will be informed by a wealth of information that DTSC will obtain from the public domain. In addition, DTSC will request information from chemical and product manufacturers, importers, assemblers, and retailers. DTSC will maintain on its website a Response Status List that provides information as to how a person has or has not responded to a request for information from DTSC. DTSC will also maintain on its website a Safer Consumer Products Partner Recognition List that identifies persons that have voluntarily provided DTSC with information that advances the quest for safer consumer products.

F. Information on DTSC's Website *[Section 69501.5]*

The regulations require DTSC to post on its website a comprehensive list of information pertaining to implementation of the regulations. In some cases, a notice of the availability of the information will be provided to persons on DTSC's electronic mailing list for these regulations. This will be DTSC's main avenue of communication with responsible entities and the public.

G. Disputes *[Article 7, commencing with Section 69507]*

The regulations provide a process for a responsible entity to dispute an action taken by DTSC. A requirement imposed on the responsible entity by DTSC, and posting of information on the Failure to Comply list concerning the non-compliance with that requirement, will be stayed while a dispute is pending. (The dispute process does not apply to actions taken by DTSC with regard to the listing of Candidate Chemicals, petitions concerning the chemicals and products lists, and trade secret protection claims.)

H. Trade Secret Protection *[Article 9, commencing with Section 69509]*

The regulations set out provisions for the treatment of information submitted under the regulations for which a claim of trade secret protection is asserted by the submitter. The regulations are based on the authorities for handling trade secrets found in Health and Safety Code section 25257 and the California Public Records Act.

II. Chemical and Product Prioritization

A. Candidate Chemicals (CC) Identification

(1) Initial List of CCs --- The regulations, as of their effective date, establish an immediate list of ~1,200 Candidate Chemicals (that exhibit one or more hazard traits and/or environmental or toxicological endpoints) using 23 existing authoritative body lists that: (i) list chemicals on the basis of exhibiting at least one of eight hazard traits (carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, respiratory sensitivity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity); or (ii) list chemicals on exposure indicator lists for water quality, air quality, or biomonitoring. *[Section 69502.2(a)]*
NOTE: ~500 chemicals currently used only in pesticides or drugs (and, thus, excluded from these regulations under Health and Safety Code section 25251) could be added to this list in the future if they are used in products that are not excluded under Health and Safety Code section 25251.

(2) Additions to the Initial List of Candidate Chemical --- DTSC may identify additional chemicals (that exhibit a hazard trait or an environmental or toxicological endpoint) as CCs based on consideration of the following factors for which reliable information is available *[Section 699502.2(b)]*:

- *Chemical adverse public health and environmental impacts*
- *Adverse impacts of special consideration*
  - (i) Sensitive subpopulations
  - (ii) Environmentally sensitive habitats
  - (iii) Endangered and threatened species
  - (iv) Environments in California designated as impaired
- *Adverse impacts associated with the potential for the chemical to contribute to or cause widespread adverse public health and/or environmental impacts*
- *Structurally or mechanistically similar chemicals with a known toxicity profile*
- *Exposures to the chemical*

Refer to the definitions in the regulations *[Section 69501.1]* for the list of adverse public health and environmental impacts, physicochemical properties, and environmental fate properties that will be considered during the identification of CCs and the prioritization of products/CCs.

(3) Chemicals Listing Process --- An informational list of those chemicals identified as Candidate Chemicals as of the effective date of the regulations will be posted on DTSC's website within 30 days after the regulations become effective. Any subsequent revisions to the list will be made in accordance with the following process *[Section 69502.3]*:

- Prior to finalizing each augmentation to the initial CCs list, DTSC will make the proposed list available for public review and comment for a minimum 45-day period, and will hold public workshop(s).
- After consideration of public comments on a proposed list, DTSC will finalize and post the final list on its website.

B. Candidate Chemicals and Product Prioritization

(1) Key Prioritization Factors *[Section 69503.2(a)]*: Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria:

- There must be potential exposure to the Candidate Chemical(s) in the product; and
- There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse public health and/or environmental impacts.

(2) Product Prioritization Criteria *[Section 69503.2(b) and 69503.3]*: DTSC may list as Priority Products those products that are determined to be of high priority. DTSC's decision to list a product-CC combination as a Priority Product will be based on an evaluation of the potential adverse impacts, exposures, and waste and end-of-life effects associated with the product based on consideration of the factors listed below.

(a) Adverse Impacts and Exposures: DTSC will begin the product-CC evaluation process by evaluating the potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures during the life cycle of the product. The listing of a product-chemical combination as a Priority Product shall be based on one or more potential adverse public health and/or environmental impact factors and one or more exposure potential factors in addition to other factors indicated below.

- *Adverse Impacts from the CCs* --- The potential for the CC(s) in the product to contribute to or cause adverse public health and/or environmental impacts, considering one or more specified factors, including:
  - The Candidate Chemical's hazard traits, environmental and toxicological endpoints, aggregate effects, cumulative effects, physicochemical properties, and environmental fate
  - The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms for which the Candidate Chemical(s) has/have the potential to contribute to or cause adverse impacts
  - The potential for the Candidate Chemical(s) to degrade, form reaction products, or metabolize into another Candidate Chemical or a chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints
  - Adverse impact(s) for:
    - (i) Sensitive subpopulations
    - (ii) Environmentally sensitive habitats
    - (iii) Endangered and threatened species
    - (iv) Environments in California designated as impaired
  - The adverse impacts associated with structurally or mechanistically similar chemicals for which there is a known toxicity profile

- *Exposures* --- Potential public health and/or environmental exposures to the CC(s) in the product, considering one or more of the following:
  - (i) Market presence information for the product
  - (ii) Reliable information demonstrating the occurrence or potential occurrence of exposures to the CC(s) in the product

(iii) Information concerning the household and workplace presence of the product, and other products containing the same CC(s)
(iv) Potential exposures to the CC(s) in the product during the product's life cycle

(b) Adverse Waste and End-of-Life Effects. DTSC may also consider product uses, or discharges or disposals, that have the potential to contribute to or cause adverse waste and end-of-life effects associated with the Candidate Chemical(s) in the product.

(c) Availability of Information: DTSC will consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse public health and environmental impacts, exposures, and adverse waste and end-of-life effects.

(d) Other Regulatory Programs: DTSC will consider the scope of other California State and federal laws, and treaties and international agreements, under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse public health and environmental impacts, exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product.

(e) Safer Alternatives: When deciding whether to list a product-chemical combination as a Priority Product, DTSC may also consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

C. Products Listing Process *[Section 69503.4, 69503.5, and 69503.7]*

(1) Rulemaking Process --- The Priority Products list will be established and updated through the Administrative Procedure Act's rulemaking process.

(2) Priority Product Work Plan --- Within one year after the effective date of these regulations, DTSC will issue a Priority Product Work Plan that identifies the product categories that will be evaluated to identify products to be added to the Priority Products list during the next three years. Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan. The regulations specify conditions under which DTSC may revise the work plan subsequent to its issuance.

(3) Priority Product List Revisions --- DTSC will review, and revise as appropriate, the Priority Products list at least once every 3 years.

(4) Components --- If the Priority Product is a component of one or more assembled products, the Priority Product listing will include a description of the known assembled product(s) in which the component is used.

(5) Complex Durable Products --- For a complex durable product, DTSC will not list as Priority Products, in a three-year period, more than ten (10) components contained in that product.

(6) Due Dates --- The Priority Products list will include the due dates for the Priority Product Notification (default is 60 days) and the Preliminary AA Report (default is 180 days).

(7) Priority Product Notifications --- Each responsible entity for a product listed on the Priority Products list must provide to DTSC a Priority Product Notification within 60 days after the product is listed as a Priority Product (unless DTSC specifies a later notification date in the Priority Products list).

D. Initial Priority Products List *[Sections 69503.6]*

(1) Prior to January 1, 2016, DTSC will list a product as a Priority Product only if the product is being listed on the basis of one or more Candidate Chemicals in the product that have both listed hazard trait and listed exposure concerns.

(2) The initial final list of Priority Products will include no more than five products.

(3) The initial proposed list of Priority Products will be made available for public review and comment no later than 180 days after the effective date of the regulations.

E. Petition Process *[Sections 69504 and 69504.1]*
Subject to specified limitations, a person may petition DTSC to add to or remove from the Candidate Chemicals list one or more chemicals, or to add to or remove from the Candidate Chemicals list the entirety of an existing chemicals list. A person may also petition DTSC to add to or remove from the Priority Products list a product-chemical combination. High priority will be given to petitions by federal and other California State agencies that relate to the petitioning agency's statutory and/or regulatory authorities. After granting a petition, DTSC will evaluate and, if applicable, prioritize the chemical and/or the product in accordance with the prioritization processes described above.

III. Alternatives Analyses (AAs)

A. Guidance Materials
The regulations require DTSC to prepare, and make available on its website, guidance materials to assist persons in performing AAs, and to post on its website AAs that are available in the public domain at no cost. *[Section 69505]*

B. Alternatives Analysis --- General Provisions

(1) A responsible entity for a Priority Product must conduct an AA for the Priority Product and submit a Preliminary AA Report and a Final AA Report to DTSC within specified timeframes. *[Section 69505.1(b)]*

- The Preliminary AA Report must be submitted no later than 180 days after the date the product is listed on the final Priority Products listing, unless DTSC specifies a different due date for the product in the Priority Products list.
- The Final AA Report must be submitted no later than 12 months after the date DTSC issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, and DTSC approves, a longer period of time not to exceed 24 months

(or up to 36 months if regulatory safety and/or performance testing is required for the alternatives being considered), or if DTSC specifies a longer time frame. *[Section 69505.8(b)(4)]*

(2) The regulations allow for a responsible entity to request a one-time extension, not to exceed 90 days, for submitting the Preliminary and/or Final AA Report, if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. *[Section 69505.1(c)]*

(3) DTSC will post on its website a notice regarding the availability for public review and comment (for up to 45 days) of each Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan. Public comments on these documents will be sent to the person that submitted the document with a copy sent simultaneously to DTSC. *[Section 69505.1(d)]*

C. Chemical/Product Removal/Replacement Notifications *[Section 69505.2]*

(1) An AA is not required for a Priority Product if the manufacturer submits one of the following notifications by the due date for the Preliminary AA Report (or by the due date for the Final AA Report if a Preliminary AA Report has already been submitted):

- A Chemical Removal Intent and/or Confirmation Notification, certifying that the COC(s) will be / have been removed from the product without the use of any replacement chemical(s);
- A Product Removal Intent and/or Confirmation Notification, certifying that the manufacturer will or has ceased fulfilling orders for the product from persons selling or distributing the Priority Product in California.
- A Product-Chemical Replacement Intent and/or Confirmation Notification, certifying that the COC(s) will be or have been removed from the product and any replacement chemical meets one of the following criteria:
  - The replacement chemical is not on the list of Candidate Chemicals; or
  - The replacement chemical is a Candidate Chemical that is already in use, in lieu of the Chemical(s) of Concern, to manufacture the same product by the same or a different manufacturer.

(2) An Intent Notification must be followed by submission of a Confirmation Notification within 90 days or by the due date for the Preliminary AA Report (or Final AA Report), whichever is later.

D. Alternatives Analysis Threshold Exemption *[Section 69505.3]*

(1) A product that is listed as a Priority Product and that meets the criteria for an alternatives analysis threshold exemption will be exempt from the requirement to perform an alternatives analysis if the manufacturer of the product submits an Alternatives Analysis Threshold Exemption Notification to DTSC.

(2) An alternatives analysis threshold exemption is only available for a manufacturer's Priority Product if the COC(s) are present in the product solely as contaminants, and the concentration of the COC(s) does not exceed the Practical Quantitation Limit (PQL) for

the chemical(s). NOTE: If during the product prioritization process DTSC determines that an AAT is needed for a particular intentionally added chemical in a particular product this can be addressed in the rulemaking for that Priority Product listing.

(3) The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification, including the source of the contaminant COC(s). The notification must identify the PQL(s) for the COC(s) and the methods used to determine the PQL(s). The manufacturer is required to notify DTSC if the information in the Alternatives Analysis Threshold Exemption Notification significantly changes, or the product no longer meets the criteria for an alternatives analysis threshold exemption.

E. Alternatives Analysis Process and Options

(1) Two-Stage AA: The regulations require that each AA be conducted and reported in two stages. The Preliminary AA Report is submitted to DTSC after completion of the first AA stage, and the Final AA Report is submitted after completion of the second AA stage. *[Section 69505.4(a)]*

(2) Abridged AA Report: A responsible entity that determines (after completion of steps 1 through 4 of the first AA stage as described below) that a functionally acceptable and technically feasible alternative is not available may prepare and submit a draft and final Abridged AA Report, in lieu of Preliminary and Final AA Reports, if the responsible entity meets specified requirements. *[Section 69505.4(b)]*

(3) Alternate Process AA: A responsible entity may use an AA process that differs from the process described in the regulations if certain requirements are met, including *[Section 69505.4(c)]*:

- The alternate process will provide the information needed to prepare an AA Report that substantially meets the AA Report requirements specified in the regulations.
- The alternate process will compare the Priority Product and the alternatives using at a minimum the same factors, and associated exposure pathways and life cycle segments, that would be used if the process specified in the regulations was followed.
- The responsible entity submits an Alternate Process AA Work Plan to DTSC no later than 60 days after the product is included on the Priority Products list.

(4) Previously Completed AAs: The regulations allow a responsible entity to fulfill the AA requirements by submitting a report for a previously completed AA for the Priority Product --- if DTSC determines that the report is substantially equivalent to the AA Report requirements specified in the regulations, and that the report contains sufficient information to identify regulatory response(s). *[Section 69505.4(d)]*

(5) Revised Alternative Selection Decision: After the Final AA Report is submitted, if the alternative selection decision specified in the Final AA Report changes the responsible entity is required to submit a revised Final AA Report with an explanation of the change. A revised Final AA Report is also required if the original alternative selection decision was to retain the Priority Product, and the responsible entity later decides to replace the Priority Product with an alternative product, or visa versa. This requirement only applies for 3 years after DTSC approves the original Final AA Report. *[Section 69505.4(e)]*

F. First Stage of the AA

(1) Step 1, Identification of Product Requirements and Function(s) of COCs *[Section 69505.5(a)]*:

- The function, performance, and legal requirements associated with the Priority Product that must be met by alternatives being considered.
- The function(s) of the COC(s) in meeting the Priority Product's function, performance, and legal requirements.
- A determination as to whether the COC(s) or alternative replacement chemical(s) is/are necessary to meet the Priority Product's function, performance, and legal requirements.
- If it is determined that neither the COC(s) or alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements, the removal of the COC(s) from the Priority Product without the addition of alternative replacement chemical(s) must be evaluated in the AA as one of the alternatives to the Priority Product.

(2) Step 2, Identification of Alternatives *[Section 69505.5(b)]*:
Identification of alternatives for consideration that meet the requirements for the Priority Product, and eliminate or reduce the concentration of the COC(s) in the Priority Product and/or reduce or restrict public health and/or environmental exposures to the COC(s) in the Priority Product. The responsible entity is required to include in the AA consideration of any identified existing viable alternatives.

(3) Step 3, Initial Evaluation and Screening of Alternative Replacement Chemicals *[Section 69505.(c)]*:

- The responsible entity is required to collect and use available relevant information to identify the adverse public health and environmental impacts associated with each chemical being considered as an alternative to the COC(s) in the Priority Product.
- Using this information, the responsible entity must compare each of the identified alternative replacement chemicals with the COC(s) in the Priority Product.
- The responsible entity must eliminate from further consideration in the AA any alternative replacement chemical that it determines has the potential to pose equal or greater adverse public health and/or environmental impacts as compared to the COC(s).

(4) Step 4, Consideration of Additional Information *[Section 69505.5(d)]*:
As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above, including the factors and information for the second AA stage (described below). 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.

(5) Step 5, Preliminary AA Report Preparation *[Section 69505.5(e)]*:
The responsible entity is required to prepare, and include in the Preliminary AA Report, a work plan and proposed implementation schedule for completion of the second AA stage (as described in G. below) and preparation and submittal of the Final AA Report.

G. Second Stage of the AA

(1) Step 1, Identification of Factors Relevant for Comparison of Alternatives *[Section 69505.6(a)]*:

- A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if:
  - (i) It makes a material contribution to the 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
  - (ii) There is a material difference in the factor's contribution to such impacts between the Priority Product and one or more of the alternatives being considered, and/or between two or more alternatives.

- The responsible entity must use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors listed in (i) below, and the associated exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives under consideration. The factors listed in (ii) and (iii) below are considered relevant for all comparisons.
  - (i) Multimedia life cycle impacts and chemical hazards and adverse impacts for the COC(s) and any alternative replacement chemicals:
    - ✓ Adverse environmental impacts
    - ✓ Adverse public health impacts
    - ✓ Adverse waste and end-of-life impacts
    - ✓ Environmental fate
    - ✓ Materials and resource consumption impacts
    - ✓ Physical chemical hazards
    - ✓ Physicochemical properties
  - (ii) Product function, performance, and legal requirements
  - (iii) Economic impacts

- The identification of relevant exposure pathways must consider:
  - (i) Chemical quantity information
  - (ii) Exposure factors

(2) Step 2, Comparison of the Priority Product and Alternatives *[Section 69505.6(b)]*:
The responsible entity must use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare the Priority Product and each alternative with respect to each relevant factor and associated exposure pathways and life cycle segments.

(3) Step 3, Consideration of Additional Information *[Section 69505.6(c)]*:
As part of the second stage of the AA, the responsible entity may also consider other relevant information not specifically identified above, including reconsideration of factors evaluated in the first stage of the AA.

(4) Step 4, Alternative Selection Decision *[Section 69505.6(d)]*:
The responsible entity selects the alternative(s) that will replace the Priority Product, or decides to retain the Priority Product.

(5) Step 5, Identification of Next Steps *[Section 69505.6(e)]*:
The responsible entity is required to prepare a Final AA Report.

H. Alternatives Analysis Reports

(1) The Preliminary and Final AA Reports, and draft and final Abridged AA Reports, must include the information listed below, as applicable. All differences in the information and analyses presented in the Preliminary AA Report (or draft Abridged AA Report) and the Final AA Report (or final Abridged AA Report) must be identified and explained in the final report. *[Section 69505.7(a)]*

- An **executive summary** *[Section 69505.7(b)]*. The executive summary cannot include any information for which trade secret protection is claimed --- this will enable the executive summary to be posted on DTSC's website in its entirety.
- Information regarding the **preparer** of the AA Report *[Section 69505.7(c)]*
- Information regarding the **responsible entity** and the **supply chain** for the product *[Section 69505.7(d)]*
- Information describing the **Priority Product** and the **COCs** *[Section 69505.7(e)]*
- Identification of **comparison factors**. The AA Reports must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant for evaluation and comparison of the Priority Product and its alternatives. The AA Report must explain the rationales for each factor, exposure pathway, and life cycle segment determined not to be relevant. *[Section 69505.7(f)]*
- A description of the **alternatives** chosen to be evaluated and compared, and an explanation of the rationales for selecting and screening out specific alternatives at each stage of the alternatives comparison process. *[Section 69505.7(g)]*
- Detailed information on the **evaluation and comparison of the Priority Product and its alternatives** for all of the relevant comparison factors, and associated exposure pathways and life cycle segments. *[Section 69505.7(g)]*
- A description of the **methodology** used to conduct the *AA*. *[Section 69505.7(h)]*
- Identification of all information used as **supporting information** in performance of the AA and preparation of the AA Reports. This information must be made available to DTSC, upon request. The Final AA Report must also identify any **information gaps**. *[Section 69505.7(i)]*
- Final AA Reports and final Abridged AA Reports must include a **summary of the public comments** received for the Preliminary AA Report or draft Abridged AA Report, and a description as to how the comments are addressed in the report or an explanation as to why the comments are not addressed in the AA Report. *[Section 69505.7(i)]*

- 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. The Final AA Report must include an identification and description of the **alternative(s) selected** to replace the Priority Product (or a decision to retain the Priority Product); the **implementation plan** for the selected alternative(s), if any; and any **proposed regulatory responses**. *[Section 69505.7 (j) and (k)]*

(2) The information in the Final AA Report concerning the alternative selection decision must include *[Section 69505.7(j)]*:

- A description of the alternative(s), if any, selected, and the rationales for the selection decision. This includes an analysis that evaluates and compares the selected alternative(s) against the Priority Product, and an explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable.

- A discussion of the acceptability of the selected alternative, as compared to the Priority Product, with respect to functional, performance, and legal requirements. If no alternative is selected, this information must be provided for each alternative considered.

- The rationales for selecting an alternative that retains one or more COC(s) or uses replacement chemicals, if it is determined during the AA that neither the COC(s) nor replacement chemicals are necessary to satisfy the requirements for the Priority Product (i.e., functional, performance, and legal requirements).

- A list of, and information for, all chemicals known based on available information to be in the selected alternative(s) that are COCs, 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 COC(s)). The required information includes: available environmental fate information for the chemicals; available hazard trait and environmental and toxicological endpoint information for those chemicals; and available chemical identification and description information for those chemicals.

I. DTSC Review and Determinations for AA Reports *[Section 69505.8]*

(1) Within 60 days of receiving an AA Report or Alternate Process AA Work Plan, DTSC will review the AA Report for compliance with the regulations, and issue a notice of compliance, a notice of deficiency, a notice of disapproval, or a notice of ongoing review. Notices of deficiency will give the responsible entity 60 days to remedy the deficiency (or 30 days if it is a second notice of deficiency). If the submitter of the AA Report fails to adequately and timely respond to 2 notices of deficiency for the Final AA Report (or 1 notice of deficiency for the Preliminary AA Report), DTSC will issue a notice of disapproval and the product will be placed on the Failure to Comply List (following notice to the submitter of the report). A notice of disapproval will also be issued if a revised report or work plan is not submitted by the due date.

(2) Notices of compliance for Preliminary AA Reports and Alternate Process AA Work Plans will specify the due date for submitting the Final AA Report, which will range from 12 to 24 months (or up to 36 months if regulatory safety and/or performance testing is required for alternatives being considered) after DTSC issues the notice of compliance. DTSC 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 Process AA Work Plan that more time is needed.

IV. Regulatory Responses

A. Regulatory Response Selection Principles *[Section 69506]*

(1) DTSC will require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, when such alternatives are functionally acceptable and technically and economically feasible.

(2) DTSC will give preference to regulatory responses providing the greatest level of inherent protection. More specifically, preference will be given to alternatives that avoid or reduce adverse public health and/or environmental impacts, exposures, and/or waste and end-of-life effects through product or process redesign as opposed to alternatives that use administrative or engineering controls to limit exposures to, or releases of, a COC or a replacement Candidate Chemical in a product.

(3) In selecting regulatory responses, DTSC may consider the following factors:
- The degree to which, and speed with which, the regulatory response can address the adverse public health and/or environmental impacts and/or adverse waste and end-of-life effects of the COC(s) or replacement Candidate Chemical(s);
- The ability of end-users to understand and act upon any regulatory response involving provision of information with respect to the Priority Product;
- Any adverse ecological impacts of the regulatory response on sensitive resources, or unique or additional burdens that the regulatory response would impose upon sensitive subpopulations;
- Existing federal and/or California State regulatory requirements applicable to the Chemical(s) of Concern or replacement Candidate Chemical(s);
- The cost to the responsible entity of the regulatory response(s) relative to the cost of other possible responses;
- The practical capacity of responsible entities to comply with the regulatory response(s);
- The management and clean-up costs imposed on public agencies by the ongoing sale of the Priority Product or a selected alternative;
- DTSC's administrative burden in overseeing implementation of the regulatory response(s); and
- The ease of enforcing the regulatory response(s).

B. Applicability

(1) The regulations specify regulatory responses that will, under specified conditions, apply to *[Section 69506.1(a)]*:
- Products manufactured as a selected alternative following completion of an AA;
- Priority Products for which an alternative is not selected;
- Priority Products that will remain in commerce pending development and distribution of the selected alternative; and
- Products for which the AA Report is disapproved by DTSC.

(2) A regulatory response is not required for a Priority Product if the manufacturer submits a compliant Removal or Replacement Confirmation Notification (see section III.C. above) to DTSC prior to the due date for implementing any regulatory response that would otherwise apply to the product.

C. Regulatory Response Process *[Sections 69506.1 and 69506.10]*

(1) Within 90 days after issuing a notice of compliance or a notice of disapproval for a Final AA Report or a final Abridged AA Report, DTSC will issue a notice of its proposed determination that one or more of the regulatory responses described below are required, or that no regulatory response is required.

(2) The proposed regulatory response determination will be sent to all known affected responsible parties and made available for public review and comment for a minimum 45-day period.

(3) After consideration of public comments, DTSC will send a final regulatory response determination notice to known responsible entity(ies) and post the final notice on its website. The notice will include the due date for implementing the regulatory response(s). In assigning an implementation due date, DTSC will consider the complexity of implementing the regulatory response(s).

(4) Each proposed and final regulatory response determination notice will include DTSC's determination as to whether or not the regulatory response applies to either or both of the following:
- Priority Products ordered by a retailer prior to the effective date of the Priority Product listing, and still for sale by the retailer as of the date of the final regulatory response determination notice; and/or
- Priority Products manufactured after the effective date of the Priority Product listing, but before the date of the final regulatory response determination notice.

(5) Once a final regulatory response determination notice has been issued, DTSC will not augment or revise the regulatory responses for the affected product, except as discussed in section D.(1) below or in the event of a relevant dispute.

(6) The responsible entity must notify DTSC of the applicability of regulatory responses to the responsible entity's product within 30 days. The responsible entity must send the same notice within 30 days to all persons in California (other than the final purchaser or lessee) to whom the responsible entity directly sells the product, and any other person (other than the final purchaser or lessee) to whom the responsible entity directly sells the

product if it is reasonably foreseeable that the product will be placed into the California marketplace.

(7) The responsible entity must notify DTSC upon completion of the implementation of the required regulatory response(s), and (if applicable) upon completion of the implementation of the selected alternative(s). If requested by DTSC, the responsible entity must provide periodic implementation status reports regarding the selected regulatory response(s) and/or the development and introduction into the California marketplace of the selected alternative(s).

(8) DTSC will post on its website a Regulatory Response Summary that identifies the regulatory response(s) for each selected alternative for a Priority Product (and each Priority Product, as applicable), and the implementation dates for the alternative product(s), if any, and the regulatory response(s).

D. Regulatory Responses

(1) *Supplemental AA Report Information and Regulatory Response Revisions [Section 69506.2]*:

- Prior to imposing any regulatory response for a product, DTSC may require the responsible entity to provide to DTSC any information supplementary to the AA Report that DTSC determines is necessary to select and ensure implementation of one or more regulatory responses.
- When imposing one or more regulatory responses for a product, DTSC may include a requirement that the responsible entity provide information to DTSC to fill one or more information gaps identified in the AA Report, if DTSC determines this information is necessary to re-evaluate the initial regulatory responses. Following receipt of the requested information DTSC may, based on this new information, revise the initial regulatory response(s) imposed for the product. Any revisions to the initial regulatory responses will be noticed for public review and comment no later than 90 days after receiving the requested information.
- In addition to the circumstances described above, DTSC may revise the initial regulatory response(s) imposed for a product in response to a revised AA Report submitted by a responsible entity when there is a revision to the alternative selection decision.

(2) *Product Information for Consumers*. Product information must be provided to consumers if the alternative product contains a COC or any replacement Candidate Chemicals, or if the manufacturer chooses to retain the Priority Product (indefinitely or for more than 12 months pending development and distribution of the alternative product). The regulations specify the types of information that must be provided to consumers, and the mechanisms that must be used to provide the information. [Section 69506.3]

(3) *Use Restrictions.* DTSC may impose restrictions on the use of COCs or replacement Candidate Chemicals in a product, or specified restrictions on the product, to reduce the amount of a COC or replacement CC in the product, or reduce the potential for the

product to contribute to or cause an exposure to the COC or replacement CCs in the product. *[Section 69506.4]*

(4) *Product Sales Prohibition.* If the selected alternative contains a COC or replacement Candidate Chemical (or if an alternative is not selected), and DTSC determines there is a safer alternative that does not contain a COC or replacement CC and that is functionally acceptable and technologically and economically feasible, the responsible entity must do one of the following *[Section 69506.5]*:

- Cease placing the product into the California marketplace, directly or indirectly; or
- Submit to DTSC an AA Report that selects an alternative that does not contain a COC or replacement CC.

DTSC may also impose a product sales prohibition in the absence of a determination that there is a safer, functionally acceptable, and technologically and economically feasible alternative, unless the responsible entity demonstrates to DTSC's satisfaction that: (i) the overall beneficial public health and/or environmental impacts and/or social utility of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and (ii) administrative and/or engineering restrictions on the nature and/or use of the product will adequately protect public health and the environment.

(5) *Engineering or Administrative Controls.* Under specified conditions, DTSC may require a manufacturer to engineer safety measures that integrally contain or control access to, and/or implement administrative controls that limit exposure to, the COC(s) or replacement CC(s) in a selected alternative, or the COC(s) in a Priority Product for which an alternative is not selected, to reduce the potential for adverse public health and/or environmental impacts. *[Section 69506.6]*

(6) *End-of-Life Product Management Program.* *[Section 69506.7]*

- A manufacturer must establish, maintain, and fund an end-of-life product stewardship program, and provide product information to consumers, if the alternative product (or the Priority Product, if the manufacturer chooses to retain the Priority Product) is required to be managed as a hazardous waste in California at end-of-life. The requirements for the product stewardship plan and program are specified in the regulations.
- A manufacturer may individually fulfill these requirements, or may join with other manufacturers to form a non-profit third-party product stewardship organization, funded by participating manufacturers, to fulfill the requirements.
- A manufacturer may request DTSC's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program specified in the regulations.
- A manufacturer may request an exemption from the requirement to provide an end-of-life management program by demonstrating to DTSC's satisfaction that an end-of-life management program cannot feasibly be implemented for the product.

(7) *Advancement of Green Chemistry and Green Engineering.* When a manufacturer concludes that no safer alternative to its Priority Product is functionally acceptable and technically and economically feasible, or a manufacturer selects an alternative that reduces but does not eliminate the use of Candidate Chemicals in the product, DTSC may require the manufacturer to initiate a research and development project or fund a challenge grant pertinent to the Priority Product that uses green chemistry and/or green engineering principles to: (i) design a safer alternative; (ii) improve the performance of a safer alternative; (iii) decrease the cost of a safer alternative; and/or (iv) increase the market penetration of a safer alternative. [*Section 69506.8]*

E. Regulatory Response Exemptions *[Section 69506.11]*

The regulations provide a process for a responsible entity to request an exemption from an otherwise applicable regulatory response based on either or both of the following:

(1) The required regulatory response would conflict with a requirement of another California State or federal regulatory program, or a treaty or international trade agreement, in such a way that the responsible entity could not reasonably be expected to comply with both requirements. In this situation, DTSC may require implementation of a modified regulatory response that resolves the conflict.

(2) The required regulatory response substantially duplicates a requirement of another California State or federal regulatory program, or a treaty or international trade agreement, without conferring additional public health or environmental protection benefits.

V. Key Implementation Milestones

	MILESTONE	TIMEFRAME
1	First Candidate Chemicals list	Effective date of the regulations
2	First (proposed) Priority Products list [(1)]	180 days after the regulations effective date
3	Priority Product Notification	60 days after listing on final Priority Products list [(2)]
4	Alternate Process AA Work Plan due to DTSC	60 days after listing on final Priority Products list
5	Preliminary AA Report due to DTSC [(2) (3)] *(or Removal or Replacement Notification)*	180 days after listing on final Priority Products list
6	Final AA Report due to DTSC [(3) (4)] *(or Removal or Replacement Notification or AAT Exemption Notification)*	1 year after the notice of compliance for the Preliminary AA Report; or 18 months after the notice of compliance for the Alternate Process AA Work Plan
7	Regulatory Response Implementation *(or Removal or Replacement Notification)*	To be specified by DTSC in the regulatory response determination notice

(1) The Priority Products list will be reviewed and, if needed, revised at least once every 3 years.

(2) DTSC may specify (in the Priority Products list) a different deadline for the Priority Product Notification and/or Preliminary AA Report.

(3) A one-time 90-day extension may be requested for the Preliminary or Final AA Report, or both.

(4) The Preliminary AA Report or Alternate Process AA Work Plan may include a request (subject to DTSC approval) for up to a total of 24 months (or up to 36 months if regulatory safety or performance testing is required) to submit the Final AA Report. DTSC may specify an extended due date if determined necessary based on the information in the Preliminary AA Report or Alternate Process AA Work Plan.