Table of Contents

OVERVIEW AND ORGANIZATION

This document summarizes the External Scientific Peer Reviews (ESPR) and public comments on those reviews submitted to the Department of Toxic Substances Control (DTSC) in relation to the Proposed Rulemaking titled *Safer Consumer Products,* which was released for public review and comment on January 29, 2013. This is the second ESPR solicited by DTSC; an initial ESPR was conducted for the proposed regulations dated July 27, 2012. The proposed regulations were subsequently revised in response to comments from the ESPR and the public. The proposed regulations are process in nature. And while the regulations have a scientific foundation, they do not establish a regulatory threshold for protection of human health and/or the environment. In accordance with Health and Safety Code section 57004(a)(2), DTSC submitted four key topics from the proposed regulations that comprise the "scientific basis" and/or "scientific portions" of the proposed rule for review by the ESPR entities. These four topics address the aspects of the proposed regulations that are premised upon, or derived from, empirical data or other scientific findings.

DTSC requested the ESPR entities to begin their reviews on January 30, 2013 and submit their reviews by March 4, 2013 on the four topics listed below.

TOPIC 1

The initial Candidate Chemicals are chemicals listed by one or more of the sources named in the regulations and have hazard traits that have public health and environmental concerns.

The broad list of chemicals is now called the "Candidate Chemicals" list. The regulations define "Candidate Chemical" as a chemical that is a candidate for designation as a "Chemical of Concern" (COC). A "Candidate Chemical" that is the basis for a product-chemical combination being listed as a Priority Product is designated as a "Chemical of Concern" with respect to that product. NOTE: For virtually all practical purposes, this change in terminology does not affect the duties of responsible entities that are subject to the regulations.

Revised regulations include the following two additional lists from authoritative organizations to the initial Candidate Chemicals list:

1. *Chemicals classified as Category 1 respiratory sensitizers by the European Union in Annex VI to European Commission Regulation 1272/2008.*

2. *Chemicals identified as priority pollutants in California under the federal Clean Water Act has been expanded to include section 303(d) chemicals, in addition to the section 303(c) chemicals.*

These lists of chemicals meet the same criteria that were used to identify the sources of chemicals that were in the July proposal. The lists are supported by an authoritative organization, used to limit exposure, and are consistent with similar programs in other states. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are reviewed and updated periodically.

TOPIC 2
Evaluation criteria for prioritizing the product-chemical combinations in Article 3 are sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products. Revised regulations specify the key prioritization criteria as critical factors necessary to identify potential Priority Products. The product-chemical combination identified and nominated for Priority Product listing must meet the key prioritization criteria.

The language for the key prioritization criteria have been clarified to illustrate that they must be met for proposing any Priority Product. Also, the phrase "ability to", as in "The Chemical(s) of Concern in the product have a significant ability to *contribute to or cause adverse public health and environmental impacts" has been replaced with "potential": "There must be* potential *public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product." The revised proposed regulations define "potential" to mean that "the phenomenon described is reasonably foreseeable based on reliable information."*

The revised proposed regulations require DTSC to evaluate product-chemical combinations to determine potential *adverse impacts posed by the Candidate Chemical(s) in the product due to* potential *exposures which must contribute to or cause significant or widespread adverse impacts in order to be prioritized as a Priority Product.*

TOPIC 3

The principles outlined in the proposed regulations that establish the Alternatives Analysis Threshold for COCs that are contaminants in Priority Products is scientifically understood and practical.

In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There is no default Alternatives Analysis Threshold provision for an intentionally added chemical. The list of proposed Priority Products will be subject to California's Administrative Procedure Act (APA). The APA requires proposals to be made public (public noticed) along with various supporting documentation, including statements establishing the necessity of the new requirements. DTSC may use the APA rulemaking process in the future to establish an Alternatives Analysis Threshold for an intentionally added ingredient or to set the applicable level above the PQL for a contaminant, should DTSC determine these to be appropriate.

TOPIC 4
The definitions of the various "adverse" impacts and general usage of the terms "adverse" impacts and "adverse effects" is used throughout the proposed regulations. A qualitative or quantitative determination of adverse impact or effect can be made, and is adequately protective of public health and the environment when reliable information is available.

Minor clarifications were made to these terms, including, in some instances, changing "impact" to "effect", where appropriate.

A list of the ESPR entities and the number assigned to their correspondence is included in Table 1. Each ESPR entity was issued an alpha designation based on their initials and the ESPR entities are listed in alphabetical order. DTSC subsequently numbered each of the comments contained in the letter and collated similar comments together. The designation "JA-1" means comment letter from John Applegate, comment 1 and so forth.

In addition, for the purpose of orderly presentation, the comments have been categorized by the four (4) topic areas submitted for review by the ESPR entities. An index has been provided at the end of the document for quick reference to the page number(s) on which responses to the comments appear.

ENTITY #	TABLE 1 EXTERNAL SCIENTIFIC PEER REVIEW ENTITIES	NUMBER OF COMMENTS
JA	John S. Applegate, J.D.	12
NA	Nicholas A. Ashford, Ph.D.	10
DB	Deborah H. Bennett, Ph.D.	7
NC	Norman L. Christensen, Jr., Ph.D.	4
WF	William H. Farland, Ph.D.	11
GG	George M. Gray, Ph.D.	10
DH	Dale Hattis, Ph.D.	10
OR	Ortwin Renn, Ph.D.	9
JS	Jennifer Sass, Ph.D.	7

Given the narrowed scope of review for the ESPR entities, comments related to topics that were outside of the scope for the ESPR were retained by DTSC for further consideration and are addressed separately in this document. Comments that were out of scope for the ESPR review are also out of scope for the public to comment on as part of the ESPR process and are identified accordingly later in the document.

A public comment period on the ESPR Findings for the January 2013 version of the proposed regulations was held from March 13, 2013 through March 28, 2013. Each comment letter was issued a number in alphabetical order. DTSC subsequently numbered each of the comments contained in the letter and collated similar comments together. The designation “1-1” means comment letter 1, comment 1 and so forth. A list of the public commenters is provided in Table 2.

#	TABLE 2 PUBLIC COMMENTS TO ESPR FINDINGS	NUMBER OF COMMENTS
1	Airlines for America	2
2	Alliance of Automobile Manufacturers	2
3	American Chemistry Council	2
4	Association of Global Automakers	4
5	Boots Retail USA	1

#	TABLE 2 PUBLIC COMMENTS TO ESPR FINDINGS	NUMBER OF COMMENTS
6	Consumer Specialty Products Association	23

TOPIC 1

THE INITIAL CANDIDATE CHEMICALS ARE CHEMICALS LISTED BY ONE OR MORE OF THE SOURCES NAMED IN THE REGULATIONS AND HAVE HAZARD TRAITS THAT HAVE PUBLIC HEALTH AND ENVIRONMENTAL CONCERNS.

The broad list of chemicals is now called the "Candidate Chemicals" list. The regulations define "Candidate Chemical" as a chemical that is a candidate for designation as a "Chemical of Concern" (COC). A "Candidate Chemical" that is the basis for a product-chemical combination being listed as a Priority Product is designated as a "Chemical of Concern" with respect to that product. NOTE: For virtually all practical purposes, this change in terminology does not affect the duties of responsible entities that are subject to the regulations.

Revised regulations include the following two additional lists from authoritative organizations to the list of lists for the initial Candidate Chemicals list:

1. *Chemicals classified as Category 1 respiratory sensitizers by the European Union in Annex VI to European Commission Regulation 1272/2008.*
2. *Chemicals identified as priority pollutants in California under the federal Clean Water Act has been expanded to include section 303(d) chemicals, in addition to the section 303(c) chemicals.*

These lists of chemicals meet the same criteria that were used to identify the sources of chemicals that were in the July 2012 proposed regulations. The lists are supported by an authoritative organization, used to limit exposure, and are consistent with similar programs in other states. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are reviewed and updated periodically.

ESPR Findings on Topic 1

Findings: JA-1, JA-2, JA-4, DB-1, DH-1, NC-1, WF-2, WF-3, OR-1, OR-2, OR-4, JS-1

Findings Summary:

The above findings expressed concern or support in response to Topic 1. In summary, the following findings of support were submitted:

- On the addition of the two new source lists for Candidate Chemicals:
  - The lists are well-founded as they provide additional useful perspective on additional chemicals;
  - The addition of the lists represents a significant improvement and will provide a more comprehensive scientific listing of Candidate Chemicals;
  - The new lists appropriately broaden the Candidate Chemicals list because they will provide for a more complete listing of chemicals that cause potential harm;
  - The new lists are appropriate for the purpose of identifying Candidate Chemicals; and
  - One ESPR entity sees no problem with the addition of the two lists to the list of Candidate Chemicals.
- The use of chemical lists developed by authoritative bodies in California as well as elsewhere in the US and internationally is a scientifically defensible approach to identifying “Candidate Chemicals;”
- One ESPR entity does not see any reason for further changes to the Candidate Chemicals list;
- The revised proposed regulations include no substantial changes in the criteria for selection of lists and chemicals, and they are appropriate;
- The change in terminology from "Chemicals of Concern" to "Candidate Chemicals” provides a clarification. It is now clearer that chemicals only become Chemicals of Concern when they are associated with a product;
- The changes are consistent with the scientific understanding of the potential impacts of these chemicals on human and ecosystem health; and
- The proposed regulations’ consideration of potential identification pathways specified for the European Union’s Registration Evaluation and Authorisation of Chemicals (REACH) regulation, as well as for the existing Federal and state legislations, is sufficient to identify and characterize chemicals.

The ESPR entities also expressed the following concerns and recommendations:

- An ESPR entity recommended using two main criteria for characterizing hazards, such as pervasiveness and ubiquity of exposure; and
- An ESPR entity questioned why the addition is limited to chemicals classified as Category 1 respiratory sensitizers when the same Regulation (EU Regulation 1272/2008) also includes a list of Category 1 skin sensitizers.

Response:

DTSC agrees with the ESPR entities' findings that the addition of these two new lists will provide a more complete listing of chemicals that cause potential harm, and is well founded and scientifically defensible. DTSC also agrees with the findings that the change in terminology from Chemicals of Concern to Candidate Chemicals provides more clarity to the regulated community and the public.

DTSC acknowledges and agrees with the finding that there are Category 1 skin sensitizers in the referenced European Regulations list. DTSC endeavored to start the Safer Consumer Products program with hazard traits, chemicals, and chemical lists that were generally in agreement with the recommendation of the Green Ribbon Science Panel (GRSP) and stakeholders to allow all parties to learn, gain experience, build a knowledge base, and make informed decisions before full scale implementation of these regulations. Also, DTSC sought to have a "manageable" number of chemicals; consideration was given to whether the chemical list adds value to the initial list of Candidate Chemicals; that is, the given chemical list does not excessively duplicate chemicals that are already named by other chemical lists; as well as availability of state resources to implement the Safer Consumer Products program in harmonization with other state programs. No change in the proposed regulations is necessary since many of the skin sensitizers have already been captured by other authoritative lists in the regulations. In addition, there are other opportunities for stakeholders and the 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.

As explained in the ISOR, the Candidate Chemicals list is intended to be revised to reflect updates in the science that forms the basis for the source lists. As new chemicals are found to be important for the purposes of these regulations, DTSC may revise the Candidate Chemicals list using the procedures specified in section 69502.3. This provision requires notice to stakeholders and consideration of public comments prior to amending the Candidate Chemicals list. DTSC may also consider adding chemicals to the Candidate Chemicals list based on petitions received under the petition process set out in Article 4 of the proposed regulations.

DTSC agrees with the finding that pervasiveness and ubiquity of exposure to chemicals should be considered. The evaluation of chemicals for subsequent identification and listing as Candidate Chemicals is based on the chemicals' hazard traits and exposure potential. Section 69502.2(a)(1) of the proposed regulations specifies the hazard traits

to be considered, and section 69502.2(a)(2) addresses exposure potential of the listed chemicals.

Also, when adding additional chemicals to the list of Candidate Chemicals, DTSC will consider reliable information regarding public or environmental exposures to the chemical and reliable information demonstrating the occurrence of exposures to the chemical. As explained in the Initial Statement of Reasons (ISOR) discussion of section 69502.2(b), both a hazard trait and potential exposure are necessary to identify a new chemical as a Candidate Chemical to be added to the Candidate Chemicals list because without exposure, adverse impacts would not occur.

As described in detail in the discussion of section 69502.2(b) of the ISOR, DTSC will consider one or more of the following factors in order to evaluate the potential of any chemical to contribute to or cause adverse public health and/or environmental impacts using reliable information:

1. The chemical's hazard trait(s) and/or environmental or toxicological endpoint(s);
2. The chemical's aggregate effects;
3. The chemical's cumulative effects with other chemicals with similar hazard traits and/or environmental or toxicological endpoints;
4. The chemical's physicochemical properties;
5. The chemical's environmental fate;
6. The chemical's potential to affect human populations and/or aquatic, avian, or terrestrial animal or plant organisms; and
7. The chemical's potential to degrade, form reaction products, or metabolize into another chemical that exhibits one or more hazard trait and/or toxicological endpoint.

One of the basic factors in determining whether or not a chemical should be a Candidate Chemical to consider in evaluating adverse impacts is the chemical's hazard trait(s) and/or environmental or toxicological endpoint(s). A chemical's physicochemical properties provide basic information on a chemical and its behavior in manufacture and uses. Also, physicochemical properties may be used to some extent as predictive indicators of behavior in humans, wildlife, ecosystem, and the environment. The chemical's environmental fate identifies a chemical's behavior and its exposure potential hazard trait, as defined in Chapter 54. The chemical's potential to affect human populations and/or aquatic, avian, or terrestrial animal or plant organisms is also a consideration in the evaluation of adverse impacts.

DTSC is not making any change to the regulations in response to these Findings.

Public Comments on ESPR Findings Topic 1

Comments: 4-1**,** 6-6, 6-20

Comments Summary:

The above comments expressed support or concern with the Findings made by the ESPR related to Topic 1. Commenters agree with the following findings by the ESPR:

- Dr. Applegate –
    - Support for the finding that it is clearer that chemicals only become Chemicals of Concern when they are associated with a product, and thus with exposure from a product; and
- Dr. Sass –
    - Disagree with the finding that the addition of the pollutants from the 303(d) list of the Clean Water Act is a significant improvement to the proposed regulations. Commenter states that this reflects the apparent bias and lack of impartiality of this ESPR entity, and recommends that the 303(d) list be removed.
- Comment notes that a number of ESPR entities have identified concerns about the magnitude of the lists and the substantial burden this will place on DTSC and the regulated community in trying to winnow those lists down to a focused, risk based and high priority set of Chemicals of Concern;
- Commenters recommend that DTSC carefully consider and address the concern of effective use of departmental resources. Related comments suggest that DTSC:
    - Focus on a smaller set of chemicals and endpoints;
    - Remove from consideration chemicals that are under review by international or federal regulatory authorities;
    - Provide exemptions for chemicals in products where there is no exposure pathway;
    - Provide exemptions for chemicals that are present unintentionally; and
    - Refrain from recommending untested alternatives as viable replacement chemicals.

Response:

DTSC agrees with the commenters' support of ESPR entity's finding that the change in terminology, from "Chemicals of Concern" to "Candidate Chemicals" provides a clarification in the proposed regulations.

DTSC has drafted the proposed regulations to comply with the statutory mandates and limitations. By including the chemical lists specified in section 69502.2(a), DTSC accepts the chemical's hazard trait identification by each authoritative organization that is responsible for the particular chemical list. The chemicals on these chemical lists exhibit strong evidence for toxicological hazard traits and evidence for potential exposure to hazard traits. Each of these chemicals lists was evaluated and analyzed for conformance with scientific and policy principles, and each is consistent with the statutory mandate to advance the search for safer chemicals in consumer products.

Thus, the process laid out in section 69502.2(a) identifies chemicals with hazard traits and/or environmental or toxicological endpoints and chemicals with exposure potential. This process establishes a robust list of approximately 1,200 chemicals and identifies the scope of the Safer Consumer Products regulations. A further ranking of chemicals is not conducive to jumpstarting the program. Having a robust list of Candidate Chemicals is necessary for the regulations to send immediate signals to the marketplace about chemicals subject to this program. Manufacturers who wish to begin proactive efforts and voluntarily redesign their products may use this initial list as part of their process to make informed decisions regarding potential chemical alternatives or substitutions to consider.

DTSC notes that the prioritization process will ultimately focus the efforts of the proposed regulations on a much smaller list of Chemicals of Concern in Priority Products, and DTSC is confident that this process will allow for effective use of departmental resources.

DTSC respectfully disagrees with the commenter's objection to Dr. Sass's finding that the addition of the pollutants from the 303(d) list of the Clean Water Act is a significant improvement to the proposed regulations. In support for addition of the 303(d) list, Dr. Sass went on to state that this list includes contaminants that contribute to an impaired water designation. Also, the incorporation of the 303(d) list will address product contaminants such as copper that are recognized by the State of California as a threat to environmental quality.

Further, Dr. Sass highlighted the importance of adding the list of contaminants that impair the quality of water bodies in California by referring to the concern of Tri-TAC (a Technical Advisory Committee representing three California associations: the League of California Cities, California Association of Sanitation Agencies, and the California Water Environment Association) that the "growing tide" of chemical contaminants in receiving waters may compromise the ability of wastewater treatment technologies to operate

effectively. It is unclear what "apparent bias and lack of impartiality" in Dr. Sass the commenter is referring to.

No changes to the proposed regulations are necessary in response to these comments.

TOPIC 2

EVALUATION CRITERIA FOR PRIORITIZING THE PRODUCT-CHEMICAL COMBINATIONS IN ARTICLE 3 ARE SUFFICIENT TO IDENTIFY ALL TYPES OF CONSUMER PRODUCTS CONTAINING CANDIDATE CHEMICALS AS POTENTIAL PRIORITY PRODUCTS. REVISED REGULATIONS SPECIFY THE KEY PRIORITIZATION CRITERIA AS CRITICAL FACTORS NECESSARY TO IDENTIFY POTENTIAL PRIORITY PRODUCTS. THE PRODUCT-CHEMICAL COMBINATION IDENTIFIED AND NOMINATED FOR PRIORITY PRODUCT LISTING MUST MEET THE KEY PRIORITIZATION CRITERIA.

The language for the key prioritization criteria have been clarified to illustrate that they must be met for proposing any Priority Product. Also, the phrase "ability to", as in "The Chemical(s) of Concern in the product have a significant ability to contribute to or cause adverse public health and environmental impacts" has been replaced with "potential": "There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product." The revised proposed regulations define "potential" to mean that "the phenomenon described is reasonably foreseeable based on reliable information."

The revised proposed regulations require DTSC to evaluate product-chemical combinations to determine potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures which must contribute to or cause significant or widespread adverse impacts.

ESPR Findings on Topic 2

Findings: JA-5, JA-6, JA-7, JA-8, DB-2, DB-3, DB-4, DB-5, NC-2, WF-5, WF-6, WF-7, GG-5, DH-3, OR-5, JS-2, JS-3, JS-4

Findings Summary:

The above findings expressed support or concern regarding Topic 2. In summary, the following findings of support were expressed:

- ESPR entity is pleased with the addition of evaluating chemicals with structurally or mechanistically similar chemicals, the addition of workplace presence of the chemical, and the inclusion of releases of the product in schools;

- The descriptions of adverse impacts and exposures are comprehensive and will be effective at identifying potential Priority Products;
- ESPR entity supports the addition of the word “potential;”
- ESPR entity agreed with the change of language from "ability" to "potential;"
- ESPR entity supports the anti-duplication provisions where DTSC will not act on products that are adequately regulated by other governmental agencies;
- ESPR entity found that the changes are important and founded in sound science, and that replacing “a significant ability” with “potential” was especially important;
- ESPR entity found that the regulations provided a scientifically sound approach to prioritizing product-chemical combinations to identify consumer products containing Candidate Chemicals as potential Priority Products;
- ESPR entity found that the approach seems comprehensive, scientifically-sound and should be applicable to a wide range of products; and
- ESPR entity found that DTSC is clearer in its position that the impacts and exposure are “reasonably foreseeable” rather than simply hypothetical when it considered “potential” for adverse impacts or widespread exposure rather than using the term “ability to” cause. This is an important distinction in establishing the criteria for listing Priority Products.

In summary, the following findings of concern were expressed by the ESPR entities:

- There is still much to be defined in determining how DTSC will actually set its priorities in designating particular chemicals with particular hazard traits in particular products. The ESPR entity presented a priority scoring formula that is based on the chemical's potency, intake fraction, and use volume;
- An ESPR entity is concerned with the language in 69503.2(a)(2) noting there appears to be no definition for “significant” or “widespread.” The ESPR entity believes that this criteria is open to variable interpretation;
- The provisions of section 69503.3(b)(4)(B) and (C) are now part of the list of factors to be considered for exposures, which were exemptions in the previous version of the regulations. By placing them in this current list, it seems like one would be expected to evaluate exposures related to these compounds even though there is little chance for exposure. If the desire is to not have these as exemptions, but in some way have some sort of minimal evaluation, this intent should be made more clearly;
- Aggregate exposure for multiple use categories of products containing the same Chemical of Concern should be considered;
- The change of the criterion from "ability to" to "potential" decreases the precision with which Priority Products can be identified. The change makes interpretation

difficult, and increases the possibility of arbitrary judgments about what constitutes "potential" in both adverse and exposure contexts; urged return to the "ability to" language;

- “Significant” or “widespread” adverse impact is not well-defined; recommends prioritization criteria be applied to the chemical, not the product-chemical combination;
- The challenge confronting rule makers is how to assure that the term “potential” means something more substantial than speculation; cautioned that "foreseeability" and "potential" will itself become a point of contention and legal wrangling; "significant and widespread" is undefined, and how much may be open to debate; and
- Presumably, the purpose of 69503.2(b)(3) is to allow the inclusion of a chemical-product combination as a Priority Product if there is such an alternative, or to allow exclusion if no such alternative exists. How is this provision in Article 3 related to the Alternatives Analysis in Article 5? Is it a preliminary alternatives analysis that will be repeated more fully later in the process?

Response:

DTSC agrees with the ESPR entities’ findings that the change from “ability” to “potential” is appropriate and that the regulations clarified that the term reflects when “the phenomenon described is reasonably foreseeable based on reliable information.”

DTSC acknowledges the entity’s finding and the suggested approach in setting priorities on chemicals in products. DTSC, however, respectfully disagrees with the suggested quantitative scoring. DTSC must be mindful that exposure data may not be readily available. The approach of using numerical ranking had been considered before, but DTSC opted to use a narrative approach when prioritizing product-chemical combination.

While there is some value in greater certainty and predictability with a prescriptive process than with a narrative approach, there may also be some negative consequences. More specifically, by definition, a prescriptive process for decision-making entails a fairly rigid adherence to a set of steps and/or specific weighing of factors or criteria. A prescriptive regulatory process can only reflect current science, and creates the likelihood that the process adopted in the proposed regulations would ignore advances in science. While the regulations may be amended to reflect advances in science, by the time the regulations are amended, the regulations may become quickly outdated and need further amendment. Under a prescriptive approach, DTSC

could be constantly behind advances in science and understanding. Not only would this constitute a poor use of limited state resources, it would also limit the regulated community from making positive changes in the chemicals and products that are manufactured.
The regulations need to remain relevant and appropriate as the Safer Consumer Product program grows and matures. The GRSP, while not a consensus-forming body, overwhelmingly supported DTSC's decision not to specify a prescriptive process with numerical weighting or ranking system for chemicals and products. Instead, the GRSP and DTSC both supported the use of a narrative approach that allows DTSC to use best available scientific information and practices to identify and prioritize chemicals and products. It is necessary that DTSC employ a narrative approach to decision-making to effectuate the statutory provisions in a timely and meaningful way.

DTSC is mindful of the ESPR entities' findings on the definitions of "significant," "widespread," and "foreseeable." However, DTSC respectfully disagrees that they require defining in the proposed regulations to meet the intended goals of the program. The terms are used in the proposed regulations in the context of establishing principles that will govern the prioritization process. The terms, as used, have the same meaning as is commonly understood without necessitating a prescriptive threshold to trigger consideration of those factors. A defined threshold would limit DTSC in the application of these terms.

Although there was some support with the change from "potential" to the term "ability to cause," DTSC determined it created more confusion than clarity or specificity. The term "potential," used in earlier versions of the proposed regulations, has been retained in the revised proposed regulations. It is DTSC's intent to consider "potential" for adverse impacts or widespread exposure rather than using the term "ability to" cause; and the term "potential" makes it clear that the impacts and exposure are "reasonably foreseeable" rather than simply hypothetical, given available information. This is an important distinction in establishing the criteria for listing Priority Products. For a more detailed discussion on the appropriateness of the use of the term "potential" please refer to the discussion of Causation in the Response to Comments for the July 2012 version of the proposed regulations.

DTSC agrees with the ESPR entity's finding on section 69503.3(b)(4)(B) and (C) that DTSC is required to evaluate these factors when evaluating exposures. These conditions were exemptions in the regulations dated July 2012, but were subsequently removed in the January 2013 version in response to comments. DTSC agrees that even though a product with Candidate Chemical(s) will be used outside of California, manufacturing, storing, or transporting such product in California exposes workers to

the hazards posed by the chemicals. This provision also addresses life cycle consideration when evaluating products. DTSC does not intend to minimize the importance of these two factors; rather, they will be part of the evaluation, considering all the other factors listed in section 69503.3(b) where no weight of importance will be assigned to each factor.

DTSC agrees that aggregate exposure for multiple use categories of products containing the same Chemical of Concern should be considered. This was made clear in the ISOR example of an exposure to DEHP, a plasticizer that comes from a number of sources. Multiple exposure sources will be considered in assessing a chemical's ability to contribute to or cause adverse public health impacts.

DTSC agrees in part with the ESPR entity's recommendation that the prioritization criteria be applied to the chemical, not the product-chemical combination. Or, more precisely, the proposed regulations require DTSC to evaluate product-chemical combinations in a manner that includes evaluation of the chemicals to identify consumer products containing Candidate Chemical(s) and propose listing as a Priority Product. The product-chemical combination must meet both of the following criteria:

1. Potential public and/or aquatic, avian or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
2. Potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

The relevant information that is obtained on the Candidate Chemical is further evaluated for its physical traits and toxicity profile that may have an impact when it is in a consumer product. Additionally, when there are a number of products being evaluated at the same time that contain the same Candidate Chemical, this information may, in balancing information throughout the entire evaluation process, serve to tip the scales to list one particular product, containing a Candidate Chemical, as a Priority Product over another. This is necessary to further evaluate the public health and environmental significance of the Candidate Chemical in a given consumer product—as opposed to the chemical in the abstract.

As stated above, the regulations require consideration of information about both Candidate Chemicals per se` and consumer products and chemicals in combination. Evaluating and examining the information about both these aspects, will allow for flexible decision-making regarding which of the products should be listed as Priority Products. Because the decision-making process to designate a product as a "priority" is based on a variety of non-weighted information, DTSC has continued to use a narrative

approach to describe its priority setting decisions. This is more appropriate for this program than a quantitative weighting scheme, given the typical available information and the differences one would see from product to product. As indicated in section 69503.3, DTSC will use a wide-range of available information to consider and evaluate the potential adverse impacts and widespread exposure. Given the broad range of characteristics related to adverse impact and exposure parameters specified for evaluation over the lifecycle of the product within the regulations, this approach is comprehensive, scientifically-sound and should be applicable to a wide range of products for prioritizing diverse patterns of product-chemical combinations.

DTSC agrees with the ESPR entity's interpretation of section 69503.2(b)(3). When identifying a product-chemical combination, DTSC may, consistent with section 69503.2(b), consider whether there is a readily available safer alternative. DTSC also clarified that this provision is not a substitute for the Alternatives Analysis process required under Article 5. Identification of available safer alternatives may be done through available information, including, but not limited to, literature review, or information from manufacturers or vendors on existing products not using Chemicals of Concern or Candidate Chemicals. DTSC acknowledges the ESPR entity's recommendation that the provisions of this section and Article 5 should be clarified. DTSC disagrees that the regulations text lacks clarity. Therefore, no changes were made to the regulations. But DTSC will again work to make this as clear as possible in the Final Statement of Reasons.

Public Comments on ESPR Findings Topic 2

Comments: 4-2, 5-1, 6-9, 6-10, 6-11, 6-12, 6-21

Comments Summary:

The above public comments related to Topic 2. Commenters agree with the following ESPR findings:

- Mr. Applegate
  - Commenter agrees that the challenge confronting the rule makers is how to ensure that the term "potential" means something more substantial than mere speculation, without depriving "potential" of the expansiveness necessary to fulfill the preventive legislative mandate.
- Dr. Gray

  - Commenter agrees that the change of the criterion from “ability to” to “potential” decreases the precision with which Priority Products can be identified, and it increases the possibility of arbitrary judgments;
  - Commenter agrees that there will be heightened expectations when the presence of this large number of potential Chemicals of Concern is identified. Yet the priority setting and listing process will begin with only five priority products.
- Dr. Bennett –
  - Commenter agrees with the concern regarding the language in 69503.2(a)(2), specifically where there is a potential for one or more exposures to contribute to or cause significant or widespread adverse impacts;
  - Commenter agrees that “Products” is not well-defined;
  - Commenter agrees with the finding that a chemical with multiple routes of exposure would result in higher priority over a product with a single route of exposure.
- Dr. Sass –
  - Commenter agrees with the finding that it is not clear what either "significant" or "widespread" means;
  - Commenter agrees with the finding that prioritization criteria should be applied to the chemical, not the product-chemical combination.

Response:

DTSC appreciates the public feedback on the ESPR Topic 2 findings. For a detailed discussion on the rationale for accepting or rejecting the ESPR Findings, please see the responses to the ESPR Findings for Topic 2, above. Those responses are applicable here as well, and any further responses on those issues would be redundant.

TOPIC 3

THE PRINCIPLES OUTLINED IN THE PROPOSED REGULATIONS THAT ESTABLISH THE ALTERNATIVES ANALYSIS THRESHOLD FOR COCS THAT ARE CONTAMINANTS IN PRIORITY PRODUCTS IS SCIENTIFICALLY UNDERSTOOD AND PRACTICAL.

In the revised proposed regulations, the Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not be a default Alternatives Analysis Threshold provision for an intentionally added chemical. The listing process for Priority Products will be subject to California’s Administrative Procedure Act (APA). The APA requires proposals to be made public (public notice) with supporting documentation, including statements as to the necessity of the new

requirements. The regulations also provide that DTSC may use the APA rulemaking process in the future to establish an Alternatives Analysis Threshold for an intentionally added chemical in a Priority Product and/or to set an Alternatives Analysis Threshold for a contaminant at a level higher than the PQL (April 2013 version).

ESPR Findings on Topic 3

Findings: JA-9, JA-10, DB-6, NC-3, WF-8, WF-9, GG-7, DH-4, OR-6, OR-7, JS-5, JS-6
Findings Summary:

The above findings expressed support or concern regarding Topic 3. In summary, the following supportive findings were expressed:

- Use of the Practical Quantitation Limit (PQL) as the Alternatives Analysis Threshold (AA Threshold), which the regulations limit to contaminants, is sensible;
- Changes to the AA Threshold were very clear and appropriate;
- The PQL is scientifically sound and it is logical that the AA Threshold would apply only to contaminant chemicals and not to chemicals intentionally added to the product;
- Using the PQL as the AA Threshold limited to contaminant chemicals is scientifically defensible and understandable by the analytic community;
- The new AA Threshold definition in the proposed regulations is reasonable since it removes the issue of the degree of hazard posed by analytically detectable amounts of a Chemical of Concern;
- Supports the changes made to the AA Threshold and the narrow list of exemptions inserted in the language of the regulations; and
- Agrees that the principles outlined in the proposed regulations that establish the AA Threshold as a PQL for a chemical that is present in a Priority Product solely as a contaminant and not intentionally added, is scientifically understood, and may be practical in the majority of cases.

In summary, the following findings of concern were expressed by the ESPR entities:

- The narrowing of the AA Threshold-PQL process will likely result in fewer exclusions from the Priority Products List; so, more Priority Products will be subject to the APA procedures. Consequently, the California Safer Consumer Product Alternative Regulations (CCSPAR) process will be an enormous undertaking requiring greater departmental resources;

- Introduction of new analytical methods may result in possible reduction of the PQL for a COC in a Priority Product. However, such change may not translate to improved analytical performance until sufficient experience is gained with the method and adoption is widespread. Changes in the PQL should be considered at the time of review of the notification;
- Disagrees with an approach focused only on the detection of the chemical, indicating that an approach identifying a significant risk threshold would be more scientifically sound. An approach focused exclusively on detection would be difficult to administer due to the constant advances in analytical chemistry that would make the PQL a moving target;
- A volume-based threshold may be irrelevant for nanoparticles since most of these nanoparticles may have an impact on the environment or inflict harm on human health on the basis of surface exposure rather than on the overall dose; and
- A contaminant chemical may be potentially harmful at trace levels, even below the PQL. When there are "reasonable grounds to believe" that a COC may be present in a product, even as contaminant, and if there is the potential that the product-chemical combination may present a risk even at levels below the PQL, then a threshold exemption should not be issued and DTSC should retain the right to not issue a threshold exemption.

Response:

DTSC agrees with the ESPR entities' findings that the changes made to the AA Threshold as being applicable only to contaminants, and the use of the PQL, is scientifically defensible.

DTSC disagrees that the AA Threshold-PQL will result in fewer exclusions from the Priority Products listing, leading to more Priority Products subject to the APA process and a greater workload for DTSC. The regulations require the APA process for adoption of any Priority Product; the AA Threshold does not exclude a Priority Product from rulemaking. The purpose of the AA Threshold is that once a Priority Product has been listed, the AA Threshold sets a concentration that differentiates between those Priority Products subject to the Alternatives Analysis requirements and those Priority Products that are exempt from the Alternatives Analysis. For example, if the Priority Product listed is any rattle containing arsenic, the AA Threshold level determines which rattles are subject to the Alternatives Analysis. Rattles with no arsenic or with a concentration of arsenic as a contaminant at less than the PQL are not subject to the requirement to undergo an Alternatives Analysis.

The Priority Product rulemaking record will contain supporting documentation that shows that each proposed Priority Product has met the prioritization criteria set out in Article 3. The supporting documentation will include DTSC's rationale and a bibliography of the supporting information and reliable information that the proposed Priority Product causes "adverse impacts." The rulemaking process is an open, public process, with sufficient review times to provide opportunity for stakeholder and public input, review, comment, and debate before finalizing the adoption of a Priority Product.

Furthermore, the regulations have been revised and the April 2013 version of the regulations allows DTSC to establish an AA Threshold for intentionally added ingredients or to set an AA Threshold for contaminants above the PQL. If DTSC proposes a Priority Product with a contaminant chemical, this public process will allow for public vetting of any issue that may require adjusting the AA Threshold.
DTSC agrees that changes in the PQL should be considered when reviewing AA Threshold notifications. At the onset, DTSC will develop guidance materials to address the preparation of the Alternatives Analysis and will provide examples of how to demonstrate compliance with AA Threshold requirements, if applicable. The AA Threshold will be a case-by-case determination based on the presence of contaminants, the minimum detection limit, and criteria for the protection of public health and the environment.

DTSC respectfully disagrees that identification of a significant risk threshold would be more scientifically sound than the method DTSC has selected for setting the AA Threshold. While an approach identifying a significant risk threshold has a certain appeal, it is certainly not advantageous to expedite the quest for safer alternatives. A risk-based threshold would strap DTSC and taxpayers with demonstrating risk and harm before prioritizing consumer products containing Candidate Chemicals that have reliable information demonstrating hazard traits and/or endpoints.

DTSC believes that the proposed regulations strike a necessary and scientifically sound and balanced approach for the following reasons. First, the prioritization process in Article 2 identifies chemicals that have been placed on authoritative lists as having adverse impacts on the human health and/or the environment. Those chemicals are designated as Candidate Chemicals. When consumer products are identified as a source of the Candidate Chemicals, those products may be evaluated and prioritized using the factors specified in sections 69503.2(a)(1) through (3). Collectively, these provisions carry out the legislative mandate to establish an identification and prioritization process that includes, but is not limited to:

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.

Second, the April version of the regulations has been revised to allow for Priority Product- specific AA Thresholds. If the science demonstrates at the time of adoption of the Priority Products listing that an AA Threshold is appropriate for an intentionally added chemical or that a level higher than the PQL for a contaminant is called for, DTSC may make these adjustments to the default approach to the AA Threshold mechanism. That is, DTSC may set an AA Threshold for intentionally added Chemicals of Concern or set an AA Threshold higher than the PQL for a Chemical of Concern that is a contaminant.

DTSC is mindful that a volume-based threshold may be irrelevant for nanoparticles and that contaminant Chemical(s) of Concern may be potentially harmful even at trace levels, even below the PQL. DTSC believes that the AA Threshold as the PQL is an appropriate approach that is sufficiently protective. The proposed regulations (April 2013) do not limit or restrict DTSC to be able to take this into account as AA Thresholds are adopted in the future.

Public Comments on Topic 3

Comments: 4-3, 6-5, 6-7, 6-16, 6-19, 6-22

Comments Summary:

The above comments related to Topic 3.

- The commenters state that DTSC should consider the disparate views of the ESPR about the intelligence, benefit, practicality and cost involved in adopting the practical quantitation level PQL as the AA Threshold for Chemicals of Concern. These commenters recommend that DTSC should reconsider this provision.
- Support the finding that “the CCSPAR process will be an enormous undertaking at best, and this will require greater departmental resources.”

Response:

DTSC is cognizant of the disparate ESPR Findings related to the AA Threshold. For a detailed discussion on the rationale for accepting or rejecting the ESPR Findings please review the responses to the ESPR Topic 3, above. Since those responses are

applicable here as well, further responses here would be redundant. DTSC also notes that there are detailed discussions in the January 2013 and April 2013 Response to Comments documents regarding the rationale for the AA Threshold available for a manufacturer's Priority Product only if the Chemical(s) of Concern are present in the product solely as contaminants, and the concentration of the Chemical(s) of Concern(s) does not exceed the Practical Quantitation Limit (PQL) for the chemical(s).

Please refer to DTSC's response above on "ESPR Findings on Topic 3" regarding the regulations requiring greater departmental resources.

TOPIC 4

THE DEFINITIONS OF THE VARIOUS "ADVERSE" IMPACTS AND GENERAL USAGE OF THE TERMS "ADVERSE" IMPACTS AND "ADVERSE EFFECTS" IS USED THROUGHOUT THE PROPOSED REGULATIONS. A QUALITATIVE OR QUANTITATIVE DETERMINATION OF ADVERSE IMPACT OR EFFECT CAN BE MADE, AND IS ADEQUATELY PROTECTIVE OF PUBLIC HEALTH AND THE ENVIRONMENT WHEN RELIABLE INFORMATION IS AVAILABLE.

Minor clarifications were made to these terms, including, in some instances, changing "impact" to "effect", where appropriate.

ESPR Findings on Topic 4

Findings: JA-11, JA-12, DB-7, NC-4, WF-10, WF-11, GG-8, GG-9, DH-6, OR-9, JS-7

Findings Summary:

The above findings expressed support or concern regarding Topic 4. In summary, the following supportive findings were expressed:

- "Adverse effects" and "adverse impacts" comprehensively cover the impacts and effects that AB 1879 and the regulations seek to prevent, and the recent changes in the definitions do not appear to change the broad scope at all;
- ESPR entity agrees that a qualitative or quantitative determination of adverseness can be made, and that either is adequately protective if reliable information is available. Qualitative information must frequently be relied upon when quantitative information is absent, limited, or of questionable reliability. This situation is common, if not typical, among toxics;
- With the exception of the statement "cause significant or widespread adverse impacts," in which "significant" and "widespread" were not defined, the uses of adverse in the document were clear and appropriate;

- Changes to the draft regulations were appropriate and the terms “impact” and “effect” are often used as synonyms, and the difference between them is subtle;
- Changes in the use of “impact” and “effect” are minor clarifications that do not pose significant problems; and
- The proposed regulations adequately describe measures of adverse impacts so that a scientifically-defensible determination can be made.

In summary, the following findings of concern were expressed by the ESPR entities:

- The scientific or toxicological definition of “adverse” impacts/effects is less clear. The ESPR entity is concerned with the distinction between what constitutes “adverse impacts” versus “adaptive responses.” While the ESPR entity feels that issue needs to be addressed in order to make a scientifically defensible case for potential “adverse impacts” of product-chemicals combinations, he indicates that the statement “The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts …” is neither indicative of difficulty nor explicit about the role that scientific judgment will need to play in many of these decisions;
- The terms “impact” and “effect” were used interchangeably with no conventions as to when one is used over the other. Unless the rationale for the use is presented, the ESPR entity indicated the preference for the use of effect;
- The term “adverse” is a confusing mix of qualitative, quantitative, and theoretical effects with no concrete standard that must be met. The ESPR entity finds a lack of clarity as to who makes the designation to identify “cumulative effects,” “aggregate effects “or “potential to contribute to or cause adverse impacts” under section 69503.3 and which method will be used. In addition, the use of the term “potential” exacerbates the problem because the word has no generally agreed upon scientific meaning;
- The loose language describing “adverse” will lead to either very little prioritization or accusations of arbitrary behavior in prioritization because some assertions of “potential” put forward will be accepted and some will not; and
- ESPR entity recommends specifying the term “adverse” to denominate “negative impacts on ecosystem services, landscape appearance and biodiversity in relation to environmental impacts and on human health and well-being in relation to life quality.”

Response:

DTSC agrees that the changes and use of the terms “impacts” and “effects” in the proposed regulations are minor clarifications, and do not pose significant problems.

While some ESPR entities thought that the two terms “adverse impacts” and “adverse effects” were used synonymously, there is a critical distinction between the two terms in the regulations. The regulations define “adverse impacts” to mean “adverse public health impacts” and/or “adverse environmental impacts.” Both “adverse public health” and/ “adverse environmental impacts” are then defined more specifically. As such, the term “adverse impacts” encompasses more than forty human toxicological hazard traits, environmental hazard traits, and exposure potential traits defined in Chapter 54, Title 22, California Code of Regulations and additional factors listed in these regulations under the various definitions for “adverse impacts” listed in the regulations as sections 69501.1(a)(2) through (9). As a result, when the regulations use the term “adverse effect,” it is to avoid bringing in the entire regulatory definition of “adverse impacts.” DTSC revised the term “adverse impact” to “adverse effect” in only two places in the regulations. First under “adverse ecological impacts,” the phrases “adverse impacts to aquatic life,” “adverse impacts on ecosystems,” and “adverse impacts on the environment” were all amended to “adverse effects.” All these “adverse ecological impacts” are a subset of “adverse impacts;” so, the term “adverse impact” was replaced with “adverse effect.”

The second revision was in the definition of “adverse waste and end-of-life effects.” The previous version of this definition included “adverse impacts,” which has been revised to “adverse effects means waste materials and byproducts generated during the life cycle of a product, and the associated adverse effects…” “Adverse waste and end-of-life effects” does not mean adverse public health or environmental impacts and the definition was revised to remove references to “adverse impacts.” “Adverse waste and end-of-life effects” is used as a factor for product-chemical prioritization and for the Alternatives Analysis.

DTSC is cognizant that what is typically understood in toxicology is that adverse effects are “the empirical manifestation of experienced harm.” In the regulations, the term “adverse impact” means a potential for adverse effects (toxicological definition). The regulations include the concept that chemicals and chemicals in consumer products will be evaluated for the potential to contribute to or cause adverse impacts (§§69501.1(a)(58), 69503.2(a)(2), and 60503.3(a)(2)) to public health and/or the environment. The various adverse terms are used throughout the regulations with a qualification that these terms include not only the actual harm (adverse effect – toxicology) but the potential of an exposure to a chemical to contribute to or cause adverse impacts. Unlike toxicological studies that use weight of evidence to prove an adverse effect (toxicological definition) in the context of human hazard, the regulations focus on the potential of a chemical in a consumer product to potentially contribute to or cause impacts.

One of the ESPR entities recommended that the regulations should consider the difference between adverse impacts and adaptive response. Adaptive response to exposure would augment traditional weight of evidence approaches to include an effect that is potentially adverse or potentially indicative of adaptability. The ESPR entity suggested, "Discussion of this type of thinking should be presented, at least in the ISOR, so that the public recognizes that the State's flexible approach to assessing safer alternative chemicals will evolve with the evolving science to be fully protective of human health and the environment." DTSC has developed a framework to integrate and prioritize information that covers a continuum of impacts. Impacts can range from those causing changes (such as adverse effect in toxicology) to those having a likelihood to cause changes (potential adverse impacts). On one end of the range is "cause adverse impacts" which includes the weight of evidence to prove harm. On the other end of the range is "potential to cause adverse impacts" which includes the presence of a hazard or the presence of a chemical in the environment that could lead to harm.

The regulations are designed to take into account current and advances in scientific data and information by using a narrative approach when evaluating chemicals and products. Advanced toxicological testing may lead to different endpoints as testing protocols change and traditional endpoints that were recognize as "adverse" will change. DTSC will use available data and evaluate them with scientific knowledge to ensure that appropriate, reliable information is used when evaluating human health and environmental effects.

Although the term "potential" may have no universally agreed upon scientific meaning, the term "potential" has been defined in the regulations to mean that the phenomenon described is reasonably foreseeable based on reliable information. The term "reasonably foreseeable" is not defined in these regulations, but has the same meaning as is commonly understood. That is, a reasonable person would be able to predict or expect the ultimately harmful result. Similarly, the term "adverse" has the same meaning as is commonly understood, which is negative, detrimental, harmful, etc... DTSC disagrees with the suggested definition of "adverse" that includes ecosystem services, landscape appearance, and biodiversity in relation with the use of the term throughout the regulatory text. For example, the suggested definition of "adverse" is inconsistent with "adverse air quality impacts."

DTSC agrees with the ESPR entities' findings that the term "adverse" is scientifically debated. These regulations are designed to take into account current knowledge and advances in scientific data and information on a case-by-case basis by using a narrative

approach to evaluate human health and environmental effects. The various definitions for adverse impacts listed in the regulations as sections 69501.1(a)(2) – (9) are broad. And that the breadth of coverage of the relative impacts and effects cover all environmental media and objects of protection. These terms are used in the proposed regulations to consider when identifying Candidate Chemicals, prioritizing Priority Products, conducting Alternatives Analyses, and assigning regulatory responses. These definitions incorporate the hazard traits and environmental/toxicological endpoints developed by OEHHA (Chapter 54, Title 22, California Code of Regulations), which meets the mandate in Health and Safety Code section 25252(b). OEHHA uses the term “adverse effects” to clarify the definitions of “hazard traits” and “environmental/toxicological” endpoints.

Public Comments to Topic 4

Comment: 4-4, 5-1

Comments Summary:

Commenters support a more quantitative approach to determine adverse impacts or effects. As currently proposed, the regulations allow for so much flexibility on DTSC's determinations that there is no transparency in the process and no opportunity for replication. Commenters believe a number of ESPR entities share these concerns, and urge DTSC to reconsider the qualitative aspects of the priority setting approach and to the extent possible, build in quantitative criteria.

Response:

Initially, DTSC notes that it has addressed this issue in its responses above to the Findings regarding Topic 4. But DTSC offers the following response as well. DTSC recognizes that the available scientific information must be reliable and has to be viewed in the overall context of other available, relevant, and reliable product information on a specific chemical in deciding whether or not a chemical has a hazard trait.

It is widely recognized that information about chemicals in consumer products on everything from: the nature of the chemical’s presence in a product, product concentrations, toxicity, exposure, fate and transport that is available in the open literature, to the government, or in private holdings ranges from nothing to very substantial.

In anticipation of the variability of available information on chemicals and products, DTSC's regulations do not specify a formulaic process or quantitative criteria to explicitly prioritize Chemicals of Concern or to make regulatory decisions on chemicals in consumer products. Since a full complement of toxicity and exposure information has rarely followed the placement of every chemical or product in the marketplace by manufacturers, such an approach would be impractical to implement. It will likely take time for manufacturers to generate scientific information to fill in these knowledge gaps.

The proposed regulations employ flexible, narrative, and objective standards. In fulfilling requirements and responsibilities under these regulations, DTSC, manufacturers, responsible entities, and those acting on their behalf will in essence conduct analyses and make decisions and determinations based on the best scientific principles and practices. The regulations do not preclude a responsible entity from using qualitative or quantitative methods to comply with any of the Alternatives Analysis requirements.

While there is some value in greater certainty and predictability with a prescriptive process with defined thresholds, than with a narrative approach, there may also be some negative consequences as well. Specific integration of the prioritization factors into a generic static prioritization system for all chemicals (*and products*) in the marketplace would only reflect decisions based on current science and understanding. This would create the possibility of the process remaining ignorant to new science and understanding for future decisions. There is valid concern that under a prescriptive approach, DTSC will constantly be behind new science and understanding, will constantly be amending regulations, and will be strapped into making regulatory decisions knowing that the regulatory process will not allow consideration of new scientific understanding of chemicals and products.

ESPR on Big Picture Issues

Findings: NA-1, NA-10, WF-1

Findings Summary:

- In general, the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices. However, while the rule is basically sound, some clarifying changes need to be made.
- The proposed rule is based upon sound scientific knowledge, methods and practices.

  - The regulations rely on work of others on lists of potentially hazardous substances; these other groups have relied on public process and scientific peer review in their construction;
  - The evaluation criteria for prioritizing the product-chemical combinations are robust and comprehensive;
  - The use of the PQL is an improvement for establishing an AA Threshold; and
  - Slight changes to the use of "impact" versus "effect" have done nothing to bring about clarification.
- The proposed rule advances regulations on chemical safety from an exclusively risk-driven process towards a technology-based process, which is less expensive by not requiring a full-fledged risk analysis and fostering instead comparative risk analysis and functional analysis and the identification of better technologies and approaches.

Response:

DTSC agrees with the findings that the regulations are based upon sound scientific knowledge, methods and practices. DTSC has responded to the specific findings that call for some clarifying changes. See those responses above under the appropriate topics.

DTSC agrees with the finding that the proposed regulations advance chemical safety by fostering comparative risk analysis, functional analysis, and identification of better technologies and approaches that would provide safer consumer products.

ESPR Findings Outside the Topic Questions

THESE ARE FINDINGS BY ESPR ENTITIES ON ISSUES THAT WERE NOT RELATED TO THE TOPICS FOR WHICH DTSC ASKED FOR SCIENTIFIC REVIEW. THEY HAVE BEEN ORGANIZED BY THE ARTICLE TO WHICH THEY PERTAIN.

ESPR Findings on Article 1

ESPR Findings: DH-2, DH-7, DH-9

Findings Summary:

- ESPR entity is concerned that the current definition of "chemical" may not include those with no particular defined chemical structure (e.g., toxaphene);

- ESPR entity is concerned about the specificity of "significant" used in the definition of "economically feasible." One could argue that an alternative or replacement chemical could be "economically infeasible" when the manufacturer's operating margin is decreased by 1-5%.
- ESPR entity is concerned about the last sentence providing exclusion in the definition of "importer." Such exclusion may result in significant exposure by consumers to chemicals present in the product (which is not distributed or sold as such) and incorporated in another product that is sold or distributed to others.
- ESPR entity supports the definition of "functionally acceptable" as described in the regulations.

Response:

DTSC respectfully disagrees that the definition of "chemical" excludes those chemicals with no particular defined chemical structure. Subparagraph 69501.1(a)(20)(A)2, the second part of the definition of "chemical," includes substances comprising one or more substances described in subparagraph 69501.1(a)(20)(A)1. This provision captures, among other things: mixtures, such as toxaphene, hydrates, metal alloys, and gasoline.

The definition of "economically feasible" uses the term "significant "which has the same meaning as is commonly understood. This avoids use of a prescriptive threshold to quantitatively specify what would be considered a significant reduction of a manufacturer's operating margin. The responsible entity uses "economically feasible" as one of the factors to assess potential alternatives during the second stage of the AA. As such, it will be the responsible entity that will make the determination as to what is considered a significant reduction in operating margin. DTSC will not dictate to the responsible entities what is or is not economically feasible, but DTSC retains the authority to impose a regulatory response according to the criteria and processes specified in Article 6 of the regulations. All these determinations will be posted on DTSC's website and will be subject to public input and scrutiny.

The last sentence of the definition of "importer" states, that importer" does not include a person that imports a product solely for use in that person's workplace if that product is not sold or distributed by that person to others." This conditional exclusion is only allowed if the product is not sold or distributed. So if the product is incorporated in another product that is then sold, then the exemption no longer applies. If the Priority Product is a chemical ingredient and it is then incorporated into another product, then the Priority Product is no longer exempt.

DTSC appreciates the support for the definition of “functionally acceptable.”

Public Comments on Article 1

Comments: 1-2, 6-10, 6-17

Comments Summary:

These commenters expressed concern with the definitions of “importer,” “assemble,” and “product” in the proposed regulations in response to the ESPR findings as follows:

- Dr. Hattis on definition of “importer” – “I am concerned that the last sentence in this definition could cause problems;”
- Dr. Hattis finding in topic 3 of the charge question to ESPR AA Threshold on product-chemical combination – “it does beg the question of how broad the definition of a 'product' is;” and
- Dr. Bennett on ‘product categories” – “It is not clear from the regulations how broadly the product categories are defined.”

Response:

Please see the discussion of “importer” in the previous response.

The definition of “consumer product” or “product” is consistent with the enabling statue and clarifies which consumer products will and will not be subject to the requirements of the regulations. Health and Safety Code section 25251(e) defines “consumer products” to mean “a product or part of the product that is used, brought (sic), or leased for use by a person for any purpose.” “Consumer product” does not include: prescription drugs, medical devices, dental restorative materials, diagnostic or treatment instruments, packaging (for prescription drugs and devices, dental restorative materials, and medical instruments), food, or pesticides. The definition of “consumer product” also provides DTSC flexibility to name any identifiable part in the finished product or that makes up the finished product as a Priority Product. For example, DTSC could name a formulated product, a bulk chemical, the packaging of an article, or an assembled product as a Priority Product.

DTSC will name specific product-chemical combinations as Priority Products and will name product categories in the Priority Product Work Plan. These are two different concepts in the regulations. DTSC may use the global product classification standards to describe product categories that will be listed on the Priority Product Work Plan. This work plan is intended to provide interested parties some certainty as to what type of

products will be under consideration for the next three-year period. Consumer products that go on to be listed as Priority Products will be much more specific than a general product category. For example, a product category may be as broad as cleaning products, but a Priority Product would be defined as a product-chemical combination—e.g. a hand dish washing soap (consumer product) with a specific surfactant (Chemical of Concern).

ESPR Findings on Article 2

ESPR Findings: GG-1, GG-2

Findings Summary**:**

- ESPR entity is concerned with the difference between the large number of chemicals that will be identified in the initial list of Candidate Chemicals and the fact that the priority setting and listing process will begin on no more than five Priority Products. This creates a very high potential for citizen frustration and dissatisfaction with the process; and
- A more targeted and risk-based approach to identifying Candidate Chemicals would be a more logical approach and would not focus mainly on chemicals with the greatest availability of information.

Response:

DTSC agrees with the finding that there is a difference between the relatively large number of Candidate Chemicals identified in the initial list and that the priority setting and listing process will begin with just no more than five priority products. However, DTSC respectfully disagrees that this will result in citizen frustration and dissatisfaction with the process. The following explains the basis for the difference in the size of these two related concepts.

Section 69503.6(a) allows DTSC to winnow down the approximately 1,200 Candidate Chemicals identified in the regulations and select a few product-chemical combinations for listing as Priority Products. This approach will allow DTSC to learn while making progress in the initial years of the program, and concurrently send an important signal to the marketplace. Additionally, the proposed regulations provide a number of opportunities for the regulated community and other stakeholders to provide information on chemicals and products to DTSC throughout implementation of the regulations. There is the opportunity to petition DTSC to add a chemical or product for listing as a

Priority Product, among other public comment opportunities. Thus, in implementing the proposed regulations, DTSC and interested parties will, in a sense, together identify the chemicals that need to be addressed, based on reliable information for the factors to be considered by DTSC.

DTSC disagrees with the comment regarding a risk-based approach to identifying Candidate Chemicals and notes that the use of risk assessment in proposed regulations is not favored for the reasons stated below.

Citing the "Science and Judgment in Risk Assessment," National Academy of Sciences (NAS) Committee on Risk Assessment of Hazardous Air Pollutants, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C., 1994. As described in the NAS Committee report:

- "Human-health risk assessment entails the evaluation of scientific information on hazardous properties of environmental agents and on the extent of human exposure to those agents. The product of the evaluation is a statement regarding the probability that populations so exposed will be harmed, and to what degree. The probability may be expressed quantitatively or in relatively qualitative terms."
- *"Risk Management* is the term used to describe the process by which risk-assessment results are integrated with other information to make decisions about the need for, method of, and extent of risk reduction."

Chemical hazards come in many forms. Risk assessment can be carried out for any form of chemical toxicity and could be used to prioritize chemicals. However, risk assessment sometimes consists only of a hazard assessment designed to evaluate the potential of a substance to cause human health effects. Regulators sometimes take the additional step of ranking the potency of a number of chemicals —which is known as hazard ranking. Sometimes potency information is combined with exposure data to produce a risk ranking." It should be noted that (1) the efficacy and robustness of such process will always be dependent, in part, upon the quality and quantity of the available scientific data and, (2) in practice the use of the term "risk" is commonly associated with carcinogens and not non-carcinogens.

Prioritization is a risk management decision and is not viewed as simply a "risk ranking." It is a decision that can be informed by risk assessment like approaches, but also reflects other potential policy influences and administration priorities. Specific policy targets could move from removal of carcinogens to the removal or teratogens and then

on to the removal of neurotoxins depending on the magnitude of the issues within a specific decision or policy time frame. Prioritization is informed by science, but it is not "purely" a scientific decision.

Developing a single list with strict ordinal ranking would be irrational, since there is no accepted valuation system that allows for the strict scientific ranking of adverse outcomes that are due to different pathological mechanisms or affect different biological systems or different biological species.

DTSC has intentionally avoided relying upon terminology such as "risk" to avoid the misconception that chemicals with unlike hazard traits can be simply compared based upon a single common "risk" metric. For example, carcinogens whose adverse human health impacts are often expressed using "risk" metrics (where a common agent is presumed to operate by mechanism that have no toxicity threshold) cannot be easily compared with toxic agents that exhibit dissimilar hazard traits, such as developmental toxicity into a single list and strictly ranked. These regulations are applicable to hazard traits that include both *carcinogenic* and *non-carcinogenic* endpoints *in both human and non-human species*.

DTSC reserves the option to take regulatory action based upon newer toxicity information that is not being developed in traditional animal bioassays. Such information may not be easily integrated into the traditional paradigm of risk assessment if the expected outcome is a "risk" metric.

Therefore, absolute adoption of a quantitative risk assessment process including full uncertainty analysis as the sole approach to prioritization is neither practical nor reasonable, due to obvious gaps in scientific data. Exposure information may not be directly available within reasonable time frames to allow for preventative regulatory action. Complete information on hazard and the lack of precise information on hazard within the strict boundary of a risk assessment requirement could stifle timely responses. DTSC may use information about the magnitude of the presence in the market place as a surrogate for actual exposure data because that data may be limited or completely unavailable.

Public Comments on Article 2

Comment: 6-12

Comment Summary:

This commenter supports Dr. Gray's finding that Chemicals of Concern (now called Candidate Chemicals) list will be too large and that the prioritization criteria are too broad to improve the specificity of the list.

Response:

Please see response above under "ESPR Findings on Article 2."

ESPR Findings on Article 3

Finding: GG-10

Finding Summary:

ESPR entity is concerned with section 69503.2 and how DTSC will know that there is a "readily available safer alternative." This seems to open the potential for lobbying and strategic behavior on the part of competitors or vendors.

Response:
DTSC would like to clarify the process for how DTSC will use this criterion when identifying a product-chemical combination. When identifying product-chemical combination, DTSC may consider whether there is a readily available safer alternative. This can be done through available information, including, but not limited to, literature review, or information from manufacturers or vendors on existing products not using COCs or Candidate Chemicals. This provision is not a substitute for the Alternatives Analysis process required in Article 5. DTSC believes that the participation by vendors will be very valuable to DTSC when determining if there are available safer alternatives.

Alternatives Assessment Threshold

Finding: OR-8

Finding Summary:

The ESPR entity has reservations concerning the level of public scrutiny if a responsible entity is pursuing the AA Threshold route. It would be beneficial to expand the time and intensity for public review if such route is taken.

Response:

If DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product during the product prioritization process, this may be addressed in the rulemaking for that Priority Product listing. This option was added to the April 2013 version of the regulations in response to public comments. That is, DTSC has the authority to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals in Priority Products. If DTSC exercises this authority, it will do so at the time it lists Priority Products.

Under the rulemaking process, DTSC will first propose a Priority Products list for public review and comment, along with supporting documentation, including DTSC's rationale and a bibliography of the supporting information and information sources. DTSC will send this material to individuals on the electronic mailing list(s) that DTSC establishes, and post on its website, a notice regarding the availability of the proposed list and will allow stakeholders the opportunity to comment on the selection of the Priority Product(s). If DTSC proposes a Priority Product with a contaminant, this public process will allow for public vetting of any issue that may require adjusting the AA Threshold.

ESPR Findings on Article 5

Findings: NA-3, NA-4, NA-5, NA-6, GG-3, DH-10

Findings Summary**:**

The regulations should be clear to include non-chemical alternatives in the Alternatives Analysis and regulatory responses, allow for new Alternatives Analyses when new information become available, and focus on "material contributions to one or more adverse effects" more than on "potential" effects. In addition, there are concerns with regard of the possible implications of considering the possible costs to governmental agencies and non-profit organizations. More specifically:

- ESPR entity indicated that the Summary of Significant Changes**,** bullet 4 on page 2, only mentioned evaluation of chemicals, and missing from the statement are non-chemical alternatives;
- The expansive and inclusive definition of "alternatives" is only obliquely referenced in the section dealing with "Identification of Alternatives", section 69505.5(b)(1)(A);
- While section 60505.6(a)(2)(B) considers non-chemical alternatives, it is poorly written in bringing attention to these and should be re-written;
- ESPR entity recommended that under the discussion of Alternatives Analysis, the Summary of Significant Changes should be amended to include safer

technological or administrative approaches that deliver a comparable, but safer functional purpose as the COCs;

- Supported the idea of "potential" effects being dropped and replaced with "a material contribution to one or more adverse public health impacts." Furthermore, the ESPR entity recognized the multi-criteria nature of AA decisions with different possible outcomes to different populations. In addition, ESPR entity was struck by the recognition of the importance of quantitative analysis tools, weighing and comparing multiple attributes and optimizing decisions in contrast to the very simplistic hazard-based approach taken in developing the Candidate Chemicals list; and
- Suggested adding qualifying statements on the monetization of impacts, such as "where reasonably feasible." Concerned that issues regarding costs to governmental agencies and non-profit organizations may lead to issues such as consideration of "how much a fish in the wild is worth, or how much an uncertain mild health response is worth."

Response:

In response to the ESPR entity's findings on the lack of a statement about non-chemical alternatives in the referred bullet in the Summary of Significant Changes, DTSC would like to clarify that section 69505.5(b)(2), which was the provision referred to in the subject bullet under Summary of Significant Changes, provides that alternatives that do not involve the use of replacement chemicals, or otherwise adding chemicals to the product, do not require evaluation of chemical hazards, since there are no new chemicals involved. Responsible entities only need to do the "Initial Evaluation and Screening of Alternative Replacement Chemicals" for COCs, alternative replacement chemicals, and any other chemicals in the alternatives that differ from the chemicals in the Priority Product.

DTSC respectfully disagrees that the regulations need to be rewritten to make it clearer that "alternatives" refers to both chemical and non-chemical alternatives. DTSC believes that this has been addressed when it defined "alternative" in section 69501.1(10), and also mentioned in Article 5. No changes to the proposed regulations are necessary in response to these findings.

DTSC appreciate the support expressed by the ESPR entity on the appropriateness of the use of "material contribution to one or more adverse public health impacts."

DTSC respectfully disagrees that adding a qualifying statement on the monetization of impacts, such as" where reasonably feasible" would provide any added safeguards to prevent the argument of "how much a fish in the wild is worth, or how much an uncertain mild health response is worth".

Section 69505.4(a)(2)(C)1 - 8 of the proposed regulations dated July 2012 was amended to streamline the provisions into two primary tiers. The first tier must be addressed whether the Priority Product is retained or an alternative is selected. Section 69505.6(a)(3)(A) requires that the responsible entity evaluate, monetize, and compare the relevant exposure pathways and life cycle segments, the impacts of the Priority Product and the alternatives on:

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

Section 69505.6(a)(3)(B), the second tier, requires that if the responsible entity's alternative selection decision to retain the Priority Product is based in whole or in part on internal cost impacts, this decision must be explained in the Final AA Report. The Final AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs.

Collectively, the above amendments address the mandate in Health and Safety Code section 25253(a)(2)(M) of the authorizing legislation, that the proposed regulations require a process that takes into account the economic impacts of the Priority Product and potential alternatives using life cycle assessment tools. The economic impacts must address the impacts across the life cycle (i.e., from raw materials extraction through materials processing, manufacture, distribution, use, repair and maintenance, and disposal or recycling) associated with the Priority Product or any alternative(s) considered. The requirements specified in the proposed regulations are consistent with commonly used principles in product assessment and reformulation. While externalized costs may have been traditionally passed on to the public, taxpayers and/or government, DTSC believes it was the intent of the Legislature to depart from this paradigm. This view is consistent with the statutory requirement that economic impacts be considered as part of the Alternatives Analysis. The narrative standards of the proposed regulations as a whole, and the provisions in section 69505.6(a)(3) of the proposed regulations dated April 2013, provide the necessary latitude to include costs to government agencies dealing with environmental impacts and adverse public health impacts and its consequences.

Public Comments on Article 5

Comment: 6-8

Comment Summary:

Commenter is concerned with Dr. Ashford's findings regarding the selection of safer alternatives. Dr. Ashford contends that "the substitution criteria should not be restricted to chemical substitutes," and recommends "safer technological or administrative approach that delivers a comparable, but safer functional purpose." The commenter believes the regulations should provide the regulated entity the discretion to consider *any* option in the Alternatives Analysis process.

Response:

The proposed regulations do not specify outcomes and, therefore, allow a wide range of alternatives to be considered, dismissed, and later reconsidered. DTSC will not second guess the manufacturer; DTSC will review the Alternatives Analysis reports for compliance with the requirements of Article 5. The responsible entity has the ultimate decision on what alternatives are further evaluated and implemented as the safer alternative. While the proposed regulations do not require that one alternative be selected over another, it is quite feasible that burden shifting will occur from one alternative to another. As such, DTSC may impose regulatory responses it determines to be appropriate to mitigate any human health and environmental impacts that remain after the responsible entity selects an alternative or decides to retain the Priority Product. For a more detailed discussion on the flexibility afforded to responsible entities, please refer to the July 2012 and January 2013 Response to Comments documents concerning selection of safer alternatives.

ESPR Findings on Article 6

Findings: NA-7, NA-8, NA-9

Findings Summary**:**

- ESPR entity suggested that section 69506.6(a) of the proposed regulations dated January 2013 should read "a selected alternative technology or approach".

- ESPR entity recommended adding “or safer technological or administrative approaches that deliver a comparable, but safer functional purpose as the COCs”.
- ESPR entity questioned the limitation “DTSC not being able to require new Alternatives Assessment based on the receipt of new information” and recommends eliminating it from the regulations.

Response:

DTSC respectfully disagrees that the addition of “a selected alternative technology or approach” would add any more clarity to section 69506.6(a). The provisions specify that Engineered Safety Measures or Administrative Controls will apply to:

1) the selected alternative; or
2) the Chemical(s) of Concern in a Priority Product for which an alternative is not selected.

DTSC believes that the alternative technology or approach would be redundant in this provision.

The Summary of Significant Changes will not be revised as suggested by the ESPR entity because it was provided by DTSC at that time only as a quick reference of important changes on the revised proposed regulations. And for the same reasons cited above, DTSC does not believe that adding “or safer technological or administrative approaches that deliver a comparable, but safer functional purpose as the COCs” to the Summary of Significant Changes would provide added clarity. As stated in the ISOR, the guiding principles that DTSC must exercise in selecting regulatory responses will give preference to those that provide the greatest level of inherent protection from toxic risk, rather than relying on control systems to limit exposure to, or release of, Chemicals of Concern. This provision is likewise necessary to and intended to make plain DTSC’s policy preference for, and duty under Health and Safety Code section 25255(a) of, “encouraging the redesign of consumer products” as a means of reducing toxic risk, rather than merely encouraging the development of better control systems for existing products with known hazards.

DTSC agrees with the finding that DTSC eliminated the provision in the July 2012 version of the regulations that would have required a new AA based on receipt of new information. DTSC deleted this provision since section 69506.2(a) already specifies that DTSC may require information to be submitted if it determines that the data gaps identified in Article 5 must be filled to select the most appropriate regulatory response(s). While the regulations do not require that data gaps be filled as part of the AA conducted in Article 5, data gaps that are necessary in order for DTSC to select the

appropriate Regulatory Response(s) will be required to be filled by the responsible entity.

The amended text allows DTSC to revise the initial regulatory responses if the data gaps that are addressed demonstrate that revision to the regulatory responses is appropriate. Any proposed revision to the regulatory responses will be subject to public comment.

ESPR Comments on Economic Impact

Comment: NA-10

Comment Summary**:**

The ESPR entity offered the following remarks:

- The cost of additional tasks imposed by the proposed rule should be balanced against (1) the public health and environmental consequences of not implementing the rule, and (2) the benefit of stimulating replacement of problematic chemicals, changes in the reformulated od substitute products, process technology, and other technological and administrative practices;
- The proposed rule can be interpreted as a “modernization of the chemical industry;”
- Innovation and economic growth depends on industry and product turnover and evolution;
- The United States cannot afford to lag behind Europe and Asia in the development of environmentally safer chemicals and processes; and

Response:

The purpose of the ESPR is to address the aspects of the proposed regulations that are premised upon, or derived from, empirical data or other scientific findings. While DTSC appreciates the input on the economic input of the proposed regulations, these remarks are outside of the scope of this review.

ESPR Comments on Unchanged Portions of the Proposed Regulations

Comments: JA-3, NA-2, WF-4, GG-4, GG-6, DH-5, DH-8, OR-3

Comments Summary:

The above comments related to unchanged portions of the regulations.

- The approach of using existing lists makes a great deal of sense, because using lists rapidly generates a comprehensive list of chemicals and avoids duplication of effort;
- It is important to classify a Chemical of Concern based on the availability of a safer *chemical* substitute and this should be retained because it ties together risk assessment and alternatives assessment. More prominence needs to be given to substitutions or alternatives that include "use of safer technological or administrative approach that delivers a comparable functional purpose;"
- The regulations provide for the opportunity to add or remove chemicals from the list as new information relating to hazard traits becomes available;
- The hazard-based approach to list development is likely to lead to an unwieldy, unfocused and difficult to manage a set of Candidate Chemicals. The focus on existing lists does not address the seeming contradiction of using certain hazard traits to develop the list, while not acknowledging that many chemicals may not have been tested for the trait;
- Does not believe the use of biomonitoring data as a prioritization factor can be scientifically supported. Because biomonitoring data cannot apportion exposure to different sources, the identification of a chemical in biomonitoring studies does not indicate a product is a source of exposure;
- How broad is the definition of "product"? Gave an example of "product" as being as broad as "paint" which would include hundreds of different formulations made by different companies or very specific as "red indoor residential paint" which would be obviously much more limited; suggested adding a couple of paragraphs on the issue to guide DTSC staff in their choice of defining product categories;
- The definition of "functionally acceptable" seems good; and
- It is essential that the list is constantly monitored and updated.

Response:

The above ESPR findings expressed support or concerns with portions of the proposed regulations that have not been revised. Responses to these concerns, repeated here from the initial ESPR, may be found in the July 2012 External Scientific Peer Review Findings document.

Public Comments on Unchanged Portions of the Proposed Regulations

Comments: 4-1, 6-13, 6-14, 6-15

Comments Summary:

These comments support Dr. Gray's findings:

- Support for the finding that a list built from lists of chemicals with existing toxicological or policy concerns will encourage the use of new and less tested materials;
- Support for the finding that the focus on existing lists does not address the apparent contradiction between using certain hazard traits to develop the list while not acknowledging that many chemicals may not have been tested for the trait;
- Agrees with the finding expressing concern with over-reliance on specific hazard traits for identification and de minimis determination due to differences in dose response and unevenness in toxicology databases.
- Supports the finding that reliance on biomonitoring lists is an inefficient means of prioritizing the Chemicals of Concern (now called Candidate Chemicals).

Response:

To the extent that these comments are on ESPR findings on portions of the proposed regulations that have not been revised, DTSC will not respond to these comments. Responses to these concerns, repeated here from the initial ESPR, may be found in the July 2012 External Scientific Peer Review Findings document.

Public Comments on Administrative Procedure Act

Comments: 2-1, 2-2, 6-2
Comments Summary:

The above comments noted potential issues with DTSC's compliance with the Administrative Procedure Act (APA) throughout the rulemaking process. Specifically, these commenters found:

- DTSC has engaged in piecemeal processing and segmented public review periods for the proposed regulations. This latest release of nine external scientific peer review reports gives us only 15 days to review. It is simply not sufficient time to retain a scientist consultant to provide expert counsel, determine whether

these external opinions are scientifically supported, or how they fit into the context of the entire proposed regulations.

- By soliciting stakeholders to comment on the Alternatives Assessment guidance being prepared by Washington, DTSC is avoiding responsibility under the APA to provide a copy of the express terms of the regulations and an initial statement of reasons for proposing the regulations.
- There have been numerous comment periods on documents related to this rulemaking. At times the public comment periods have overlapped. The Department sent a request for peer review on January 30, 2013 with a review deadline of March 4, 2013. This comment period coincided with the public comment period on the Safer Consumer Products regulation, which prevented an opportunity for the public to review the external scientific peer review comments prior to commenting on the regulations or for the DTSC external peer reviewers to review the public comments.

Response:

DTSC respectfully disagrees with the assertion that the rulemaking process has not complied with the APA. Several of these comments are repetitive of the same commenters' remarks in the various public comment periods, and DTSC has responded to these in the Response to Comments for each public comment period. Please see the Procedural, Legal, and Overarching Issues section in the Response to Comments for the July 2012 and January 2013 version of the proposed regulations for a detailed discussion of the "piecemeal" objection.

DTSC respectfully disagrees that the solicitation of comments on the State of Washington's alternatives assessment guidance documents has any effect on DTSC's compliance with the APA with regards to the these proposed regulations. DTSC has not stated that the Washington guidance will form part of the regulations, but merely that the information therein "may be relevant to the Alternatives Analysis guidance" that DTSC will prepare for these regulations. DTSC sought only to make stakeholders aware of an analogous process happening in another state so that they might participate in that process as well.

All of the changes made in the January 2013 version of the proposed regulations were essentially refinements to the July 2012 initial proposal or deletion of provisions. In either case, any new concepts or requirements that were introduced could have been reasonably foreseen. By providing an additional round of ESPR for these revisions, DTSC has ensured continued compliance with the requirements of Health and Safety

Code section 57004 and the APA. There is no rule under the APA that states public comment periods for various documents must not overlap, and DTSC has attempted to move forward in a clear and transparent manner while still continuing to make progress on finalizing the rulemaking.

Public comment on ESPR Process

Comments: 1-1, 3-1, 3-2, 6-1, 6-3, 6-4, 6-18, 6-20, 6-23

Comments Summary:

These comments pertain to the External Scientific Peer Review process (ESPR) and expressed concern that DTSC has not conducted the external peer review in a manner consistent with External Scientific Peer Review Guidelines. Commenters state that exclusion from peer review of scientific portions of the proposed regulations falls short of full compliance with Health and Safety Code section *57004.* Another commenter urges DTSC to exclude certain portions of the ESPR comments that do not relate to the scientific basis of the proposed regulations as that is outside the scope of review authorized in California Health and Safety Code section 57004.

- The peer reviewers' reports are not indicative of a holistic approach to an external scientific peer review. For example, they did not address the following:
  - Ascertainment of data reliability and study quality and the processes for integrating results across studies, and
  - Evaluation of aggregate and cumulative risk;
- Disclose the criteria used to identify and select peer reviewers, including the processes used to address any conflicts of interest or bias;
- Improper external peer review process with inadequate guidance by DTSC to the external peer reviewers for appropriate consideration of the "scientific basis" and "scientific portions" of regulations; and appearance of bias or conflict of interest;
- Incomplete disposition by DTSC of the external scientific peer reviewer comments per requirements of California Health & Safety Code section 57004;
- Essentially the same charge questions were asked to the peer reviewers as in the first external peer science review;
- Explain absence of comments by peer reviewer Locke in the second round of peer review; and
- Request that DTSC empanel and complete an additional external peer review in the event of any "significant" revision to the regulations;

Response:

DTSC notes that all but two of the above comments are repetitive of comments from the first round of ESPR for these regulations. Responses to those concerns may be found in the July 2012 External Scientific Peer Review Findings document.

DTSC agrees with the comment stating that essentially the same charge questions were asked as in the first external scientific peer review. Although the second ESPR has similar topic themes as in the first ESPR, there were important changes in the January 2013 version of the regulations in the four topic areas. Because of these changes, DTSC solicited a second scientific peer review to verify the scientific validity of these changes. Specifically, the changes on the topics included:

Topic 1:

- The broad list of chemicals is now called “Candidate Chemicals” list.
- Two lists from authoritative organizations were added to the list of lists of initial Candidate Chemicals list.

Topic 2:

- Revised proposed regulations specified the key prioritization criteria as critical factors necessary to identify potential Priority Products.
- The phrase “ability to” has been replaced with “potential.”
- The term “potential” is defined.

Topic 3:

- The Alternatives Analysis Threshold definition and process was revised.

Topic 4:

- There were clarifications on the use of the terms “impact” and “effect.”

DTSC solicited Dr. Locke’s scientific review, but he was unavailable to meet the deadline DTSC established for submitting the reviews.

Index

WF-5, 12
WF-6, 12
WF-7, 12
WF-8, 19
WF-9, 19
WF-10, 23
WF-11, 23