

SAFER CONSUMER PRODUCTS
SUMMARY OF PROPOSED REGULATIONS
 Z-2012-0717-04

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.*

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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 Chemicals of Concern (~1,200) based on the work already done by other authoritative organizations, and specify a process for DTSC to identify additional chemicals as Chemicals of Concern (COCs).* *[Article 2, see section II for further details.]*
 - **DTSC** --- The regulations require DTSC to evaluate and prioritize product/COC combinations to develop a list of “Priority Products” for which alternatives analyses must be conducted.* *[Article 3, see section II for further details.]*
 - **Product Manufacturers** --- The regulations require responsible entities (manufacturers, importers, 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 the environment, and maximize the use of feasible alternatives of least concern. DTSC may require regulatory responses for a Priority Product/COC (if the manufacturer decides to retain the Priority Product), or for an alternative product/chemical 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 Chemicals of Concern 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 the list of COCs. *[Article 4]*

B. Applicability [Section 69501(b)]

Except as noted below, the regulations apply to all consumer products that contain a Chemical of Concern, 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. The regulations also do not apply to products used solely to manufacture a product exempted by law.
- (2) Products manufactured or stored in, or transported through, California solely for use outside of California.

C. Responsibility for Compliance

- (1) The regulations [Section 69501.1(a)(54)] define “responsible entity” to include:
 - (i) The manufacturer (i.e., the person that makes the product or the person who controls the specifications and design of, or use of materials in, the product).
 - (ii) The US importer of the product.
 - (iii) Retailers who sell the product in California.

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 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 [Section 69503.7], or alternatively submitting an Alternatives Analysis Threshold Exemption Notification [Sections 69503.5 and 69503.6] or a Chemical of Concern Removal Notification [Section 69505.1(g)];
 - (ii) Performing an AA, and submitting AA Reports to DTSC, for its product; and
 - (iii) Complying with regulatory responses applicable to its product.
- (3) A manufacturer or importer may opt out of complying with the above requirements by demonstrating to DTSC that the product is no longer being sold, offered for sale, distributed, supplied, or manufactured in California. [Section 69501.2 (b)]

A retailer 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 (c)]

If the manufacturer or importer subsequently introduces into the California marketplace a product that replaces (in terms of use and customer bases) the removed Priority Product, and that replacement product contains a Chemical of Concern, the manufacturer or importer must provide a notice to DTSC. [Section 69501.2 (b)]

- (4) 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 lieu of, one or more responsible entity(ies). (This does not apply to the Priority Product Notification or Alternatives Analysis Threshold Exemption Notification requirements.) [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(d)]
- (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(d)]*

- (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 9, Section 69509]*
- (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 product responsible entities and chemical manufacturers/importers. DTSC will maintain on its website a Response Status List that provides information as to how a responsible entity or a chemical manufacturer/importer 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 Chemicals of Concern, petitions concerning the chemicals and products lists, and trade secret protection claims.)

H. Certified Assessors *[Article 8, commencing with Section 69508]*

Any person with responsible charge for conducting an AA must meet specified education and experience requirements. Beginning two years after the regulations become effective, any such individual must also be certified as an assessor by a DTSC-designated accreditation body. The regulations spell out the requirements for assessors and accreditation bodies.

I. Trade Secret Protection *[Article 10, commencing with Section 69510]*

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. Chemicals of Concern (COC) Identification

- (1) Initial List of COCs --- The regulations, as of their effective date, establish an immediate list of ~1,200 chemicals of concern using 22 existing authoritative body lists that: (i) list chemicals on the basis of exhibiting at least one of seven hazard traits (carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, 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 COCs --- DTSC may identify additional chemicals (that exhibit a hazard trait or an environmental or toxicological endpoint) as COCs based on consideration of the following factors [Section 699502.2(b)]:

- Chemical adverse public health and environmental impacts
- Adverse impacts of special consideration
 - Adverse impact(s) for:
 - (i) Sensitive subpopulations
 - (ii) Environmentally sensitive habitats
 - (iii) Endangered and threatened species
 - (iv) Environments in California designated as impaired
 - Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.
- Exposures to the chemical
- Availability of substantiating reliable information
- Availability of safer, functionally acceptable, alternative chemicals

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 COCs and the prioritization of COCs/products.

- (3) Listing Process --- An informational list of those chemicals identified as COCs 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 listing process described in II.D. below. [Section 69502.3]

B. Chemicals of Concern and Product Prioritization

- (1) Product Prioritization Criteria [Section 69503.2(a)]: DTSC will evaluate products to determine the adverse impacts for, and exposures associated with the product to, the COCs in each product based on consideration of the factors listed below. Based on this

evaluation DTSC may list as Priority Products those products that are determined to be of high priority.

- (a) Adverse Impacts and Exposures [Section 69503.2(a)(1)]: The adverse public health and environmental impacts posed by the COC(s) in the product due to exposures during the life cycle of the product, considering:
- Adverse Impacts from the COCs --- The ability of the COC(s) in the product to contribute to or cause adverse public health and/or environmental impacts, considering specified factors, including:
 - Adverse impact(s) for:
 - (i) Sensitive subpopulations
 - (ii) Environmentally sensitive habitats
 - (iii) Endangered and threatened species
 - (iv) Environments in California designated as impaired
 - Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.
 - Exposures --- Public health and/or environmental exposures to the COC(s) in the product, considering:
 - (i) Market presence information for the product
 - (ii) Reliable information regarding public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product, and reliable information demonstrating the occurrence of exposures to the COC(s) in the product
 - (iii) Information concerning the household presence and use of the product, and other products containing the same COC(s)
 - (iv) Public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product during the product's life cycle
 - (v) Product uses, or discharges or disposals, in any manner that would contribute to or cause adverse waste and end-of-life impacts
- (b) Availability of Information [Section 69503.2(a)(2)]: The availability of information to substantiate the adverse impacts and exposures.
- (c) Other Regulatory Programs [Section 69503.2(a)(3)]: The scope of federal and/or other California State laws, and any applicable international trade agreements, under which the product or the COC(s) is/are regulated, and the extent to which these other regulatory requirements address, and provide protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product.
- (2) Key Prioritization Factors [Section 69503.2(b)]: DTSC will give priority to products meeting both of the following criteria:
- The COCs in the product have a significant ability to contribute to or cause adverse public health and environmental impacts.

- There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the COCs in the product in quantities that would contribute to or cause adverse public health or environmental impacts, which may include consideration of how widely the product is distributed in commerce and how widely the product is used by consumers.

C. Process to Evaluate Products *[Section 69503.3]*

- (1) Adverse Impacts and Exposures and Availability of Information --- DTSC will begin the product evaluation and identification process by using available information to evaluate the product's adverse impact and exposure factors, along with the extent of available information.
- (2) Other Regulatory Programs --- DTSC will then assess whether, and to what extent, any of these adverse impacts and/or exposures pathways are adequately addressed by other California and federal laws, and international agreements. DTSC will adjust the prioritization of the product based on whether listing the product as a Priority Product would meaningfully enhance protection of public health and/or the environment in light of any protections already provided under other laws.
- (3) Priority Products --- DTSC may list as a Priority Product one or more products determined to be of high priority after completion of steps (1) and (2) described above.
- (4) Safer Alternatives --- DTSC may consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible, to further adjust the prioritization prior to listing a product as a Priority Product.
- (5) Key Prioritization Factors --- Prior to issuing the proposed and final Priority Products lists, DTSC will evaluate the list for consistency with the key prioritization factors described in B.(2) above, and make adjustments as needed.
- (6) Priority Product Work Plan --- No later than January 1, 2014, 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. The regulations specify conditions under which DTSC may revise the work plan subsequent to its issuance. Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan.
- (7) Initial Priority Products List(s) --- 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 COCs in the product that meet specified criteria.

D. Listing Process *[Sections 69502.3 and 69503.4]*

- (1) Prior to finalizing each augmentation to the initial COCs list, and the initial and revised Priority Products list, DTSC will make the proposed list available for public review and comment for a minimum 45-day period.
- (2) After consideration of public comments on a proposed list, DTSC will finalize and post the final list on its website.

- (3) DTSC will review, and revise as appropriate, the Priority Products list at least once every 3 years.
- (4) The initial proposed list of Priority Products, which will include no more than five products, will be made available for public review and comment no later than 180 days after the effective date of the regulations.
- (5) For some products, DTSC will specify in the Priority Products list the product component, or the homogenous material within a component, that is the required minimum focus of the alternatives analysis for the product.
- (6) Each responsible entity for a product listed on the Priority Products list must provide to DTSC a Priority Product Notification, an Alternatives Analysis Threshold Exemption Notification, a Priority Product Removal Notification, or a COC Removal Notification within 60 days after the product is listed as a Priority Product.

E. Petition Process *[Sections 69504 and 69504.1]*

Any person may petition DTSC to add/remove a chemical to/from the Chemicals of Concern list, or to add the entirety of an existing chemicals list to the list of Chemicals of Concern. Petitions may also be submitted to DTSC to add/remove a product/chemical combination to/from the Priority Products list, or to establish/revise an alternatives analysis threshold for a COC in a Priority Product. A person may not petition DTSC to delist any chemical identified as a COC in the initial list of COCs established by the regulations (see II.A.(1) above), unless that chemical is no longer listed on any of the source lists identified in the regulations. High priority will be given to petitions by federal and other California State agencies that relate to the petitioning agency's legislative 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.

F. Alternatives Analysis Threshold Exemption

- (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 a responsible entity for the product submits an Alternatives Analysis Threshold Exemption Notification to DTSC. *[Section 69503.5(a)]*
- (2) An alternatives analysis threshold exemption applies only to a product in which the concentration of each COC, that is a basis for the product being listed as a Priority Product, does not exceed the applicable alternatives analysis threshold specified by DTSC. *[Section 69503.5(b)]*
- (3) The regulations specify criteria to be used by DTSC when setting the alternatives analysis threshold for each COC in a Priority Product. This includes: (i) the ease or difficulty of removing the COC from the product if the COC is a contaminant rather than an ingredient; (ii) the detection limit for the COC; and (iii) various public health and environmental protection considerations. In no case, may DTSC specify an alternatives analysis threshold that is lower than the detection limit for the COC. *[Section 69503.5(c)]*
- (4) If multiple COCs that exhibit the same hazard trait and/or environmental or toxicological endpoint(s) are identified as the basis for the product being listed as a Priority Product,

DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such COCs. [Section 69503.5(d)]

- (5) The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification [Section 69503.6(a)]. The responsible entity 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 exemption [Section 69503.6 (c) and (d)].

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 and are supported by reliable information. [Section 69505]

B. Alternatives Analyses --- General Requirements

- (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(c)]
 - 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).
- (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(d)]
- (3) Any person with responsible charge for conducting an AA must meet specified education and experience requirements. Additionally, each AA completed two years or later after the effective date of the regulations must be performed, and each Preliminary/Final AA Report submitted two years or later after the effective date of the regulations must be prepared, by or under the responsible charge of an assessor certified by an accreditation body designated by DTSC. [Section 69505.1(e)] (See Article 8, commencing with Section 69508, of the regulations for further details concerning assessor requirements and accreditation bodies.)
- (4) 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 69505.1(f)]

- (5) If a responsible entity reformulates the Priority Product to remove the COC(s), that is/are the basis for the Priority Product listing, without adding a substitute chemical, the responsible entity may submit a Chemical of Concern Removal Notification to DTSC in lieu of conducting an AA and submitting an AA Report. [Section 69505.1(g)]

C. Analysis of Priority Products and Alternatives

- (1) 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 69505.2(a)]
- (2) *The first stage of the AA includes:*
- (a) Step 1, Identification of Product Requirements and Function(s) of COCs [Section 69505.3(b)(1)]:
- 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 substitute 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 substitute 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 substitute chemical(s) must be evaluated in the AA as one of the alternatives to the Priority Product.
- (b) Step 2, Identification of Alternatives [Section 69505.3(b)(2)]:
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.
- (c) Step 3, Initial Screening of Alternative Chemicals [Section 69505.3(b)(3)]:
- 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 chemicals with the COC(s) in the Priority Product.

- The responsible entity must eliminate from further consideration in the AA any alternative chemical that it determines poses equal or greater adverse public health and/or environmental impacts as compared to the COC(s).

(d) Step 4, Consideration of Additional Information [Section 69505.3(b)(4)]:

As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above.

(e) Step 5, Identification of Next Steps [Section 69505.3(b)(5)]:

The responsible entity is required to prepare a work plan and proposed implementation schedule for completion of the second AA stage, as described in (3) below, and preparation and submittal of the Final AA Report.

Abridged AA Report [Section 69505.2(b)]:

A responsible entity, that determines (after completion of steps 1 through 4 above) that a functionally acceptable alternative is not available or feasible, may prepare and submit an Abridged AA Report, in lieu of Preliminary and Final AA Reports, if the responsible entity meets specified requirements.

(3) *The second stage of the AA includes:*

(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives [Section 69505.4(a)]:

- A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if:
 - (i) It makes a demonstrable contribution to the adverse impacts of the Priority Product and/or one or more alternatives under consideration, and
 - (ii) There is a demonstrable difference in the factor's contribution to such impacts between two or more of the alternatives being considered.
- The responsible entity must use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools, to identify the factors listed 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:
 - (i) Multimedia life cycle impacts and chemical hazards:
 - ✓ 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
 - (b) Step 2, Comparison of the Priority Product and Alternatives [*Section 69505.4(b)*]:
The responsible entity must use available quantitative information and analysis tools, supplemented by available qualitative information and analysis 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.
 - (c) Step 3, Alternative Selection Decision [*Section 69505.4(c)*]:
The responsible entity selects the alternative that will replace or modify the Priority Product, or decides to retain the Priority Product.
 - (d) Step 4, Consideration of Additional Information [*Section 69505.4(d)*]:
As part of the second stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above, including reconsideration of factors evaluated in the first stage of the AA.
 - (e) Step 5, Identification of Next Steps [*Section 69505.4(e)*]:
The responsible entity is required to prepare a Final AA Report that includes an implementation schedule for implementing the selected alternative, if any, and/or any proposed regulatory responses.
- (4) A responsible entity may use an AA process that differs from the process described above if certain requirements are met, including [*Section 69505.2(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 a work plan to DTSC for the alternate process no later than 60 days after the product is included on the Priority Products list.

D. Alternatives Analysis Reports

- (1) The Preliminary and Final AA Reports must include the information listed below. All differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report must be identified and explained in the Final AA Report. [*Section 69505.5(a)*]
- An **executive summary** [*Section 69505.5(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 69505.5(c)*]
 - Information regarding the **responsible entity** and the **supply chain** for the product [*Section 69505.5(d)*]
 - Information describing the **Priority Product** and the **COCs** [*Section 69505.5(e)*]

- 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 69505.5(f)]*
- 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 69505.5(f)]*
- 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 69505.5(g)]*
- A description of the **methodology** used to conduct the AA. *[Section 69505.5(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 69505.5(i)]*
- Identification and description of the **alternative selected** to replace or modify the Priority Product (or a decision to retain the Priority Product); the **implementation plan** for the selected alternative, if any; and any **proposed regulatory responses**. *[Section 69505.5 (j) and (k)]*

(2) The information in the Final AA Report concerning the alternative selection decision must include:

- A description of the alternative, if any, selected, and the rationales for the selection decision. This includes an analysis that evaluates and compares the selected alternative 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. *[Section 69505.5(j)(2)]*
- 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. *[Section 69505.5(j)(2)(A)]*
- The rationales for selecting an alternative that retains one or more COC(s) or uses substitute chemicals, if it is determined during the AA that neither the COC(s) nor substitute chemicals are necessary to satisfy the requirements for the Priority Product (i.e., functional, performance, and legal requirements). *[Section 69505.5(j)(2)(B)]*
- A list of all chemicals known, based on available information, to be in the selected alternative that differ in type, or are present at a higher concentration, relative to the chemicals contained in the Priority Product; 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. *[Section 69505.5(j)(2)(C)]*

- (3) After the Final AA Report is submitted, if the alternative selection decision specified in the Final AA Report changes prior to introduction of the new product into the California marketplace, 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. [Section 69505.2(d)]

E. DTSC Review and Determinations for AA Reports [Section 69505.6]

- (1) Within 60 days of receiving an AA Report, DTSC will review the AA Report for compliance with the regulations, and issue a notice of compliance, a notice of deficiency, or a notice of ongoing review. Notices of deficiency will generally give the responsible entity 60 days to remedy the 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), the product will be placed on the Failure to Comply List.
- (2) Notices of compliance for Preliminary AA Reports 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. In the notice of compliance for the Final AA Report, or in a separate notice, DTSC will provide notice of its proposed determination as to whether one or more of the regulatory responses that are triggered by a DTSC determination or other action (as described below) are required. The regulatory response determination does not become final until completion of the regulatory response public notice and comment process described below.

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, where such alternatives are 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 impacts and/or exposures through product or process redesign as opposed to alternatives that use administrative or engineering controls to limit exposures to a COC in a product.
- (3) In selecting regulatory responses, DTSC may consider any or all of the following factors:
 - The likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the product
 - The relative cost-effectiveness of the regulatory response as compared to other possible responses

- The administrative and other burdens that the regulatory response would place upon DTSC, the responsible entities, the product end-users, and the public
- Any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations
- The ease and efficacy of enforcement of the regulatory response

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; and
 - Priority Products that will remain in commerce pending development and distribution of the selected alternative.
- (2) No regulatory response (other than providing supplemental AA Report information if requested by DTSC) will be required for a selected alternative, if DTSC determines that no regulatory response is necessary to prevent or limit adverse public health or environmental impacts. *[Section 69506.3]*

C. Regulatory Response Process *[Sections 69506.1 (b)-(d) and 69506.12]*

- (1) For regulatory responses triggered by a DTSC determination or other action (including use restrictions, sales prohibitions, engineering or administrative controls, and research and development projects), DTSC will notify affected responsible entities of its proposed regulatory response determination.
- (2) The proposed regulatory response determination will also be made available for public review and comment for a minimum 45-day period.
- (3) After consideration of public comments, DTSC will send a final determination notice to the 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) The responsible entity must notify DTSC, and California retailers of affected consumer products, of the applicability of regulatory responses to the responsible entity's product within 30 days.
- (5) The responsible entity must notify DTSC upon completion of the implementation of the required regulatory response, and (if applicable) upon completion of the implementation of the selected alternative.
- (6) 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, if any, and the regulatory response(s).

D. Supplemental AA Report Information [Section 69506.2]

- (1) If required by DTSC, a responsible entity must provide any information DTSC determines is necessary to select and ensure implementation of regulatory responses.
- (2) If required by DTSC, a responsible entity must obtain/develop and provide to DTSC information to fill one or more information gaps identified during the AA, if DTSC determines this information is needed to re-evaluate the initial regulatory response(s) imposed for the product.

E. Self-Implementing Regulatory Responses

The regulations set forth specific circumstances under which the following regulatory responses will always be required, along with implementation due dates:

- (1) Product Information for Consumers. Product information must be provided to consumers (within 12 months) if the alternative product contains a COC in exceedance of the applicable alternatives analysis threshold, 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 69506.4]
- (2) End-of-Life Product Management Program. A responsible entity must establish, maintain, and fund (within 1 year) 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. [Section 69506.8]

F. Regulatory Responses Triggered by a DTSC Determination or Other Action

- (1) Use Restrictions. DTSC may impose specified restrictions on the use of COCs in a product, or restrictions on the use of the product itself, to reduce the amount of a COC in the product, or reduce the ability of the product to contribute to or cause an exposure to the COC in the product. [Section 69506.5]
- (2) Product Sales Prohibition. If the selected alternative contains a COC above the applicable alternatives analysis threshold (or if an alternative is not selected), and DTSC determines there is a safer alternative that does not contain a COC and that is functionally acceptable and technologically and economically feasible, the responsible entity must do one of the following within 1 year (or sooner if required by DTSC) [Section 69506.6]:
 - Ensure that the Priority Product is no longer sold in California; or
 - Submit to DTSC an AA Report that selects an alternative that does not contain a COC.

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 environmental impacts 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 use of the product will adequately protect public health and the environment.

- (3) *Engineering or Administrative Controls.* Under specified conditions, DTSC may impose requirements that control access to or limit exposure to COCs in a product to reduce the likelihood of adverse public health and/or environmental impacts. This may include controls that integrally contain a COC within the structure of a product. [Section 69506.7]
- (4) *Advancement of Green Chemistry and Green Engineering.* DTSC may require a manufacturer to initiate a research and development project or fund a challenge grant 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 69506.9]
- (5) *Other Regulatory Responses.* DTSC may impose one or more regulatory responses described above to situations that may differ from the specific situations described above. DTSC may periodically re-evaluate any regulatory response imposed under this provision. DTSC may also require a new AA to be performed, and new Preliminary and Final AA Reports to be submitted. [Section 69506.10]

G. 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 or federal regulatory program or an 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 or federal regulatory program or an international trade agreement without conferring additional public health or environmental protection benefits.

V. Key Implementation Milestones

	MILESTONE	TIMEFRAME
1	First COC list	Effective date of the regulations
2	First (proposed) Priority Products list ⁽¹⁾	180 days after the regulations effective date
3	Priority Product Notification, AA Threshold Exemption Notification, Priority Product Removal Notification, or COC Removal Notification due to DTSC	60 days after listing on final Priority Products list
4	Work plan proposing alternate AA approach due to DTSC ⁽⁴⁾	60 days after listing on final Priority Products list
5	Preliminary AA Report due to DTSC ^{(2) (3) (4)}	180 days after listing on final Priority Products list
6	Final AA Report due to DTSC ^{(3) (5) (6) (7)}	1 year after the notice of compliance for the Preliminary AA Report
7	Regulatory Response Implementation:	
	<ul style="list-style-type: none"> Product information for consumers (self-implementing) 	1 year after the notice of compliance for the Final AA Report
	<ul style="list-style-type: none"> End-of-life product management program (self-implementing) 	1 year after the notice of compliance for the Final AA Report
	<ul style="list-style-type: none"> Product sales prohibition ⁽⁸⁾ 	1 year after DTSC provides notice of a safer alternative – unless a new AA is submitted within 1 year ⁽³⁾
	<ul style="list-style-type: none"> All other regulatory responses 	To be specified by DTSC in the regulatory response determination notice ⁽⁹⁾

- (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 shorter or longer deadline for the Preliminary AA Report.
- (3) A one-time 90-day extension may be requested for the Preliminary or Final AA Report, or both.
- (4) DTSC review of the Preliminary AA Report (or work plan for alternate AA approach), and a one-time opportunity to correct deficiencies, could take up to 150 days.
- (5) The Preliminary AA Report 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.
- (6) If a work plan is submitted for an alternate AA approach, the time frame for submitting the Final AA Report is 18 months after the notice of compliance for the work plan; and the 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.
- (7) DTSC review of the Final AA Report, and 2 opportunities to correct deficiencies, could take up to 330 days.
- (8) DTSC may specify a shorter deadline for the product sales prohibition or new AA.
- (9) Regulatory response determination notices can be included in the notice of compliance for the Final AA Report, or issued later as a separate notice.