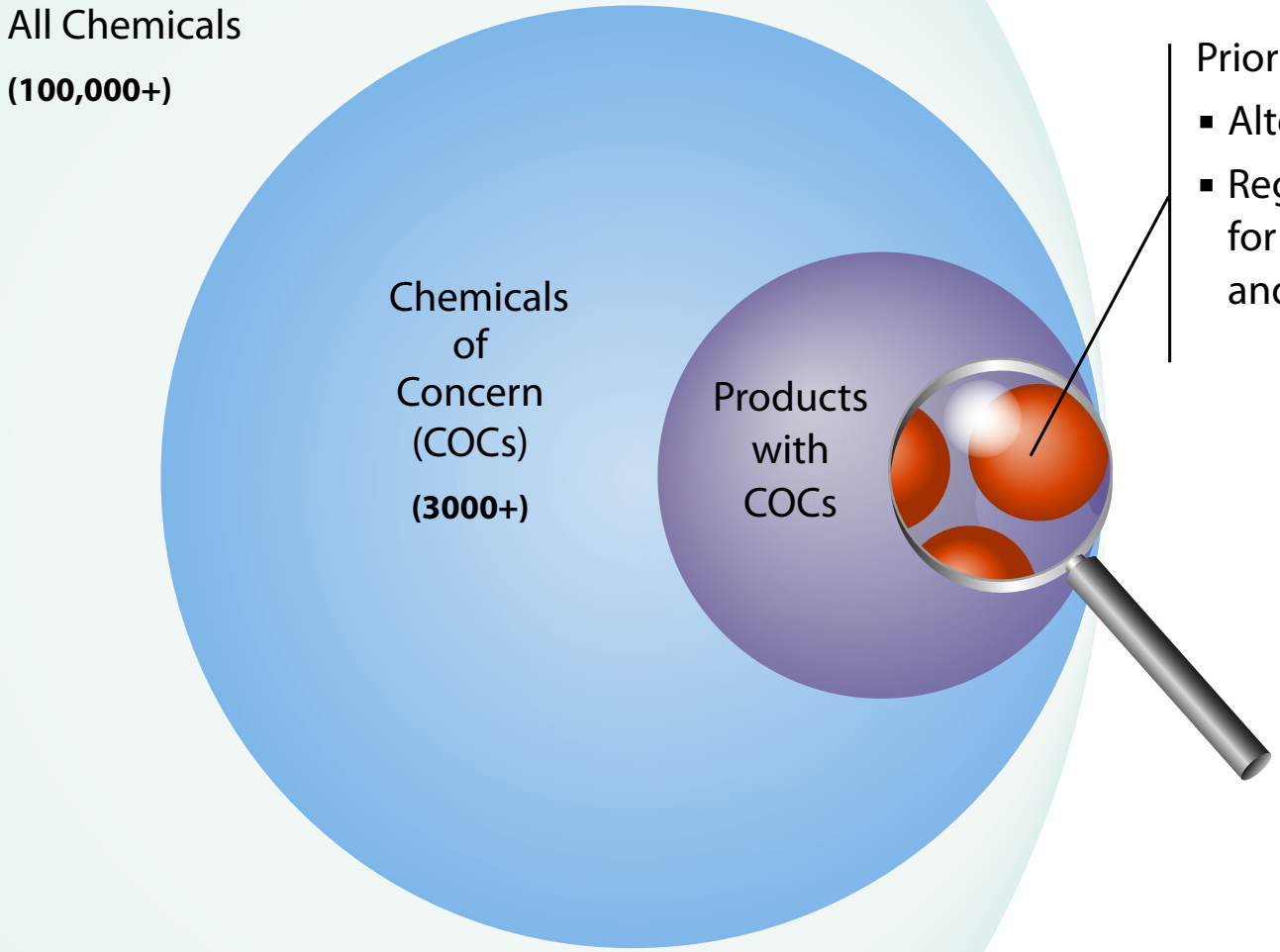
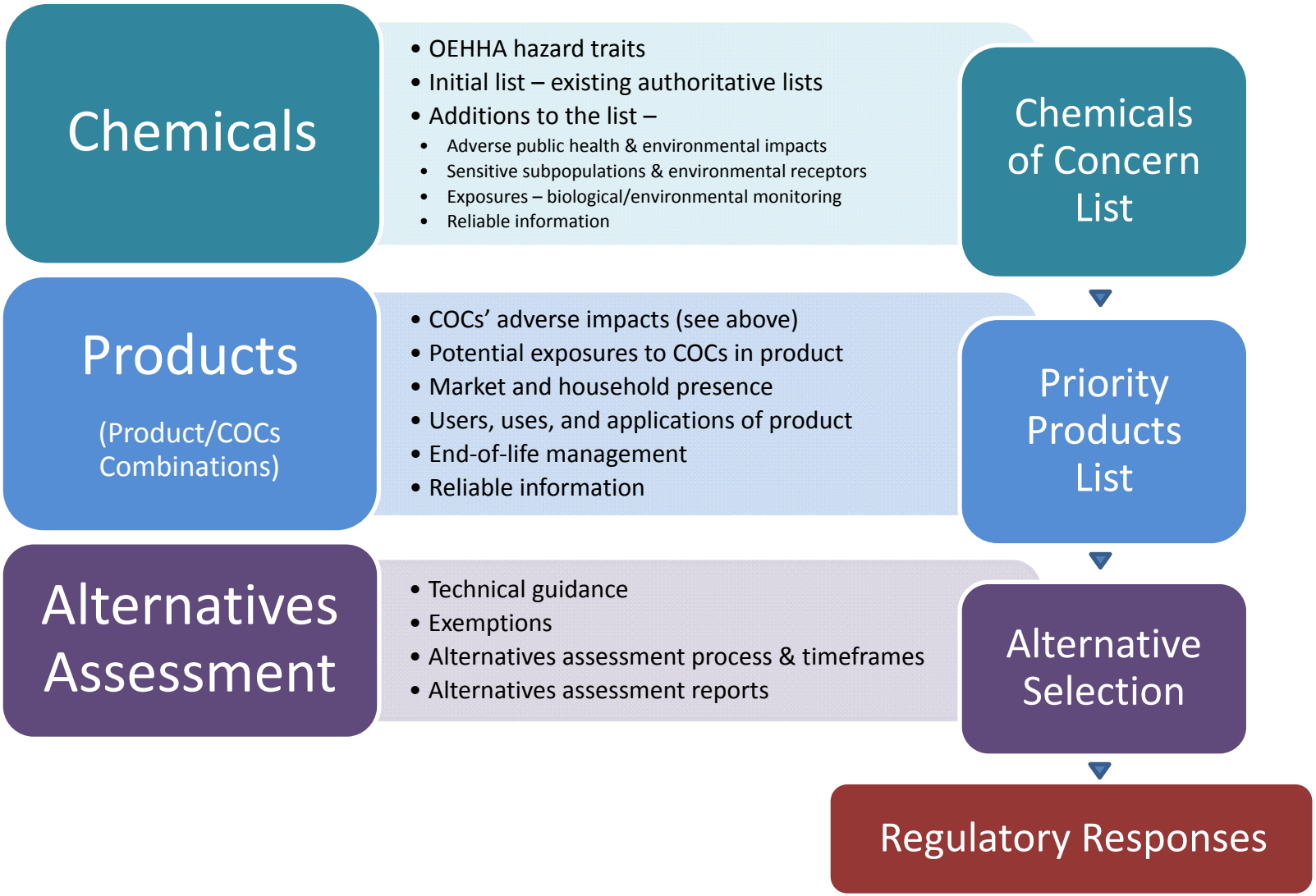
Overview: The Safer Consumer Products Regulations



How It Works: The Safer Consumer Products Regulations



Timeframes

Many **timeframes** have been shortened and/or made more specific; for example:

(1) Timing of **initial Chemicals of Concern (COC) list** --- effective date of the regulations.
[November 2010 draft --- initial COC list was due 12 months after the effective date of the regulations.]

(2) Timing of **initial Priority Products list** --- 6 months for the proposed list.
[November 2010 draft --- initial final Priority Products list was due 24 months after the effective date of the regulations.]

(3) Both the **chemicals and products lists** will be reviewed at least once every 3 years.
[November 2010 draft --- no set time was specified for reviewing and revising the lists.]

(4) The **Final Alternatives Assessment (AA) Report** will be due 12 months after approval of the Preliminary AA Report (unless DTSC determines a longer time period, not to exceed 24 months, is needed).
[November 2010 draft --- due dates set by DTSC, but no restrictions on those due dates.]

Chemical / Product Prioritization

(1) The regulations will establish an *immediate* robust (~3,000) list of **COCs**, based on work already done by numerous authoritative bodies. (DTSC can add on to this list later using a narrative prioritization standard.) This approach will:
- Send immediate signals to the marketplace
- Enable DTSC to immediately start work on evaluating product/COC combinations to create the first Priority Products list
- Stimulate an AA economy
- Be much less likely to motivate early (sometimes regrettable) chemical substitutions

[November 2010 draft --- the initial and subsequent COCs lists would be much smaller, and both would be established using a narrative prioritization standard.]

(2) The list of **hazard traits** has been expanded to include all hazard traits and environmental and toxicological endpoints specified by OEHHA. Additionally, the universe of chemicals considered to be **carcinogens and reproductive toxins** is no longer limited to only those chemicals listed on a short list of lists.
[November 2010 draft --- consideration of chemicals for the first COC list would be limited to carcinogens, mutagens, reproductive toxins, and persistent bioaccumulative toxic chemicals appearing on a very short list of lists. For all subsequent COC lists, consideration of carcinogens and reproductive toxins would continue to be limited to chemicals appearing on a very short list of lists.]

(3) The regulations no longer limit the product categories that DTSC can consider when listing **Priority Products** during the first 5 years.
[November 2010 draft --- for the first 5 years, DTSC would be limited to consideration of only children's products, personal care products, and household cleaning products.]

(4) **Worker exposure** has been added as a product prioritization factor.
[November 2010 draft --- only service-provider worker exposures were specifically included in the product prioritization factors.]

(5) The *requirement* for responsible entities to provide **chemical and product information** during the prioritization process has been eliminated. (DTSC will *request* this information and list anyone who does not provide the information on a Failure to Respond list.)

[November 2010 draft --- providing this information when requested by DTSC would be a regulatory requirement. Any one not complying with this requirement would be listed on the Failure to Comply list and potentially subject to other consequences for non-compliance.]

Alternatives Assessments

(1) The regulations expand the primary **responsibility for compliance** beyond the product producer to also include: (i) the person who controls the product design; and (ii) the U.S. importer.

[November 2010 draft --- primary responsibility for compliance was limited to the product producer.]

(2) The **alternatives assessment** (AA) process is more specific and structured, but allows for flexibility.

[November 2010 draft --- required AA process was much less clearly defined, and less flexibility was provided for using an alternate process.]

(3) There is no requirement to fill **information gaps** during the AA --- instead DTSC has the option to require this as a regulatory response (in conjunction with other appropriate regulatory responses).

[November 2010 draft --- the AA process would have essentially required the generation of new data to fill all data gaps before submitting the AA Report to DTSC.]

(4) The **third-party verification** requirement for AAs has been eliminated --- instead AAs are required to be conducted by a **certified assessor**. Also, DTSC will play a greater role in auditing AAs.

[November 2010 draft --- third-party verification would have been required for all AAs performed in-house. The regulations did not include a certification requirement for persons performing AAs.]

Exemptions

(1) The default **de minimis** level is 0.01% for chemicals with one of 9 specified hazard traits, and 0.1% for all other chemicals --- DTSC can set a lower or higher de minimis level.

[November 2010 draft --- the de minimis level was 0.1% (or the applicable hazardous waste threshold, if lower) for all chemicals.]

(2) The exemption for **unintentionally-added** chemicals has been eliminated. However, these chemicals are a consideration for setting a higher de minimis level.

[November 2010 draft --- unintentionally-added chemicals were exempted from the regulations under specified conditions.]

(3) The **"no exposure pathway"** exemption has been eliminated. However, exposure potential will still be considered during the chemical/product prioritization process.

[November 2010 draft --- the regulations did not apply to a product if DTSC determined that there was no possible exposure pathway by which the COC in the product might impose adverse impacts.]

(4) A manufacturer can no longer avoid doing an AA by simply **removing the COC** once the product is listed as a Priority Product. Removing the product from the California marketplace and introducing another similar product containing a COC will require a notice to DTSC.

[November 2010 --- an exemption from the AA requirement was allowed if DTSC was notified that the COC was removed from the product within 180 days after the product was listed as a Priority Product.]

SAFER CONSUMER PRODUCTS
SUMMARY OF INFORMAL DRAFT REGULATIONS

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

Table of Contents

NOTE: References in the informal draft regulations to Chapter 54 and its sections (69401 through 69407.2) refer to OEHHA's draft regulations entitled "Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse" (dated October 7, 2011).

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 (~3,000) 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 an alternatives assessment 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) for a product listed as a Priority Product must perform an alternatives assessment (AA) for the product and the Chemicals of Concern in the product to determine how best to limit potential exposures to, or the level of potential adverse public health and environmental impacts posed by, the Chemicals of Concern in the product. *[Article 5, see section III for further details.]*

- *DTSC* --- The regulations require DTSC to identify and impose regulatory responses to effectively limit potential adverse public health and/or environmental impacts, if any, posed by the Priority Product/Chemical of Concern (if the manufacturer decides to retain the Priority Product), or the potential adverse impacts posed by the alternative chemical/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 a chemical to the Chemicals of Concern list or a product/chemical combination to the Priority Products list. *[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, supplied, distributed, 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 out-of-state.

(3) A product that DTSC determines is regulated by other federal or California State regulatory programs, or international trade agreements, for the same adverse public health and/or environmental impacts and exposure pathways 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 was listed as a Priority Product.

C. Responsibility for Compliance

(1) The regulations *[Section 69501.2(a)(68)]* 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 a 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 69501.3(a)(1)]*

(2) The regulations *[Section 69501.3(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 69503.6]*, or alternatively submitting a De Minimis Exemption Notification *[Sections 69503.4 and 69503.5]*;
   (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 requirements by demonstrating to DTSC that the product is no longer being sold, offered for sale, supplied, distributed, or manufactured in California. *[Section 69501.3 (b)]*

A retailer may opt out by ceasing to order the product and providing a notification to DTSC, or if the manufacturer/importer ultimately complies. *[Section 69501.3 (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 69501.3 (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). *[Section 69501.3(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 69501.3(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 69501.3(d)]*

(3) DTSC may conduct audits to determine compliance with the requirements of the regulations pertaining to alternatives assessments and regulatory responses. *[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 69501.5]*

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. If a person subject to a request for information fails to provide the information, their failure to do so will be posted on DTSC's website on a Failure to Respond List.

F. Information on DTSC's Website *[Section 69501.6]*

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 in the California Regulatory Notice Register (CRNR) and to persons on DTSC's listserv 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. Any requirement imposed on the responsible entity by DTSC, and posting of information in the Failure to Comply list concerning the non-compliance with that requirement, will be stayed while a dispute is pending.

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

Beginning January 1, 2015, any person with responsible charge for conducting an AA must be certified as an assessor by a DTSC-designated accreditation body. The regulations spell out the requirements for certified 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 --- As of the effective date of the regulations, a chemical is identified as a Chemical of Concern if it exhibits a hazard trait or an environmental or toxicological endpoint (listed in OEHHA's regulations), and is listed or identified by one or more authoritative bodies specified in the regulations. *[Section 69502.2(a)]*

(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)]*:

- Potential chemical adverse public health and environmental impacts
- Adverse impacts of special consideration --- Potential adverse impact(s) for:
  (i) Children, pregnant women, and other sensitive subpopulations;
  (ii) Environmentally sensitive habitats, endangered and threatened species, and environments in California designated as impaired; and
  (iii) Widespread adverse public health and/or environmental impacts.
- Potential and documented exposures
- Availability of substantiating reliable information
- Availability of safer, functionally acceptable, alternative chemicals

Refer to the definitions in the regulations *[Section 69501.2]* 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 additions to the list will be made in accordance with the listing process described in II.C. 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 potential adverse impacts for, and potential exposures 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) Potential Adverse Impacts and Exposures *[Section 69503.2(a)(1)]*: The potential adverse public health and environmental impacts posed by the COC(s) in the product due to potential exposures during the manufacture, useful life, and end-of-life disposal or management of the product, considering:

- Potential Adverse Impacts from the COCs --- The potential for the COC(s) in the product to cause adverse public health and/or environmental impacts, considering

specified factors. This includes consideration of the type and severity of potential adverse impact(s) for:

(i) Children, pregnant women, and other sensitive subpopulations;
(ii) Environmentally sensitive habitats, endangered and threatened species, and environments in California designated as impaired; and
(iii) Widespread adverse public health and/or environmental impacts.

- Potential Exposures --- The potential for public health and/or environmental exposures to the COC(s) in the product in quantities that could result in adverse impacts, considering:
  (i) Market presence information for the product;
  (ii) Reliable information indicating the possibility for public or environmental exposures to the COC(s) in the product, and reliable information demonstrating the occurrence, or potential 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); and
  (iv) The potential for public or environmental exposures to the COC(s) in the product, during the useful life of the product and end-of-life disposal or management of the product.

(b) Availability of Information *[Section 69503.2(a)(2)]*: The availability of reliable information to substantiate the potential adverse impacts and exposures.

(c) Other Regulatory Programs *[Section 69503.2(a)(3)]*: The scope of federal and/or other California State regulatory programs, 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 potential basis for the product being listed as a Priority Product.

(d) Safer Alternatives *[Section 69503.2(c)(4)]*: The existence, if any, of a known readily available safer alternative, that is functionally acceptable and technologically and economically viable.

(2) Key Prioritization Criteria *[Section 69503.2(b)]*: DTSC will give priority to products meeting one or more of the following criteria:

- The COCs in the product pose a significant potential to cause adverse public health and environmental impacts.
- The product is widely distributed in commerce, and widely used by consumers.
- There is a significant potential for public and environmental exposures to the COC(s) in quantities that can result in adverse public health or environmental impacts.
- For assembled products, the product contains COC(s) that may present potential exposures through inhalation or dermal contact.

- For formulated products, the product is intended to be:
  (i) Applied directly to the body;
  (ii) Dispersed as an aerosol or a vapor; or
  (iii) Applied to hard surfaces with the likelihood of runoff or volatilization.

C. Listing Process *[Sections 69502.3 and 69503.3]*

(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 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 COCs and Priority Products lists as least once every 3 years.

(4) The initial 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. *NOTE: DTSC anticipates that the initial list of Priority Products will include 2 to 5 products.*

(5) Each responsible entity for a product listed on the Priority Products list must provide to DTSC a Priority Product Notification or a De Minimis Exemption Notification within 60 days after the product is listed as a Priority Product.

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

Any person may petition DTSC to evaluate a chemical or a product using the chemical identification and/or chemical/product prioritization processes described above. High priority will be given to petitions by federal and other California State regulatory programs that relate to the petitioning agency's legislative and/or regulatory mandates. 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.

E. De Minimis Exemption

(1) A product that is listed as a Priority Product and that meets the criteria for a de minimis exemption will be exempt from the requirement to perform an alternatives assessment, if the responsible entity submits a De Minimis Exemption Notification. *[Section 69503.4(a)]*

(2) A de minimis exemption applies only to products meeting one of the following criteria *[Section 69503.4(b)]*:

- Formulated products --- The cumulative concentration in the product of all COCs that are a basis for the Priority Products listing, and that exhibit the same hazard trait (or environmental or toxicological endpoint) and mode of action does not exceed the applicable de minimis level.
- Assembled products --- The cumulative concentration in each product component that is a basis for the Priority Products listing, of all COCs that are a basis for the Priority Products listing, and that exhibit the same hazard trait (or environmental or toxicological endpoint) and mode of action does not exceed the applicable de minimis level.

(3) The regulations *[Section 69501.2(a)(25)]* define "de minimis level" as a concentration equal to whichever of the following is applicable:
- 0.01% by weight for chemicals exhibiting one of 9 specified hazard traits or endpoints --- bioaccumulation, carcinogenicity, developmental toxicity, endocrine toxicity, genotoxicity, immunotoxicity, neurotoxicity, persistence, or reproductive toxicity.
- 0.1% by weight for chemicals that do not exhibit any of the 9 specified hazard traits and environmental and toxicological endpoints.
- A lower or higher concentration if specified by DTSC in the Priority Products list.

(4) The regulations specify criteria to be used by DTSC when setting a de minimis level that is lower or higher than the default concentration of 0.01% or 0.1%, whichever is applicable. *[Section 69503.4(c)]*

(5) The regulations specify the information that must be included in a De Minimis Exemption Notification *[Section 69503.5(a)]*. The responsible entity is required to notify DTSC if the information in the De Minimis Exemption Notification significantly changes, or the product no longer meets the criteria for a de minimis exemption *[Section 69503.5 (c) and (d)]*.

III. Alternatives Assessments (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 Assessments --- 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(a)]*

- 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.

(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) Each AA completed after January 1, 2015 must be performed, and each Preliminary and Final AA Report submitted after January 1, 2015 must be prepared, by or under the responsible charge of an assessor certified by an accreditation body designated by DTSC. *[Section 69505.1(d)]* (See *Article 8, commencing with Section 69508,* of the regulations for further details concerning certified assessors 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 the most appropriate regulatory response(s). *[Section 69505.1(e)]*

C. Assessment of Priority Products and Alternatives

(1) The regulations require that each AA be conducted 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 *[Section 69505.3(b)(1)]*:

- The function, performance, technical feasibility, and legal requirements associated with the Priority Product that must be met by any potential alternative.
- The function of the COC(s) in meeting the Priority Product's function, performance, technical feasibility, 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, technical feasibility, and legal requirements.
- If it is determined that neither the COC(s) or substitute chemical(s) is/are necessary to meet the Priority Product 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 the potential for 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 potentially 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 information to identify the adverse public health and environmental impacts associated with each chemical being considered as a possible alternative to the COC(s) in the Priority Product.
- Using this information, the responsible entity must compare each of the potential 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 may pose greater adverse public health and/or environmental impacts than the COC(s).

(d) Step 4, Next Steps *[Section 69505.3(b)(4)]*:
The responsible entity is required to develop a work plan and proposed implementation schedule for completion of the second AA stage, as described in (3) below. The work plan must ensure that the Final AA Report is submitted no later than 12 months after DTSC issues a notice of compliance for the Preliminary AA Report, or the responsible entity may request approval for a longer period of time to submit the Final AA Report, not to exceed an additional 12 months.

(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 it would constitute both:
  (i) A demonstrable contribution to the adverse impacts of the Priority Product and/or one or more alternatives under consideration, and
  (ii) A demonstrable difference between two or more of the alternatives being considered, including the Priority Product.

- The responsible entity must use available quantitative information, supplemented by available qualitative information and analysis, 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:
    - ✓ Physical chemical hazards
    - ✓ Adverse public health and environmental impacts
    - ✓ Physicochemical properties
    - ✓ Environmental fate properties
    - ✓ Materials and resource consumption impacts
    - ✓ Adverse waste and end-of-life impacts
  (ii) Product function and performance
  (iii) Economic impacts

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

(b) Step 2, Comparison of the Priority Product and Alternatives *[Section 69505.4(b)]*:
The responsible entity must use available quantitative information, supplemented by available qualitative information and analysis, 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.

(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(b)]*:

- 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 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 Assessment 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 **supply chain** for the product *[Section 69505.5(d)]*
- Information regarding the **facility(ies)** where the Priority Product is produced *[Section 69505.5(e)]*
- Information describing the **Priority Product** and the **COCs** *[Section 69505.5(f)]*
- A description of the **methodology** used to conduct the *AA* *[Section 69505.5(g)]*
- 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(h)]*
- 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(i)]*
- 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 be relevant. *[Section 69505.5(j)]*
- 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(k)]*
- Identification and description of the **alternative selected** to replace, reformulate, or redesign the Priority Product; the **implementation plan** for the selected alternative; and any **proposed regulatory responses**. *[Section 69505.5 (l), (m), and (n)]*

(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 assessment 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(l)]*

- A discussion of the functional acceptability of the selected alternative as compared to the Priority Product, and an assessment of the technological and economic feasibility for the selected alternative. If no alternative is selected, this information must be provided for each alternative considered. *[Section 69505.5(l)(1)]*

- 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, technical feasibility, and legal requirements). *[Section 69505.5(l)(2)]*

- A demonstration that the manufacture, use, and disposal of the selected alternative, in conjunction with any proposed regulatory response(s), will have no greater significant adverse public health or environmental impacts than the impacts associated with the Priority Product. *[Section 69505.5(l)(3)]*

- A list of all chemicals known, based on available information, to be in the selected alternative that differ in type, or are present in a higher concentration, relative to the chemicals contained in the Priority Product; available chemical identification and description information for those chemicals; and available hazard trait and environmental and toxicological endpoint information for those chemicals. *[Section 69505.5(l)(4)]*

(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 69505.3(a)(6)]*

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 or a notice of deficiency. 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 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 finding (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. Applicability

(1) The regulations specify regulatory responses that will, under specified conditions, apply to *[Section 69506]*:
- 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) The regulatory responses include self-implementing regulatory responses and regulatory responses triggered by DTSC determinations.

(3) Regulatory responses (other than providing additional information to DTSC per *Section 69506.1*) will not be required for a selected alternative product, if both of the following are demonstrated to DTSC's satisfaction *[Section 69506.2]*:
- The selected alternative does not contain a COC (or a combination of COCs exhibiting the same hazard trait, or environmental or toxicological endpoint, and mode of action) above the applicable de minimis level; and
- The selected alternative does not pose a potentially significant adverse public health or environmental impact.

B. 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 de minimis level, or if the manufacturer chooses to retain the Priority 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]*

(2) *End-of-Life Product Management Program.* A responsible entity must establish, maintain, and fund (within 2 years) 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 69506.4]*

C. Regulatory Responses Triggered by Specified DTSC Determinations
Each of the following regulatory responses will be triggered by DTSC determinations:

Additional Information. *[Section 69506.1]*

- If required by DTSC, a responsible entity must provide any information DTSC determines is necessary to determine and ensure implementation of regulatory responses.
- 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.

Product Sales Prohibition. If the selected alternative contains a COC (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 69506.5]*:

- Ensure that the Priority Product is no longer sold in California, and ensure that an inventory recall program for the Priority Product is implemented and completed within 3 years; or
- Submit to DTSC an AA Report that selects an alternative that does not contain a COC.

Other Regulatory Responses. DTSC may also require any of the following as regulatory responses that it determines are necessary to limit potential exposures to, and reduce the level of potential adverse public health or environmental impacts posed by, a selected alternative or a Priority Product *[Section 69506.6]*:

- Additional information as required by DTSC
- Product information for consumers
- End-of-life product management program
- Product sales prohibition
- Engineered safety measures to control access or limit exposure to the COC in a product
- Restrictions on the use of the COC
- Research and development project or challenge grant
- New alternatives assessment

D. Regulatory Response Exemptions *[Section 69506.7]*
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.

E. Regulatory Response Process *[Sections 69506.8 and 69508.9]*

(1) For the non-self-implementing regulatory responses (i.e., the responses triggered by a DTSC determination), 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 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.

(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 Report 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).

V. Key Implementation Milestones

	MILESTONE	TIMEFRAME
1	First COC list [(1)]	Effective date of the regulations
2	First (proposed) Priority Products list [(1)]	180 days after the regulations effective date
3	Priority Product Notification or De Minimis Exemption Notification due to DTSC	60 days after the Priority Products listing
4	Work plan proposing alternate AA approach due to DTSC [(4)]	60 days after the Priority Products listing
5	Preliminary AA Report due to DTSC [(2) (3) (4)]	180 days after the Priority Products listing
6	Final AA Report due to DTSC [(3) (5) (6) (7)]	12 months after the notice of compliance for the Preliminary AA Report
7	Regulatory Response Implementation:	
	• Product information for consumers (self-implementing)	12 months after the notice of compliance for the Final AA Report
	• End-of-life management program (self-implementing)	2 years after the notice of compliance for the Final AA Report
	• Product sales ban and inventory recall [(8)]	1 year (sales ban) and 3 years (inventory recall) after DTSC provides notice of a safer alternative -- unless a new AA is submitted within 1 year [(3)]
	• All other regulatory responses	To be specified by DTSC in the regulatory response determination notice [(9)]

(1) The COCs and Priority Product lists 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 to submit the Final AA Report.

(6) If a work plan is submitted for a proposed 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 30 months 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 ban and/or inventory recall, 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.