

ADDENDUM
FINAL STATEMENT OF REASONS
Safer Consumer Products Regulations

DEPARTMENT OF TOXIC SUBSTANCES CONTROL REFERENCE NUMBER: R-2011-02
OFFICE OF ADMINISTRATIVE LAW NOTICE FILE NUMBER: Z-2012-0717-04
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The Department of Toxic Substances Control (DTSC) is adding the information presented in this Addendum to the final rulemaking file for the proposed Safer Consumer Products Regulations to supplement the Final Statement of Reasons document submitted to the Office of Administrative Law on July 18, 2013.

I. COST IMPACTS

Section III, Economic Impact Analysis, and Section VI, Evidence Supporting A Determination That The Regulations Will Have No Significant Adverse Economic Impact On Business, of the Final Statement of Reasons are supplemented by incorporation by reference of the following sections of the Updated Informative Digest found at Tab T:

- Cost Impacts Background Information
- Impacts on Local Agencies or School Districts
- Fiscal Impact
- Housing Costs
- Determination of Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete
- Statement of the Results of the Economic Impact Assessment
- Cost Impacts on Representative Person or Business
- Business Report
- Small Business

The above listed information incorporated by reference addresses the full range of cost impact information concerning the proposed regulations, and provides more in-depth information to supplement the information found in the Final Statement of Reasons.

II. ALTERNATIVES DETERMINATION

Section V, Reasonable Alternatives Considered, of the Final Statement of Reasons is supplemented by incorporation by reference of the section entitled "Alternatives Determination" from the Updated Informative Digest found at Tab T. The incorporated language reads:

“DTSC has determined that no reasonable alternative considered by DTSC or that has otherwise been identified and brought to DTSC's attention would be: (i) more effective in carrying out the purpose for which this regulation is proposed; (ii) as effective as and less burdensome to affected private persons than this regulation; or (iii) more cost-effective to affected private persons and equally effective in implementing the statutory policy of other provision of law implemented by this regulation.

Alternatives considered are described in the Final Statement of Reasons for these regulations.”

III. DETAILED STATEMENT OF REASONS

Updated Summary of Nonsubstantive Changes to the Regulations

(1) Section 69505.9(a)(4)

The Final Statement of Reasons noted that this subsection was deleted from the regulations for the following reason:

“Section 69505.9(a) specifies the factors for DTSC to consider when reviewing Alternatives Analysis Reports for compliance with the requirements of Article 5 of the regulations. The stricken text read – “Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA Report were determined using reliable information.” Section 69505.9(a)(3) reads – “Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable.” Although there is a very minor difference in the wording of these two provisions, there is no difference in the meaning and effect of the provisions. Therefore, section 69505.9(a)(4) has been deleted to avoid unnecessary and confusing duplication.”

After further review of the explanation provided for this change, DTSC is clarifying that while Sections 69505.9(a)(3) and (a)(4) are not absolutely identical in their wording and could potentially be viewed as having minor differences in meaning, Section 69505.9(a)(4) nonetheless is unnecessary as the same ultimate objective is achieved under 69505.9(a)(3).

(2) Additional Nonsubstantive Changes

Since submittal of the Final Statement of Reasons to the Office of Administrative Law, the following additional nonsubstantive changes have been made to the proposed regulations:

- Section 69501.1(a)(18) defined "bioaccumulation" to mean "bioaccumulation, as specified in section 69405.2." However, Title 22, California Code of Regulations, section 69405.2, which is part of the Office of Environmental Health Hazard Assessment's hazard trait regulations, uses the term "bioaccumulation hazard trait" instead of "bioaccumulation." Therefore, for clarity and consistency, section 69501.1(a)(18) has been revised to define "bioaccumulation" (for purposes of the Safer Consumer Products regulations) to mean "the bioaccumulation hazard trait, as specified in section 69405.2." For the same reason, a comparable revision has been made to section 69501.1(a)(46), which defines the term "persistence."
- Former section 69501.3(b) has been stricken from the regulations. This section would have required all documents submitted to DTSC under the regulations to be in English, and in an electronic format specified by DTSC. The reference to "specified by the Department" was intended to provide for a case-by-case specification worked out between the individual submitting the information and DTSC. However, after consultation with the Office of Administrative Law, DTSC has decided to delete subdivision (b) because the intent of this provision was not made clear by the actual text. DTSC will be proposing future revisions to section 69501.3 to reinstate this provision using wording that more clearly expresses the intent.
- Paragraphs (C) and (D) of section 69501.4(a)(1) have both been revised by adding "for each person from whom information is requested" at the end of each paragraph. This language is being added to make it clearer that, when requesting the submission of information under these paragraphs, DTSC will identify a case-by-case submission due date specific to each person from whom information is requested.
- Subsections (c) and (d) of section 69502.3 (and the cross-references to these provisions in section 69502.3(a) and (b)) have been stricken from the regulations. The procedures specified in section 69502.3(c) and (d) were intended to apply to additions to the Candidate Chemicals list made using the criteria in section 69502.2(b). Since additions to the Candidate Chemicals list based on the criteria in section 69502.2(b) will be done using the Administrative Procedure Act process, the provisions of sections 69502.3(c) and (d) are unnecessary and confusing. To provide further clarity, section 69502.3(b) has been revised to explicitly require that additions to the Candidate Chemicals list, based on the criteria in section 69502.2(b), be made using the Administrative Procedure Act rulemaking process.

- Section 69504(b)(1) has been stricken from the regulations (and the subsequent paragraphs in section 69504 renumbered). The deleted language stated that a person may not petition DTSC to delist any chemical identified as a Candidate Chemical because it was listed on one of the lists specified in section 69502.2(a) unless the chemical is no longer listed on any of these lists. This provision is unnecessary and confusing since a chemical that is removed from all lists specified in section 69502.2(a) on which the chemical previously appeared would automatically be removed from the Candidate Chemicals list. Most of the lists identified in section 69502.2(a) are essentially "living" lists, and so by operation of section 69502.2(a), a chemical added to these lists becomes a Candidate Chemical by definition; and if a chemical is no longer on any of the lists, the chemical is no longer a Candidate Chemical by definition. (For those lists identified in section 69502.2(a) with a specific date or report number, the concept of a chemical being removed from such a list does not apply, as these lists are essentially "frozen in time" for purposes of section 69502.2(a).)
- Section 69509.1(a) has been stricken from the regulations. The deleted language provided that DTSC may review a trade secret claim for compliance with the regulations upon receipt of the trade secret claim or at any time thereafter. This language is being deleted since it does not provide clarity as to when or under what circumstances DTSC will review trade secret claims. However, DTSC will propose future revisions to section 69509.1 to require that DTSC review a trade secret claim prior to disclosure of information subject to the claim of trade secrecy. This will assure information submitters that DTSC will not release information that is covered by a valid trade secrecy claim, and assure the public that DTSC will not withhold information based on an invalid trade secrecy claim.
- Section 69509.1(c) has been stricken from the regulations. The deleted text required DTSC to provide notice to the submitter of a trade secret claim if DTSC determines that the information provided in support of the trade secret claim does not meet the substantive criteria for trade secret designation. This language is being deleted because it does not provide sufficient clarity as to the criteria to be used by DTSC for denial of a trade secret claim. DTSC will propose future revisions to section 69509.1 to specify the trade secret denial criteria.
- The reference to section "69501.1(a)(1)(58)(E)6." in the Final Statement of Reasons actually refers to section "69505.1(a)(58)(E)6."

- Minor grammatical, sentence structure, section numbering, cross-reference corrections, and other non-substantive corrections and clarifications have been made to the following sections of the regulations (in addition to those sections previously identified in the Final Statement of Reasons), without impact to the effect of the regulations: 69501.1(A)(62), 69501.3(b), 69503.4(d), 69503.5(a)(2) and (b)(3), 69504.1(a), 69505.4(c)(1)(E)2., 69505.9((b)(2) and (b)(3), 69505.9(c)(2)(B)2. and (c)(3), 69506.1((a)(4) and (d), and 69506.6 (title).

Updated Summary and Rationale

The information below replaces and/or updates the summary and rationale provided in the Final Statement of Reasons for the following sections of the proposed regulations, consistent with the nonsubstantive changes identified above for these sections:

Section 69501.1(a)(18) – The following text replaces the first paragraph of the summary and rationale for section 69501.1(a)(18):

Section 69501.1(a)(18) defines “**bioaccumulation**” to mean the same as OEHHA’s definition of "bioaccumulation hazard trait" found in section 69405.2. “Bioaccumulation” is used in this regulation as both a hazard trait and an environmental fate property. Defining bioaccumulation in this manner is necessary to be consistent with the OEHHA hazard traits, as is required by the authorizing legislation.

Section 69501.1(a)(46) – The following text replaces the first paragraph of the summary and rationale for section 69501.1(a)(46):

Section 69501.1(a)(46) defines “**persistence**” to mean the same thing as the definition of “environmental persistence hazard trait” in section 69405.3 of OEHHA’s regulations. In effect, this cross reference is necessary to ensure the term is consistent with the related Chapter 54 regulations regarding hazard traits.

Section 69501.3(b) – The summary and rationale for this section is no longer necessary or pertinent since this section has been deleted from the regulations.

Section 69501.4(a)(1)(C) and (D) – The summary and rationale provided below replace the summary and rationale provided in the Final Statement of Reasons for these two sections:

Section 69501.4(a)(1)(C) specifies that DTSC may request a product or chemical manufacturer, importer, assembler, or retailer to make existing information available to DTSC in accordance with a schedule specified by DTSC for each person from whom information is requested. This provision is necessary

to establish this important information-gathering tool to assist DTSC in accessing information critical to implementation of these regulations in a time frame that enables DTSC to fulfill its regulatory responsibilities without undue delays due to lack of information. This provision is also necessary to put the affected parties on notice that DTSC may be making these types of information-gathering requests to help implement an effective regulatory program. Note that persons receiving such a request may satisfy the request by either sending the information to DTSC or giving DTSC access to view the information. This provision is also necessary to enable DTSC to work with each person from whom information is requested to determine a time frame for submission of the information that takes into consideration DTSC's information needs, as well as factors affecting the amount of time for the information submitter to make the information available.

Section 69501.4(a)(1)(D) specifies that DTSC may request a product or chemical manufacturer, importer, assembler, or retailer to generate new information and provide it to DTSC in accordance with a schedule specified by DTSC for each person from whom information is requested. This provision is necessary to allow DTSC to request information that is important for its decision-making but that does not yet exist, and to put affected parties on notice that DTSC may be making these types of information-gathering requests to accelerate the chemical/product identification and prioritization, Alternatives Analysis, and regulatory response processes. This provision is necessary to establish this important information-gathering tool to assist DTSC in accessing information critical to implementation of these regulations in a time frame that enables DTSC to fulfill its regulatory responsibilities without undue delays due to lack of information. This provision is also necessary to enable DTSC to work with each person from whom information is requested to determine a time frame for submission of the information that takes into consideration DTSC's information needs, as well as factors affecting the amount of time for the information submitter to generate the new information.

Section 69502.3 – The summary and rationale provided below replace the summary and rationale provided in the Final Statement of Reasons for section 69502.3:

§ 69502.3. Candidate Chemicals List

Section 69502.3(a) specifies that DTSC will make available on its website an informational list of the chemicals initially identified as Candidate Chemicals under section 69502.2(a) within thirty (30) days after the effective date of these regulations. This provision is necessary to ensure that all stakeholders – including responsible entities and other interested parties – are informed as to

the chemicals identified as Candidate Chemicals as of the effective date of the regulations.

This section also requires DTSC to periodically update the informational Candidate Chemicals list to reflect changes to the underlying lists and sources. This provision is necessary to ensure that the informational list of Candidate Chemicals is kept current.

Section 69502.3(b) specifies that DTSC may make additions to or deletions from the Candidate Chemicals list using the factors specified in section 69502.2(b) and the Administrative Procedure Act rulemaking procedures. This provision is necessary to make it clear that DTSC may revise the Candidate Chemicals list to either add or remove chemicals, and to establish the criteria and procedures that DTSC will use for revising the list.

Note that the Administrative Procedure Act rulemaking process will also apply to the addition or removal of chemicals lists to/from the lists identified in section 69502.2(a), as well as the addition or removal of an individual chemical on the basis of the chemical being added to or removed from an update of one of the lists identified in section 69502.2(a) with a specific date or report number.

Section 69504(b) – The summary and rationale for **section 69504(b)(1)** is no longer necessary or pertinent since this section has been deleted from the regulations. Additionally, the summary and rationale provided in the Final Statement of Reasons for **sections 69504(b)(2) and (b)(3)** now apply to renumbered **sections 69504(b)(1) and (b)(2)**, respectively.

Section 69509.1(a) – The summary and rationale for **sections 69509.1(a) and 69509.1(c)** are no longer necessary or pertinent since these sections have been deleted from the regulations.

IV. RESPONSE TO COMMENTS

The summaries and responses to comments found at Tabs D, H, J, L, Mc, O, Q, and S are incorporated by reference into the Final Statement of Reasons. In addition, the responses provided below replace the previously provided responses to the comments identified below that were submitted regarding the July 2012 proposed regulations. The replacement responses supplement, clarify, and/or update the previously provided responses.

- ***In Tab D, Subsection V, “Response to Comments”:***

- (1) The following response replaces the response provided on page 136, in response to comments under “§ 69501.3(b) Format,”:

Implementing these regulations will require extensive coordination between all entities involved. Prior to implementation, there is no way for DTSC to anticipate which format submittals should take and as a result, DTSC has not specified what format information submittals must take in these regulations. There is no reason to conclude it will be identical for all required submittals. DTSC will work with each person from whom information is requested to ensure the accessibility and compatibility of information submitted under the regulations. (As suggested in the comment, internationally recognized formats, such as the International Uniform Chemical Information Database, can be evaluated by DTSC for accessibility and compatibility.)

- (2) The following response replaces the response provided on page 154, in response to comment 5-149 under “§ 69501.5(a)(8) Regulatory Response Exemption Requests and Notifications,”:

In comment 5-96, the commenter recommended that the provision for “regulatory response exemption” under section 69506.11 in the July 2012 version be deleted and be made self-implementing, thus making section 69501.5(a)(8) unnecessary because there would be no regulatory response exemption provision. This comment suggested making the corresponding conforming change to delete section 69501.5(a)(8). However, DTSC did not delete the provision for the regulatory response exemption in the proposed regulations (January 2013) to make it self-implementing, so no conforming changes are needed in section 69501.5(a)(8). For discussion of DTSC’s reasons it chose not to delete section 69506.11, refer to the response to comments on section 69506.11(a) & (b) in this response to comments document.

- (3) The following response replaces the response provided on pages 185-187, in response to comments under “Two-Step Prioritization,”:

DTSC respectfully disagrees with the suggestion to work on only one chemical at a time. This suggestion is short-sighted and does not take into account that the proposed regulations will establish a regulatory program for the long-term. Hence, the regulations include process language that reflect the long-term function of the regulations rather than a “start off slow and then build” approach.

Nonetheless, DTSC has incorporated into the regulations some provisions that accommodate these competing tensions. That is, some provisions reflect an approach that “starts off slow” to accommodate industry concerns of regulating everything at once. For example, in proposed section 69503.6(a), scope of Candidate Chemicals (previously known as COCs) to be considered has been narrowed for the Priority Products list adopted prior to January 1, 2016. Further, section 69503.6(b) limits the initial final list of Priority Products to no more than five (5) Priority Products. DTSC has indicated that it will work on a number of chemicals and products “as resources permit.” Much will depend on the depth and breadth of information known about the chemical.

In response to comments suggesting that DTSC start with well-established hazard traits, that is exactly what DTSC has done in the proposed regulations. The proposed initial list of Candidate Chemicals (previously known as COCs), which is a compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a), has only nine (9) hazard traits out of over 40 different hazard traits identified in Chapter 54.

As expressed in the comment, OEHHA uses the “authoritative bodies” mechanism under Proposition 65. OEHHA notices chemicals under the Proposition 65 program and accepts public comment before the final listing of chemicals on the Proposition 65 list based on the “authoritative bodies” mechanism. In a similar vein, additions to the list of Candidate Chemicals pursuant to section 69502.2(b) will be made through rulemaking under the Administrative Procedure Act (commencing with Government Code section 11340).

In addition, there are many other opportunities for regulated entities to submit information and data (*e.g.*, proposed sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals should or should not be on the finalized list of Candidate Chemicals and/or the Priority Products list.

The initial list of Candidate Chemicals (previously known as COCs) which is a compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a), is intended to set out a scope of chemicals and “jumpstart” the Safer Consumer Products program. The lists are from authoritative organizations charged with protecting public health and the environment and have identified chemicals with regulatory or risk management consequences. These chemicals have in turn been identified in section 69502.2(a) of the proposed regulations. DTSC sought to use the evaluative work these authoritative organizations have done. These authoritative organizations use deliberative scientific processes with opportunity for stakeholder input and comment. By relying

on other authoritative organizations' work, including their recommendations and regulations that support protecting human health or the environment to identify the initial list of Candidate Chemicals, DTSC is able to maximize resources, while minimizing DTSC staff time and costs to California in establishing an initial list of chemicals subject to further requirements under the proposed regulations.

It is important to note that all of the chemicals on the lists in regulations meet criteria as "strong evidence" for toxicological hazard traits or as "evidence" for the exposure potential hazard trait in Chapter 54.

Further, this approach in identifying chemicals with hazard traits for these regulations, is consistent with the authorizing legislation at Health and Safety Code section 25252(b)(2), "In adopting these regulations, the Department shall reference and use, to the maximum extent feasible, available information from other nations, governments and other authoritative bodies that have undertaken similar chemical prioritizations processes...."

Please refer to the Response to Comment 101-21 in Article 5 for discussion on the AA provisions of the regulations. DTSC is not making any changes to the proposed regulations in response to this comment.

- (4) The following response replaces the response provided on pages 188-190, in response to comments under "Narrative Standard,":

DTSC respectfully disagrees that just because the identification and prioritization process identifies many chemicals within its scope, it is inappropriate. The initial Candidate Chemicals list (previously known as COCs list) of approximately 1,200 chemicals is comparable to other chemicals lists from other jurisdictions.

DTSC acknowledges that some manufacturers may wish to take proactive steps to evaluate and possibly remove Candidate Chemicals from their products, even though they are under no obligation to do so. A prescriptive process for identifying and prioritizing chemicals and products, with rigid criteria for DTSC to evaluate and make decisions, may provide a greater level of predictability and certainty to manufacturers for chemicals and products not yet listed as Chemicals of Concern or Priority Products. However, there may also be some negative consequences to that approach as well. More specifically, by definition, a prescriptive process for decision-making entails a fairly rigid adherence to a set of steps and/or specific weighting of various factors or criteria. This, in turn, can be challenging to DTSC, especially since it greatly restricts DTSC from bringing its particular expertise and judgment to bear on a decision.

In addition, a prescriptive process would only reflect decisions based on current science and understanding and creates the possibility that a prescriptive process could ignore new science and understanding for future decisions. While regulations could be amended to reflect new science, by the time the regulations are amended, the regulations may need further amendment because the science has progressed again. There is a valid concern that under a prescriptive approach, DTSC will constantly be behind new science and understanding, will constantly be amending regulations, and will be trapped into making regulatory decisions knowing that the regulatory process will not allow consideration of new scientific understanding of chemicals and products.

In addition, there is a lack of knowledge and experience with a regulatory program of this scope and breadth since this regulatory program is the first of its kind in the world. DTSC consulted with the GRSP, and it was recognized that the processes in regulations need a measure of predictability and certainty. However, the regulations also need to remain relevant and appropriate as the Safer Consumer Products program grows and matures with the need to incorporate advances in science, knowledge, and experience. After considering extensive GRSP and stakeholder input on this issue, DTSC determined that any such benefits would be outweighed by the negative consequences.

For all these reasons, DTSC is not specifying a prescriptive process with a numerical weighting or ranking system for chemicals and products but is instead using a narrative approach that allows DTSC to use best available scientific information and practices to identify COCs (Article 2) and prioritize product-chemical combinations (Article 3). It is necessary for the DTSC to employ a narrative approach to decision-making to effectuate the statutory provisions in a timely and meaningful way, and DTSC takes its responsibility very seriously.

With regards to the commenters' views that the process should be objective, repeatable and transparent, the initial list is a compilation of the chemicals listed on authoritative organizations' lists identified in section 69502.2(a), of the proposed regulations. DTSC sought to use the evaluative work done by the authoritative organizations using deliberative scientific processes with opportunity for stakeholder input and comment. It is important to note that all of the chemicals on the lists in regulations meet criteria as "strong evidence" for toxicological hazard traits or the "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54. In addition, the rationale for inclusion of each of these lists was set out in detail in the ISOR. The process for including these existing chemical lists into these regulations is also transparent and repeatable. That is, the lists are all subject to public notice and comment as a component of the rulemaking package.

As such, DTSC has given extensive explanation regarding why each of the lists was included and describing how each of the authoritative organizations conducts its work and makes scientific judgments. Of course, this process of explanation and inclusion could be repeated any number of times. DTSC does not know what is meant by the process being “objective.” The work of the underlying authoritative organizations is conducted without there being a pre-selected desire or outcome. There is no purely objective means of evaluating chemicals that is universally agreed on or whose results are universally accepted.

Any revisions to the initial list of Candidate Chemicals (previously known as COCs), made pursuant to section 69502.2(b) will be made through rulemaking under the Administrative Procedure Act (APA) (commencing with Government Code section 11340). As mentioned before, there are other opportunities also for the regulated entities to submit information and data (sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals and products should not be in the finalized lists.

A robust list of Candidate Chemicals (previously known as COCs) serves as a market signal for consumers to be aware of what chemicals are in the consumer products they purchase and for manufacturers to take voluntary actions before they may be compelled to do so by the regulations, if they so choose. The compliance requirements are only applicable to the COCs (new definition) present in Priority Products, and the Priority Product listing requires rulemaking pursuant to the APA (commencing with Government Code section 11340). Therefore, there are ample and redundant protections to provide opportunities for public notice and comment before any chemicals and products are subject to regulatory action as Priority Products.

The revisions to both Articles 2 and 3 embody the goals and intent of the authorizing legislation and have clarified the prioritization process to provide regulated entities a more defined prioritization process for screening potential product-chemical combinations and opportunities to review product-chemical combinations proposed by DTSC which are subject to public comment. Accordingly, DTSC is making no changes to the regulations in response to these comments. Please also see the Response to Comment 1-3 under Chemical Prioritization.

- (5) The following response replaces the response provided on pages 228-229, in response to comments under “§ 69502.2(b) Additions to the Chemicals of Concern List,”:

DTSC will further clarify the process for adding chemicals to the Chemicals of Concern list.

In order for a chemical to be identified as a Candidate Chemical (previously known as COC), the chemical must exhibit a hazard trait and/or environmental or toxicological endpoints by considering reliable information on the factors specified in section 69502.2(b).

As explained in the ISOR, section 69502.2(b) specifies the process for adding chemicals to the Candidate Chemicals list (previously known as COCs list) to ensure that the list is updated and relevant. It is important to note that DTSC is not required to consider *all* the factors listed in this section, in *every instance*, for a chemical to be identified as a Candidate Chemical (previously known as COC). But DTSC is required to consider at least one factor for which reliable information is available and to consider potential exposures based on reliable information.

“Reliable information,” as defined, includes studies, information, or reports conducted by or submitted to a local, state, national, or international government agency. The methods and analyses must be scientifically valid and conducted according to generally accepted principles. This would include monitoring data submitted to or conducted by local, state, or international government agencies that would indicate widespread impacts (January 2013). Section 60503.2(b)(1)(C) has been revised to specify the criteria for determining reliability of the non-scientific information in the proposed regulations (April 2013).

It is Important to note that the sources of information specified in the definition of reliable information (section 69501.1(a)(57) in the January 2013 version of the regulations) are viewed by the scientific community as reliable sources for supporting sound, science-based decisions. DTSC has its own expert scientists and toxicologists on staff and is confident that it has the resources that can evaluate scientific studies, whether a single study or multiple studies, to determine the quality of the study and data and make decisions by balancing science and regulatory goals. Further, any revisions will be made with public comment and stakeholder input, thus providing stakeholders the opportunity to review the proposed changes, for quality, reliability, and reproducibility.

Article 4 specifies the petition process for the addition to or removal of chemicals and products from the Candidate Chemical list and the Priority Products list. Article 4 specifies the type of information necessary to be provided to DTSC, such as information that demonstrates a chemical or product poses a threat and should be evaluated for its potential listing as a Candidate Chemical (previously known as COC) or Priority Product, as well as to remove a chemical. Such information may reflect increased knowledge about or a change in market circumstances with

respect to a chemical or product that was original added to either the Candidate Chemical list or the Priority Product list.

DTSC will post an informational list of chemicals identified as Candidate Chemicals (previously known as COCs), under section 69502.2(a), on its website within 30 days of the effective date of these regulations. As specified in section 60502.3(a), DTSC will periodically update this list to reflect changes to the underlying lists and sources from which it is drawn. Proposed revisions made pursuant to section 69502.2(b) will be made through rulemaking under the Administrative Procedure Act (commencing with Government Code section 11340). For these reasons, DTSC is making no changes to the proposed regulations in response to these comments.

- (6) The following response replaces the response provided on pages 235-236, in response to comments under “Delist Chemicals,”:

In response to similar comments, DTSC has revised the proposed regulations to provide greater clarity. The revised language in section 69504(b) institutes a more streamlined approach to delisting as follows:

- The previous version specified:
“A person may not petition the Department to delist any chemical identified as a Chemical of Concern under section 69502.2(a), unless that chemical is no longer listed on any of the lists identified in section 69502.2(a).”
- Revised section 69504 includes the following criteria for limitations on petitions:
 - 1) *A person may not petition the Department to remove an entire chemicals list from the lists specified in section 69502.2(a) until three (3) years after the effective date of these regulations.*
 - 2) *A person may not petition the department to remove a product-chemical combination from the Priority Products list until three (3) years after the effective date of these regulations.”*

This provision is necessary to preclude a wasteful expenditure of scarce DTSC resources during the initial implementation of the regulations on petitions for removal of chemical lists that have been well-established as possessing one or more hazard traits and that are appropriately captured as Candidate Chemicals.

DTSC respectfully declines the suggestion to have a California list-specific process in the regulations for delisting chemicals for the reason stated above. DTSC is making no further changes to the regulations in response to these comments. Please also see Response to Comment 9-54 under Article 4.

- (7) The following response replaces the response provided on pages 253-254, in response to comments under “Update the List,”:

DTSC has considered the recommendations for updating the list of Candidate Chemicals (previously known as COCs). As explained in the ISOR, the initial informational list of Candidate Chemicals is intended to be revised to reflect updates in the science that forms the basis for the source lists.

While DTSC shares a preference with the commenter for a specific schedule for updating the list of Candidate Chemicals (previously known as COCs), DTSC has limited resources to implement the proposed regulations. DTSC does not believe that there is a need or ability to schedule regular updates for the Candidate Chemicals list, as DTSC has no way of knowing how often source lists will be updated. DTSC will monitor the source lists in the early phases of implementation to get a sense for how often the lists are updated. Where appropriate, DTSC will update the Candidate Chemicals list to reflect updates to the sources lists.

The proposed regulations confer a great deal of flexibility on DTSC regarding the scope and number of tasks that it takes on at key points of the regulations’ implementation. Thus, DTSC may shape its workload on major tasks “as resources allow” to ensure that DTSC maximizes the effective use of its resources in implementing the regulations effectively.

- (8) The following response replaces the response provided on page 254, in response to comments under “§ 69502.3(c) Public Notice of Proposed List Revisions,”:

DTSC acknowledges the support. The proposed regulations incorporated extensive input in the process for transparency and information gathering. DTSC will continue to work with stakeholders and interested parties during the implementation of these regulations. Again, no change to the regulations was urged, or is being made in response to these comments.

- (9) The following response replaces the response provided on pages 254-255, in response to comments under “§ 69502.3(c) Public Notice of Proposed List Revisions,”:

DTSC respectfully declines to make any changes to the proposed regulations in response to these comments. The proposed regulations have been crafted in a manner that maximizes the use of existing information. They also include provisions for DTSC to gather information and confer a great deal of flexibility, and include time lines that are reasonable.

In response to the chemical identification process, DTSC respectfully disagrees with the commenter. While these regulations require DTSC to identify the Candidate Chemicals (previously known as COCs), the process involves public comment and stakeholder input. The initial list of Candidate Chemicals (previously known as COCs List) is a compilation of chemicals listed on the authoritative organizations' lists identified in section 69502.2(a) of the proposed regulations. All of the source lists are from authoritative organizations that have been charged with protecting public health and the environment and have identified chemicals with regulatory or risk management consequences. DTSC sought to use the evaluative work of these authoritative organizations that use deliberative scientific processes with opportunity for stakeholder input and comment. As part of these regulations, all of these lists have been subject to extensive public comment opportunities, both during the informal, non-APA public comment periods and under public comment periods in July 2012, January 2013 and April 2013 held under the APA.

For any revisions to the initial list of Candidate Chemicals (previously known as COCs), factors listed in sections 69502.2(b) will be considered to the extent relevant reliable information is available. The choice of chemicals to be identified and placed on the list will be based on the decision-making factors specified in revised, renumbered sections 69502.2(b) and the process specified in section 69502.3. DTSC will consider the factors specified in these sections to sequentially evaluate the chemicals and propose them for listing as Candidate Chemicals (previously known as COCs).

When DTSC makes revisions to the Candidate Chemicals list (previously known as COCs list) pursuant to section 69502.2(b), these revisions will be made through rulemaking under the Administrative Procedure Act (commencing with Government Code section 11340). Stakeholders will have the opportunity to review the proposed revisions and provide comments at that time.

Stakeholders have other opportunities to submit information and data (e.g., sections 69501.4 and 69503.3) to inform DTSC why chemicals and products should or should not be in the finalized lists, as specified in the ISOR. Further, stakeholders may also petition DTSC (Article 4), use the dispute resolution processes (Article 7) or Government Code section 11340.6 to interact with DTSC regarding potential additions to the Candidate Chemicals list. Note, the commenter may also petition DTSC to remove chemicals from the list of Candidate Chemicals (previously known as COCs). Please also refer to Response to Comment 86-17 under section 69502.2(b)(2).

- (10) The following response replaces the response provided on pages 256-257, in response to comments under “§ 69502.3(c) Public Notice of Proposed List Revisions,”:

DTSC respectfully declines to make any changes to the proposed regulations in response to these comments for the reasons set forth below.

Although the two programs, California’s Safer Consumer Products program and the European Union’s REACH program sound similar, the similarity really ends at the goal—“to improve the protection of human health and the environment” and intent of the two programs - “ to enhance innovation and competitiveness of the industry.” The proposed regulations are focused on the quest for safer consumer products in California, while the aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances.

REACH places the burden on chemical companies to provide information on how the chemicals they make affect human health and the environment. REACH has two parts: the collection and sharing of data throughout supply chains, and the authorization of chemicals of higher concern to human and environmental health. REACH time frames are staggered based on volume of chemicals that must be registered for a subsequent risk analysis, which is very different from the Alternatives Analysis required in these proposed regulations for the Safer Consumer Products program. Longer time frames in REACH are necessary, as it tries to fill the data gaps to ensure that industry is able to assess hazards and risks of the substances and to identify and implement the risk management measures to protect humans and the environment.

The proposed regulations focus on all available reliable information to evaluate and identify adverse impacts, as well as substantiating the lack of potential exposure or adverse impacts, including identification of lack of reliable information. The statute mandates DTSC to minimize costs and maximize efficiencies. Clearly, it is more cost-efficient to work with existing data than to have to order, wait for, and create costs for the generation of new data.

The 45-day public notice and comment period is the minimum comment period, and DTSC has the ability to provide a longer comment period if needed. When DTSC proposes revisions to the Candidate Chemicals list (previously known as COCs list) pursuant to section 69502.2(b), this process will be made through rulemaking under the Administrative Procedure Act (commencing with Government Code section 11340). This will provide opportunity for public input on revisions to the Candidate Chemical list pursuant to section 69502.2(b).

As specified in the proposed regulations at section 69502.3(a), DTSC will post an informational list of Candidate Chemicals (previously known as COCs) on DTSC's website within 30 days of the effective date of these regulations.

- (11) The following response replaces the response provided on pages 257-258, in response to comments under “§ 69502.3(d) Website Posting of Final List Revisions,”:

When DTSC proposes to revise the Candidate Chemicals list (previously known as COCs list) pursuant to section 69502.2(b), the process will be made through rulemaking under the Administrative Procedure Act (commencing with Government Code section 11340). As a result, DTSC will solicit, consider, and respond to public comments on these proposed revisions before adopting the revised Candidate Chemicals list. DTSC is not making any changes to the regulations in response to these comments.

- (12) The following response replaces the response provided on pages 266-267, in response to comment 7-3 under “Timeline”:

DTSC notes that although the commenter's point is not completely clear, DTSC will attempt to clarify the process regarding identifying and prioritizing chemicals.

Article 2 describes the process to identify chemicals as Candidate Chemicals (previously known as COCs). This process as laid out in section 69502.2(a) of the proposed regulations for identifying chemicals, establishes a robust initial list of Candidate Chemicals (previously known as COCs) compiled from lists by authoritative organizations.

As explained in the ISOR, DTSC is relying on other authoritative organizations' work, recommendations, and regulations that support protecting human health and the environment to identify the initial list of Candidate Chemicals (previously known as COCs). This will allow DTSC to focus its limited resources, in evaluating product-chemical combinations for listing as Priority Products, on those product-chemical combinations that contain COCs (new definition).

Implementation of the Safer Consumer Products Regulations will be initiated by publishing an informational list of Candidate Chemicals (previously known as COCs list) within 30 days of the effective date of these regulations.

The manufacturers who wish to begin proactive efforts and voluntarily redesign their products may use this initial informational list of Candidate Chemicals (previously known as COCs) as part of their process to make informed decisions regarding

potential chemical alternatives or substitutions, before the regulations compel them to do so. (Note: it is not a given that a product containing a Candidate Chemical will inevitably be identified as a Priority Product.)

Next, DTSC will make the initial proposed Priority Products list available for public review and comment within 180 days after the effective date of these regulations. The proposed regulations require DTSC to establish the Priority Products list through rulemaking pursuant to the APA.

There are many other opportunities for regulated entities to submit information and data (sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals and products should or should not be in the finalized lists. The proposed regulations have been crafted in a manner that maximizes the use of existing information, confers a great deal of flexibility, and time lines are reasonable, with allowance for petitions and extension requests. DTSC is making no changes to the regulations in response to this comment. Please also see Response to Comment 7-3 under Chemical Prioritization and section 69502.2(b).

- (13) The following response replaces the response provided on pages 370-371, in response to comments under “§ 69504 Applicability and Petition Contents,”:

DTSC respectfully disagrees. As stated in the Initial Statement of Reasons (ISOR), the information requested in sections 69504(a)(4) and (a)(5) is necessary to understand the petitioner’s rationale and to deter frivolous petitions. Given that petitions must be submitted with the basis for the petition, it is unlikely that competitors or other organizations would launch frivolous efforts to burden their competitors. The burden would be on the petitioner to provide “reliable information” to DTSC.

Two additional limitations on petitions were added to the January 2013 revision of the proposed regulations regarding chemical lists and Priority Products. As outlined in section 69504(b)(2), a person may not petition DTSC to remove an entire chemicals list from the lists specified in section 69502.2(a) until three years after the effective date of the regulations. Similarly, section 69504(b)(3) now states that a person may not petition DTSC to remove a product-chemical combination from the Priority Products lists until three years after the date the product-chemical combination was placed on the Priority Products list. Because of these limitations set in the petition process, DTSC does not feel that the petition process will allow for effective reopening of the rulemaking process. Accordingly, DTSC is making no changes in response to these comments.

- (14) The following response replaces the response provided on pages 371-372, in response to comments under “§ 69504 Applicability and Petition Contents,”:

The proposed regulations have been revised to limit the petition process and the timing of petitions. Two additional limitations on petitions were added to the January 2013 revision of the proposed regulations regarding chemical lists and Priority Products. As outlined in section 69504(b)(2), a person may not petition DTSC to remove an entire chemicals list from the lists specified in section 69502.2(a) until three years after the effective date of the regulations. Similarly, section 69504(b)(3) now states that a person may not petition DTSC to remove a product-chemical combination from the Priority Products lists until three years after the date the product-chemical combination was placed on the Priority Products list. DTSC believes these limitations will allow the program to unfold without undue delay. Thus, DTSC is making no changes in response to these comments.

- (15) The following response replaces the response provided on pages 375-376, in response to comments under “§ 69504 Applicability and Petition Contents,”:

DTSC respectfully disagrees. The proposed regulations have been revised in response to comments about the large list of chemicals identified as “Chemicals of Concern” and negative implications about products containing chemicals on that list. The proposed regulations have redefined “Chemical of Concern” and the previous definition of Chemical of Concern applies to a new term “Candidate Chemical.” A Candidate Chemical is one that “exhibits a hazard trait or an environmental or toxicological endpoint and is listed on one or more of the enumerated authoritative organizations’ list in section 69502.2(a).” “Chemicals of Concern” and “Priority Products” are listed as such only after DTSC determines that a product contains a Candidate Chemical and that there is the ability for that chemical to contribute to or cause adverse impacts due to exposure to the chemical in the Priority Product. Thus, by definition, a Priority Product containing a Chemical of Concern is a product-chemical combination that poses a threat to human health and/or the environment such that it has been prioritized for the completion of an AA.

With this new structure in mind, DTSC does not find it necessary to “take ownership” of the Candidate Chemical list to allow for removal when chemicals still appear on an enumerated list. The source lists are comprised of chemicals that have been well established as possessing one or more hazard traits and are appropriately captured as Candidate Chemicals. Of course, DTSC will continue to comply with all requirements under the APA to the extent that they are applicable to revisions of the Candidate Chemicals list. DTSC is making no changes to the regulations in response to these comments.

- (16) The following response replaces the response provided on page 450, in response to comment 107-68 under “§ 69505.4(e) Create a Process to Deselect a Priority Product,”:

As indicated in the ISOR, the proposed regulations are consistent with Health and Safety Code section 25252 of the authorizing legislation. The prioritization processes in Articles 2 and 3 focus on Candidate Chemicals that have adverse impacts on public health and the environment. When consumer products are identified as the source of exposure to the Candidate Chemical(s), those products may be listed as Priority Products containing Chemical(s) of Concern (January 2013). They are prioritized, at a minimum, by the following factors:

- (1) The volume of a chemical in commerce in California;
- (2) The potential for exposure to a chemical in a consumer product; and
- (3) Potential effects on sensitive subpopulations, including infants and children.

The goals and intent of AB 1879 are to find alternatives to Chemicals of Concern to reduce adverse public health and environmental impacts, regardless of whether alternatives have been identified or not. Priority Products will be listed with the Chemical(s) of Concern, their hazard traits, and if applicable, whether the entire product or components of the products are under scrutiny. Thus, if a household cleaning product containing a Chemical of Concern is named a Priority Product, household cleaning products containing those Chemical(s) of Concern will be of concern. As such, it is impractical to create a delisting process. However, if a similar cleaning product is manufactured that does not contain the Chemical(s) of Concern, the product will not be a Priority Product. DTSC is making no changes to the regulation in response to this comment.

- (17) The following response replaces the response provided on page 522, in response to comments under “§ 69506.6(d)(1) Notification Product May No Longer be Placed into the Stream of Commerce in California,”:

As stated in the ISOR and pursuant to section 69506.1, prior to issuing or modifying the regulatory response(s) applied to any Priority Product, DTSC will notice and inform all known responsible entities for the product and make the proposed regulatory responses available on its website for public review and comment. Once a regulatory response is applied, it will not be re-evaluated or new ones applied, unless the Priority Product is re-listed and after public comment received, new regulatory responses applied. This approach ensures that factors such as public safety, economics, and societal impacts are adequately balanced and the concerns of stakeholders are voiced and addressed. Product sales restrictions apply to the

product regardless of where the product is sold in California. As such, language specific to discount stores and low-income areas is not necessary.

As stated in the ISOR, the goals and intent of the proposed regulations are to compel the quest toward safer alternatives. As such, it is likely that there will be instances where safer alternatives do not readily exist but the impacts of the Priority Product are so compelling that a product sales prohibition must be applied. Different regulatory agencies have different mandates such as protection of air, water, or public health but seldom a comprehensive mandate to address all media and impacts simultaneously. The approach in Health and Safety Code sections 25251 through 25257.1 that make up the authorizing legislation is the first comprehensive approach taken thus far in the California. Products that have impacts in all media or various stages of their life cycle but whose impact are not comprehensively addressed or seen because of the divergent mandates on multiple agencies will now be evaluated across the life cycle of the product and in all media to more accurately account for the total impacts of the product.

As stated in the ISOR, if a product is adequately regulated and/or it does not pose adverse public health and environmental impacts, it will not get prioritized. However, if a product is not adequately regulated and public health and/or environmental impacts are observed, it may get prioritized. Generally, existing regulatory frameworks address a single medium or a discrete subpopulation and fail to take into account the life cycle impacts which yield a false low impact. The proposed regulations are more comprehensive and will begin to demonstrate that when impacts are combined across the life cycle, impacts that were seen as marginal are in fact of higher concern.

Section 69506.6(b) provides that, in making a determination, DTSC would consider the exposure pathways and the ability to contribute to or cause adverse public health impacts and/or environmental impacts associated with an alternative product or the Priority Product. In response to overarching concerns regarding the use of the term “ability to” in lieu of “potential,” the provisions have been amended, and the term “ability to” has been deleted and “potential” inserted in its place (January and April 2013).

In addition, in response to comments received on section 69506.6(b) and (c) the provisions specifying that the responsible entity must cease placing the product into the stream of commerce in California within one (1) year, unless the notification specifies a shorter period of time, were deleted. As stated earlier, DTSC will take into account the complexity of a Priority Product being removed from the stream of commerce in setting the time line for compliance. Input from all stakeholders

related to a priority product's complexity will be taken into account during the public comment process prior to imposing the applicable regulatory responses.

Section 69501.2, Duty to Comply and Consequences of Non-Compliance, place the primary responsibility to comply on the manufacturer of a Priority Product, meaning a manufacturer must cease placing a Priority Product in the stream of commerce within the period specified when the regulatory response is imposed. However, if a manufacturer fails to comply, the responsibility falls on the importer, and then if still not met, the assembler and/or retailer of the consumer product. A "responsible entity" as defined, means any manufacturer, importer, assembler, or retailer of the consumer product. For a more detailed discussion on the hierarchy of these responsibilities, refer to the ISOR for Article 1 and/or the Article 1 portion of this Response to Comments document and/or the Final Statement of Reasons (FSOR) for Article 1. Retailers of Priority Products that DTSC has listed may wait until the manufacturer and/or importer complies with the Priority Product Notification requirement or must cease ordering the Priority Product within ninety (90) days of DTSC's notice of non-compliance issued to the manufacturer and importer and posted on DTSC's website. The retailer must submit a Priority Product Cease Ordering Notification.

In response to overarching comments related to Article 6, the provisions in Product Sales Prohibition have been moved to section 69506.5 (January and April 2013).

- ***In Tab L, Subsection I, "Response to Comments":***

- (1) The following response replaces the response provided on pages 115-116, in response to comments under "§ 69501.3(b) Format,":

DTSC also recognizes that there may be some instances in which the manufacturer operating outside of California may not speak English as the first language. Despite this situation, section 69501.3(b) requires that all documents submitted to DTSC be in a format accessible to DTSC and in English. This is necessary so as not to burden California taxpayers with having to pay for translation services. DTSC believes the burden is appropriately placed on the manufacturers to seek and hire individuals that can assist them with meeting all of the requirements, including the requirement to submit documents in English.

DTSC is not making any changes to the regulations in response to these comments.

- (2) The following response replaces the response provided on pages 130-131, in response to comments under "§ 69502.2(a) Candidate Chemicals List,":

These comments relate to a previous version of the regulations and do not address a change made in the January 2013 version of the proposed regulations. Thus, these comments address a topic that is outside the scope of the public comment period. Nonetheless, DTSC notes that these comments have been addressed in Article 2 of the July 2012 Response to Comments document. Please see the discussions of Chemical Prioritization, Risk Assessment, and Narrative Standard under section 69502.1, and the discussion of the Initial list of Candidate Chemicals under section 69502.2(a) in the July 2012 Response to Comments document.

DTSC reiterates that the initial list of Candidate Chemicals established by the proposed regulations will be published as informational list of Candidate Chemicals within thirty (30) days after the effective date of the regulations. This informational list will include the hazard traits associated with the chemicals, as identified by the authoritative organization that developed the source list. When DTSC proposes revisions to the Candidate Chemicals list pursuant to section 69502.2(b), this process will be made through rulemaking under the Administrative Procedure Act (commencing with Government Code section 11340).

DTSC is making no changes to the regulations in response to these comments.