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## OVERVIEW AND ORGANIZATION

This document summarizes the External Scientific Peer Reviews (ESPR) and 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 July 27, 2012. The proposed regulations are in the nature of process regulations. That is, while they 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 are 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.

On July 18, 2012, DTSC requested the ESPR entities to begin their reviews and to submit their reviews by August 30, 2012 on the four statements listed below that DTSC drafted.

### TOPIC 1

The use of the chemicals lists developed by the sources named in the regulation identifies chemicals with hazard traits that have public health and environmental concerns to produce an initial Chemicals of Concern list.

### TOPIC 2

Use of the initial product prioritization criteria in the chemical and product prioritization process in Article 3 are sufficient to identify all types of consumer products with Chemical(s) of Concern as potential Priority Products. Use of the key prioritization criteria considers those critical factors that identify the potential Priority Products during the initial phase as high priority.

### TOPIC 3

The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold based on best available technologies is scientifically understood.

### TOPIC 4

> The definitions of the various "adverse" impacts and general usage of the term "adverse" impacts is used throughout the regulations. Within the context of the definitional and general use of the term "adverse" impacts in the regulations and when scientific information is available, a qualitative or quantitative determination of adverse impact can be made, and is adequately protective of public health and the environment.

To ensure that the ESPR entities had the opportunity to comment on all aspects of the scientific basis of the proposed DTSC action, the ESPR entities were instructed to review other aspects of the proposed regulations that were not specifically referenced in the four specific topic areas. Under this "Big Picture" question, the ESPR entities were asked to contemplate the following questions:

> (a) In reading the supporting documentation [in an attachment to the ESPR package] and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.
>
> (b) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

A list of the ESPR entities and the commenter numbers assigned to their correspondence is included in Table 1 immediately below. Each ESPR entity was issued an alphabetical designation based on his or her initials and 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<br>EXTERNAL SCIENTIFIC PEER REVIEW ENTITIES | NUMBER OF COMMENTS |
|---|---|---|
| JA | John S. Applegate, J.D. | 23 |

| ENTITY # | TABLE 1<br>EXTERNAL SCIENTIFIC PEER REVIEW ENTITIES | NUMBER OF COMMENTS |
|---|---|---|
| NA | Nicholas A. Ashford, Ph.D. | 22 |
| DB | Deborah H. Bennett, Ph.D. | 23 |
| NC | Norman L. Christensen, Jr., Ph.D. | 9 |
| WF | William H. Farland, Ph.D. | 12 |
| GG | George M. Gray, Ph.D. | 14 |
| DH | Dale Hattis, Ph.D. | 20 |
| PL | Paul A. Locke, MPH, DrPH | 9 |
| OR | Ortwin Renn, Ph.D. | 9 |
| JS | Jennifer Sass, Ph.D. | 14 |

Given the focused scope of review for the ESPR entities, comments related to topics that were outside of the scope of the charge 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 and are identified accordingly later in the document.

A public comment period on the ESPR Findings was held from November 30, 2012, through January 4, 2013. Each comment letter was issued a number in alphabetical order. DTSC subsequently numbered each of the comments contained in the letters 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<br>PUBLIC COMMENTS ON ESPR FINDINGS | NUMBER OF COMMENTS |
|---|---|---|
| 1 | American Chemistry Council | 14 |
| 2 | American Cleaning Institute | 11 |
| 3 | American Forest & Paper Association | 5 |
| 4 | Amway | 6 |
| 5 | California Council for Environmental & Economic Balance | 1 |
| 6 | California Industrial Hygiene Council | 4 |
| 7 | Californians for a Healthy and Green Economy (CHANGE) | 46 |
| 8 | Consumer Specialty Products Association | 83 |
| 9 | European Union | 1 |
| 10 | Grocery Manufacturers Association | 26 |
| 11 | Rubber Manufacturers Association | 23 |

| | TABLE 2<br><br>PUBLIC COMMENTS ON ESPR FINDINGS | NUMBER OF COMMENTS |
|---|---|---|
| 12 | SNR Denton | 1 |
| 13 | Unifrax | 10 |
| 14 | Western States Petroleum Association | 21 |

## TOPIC 1

THE USE OF THE CHEMICALS LISTS DEVELOPED BY THE SOURCES NAMED IN THE REGULATIONS IDENTIFIES CHEMICALS WITH HAZARD TRAITS THAT HAVE PUBLIC HEALTH AND ENVIRONMENTAL CONCERNS TO PRODUCE AN INITIAL CHEMICALS OF CONCERN LIST.

### ESPR Findings on Topic 1

**Findings:** JA-1, JA-14, JA-15, JA-16, NA-4, NA-5, NA-6, NA-7, NA-8, NA-10, DB-1, DB-2, DB-3, DB-4, NC-1, NC-2, NC-3, WF-2, WF-3, WF-4, GG-1, GG-3, GG-4, DH-1, PL-1, OR-1, OR-2, OR-3, OR-4, JS-1, JS-2, JS-3, JS-4, JS-5, JS-6

Findings Summary:

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

- The list of resources that are named to identify chemicals that should be on the Chemical(s) of Concern list, and the use of the lists:
    - Is appropriate for the purposes of this regulation;
    - Is thorough and comprehensive;
    - Is an efficient and effective manner for developing a screening list of potential Chemicals of Concern;
    - Provides a firm basis for consideration and for regulating products on a large scale and in a timely manner;
    - Is a scientifically defensible approach; and
    - Is appropriate as the lists have undergone public vetting, and are frequently referenced.
- The individual lists are not overly redundant;
- The lists appropriately include emerging chemicals for which there might be significant exposure due to their use in consumer products or their persistence in the environment;

- By including lists that are updated by the organization overseeing them, the lists include chemicals that are persistent and bioaccumulative, and chemicals that are demonstrated to have widespread exposure through national and state biomonitoring programs;
- The list of chemicals considered appears quite exhaustive and complete;
- Using available and reliable information is a good technique for moving forward;
- The criteria for defining a Chemical(s) of Concern are clear, comprehensive and based on sound science; and
- It does not seem necessary to establish a rigid set of rules for classifying Chemical(s) of Concern; these rules will likely emerge, if needed, as the regulations are implemented.

The ESPR entities expressed the following findings of concern:

- The lists from the European Union should include in the definition "identified as chemicals of concern by the European Commission under the Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) initiative";
- Limiting listing of some endocrine disruptors based on volume produced per year is too permissive, some kind of schedule to reduce the volume over time could be used to address the issue;
- It is unclear how compounds with similar toxicity profiles will be assessed;
- The criteria for adding chemicals to the list is complete and necessary to meet the mandate of AB 1879[1]; however, there is a need for more data to be available for chemicals;
- As the paradigm for identifying chemical hazards changes, DTSC may need to rethink the interpretation of existing data;
- Updating the Chemical(s) of Concern list will be important because of the infrequency of updating individual lists and the evolution of testing and assessment methods;
- The effort to determine Chemical(s) of Concern casts a very wide net by combining lists of chemicals developed for other purposes and will fail to appropriately focus this effort. It is virtually certain that the list will be too large. If everything is a Chemical(s) of Concern, then nothing will be a chemical of concern;

[1] California Health and Safety Code sections 25251 et seq.

- The use of chemicals that have been put on biomonitoring lists by California or the Centers for Disease Control seems to lack connection to exposure from products;
- DTSC should look more to potency and levels of exposure than hazard traits;
- There should be a sunshine clause that additional chemicals may be included in or removed from the list if new data or insights into toxic or eco-toxic consequences are available or the lists mentioned are augmented;
- DTSC should consider including all chemicals in United States (US) Environmental Protection Agency's (EPA's) Integrated Risk Information System chemicals, not just those with Reference Dose or Reference Concentration limits based on neurotoxic endpoints. There are many chemicals that have been assessed by US EPA in its Integrated Risk Information System and assigned an exposure limit, Reference Concentration or Reference Dose, based on organ toxicity, immune toxicity, reproductive toxicity, etc.; and
- DTSC should be required to update the Chemical(s) of Concern list regularly.

**Response**:
DTSC agrees with the ESPR entities' findings that the criteria for defining Candidate Chemicals (formerly referred to as Chemicals of Concern) are efficient, scientifically sound, and necessary to meet the mandate of AB 1879. Revisions were made to the list of Candidate Chemicals, and updates to ESPR review topics are reflected in the second request for ESPR review. These revisions may be found in the January 2013 External Scientific Peer Review Findings R-2011-02 and corresponding Public Comments.

The proposed regulations retain the term "Chemicals of Concern," but the definition has been revised. The January 2013 version of proposed section 69501.1(a)(19) and sections 69501.1(a)(21) has been revised to include new definitions as follows:

i) Candidate Chemical (previously known as Chemical of Concern) – "'Candidate Chemical' means a chemical that is a candidate for designation as a Chemical of Concern, and that is identified as a Candidate Chemical under section 69502.2."
ii) Chemical of Concern (new definition) "'Chemical of Concern' means a Candidate Chemical that has been designated as a Chemical of Concern under section 69503.5(b)(2)(B)."

The proposed regulations illustrate how Candidate Chemicals and their corresponding hazard traits will be identified in a way that is generally in agreement with the

recommendations 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 undertaking full scale implementation of these regulations. The Candidate Chemicals list captures the following hazard traits identified by the Office of Environmental Health Hazard Assessment (OEHHA) in Chapter 54 of Title 22 of the California Code of Regulations: Carcinogenicity; Developmental Toxicity; Endocrine Disruption; Mutagenicity; Neurotoxicity; Persistence and Bioaccumulation; Reproductive Toxicity; and Respiratory Toxicity. Neuro-Developmental toxicants are included only when identified by the authoritative organization(s) on the lists specified in section 69502.2(a). It is important to note that all of the chemicals on the lists in the proposed regulations meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait as identified by OEHHA (Chapter 54).

Within 30 days after the regulations are in effect, DTSC will post an informational list of Candidate Chemicals on its website. This list may include the hazard trait(s) associated with the chemical names. During the prioritization process, DTSC will review product-chemical combinations in detail, and will identify the hazard traits and/or environmental or toxicological endpoints associated with the Candidate Chemical(s) that is/are the basis for a product being listed as a Priority Product. As a result of the detailed evaluation, DTSC may agree, disagree, or expand upon the hazard traits and/or environmental or toxicological endpoints that other authoritative bodies have used in evaluating chemicals. DTSC agrees that there may be limited data to perform such evaluations; however, the proposed regulations will undoubtedly create the demand and the information while slow to obtain at the onset, will become more and more available in the later years.

DTSC agrees with findings that DTSC ought to have a “manageable” number of chemicals. Starting with a manageable number of chemicals identified as Candidate Chemicals, with hazard traits and indicators of exposure based on deliberative work done by authoritative organizations, will allow the DTSC to learn while making progress in the initial years of the program, and concurrently send an important signal to the marketplace. DTSC believes that the current list of Candidate Chemicals is manageable. In addition, there will only be a virtual handful of chemicals that go on to be listed as Chemicals of Concern and assessed in the prioritization process in the early stages of implementation of these regulations. This is because the regulations limit the number of Priority Products that DTSC may identify in the early phase of implementation to no more than five.

DTSC respectfully disagrees that the Candidate Chemicals list is too broad. The Initial Statement of Reasons (ISOR) sufficiently outlines the rationale for identifying the lists used. After removing chemicals duplicated between the lists, and pesticides and prescription drugs (which are excluded from the definition of "consumer product" in the authorizing statute and thus are excluded from these regulations), the number of Candidate Chemicals is approximately 1,200. This "list of lists" approach in identifying chemicals with hazard traits for these regulations is also consistent with Health and Safety Code section 25252(b)(2) of the authorizing legislation. This provision reads "In adopting these regulations, the department shall reference and use, to the maximum extent feasible, available information from other nations, governments and other authoritative bodies that have undertaken similar chemical prioritizations processes …."

DTSC acknowledges the recommendation, but respectfully declines to include all of the chemicals in US EPA's Integrated Risk Information System that include reference concentration or reference dose values for other toxicological endpoints. It is very likely that the Integrated Risk Information System chemicals with endpoints other than neurotoxicity have already been captured by the other authoritative lists in the proposed regulations. So, there would little value added by including this additional list. Additional chemicals or lists of chemicals may be added to the Candidate Chemicals list via the petition process in Article 4 of the proposed regulations.

DTSC agrees with the finding that many chemicals lists specified in section 69502.2(a) overlap, but disagrees that the biomonitoring lists should not be included. The biomonitoring lists in sections 69502.2(a)(2)(F) and 69502.2(a)(2)(G) are included in the Candidate Chemicals list because there is demonstrated exposure to these chemicals that is established by the California and federal biomonitoring programs. The manner in which the biomonitoring lists are used in the early implementation years is to narrow the focus for further prioritization from all Candidate Chemicals to only those chemicals that appear on lists under *both* 69502.2(a)(1) and (2). For those chemicals that are not listed in 69502.2(a)(1), DTSC is able to add chemicals using the process set out in these regulations if it determines that additional chemicals should be added to the Candidate Chemicals list. DTSC finds that possible exposure through identification of chemicals on the California and federal Centers for Disease Control and Prevention (CDC) biomonitoring lists is an efficient method to identify potential Candidate Chemicals. The chemicals on the biomonitoring lists are indices of exposure, which greatly assists with the prioritization process. Also, despite the presence of these chemicals on a number of lists, little has been done to reduce their presence or use in

commerce. Therefore, no change has been made to the regulations to exclude these lists from the Candidate Chemicals list.

DTSC agrees with the ESPR entities' findings regarding new information, and recognizes the importance of reviewing and updating the Candidate Chemicals list to reflect the most current versions of lists and emerging data. In additional to periodic updating of the source lists, as appropriate, by DTSC, the petition process in Article 4 allows any person to petition for the addition of chemicals or entire lists of chemicals that the person believes should be added to the Candidate Chemicals list.

DTSC acknowledges the suggestion that the lists from the European Union should include in the reference "identified as chemicals of concern by the European Commission under the REACH initiative." After careful consideration and input from the European Union, DTSC revised the proposed regulations (April 2013) as follows:

- Revised section 69502.2(a)(1)(B) -
  "Chemicals classified by the European Commission as carcinogens, mutagens and/or reproductive toxicants Categories 1A or 1B in Annex VI to Regulation (EC) 1272/2008;"

- Revised section 69502.2(a)(1)(C) -
  "Chemicals included as Category 1 endocrine disruptors by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006;"

- Revised section 69502.2(a)(1)(G) -
  "Chemicals included as persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006".

In response to the finding that it is unclear how compounds with similar toxicity profiles would be assessed based on the July 2012 version of the proposed regulations, DTSC revised the regulations in January 2013, to clarify that based on reliable information, DTSC may evaluate structurally or mechanistically similar chemicals for which there is a known toxicity profile. In addition, the narrative nature of the regulations also allows DTSC to use best scientific information and practices to evaluate chemical toxicity when identifying and prioritizing Candidate Chemicals. This comment and DTSC's response

will become a part of the final regulatory documents. This will help establish and confirm the rationale for the regulations and aid in program implementation.

While DTSC agrees with the finding that limiting listing of some endocrine disruptors based on volume produced per year is not optimal, DTSC is bound to the authoritative organization's determination in developing the source list. Any other approach would be unworkable. There may be opportunities to address lower volumes of endocrine disruptors in the future when DTSC updates the Candidate Chemicals list.

In response to the recommendation that DTSC should look more to potency and levels of exposure than hazard traits, the evaluation of chemicals for subsequent identification and listing as Candidate Chemicals (previously known as Chemicals of Concern) is based on the chemicals' hazard traits and exposure potential. This is consistent with the Health and Safety Code section 25252(b)(1), which states – "the department shall develop criteria by which chemicals and their alternatives may be evaluated. These criteria shall include, but not be limited to, the traits, characteristics, and endpoints established by OEHHA in its companion regulations." No changes have been made to the regulations in response to this comment.

**Public Comments on ESPR Findings Topic 1**
**Comments:**
1-10, 3-4, 4-4, 6-2, 7-2, 7-4, 7-7, 7-13, 7-14, 7-16, 7-20, 7-23, 7-26, 7-34, 7-35, 7-41, 7-42, 7-43, 8-9, 8-22, 8-36, 8-37, 8-45, 8-48, 8-56, 8-63, 8-73, 8-74, 8-75, 8-76, 10-12, 10-13, 10-14, 10-15, 11-3, 11-15, 13-4, 13-6, 14-5, 14-6, 14-7, 14-8

Comments Summary:

The above comments expressed support or concern with the Findings made by the ESPR related to Topic 1. In summary, the following were expressed on these ESPR Findings:

- Dr. Applegate –
    - Support for the finding that existing lists are efficient use of scientific efforts of other bodies; effective method to focus regulations; effective method to generate information; aids in simplifying compliance strategies for regulated entities; and
    - Support and disagreement for the finding that lists chosen are comprehensive, well considered and create a firm basis for the initial list;
- Dr. Ashford –

  - Support for the finding that Chemical(s) of Concern list is "comprehensive;"
  - One statement of support and one of disagreement that the lists chosen are comprehensive, well-considered and provide "as firm a basis as exists" for creating an initial list of Chemical(s) of Concern;
  - Support for the finding that DTSC's reliance on lists of chemicals prepared by authoritative bodies is:
    - An efficient use of great scientific efforts expended by those bodies in preparing the list;
    - An effective method of focusing regulators across programs on the same problems;
    - An effective method of generating information and control strategies on common Chemical(s) of Concern;
    - Aids in simplification of compliance strategies for regulated entities; and
  - One comment disagrees with the suggestion that DTSC should not limit the listing of some possible endocrine disruptors to those produced in amounts exceeding 1,000 tons per year.
- Dr. Bennett –
  - Support for the finding that DTSC's proposal to use a list of lists to create a Chemical(s) of Concern list is "efficient and effective;"
  - Support for the recommendation for inclusion of emerging chemicals where there is potentially significant exposure or persistence in indoor or outdoor environments, even if limited toxicological data is available; one commenter believed this finding was supported by scientific and/or other relevant data;
  - Support for the recommendation of using indoor air modeling to determine risks from products;
  - Support for the recommendation of using the list of lists as a "screening list" from which a more focused Chemical(s) of Concern list is developed that considers the potential for exposure; and
  - Support for DTSC's approach to focus on chemicals with available data, contrary to Dr. Bennett's policy consideration to include "emerging chemicals" with limited data.
- Dr. Christensen –
  - Support for the finding that DTSC's criteria for identifying Chemical(s) of Concern is straight forward, thorough and scientifically sound.
- Dr. Farland –

  - Support for the finding that the proposed Chemical(s) of Concern list is valuable, not redundant and scientifically defensible as "each list was the product of a rigorous process for determining criteria for inclusion and all have undergone independent peer review at the process level if not at the individual listing step"; and
  - Support for the finding that the process of data evaluation and DTSC's determination of potential hazard compared to the original source list needs to be addressed.
- Dr. Gray –
  - Support and disagreement for the finding that the Chemical(s) of Concern list is too large and makes it difficult to appropriately focus the effort;
  - Support for the finding that using biomonitoring lists to identify Chemical(s) of Concern is likely to be duplicative of Chemical(s) of Concern already found on the other lists of chemicals in section 69502.2(a)(1); and
  - Support for the finding that reliance on specific hazard traits is cause for concern due to differences in dose response and unevenness in toxicology databases, and recommends utilizing potency and levels of human or environmental exposure as better means of prioritizing the Chemicals of Concern list.
- Dr. Hattis –
  - Statements of support and one of disagreement that DTSC "does not need to reinvent the wheel" in developing a Chemical(s) of Concern List; it is "reasonably assembled" and a "sensible starting point."
- Dr. Locke –
  - Support for the finding that DTSC's proposed method for identifying Chemical(s) of Concern "is appropriate for the purposes of this regulation and the processes are science- based and reasonable."
  - Comment noted that the suggestion to confirm each chemical is tied to a hazard trait is unnecessary and the lists inherently assure this link; one comment supported this suggestion.
- Dr. Renn –
  - Support for the finding that Chemical(s) of Concern list is "complete;"
  - Support for the finding that all chemicals and/or chemical combinations have the ability to cause harm. The dose and exposure pathways should generally be taken into account and not merely its presence; and
  - Disagree with finding that the regulations should include a "sunshine clause that additional chemicals can be included in the list," as it is duplicative with the approach specified in section 69502.3;

- Dr. Sass –
    - Support for the finding that DTSC's reliance on the science already assessed by authoritative bodies in identifying Chemical(s) of Concern and the list of resources named to identify Chemical(s) of Concern;
    - Support for the finding noting the importance of DTSC's ability to update the Chemical(s) of Concern list;
    - Support for the finding that DTSC should consider adverse impacts and exposure "so as to consider real world risks in prioritizing chemicals;"
    - Some comments agree and some disagree with finding that the inclusion of International Agency for Research on Cancer (IARC) 2A and 2B lists are appropriate;
    - Comment thought suggestion to include chemicals listed under the Safe Drinking Water Act (SDWA), and other chemicals already captured by other regulatory programs is prohibited under current regulatory scope;
    - Some comments agree and some disagree with the finding that all US EPA Integrated Risk Information System chemicals, not just those with reference concentration or reference dose values for other toxicological endpoints, should be included; and
    - Disagree that more chemicals lists should be considered to determine the Chemical(s) of Concern;
- Support for widespread agreement among ESPR entities for the list of lists approach, which creates a large Chemical(s) of Concern list.
    - Comments caution that lists must be updated regularly to reflect the most current versions of underlying lists;
- Support for the finding of multiple ESPR entities that there should be a narrower set of Chemical(s) of Concern than the full set of approximately 1,200+ chemicals to use in prioritization;
- Comment noted concerns expressed in earlier regulation evaluation processes regarding the scope of Chemical(s) of Concern being too large; and
- Comment noted that the question failed to elicit a response on the appropriateness of assembling priority compounds from such diverse sources.

**Response:**

DTSC appreciates the public feedback on the ESPR Topic 1 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 1, above. Those responses are applicable here as well, and any further responses on those issues would be redundant.

The comment regarding Dr. Sass' suggestion to regulate chemicals listed under the SDWA, and other chemicals already captured by other regulatory programs misstates Dr. Sass' suggestion. Dr. Sass suggested that DTSC include chemicals listed on the EPA Contaminant Candidate List (CCL), for which EPA *may* require regulation under the SDWA. Nonetheless, DTSC has not amended the regulations in response to the reviewer's comment that DTSC ought to include chemicals listed on EPA's CCL.

DTSC disagrees with the comment that the question failed to elicit a response on the appropriateness of assembling priority compounds from such diverse sources. Multiple ESPR entities noted that compiling chemicals lists from various sources provides a comprehensive and defensible starting point for the proposed regulations.

**TOPIC 2**

USE OF THE INITIAL PRODUCT PRIORITIZATION CRITERIA IN THE CHEMICAL AND PRODUCT PRIORITIZATION PROCESS IN ARTICLE 3 ARE SUFFICIENT TO IDENTIFY ALL TYPES OF CONSUMER PRODUCTS WITH CHEMICAL(S) OF CONCERN AS POTENTIAL PRIORITY PRODUCTS. USE OF THE KEY PRIORITIZATION CRITERIA CONSIDERS THOSE CRITICAL FACTORS WHICH IDENTIFY THE POTENTIAL PRIORITY PRODUCTS DURING THE INITIAL PHASE AS HIGH PRIORITY.

**ESPR Findings on Topic 2**

**Findings:** JA-2, JA-3, JA-4, JA-5, JA-17, JA-18, JA-19, JA-20, JA-21, NA-12, NA-13, DB-6, DB-7, DB-8, DB-9, DB-10, DB-11, DB-12, NC-4, NC-7, NC-9, WF-5, WF-6, WF-7, GG-2, GG-5, GG-6, GG-7, DH-2, DH-3, DH-4, DH-5, PL-2, PL-3, PL-4, OR-5, JS-7, JS-8, JS-9, JS-10, JS-11

Findings Summary:

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

- The criteria and process for the initial determination are clearly sufficient as they relate to effects and exposures, while allowing for consideration of aspects of products that control or reduce exposure;
- The inclusion of the "key prioritization factors" is sensible in that placement on the list should depend on the degree of potential hazard and the amount of potential exposure;
- The factors and data to be considered are thorough and comprehensive;

- The approach for listing products will create the needed incentive for data disclosure and generation;
- The prioritization allows DTSC to focus on the worst problems and address the majority of the problem expeditiously;
- The overall process for listing chemicals, products, and providing a threshold exemption allows manufacturers to change their products at multiple points to create a safer product without resource-intensive regulatory action;
- The criteria take into account when exposure to chemicals are limited by controls in products;
- Taking into consideration sensitive subpopulations is a good factor;
- The narrative approach-- rather than a quantitative weighting scheme-- is scientifically sound, given the typical available information and the differences one would see from product to product;
- The "internal consistency" and public comment steps included in the priority setting process to look across products potentially considered priorities will increase the scientific credibility of the priority setting process;
- The narrative approach is a reasonable first step to prioritization, and then allocate efforts to evaluate different kinds of effects according to the capacity of DTSC expertise and staff;
- The prioritization criteria are scientifically sound;
- The prioritization criteria are consistent with other state and federal chemical assessment approaches;
- The consideration of exposures from accidents or over-exposures resulting from unintended or improper use of the products is appropriate;
- The consideration of habitats, impaired ecological areas, and life cycle factors is appropriate;
- The approach does not include a clear standard for placement on the list, but experience in environmental regulation shows that bright lines are exceptionally difficult, time-consuming, or ultimately impossible to establish, and compliance with those bright lines is often equally challenging;
- The inclusion of market and sales data is appropriate and useful; and
- Consideration of life cycle factors creates a realistic evaluation of exposure.

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

- It is uncertain how DTSC will obtain information about products in a comprehensive or systematic way. There is a regulatory gap for obtaining information about products and product categories. However, as a practical

matter, it may not be particularly problematic, since DTSC's resources for undertaking this regulatory enterprise are limited;

- DTSC should consider using composites of various products to determine what chemicals are present in what products;
- It should be clearer in the prioritization process that pathways are an important factor, especially dermal application and chemicals applied indoors;
- The definition of "products" could be included in this section [Article 3];
- Manufacturing location should not lead to not prioritizing a product that was made outside of California;
- Exposure evaluation should consider the number of exposure routes, rather than the cumulative nature;
- DTSC should remember that people do not follow the controls listed on warning labels;
- Suggest indicating that prioritizing products based on availability of functional alternatives would infrequently come into play because DTSC will be limited in its ability to obtain data required for such a comparison. Alternatively, DTSC should include such examples in the ISOR;
- Although necessary, appropriately prioritizing products and including factors like aggregate and/or cumulative effects and sensitive subpopulations will be difficult;
- Although a sensible prioritization factor, the approach for evaluating risk reduction (hazard and exposure) is not specified. How widely a product is used is a poor surrogate for exposure, because chemical presence may not have an exposure potential;
- The prioritization criteria listed in Article 3 are too broad to help without significantly more specificity;
- The regulations should expand the type of information that is available to make determinations since "available information" does not seem to capture data obtained from the public and entities in the business community;
- For the majority of chemicals, quantitative data exist for only a small subset of these criteria and metrics, which is not a flaw in the proposed regulations. But it is, rather, a statement of the need for more data;
- Absent more detailed guidance, assumptions to assess chemicals and exposure, and how priorities will be influenced by differences in the types of toxic or ecological effects from exposure to a chemical may be imperfect or counterproductive, and will need to be further developed as the system evolves;
- The Statement of Reasons should explicitly note direct consumer exposure from the product, such as personal care products that may be applied directly to skin,

or additives to plastics either placed directly in the mouth or used in food packaging as a high priority; and

- The proposed regulations list too many criteria of high priority, many of which are redundant, or use different classification principles. A more systematic approach could follow this prioritization scheme: threat to human health, threat to environment, chemicals with long-term hazards, chemicals that can lead to likely harm. Prioritization should be performed according to the likelihood of harm experienced, the seriousness of this harm, the sensitivity of the endpoints, and the symbolic value the endpoint has for society (for example highly appreciated landscapes).

Response:

DTSC accepts the ESPR entities' findings that the list of prioritization criteria is reasonable and scientifically defensible, and that a bright- line standard for including product-chemical combinations is exceptionally difficult to establish. DTSC also accepts the finding that the criteria and process for determination are sufficient to assess effects on exposure, including accidents and/or over-exposure. DTSC is mindful of the implications regarding overexposed persons in exposure assessment and analysis. In fact, not including such exposure scenarios would be contrary to DTSC's mandate pursuant to Health and Safety Code sections 25252(a), which requires the regulations adopted pursuant to this section establish identification and prioritization process that includes, but is not limited to; considerations regarding:

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

As stated in the ISOR, the proposed regulations are consistent with Health and Safety Code section 25252(a), which mandates that DTSC adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being of concern. The prioritization processes set out in Articles 2 and 3 carry out that mandate. While Article 2 focuses on identifying the chemicals that may be of concern, Article 3 focuses on identifying the criteria and process by which DTSC will evaluate those chemicals to determine which particular consumer products that contain these chemicals should be listed as Priority Products. Priority Products must undergo further evaluation by the responsible entity under Article 5.

The provisions specify that DTSC must evaluate products to determine their adverse impacts and associated exposures, by considering the factors listed in section 69503.2(a) and (b) for which information is available. Based on the evaluation, DTSC will determine which products should be proposed and listed as Priority Products according to the process laid out in subsequent sections. While a prescriptive process with rigid criteria may provide a greater level of predictability and certainty to manufacturers who wish to evaluate their chemicals and consumer products, it does not ensure that the regulations remain flexible and current. The regulations need to remain relevant and appropriate as the Safer Consumer Products program grows and matures. Therefore, DTSC has chosen to adhere to a more nimble approach, which allows DTSC to consider emerging scientific information. (See Product Prioritization Criteria in the ISOR for a detailed discussion.

The proposed regulations provide DTSC sufficient latitude and flexibility to seek out and utilize a broad range of scientific data and other information it determines is necessary to ensure that this process and the resulting Priority Products list is based on sound science, reliable information, and relevant, dependable information. During implementation, DTSC will use existing and available authorities to gather data, as necessary, including: (1) the public process prior to listing a Priority Product where stakeholders may submit information to DTSC regarding the products being considered for listing; (2) the Priority Product work plan public process; (3) information about products obtained from a manufacturer, importer, assembler and/or retailer under section 69501.4; (4) information that is publicly accessible or purchased through a subscription; or (5) the petition process to list a chemical or consumer product. Additionally, DTSC has authority under Health and Safety Code sections 57018-57020 (“AB 289”) to obtain information about chemicals, including, but not limited to, information about analytical methods and fate and transport information. The means of gathering information, such as use of composites of various products to determine what chemicals are present in what products, is not necessary to be specified in regulation.

DTSC recognizes that while some of the information related to the factors and/or criteria that will be evaluated is currently available, some is not. However, the proposed regulations will undoubtedly create demand, and the information will become more and more available in the later years. Also, by filling data gaps using the approaches described above, DTSC may evaluate those products as data gaps are closed. Ensuring systematic implementation is something DTSC will have to gain experience with as the program matures. Nonetheless, DTSC needs some case-by-case flexibility, as there is such a wide variety of chemicals and products that may be subject to these

regulations. Therefore, no changes were made to the regulations regarding the type of information that will be used in the prioritization process, or the approach DTSC will use in compiling this information.

DTSC agrees in part with the findings that the criteria listed in the proposed regulations are broad, and may not appear to provide certainty to stakeholders. DTSC also agrees with the concern that more detailed information regarding assumptions will be needed to be made public prior to listing Priority Products to ensure decisions are sound. In other words, DTSC will need to provide its rationale for a proposed Priority Product listing when it publishes the proposed list. As stated above, these regulations use narrative criteria, rather than prescriptive criteria so that DTSC retains the flexibility to capture the wide universe of products and chemicals that may become subject to this program. DTSC made some clarifying changes to illustrate that key prioritization factors must be met for any product-chemical combination. (See section 69503.2(a).) To provide greater opportunities for public participation, the regulations were revised to explicitly state that DTSC will comply with the Administrative Procedure Act (APA) process when identifying Priority Products. This necessarily includes the requirement that DTSC prepare an Initial Statement of Reasons that explains how the chemical-product combinations meet the identification and prioritization factors in Article 3. DTSC must also engage in subsequent APA processes, including public notice and comment periods, and development of a Final Statement of Reasons, for adoption of the Priority Products specified in the regulations.

DTSC respectfully disagrees with the suggested prioritization scheme. Health and Safety Code section 25252 specifies that in establishing a prioritization process to prioritize chemicals, DTSC must include: 1) the volume of the chemical in commerce *in California,* 2) the potential for exposure to the chemical in a consumer product, 3) the potential effects on sensitive subpopulations, including infants and children. The suggested prioritization scheme would not meet this mandate.

DTSC agrees that it will be challenging to incorporate aggregate and/or cumulative effects and effects on sensitive subpopulations as part of the prioritization process. DTSC will determine, as part of the prioritization process, if evaluating aggregate and/or cumulative effects are necessary and appropriate for the consumer products under evaluation, and will evaluate the effects for which data is reasonably and reliably available. While there will be some cases when the information may be difficult to obtain, DTSC also has incorporated a number of regulatory pathways to overcome this challenge, such as voluntary data call-ins, stakeholder workshops, and the clarifying

language regarding the APA process described above. Therefore, no changes were made to these provisions as a result of this finding.

DTSC agrees with the finding that actual exposure data is better than using surrogate data. The regulations incorporate exposure factors including: containment of the chemical in the product; the potential for release of the chemical during the product's useful life and end-of-life; and administrative and engineering controls. Exposure evaluation includes the frequency, extent, level, and duration of potential exposure. However, it is necessary to include factors such as market presence, since it is a further valuable surrogate for measures of actual exposure, for which there may be scant data. These criteria are also necessary to effectuate the statutory mandate (Health and Safety Code Section 25252(a)(1)) that the regulations specifically include criteria related to volume of the chemical in commerce in California. Therefore, no revisions were made to the regulation as a result of this finding.

While the Initial Statement of Reasons could have included explicit language that "direct exposure from the product, such as personal care products that may be applied directly to skin, or additives placed directly in the mouth or used in food packaging, as a high priority," the proposed regulations dated July 2012, January 2013 and April 2013 provide DTSC the necessary language to be able to consider these routes of exposure as high priority, if necessary. Section 69503.4(a)(2)(B)4, of the proposed regulations dated July 2012, intentionally establishes a prioritization structure for two types of products;

1) Products designed or intended for children twelve (12) years of age or younger, or
2) Products worn or placed on the human body, dispersed as an aerosol or vapor, or applied to hard surfaces with the likelihood of runoff or volatilization.

This prioritization structure allows DTSC to prioritize these types of products more frequently than certain other products, if necessary, thus, in a sense, placing them on a higher priority status. In response to comments streamline and improve readability, the proposed regulations were amended and the salient provisions remain in section 69503.5(d)(3).

DTSC also recognizes that indoor environments and their influence on a chemical's persistence are relevant considerations. Thus, these routes are included in the prioritization factors that are taken into account in sections 69503.2 and 69503.3 of the proposed regulations dated July 2012, January 2013 and April 2013. As defined in

section 69501.1(a)(2) of the proposed regulations dated July 2012, January 2013 and April 2013, and as stated in the ISOR, "adverse air quality impacts" includes indoor air emissions that affect the air quality of homes, offices, transport vehicles, and public buildings. The many sources of indoor air pollution include:

- consumer products for household cleaning and maintenance, personal care, or hobbies;
- building materials and furnishings, such as carpeting and furniture made of certain pressed wood products or upholstery treated with flame retardants; and
- outdoor air pollution.

The ESPR entities' Findings and DTSC's responses are a part of the final rulemaking package. That is, they will be included in the Final Statement of Reasons to explain the rationale for the regulations and aid in program implementation. The regulatory language sufficiently includes these exposure scenarios for the purposes of meeting the intent of the authorizing statute.

DTSC is uncertain of how frequently product- chemical combinations will be prioritized based on the availability of functional alternatives or of how limited DTSC will be in its ability to obtain data required for such a comparison. As stated in the ISOR discussing section 69503.3(d), DTSC may consider the availability of a safer alternative during the prioritization process for products that contain a Chemical of Concern. Section 69503.3(d) of the proposed regulations dated July 2012, and section 69503.2(b)(2) of the proposed regulations dated January 2013 and April 2013 provides DTSC the necessary discretion to consider whether there is a readily available safer alternative that is functionally acceptable and technically and economically viable, in order to adjust the prioritization prior to listing a product as a Priority Product.

This provision allows DTSC to list a product that contains a Candidate Chemical that is not necessary for the performance and function of the product and for which a known alternative exists but which some responsible entities have chosen not to remove. The existence of a safer alternative is not a necessary requirement for listing a consumer product as a Priority Product; DTSC may list a consumer product as a Priority Product despite the absence of a known safer alternative. While it is not the goal of the proposed regulations to remove a "necessary" product from the market –meaning a product with social utility when no other alternative exists, if the concerns posed by the Candidate Chemical are significant, those products may be prioritized. In addition, if DTSC knows of an existing alternative to the Candidate Chemical even before an AA is

conducted, that product may be listed. DTSC will ensure that the FSOR make this distinction clear.

DTSC notes that the proposed regulations apply to consumer products placed into the stream of commerce in California, and do not include an exemption for products manufactured outside of the state. Further inclusion of a definition of products in this section is not only unnecessary, but may create undue confusion. This is because the definition of "consumer product" in Health & Safety Code section 25251, effectively incorporated into section 69501.1 of these regulations, makes any further definition redundant, and potentially in conflict with these other definitions. Finally, consistent with Health and Safety Code section 25252(a), the identification and prioritization process for product- chemical combinations will be limited to those products that enter the stream of commerce in California and will not extend to the manufacturing location if the product does not enter the California stream of commerce.

**Public Comments on ESPR Findings Topic 2**

**Comment:** 1-11, 2-6, 2-7, 3-4, 4-5, 6-2, 6-3, 7-4, 7-8, 7-9, 7-15, 7-17, 7-18, 7-21, 7-24, 7-36, 7-37, 7-44, 7-46, 8-13, 8-23, 8-24, 8-25, 8-26, 8-27, 8-28, 8-29, 8-38, 8-40, 8-43, 8-46, 8-50, 8-57, 8-58, 8-59, 8-60, 8-64, 8-69, 8-70, 10-16, 10-17, 10-18, 10-19, 10-20, 10-21, 10-22, 11-1, 11-9, 11-10, 11-14, 11-16, 11-17, 11-22, 13-3, 13-5, 13-7, 13-10, 14-9, 14-10

Comments Summary:

The above comments expressed support or concern with the Findings made by the ESPR entities related to Topic 2. In summary, the commenters supported or disagreed with the following ESPR Findings:

- Mr. Applegate –
    - Support for the finding that a clear standard for placement on the list is missing;
    - Support for the finding that the prioritization criteria used in evaluating adverse impacts and exposures of products are sufficient and comprehensive;
    - Support for the finding that priorities should depend on "degree of potential hazard and amount of potential exposure;"
    - While Mr. Applegate supports considerations that reduce or control exposure, a commenter cautions that assumptions about the effectiveness

of control strategies, especially in view of full product life cycle, should not be permitted to undermine the essential thrust of the regulations;
    - Support for the finding that it is over inclusive for exposure analysis to be based on mere presence;
    - Support for the finding that prioritization criteria are comprehensive and sufficient;
    - Support for the finding that consideration of aspects of products that control or reduce exposure should be a part of prioritization process, but cautions that control strategies are often ineffective;
    - Support for the finding that there is a "regulatory gap" in obtaining information about products containing Chemical(s) of Concern in a comprehensive and systematic way;
    - Support for the finding that feasibility concerns are factored into prioritization; and
    - Support for relying on DTSC's professional judgment of all competing considerations during implementation.

- Dr. Ashford –
    - Support for the finding that Priority Product prioritization factors have been assembled with "thoroughness" and are "comprehensive," including "occupational exposures", "sensitive subpopulations," as well as neurotoxicity, endocrine disruption and developmental effects in the regulations; all of which are science- based.

- Dr. Bennett –
    - Support for the finding that "product" could be more clearly defined;
    - Support for the finding questioning the applicability of the regulation to products not produced or manufactured in California;
    - Support for the finding that the proposed regulations should give more weight to indoor environmental modeling as most consumer products are often used only in an indoor environment;
    - Support for the finding that exposure from products with the same chemical in different uses may have very different likelihood of being transferred to a person;
    - Support for the finding that exposure modeling, including indoor and dermal exposure modeling and monitoring information, will be helpful to DTSC in taking a quantitative approach, and is consistent with regulatory and industry safety assessments;

  - Support for the finding that the regulations should explicitly consider and note direct consumer exposure from the product;
  - Support for the finding that cumulative exposure is an important prioritization criterion and recommends use of indoor environment modeling, because most consumer products are often used only in an indoor environment;
  - Support for the finding that there is a lack of clarity regarding evaluation of structurally similar compounds; and
  - Disagreement with the finding that DTSC need evaluate chemicals that are structurally similar to another compound with a known toxicity profile to the degree that this would expand the lists of Chemical(s) of Concern.

- Dr. Christensen –
  - Support for the finding that consideration of a chemical's physical properties, volume in commerce, impacts on sensitive subpopulations, exposure potential, and environmental impacts is appropriately included in prioritization;
  - Support for the finding that the prioritization process is "logical and scientifically sound"; and
  - Support for the finding that there are existing data gaps for a majority of chemicals; quantitative data exists for only a small subset of the criteria in the proposed regulations.

- Dr. Farland –
  - Support for the finding that a narrative process for chemical and product prioritization over a quantitative weighting scheme is a sound decision, given that available information will vary and there will be many differences from product to product and that would be difficult to compare;
  - Support for the finding that there should be an "internal consistency" step in the priority setting process and that should be transparent in DTSC's decisions, since the narrative standard is subjective. Rather, a quantitative approach to prioritization is a pathway to a more scientifically sound process;
  - Support for the finding regarding the inherent potency of a Chemical of Concern and the need for a discussion of available test data;
  - Commenter disagrees with the finding that cumulative exposures to chemicals with the same hazard trait should be considered; and

- Commenter warns against undue reliance on volume of data available as a primary criterion for setting priorities.

- Dr. Gray –
  - Support for the finding that the effort to cast a large net in choosing chemical lists could fail to appropriately focus the efforts of the proposed regulation;
  - Support for the finding that the prioritization criteria are too broad and need more specificity;
  - Support for the finding that rigorously addressing aggregate and/or cumulative effects is very difficult but a "worthy goal;"
  - Support for the finding that a focus on all populations, including those that may be more vulnerable, is important and appropriate;
  - Support for the finding that prioritization should include chemical potency and levels of human and environmental exposure, and it could be more clearly explained how this will work;
  - Support for the finding that using Chemical of Concern exposures for setting priorities is fraught with complexities, and different conclusions can be drawn from similar data;
  - Support for the finding that how widely a product is used is an inappropriate surrogate for exposure; and
  - Support for the finding that there should be a focus on potency and level of exposure rather than de minimis determinations to prioritize the Chemical(s) of Concern list.

- Dr. Hattis -
  - Support for the finding that exposure pathways and intake fractions are very different across different uses of the same chemical in different products. This should be a first step of analysis when prioritizing products.
  - Support for the finding that the "narrative" approach alludes to a weighing of differing toxicological and/or ecological effects without specifying the priority of the various effects;
  - Support for the finding that there is a "need for consistency across chemicals and chemical uses in the uncertainty metric that will be used for priority ranking" and recommends more detailed guidance;
  - Comment notes that reviewer cites an unsubstantiated calculation as a basis for revamping the prioritization process described in the regulation, while stating it is "difficult to assess a chemical without making implicit or

explicit assumptions related to use types." It is unclear what scientific point the reviewer is attempting to make in this response; and
    - Comment notes that reviewer seems to miss the product category provision of the regulation.

- Dr. Locke –
    - Support for the finding that the descriptive, narrative methodology for classifying Priority Products "is science based and makes sense given the nature of the statute and its intent."
    - Support for the finding that exposure scenarios should look at more than "reasonable use" in order to reflect accidental over-exposures that are a part of the bigger picture;
    - Support for the finding that exposure distributions may be useful in more refined assessments; however, that level of analysis is probably not needed in making priority-setting decisions on a relative ranking basis; and
    - Support for the finding that it is also appropriate and scientifically necessary to include accidents and over-exposures, even if these resulted from unintended or improper use of the products.

- Dr. Renn –
    - Support for the finding that the prioritization process has too many factors, criteria are redundant, have different classification principles and suggests a systematic approach to the priority list;
    - Support for the finding that the regulations assume there is a single threshold relevant for comparing alternative chemicals; and
    - Support for the suggestion for a scheme based on threat to human health, threat to environment, hazard traits, exposure, and probability of harm.

- Dr. Sass –
    - Support for the finding that criteria allows prioritization process to focus on relevant scientific information and evidence;
    - Support for the recommendation that DTSC build in consideration of variables such as ability to bioaccumulate, and unintended presence in body tissues, to reflect a precautionary approach to risk assessment;
    - Support use of the factors identified as a means of evaluating products to determine the adverse impacts and exposure associated with the product; and

  - Support for the finding that inclusion of markets and sales data is a very good idea; this information should be made public. Other commenters disagree with the recommendation that market and sales information be made public.

- Drs. Hattis and Bennett –
  - Support for the finding that the utilization of structure-activity models should be included; and
  - Disagree that chemicals that are structurally similar to another compound with a known toxicity profile should be included in the regulation, as it would greatly expand the list of chemicals of concern, which will reduce DTSC's ability to focus on the chemicals, and products that pose the greatest risk to the environment and human health.

- Public comments on suggestions made by several of the ESPR entities:
  - Support for the finding that there is a lot of work required to make these regulations practical, meaningful and defensible with respect to selection of Priority Products and the Alternatives Analysis (AA) Threshold;
  - Support for the finding that the availability of data will be key for the functioning of this program;
  - Support for the finding that DTSC should identify consumer product uses that are not regulated by others and focus where chemical/product combinations pose the greatest risks;
  - Support for the finding that DTSC should endeavor to protect intellectual property and confidential information;
  - Chemicals used in manufacturing may not be present in the final product and DTSC must consider this in terms of exposure; and
  - DTSC should not produce or accept information about technologically or economically feasible alternatives from third parties.
- Comment noted that without seeing the prioritization process applied to a particular product, a true evaluation of the scientific basis could not be performed.

Response:

DTSC appreciates the public feedback on the ESPR Topic 2 findings. For a more detailed discussion on the rationale for accepting or rejecting the ESPR Findings, please see the responses to the ESPR Topic 2, above. Those responses are

applicable here as well. Therefore, to a large extent further responses would be redundant. Nonetheless, DTSC offers the following in further response to these public comments.

The regulations reflect the authorizing legislation, which specifies the type of information that may be claimed as trade secret. While the proposed regulations do not require that all critical business decisions be released to external entities, they do require that information related to hazard traits for chemicals be made public. For a more detailed discussion on masking of trade secret information, please refer to the discussion of Trade Secrets under Article 10 in the Response to Comments for the July 2012 version of the regulations and Article 9 in the Response to Comments documents for the January 2013 and April 2013 versions of the proposed regulations. This aside, information submitted to DTSC with valid trade secret claims will not be made publicly available.

DTSC appreciates the concern expressed in the comment regarding accepting information about technologically or economically feasible alternatives from third parties. While no changes have been made to the proposed regulations in response to this comment, DTSC will strive to use all submitted information appropriately, and give proper consideration to the source of such information.

**TOPIC 3**

THE PRINCIPLES OUTLINED IN THE PROPOSED REGULATIONS THAT WILL ALLOW THE DEPARTMENT TO DEVELOP ALTERNATIVES ANALYSIS THRESHOLD BASED ON BEST AVAILABLE TECHNOLOGIES IS SCIENTIFICALLY UNDERSTOOD.

**ESPR Findings on Topic 3**

**Findings:** JA-6, JA-7, JA-8, JA-9, JA-10, NA-14, NA-15, NA-16, DB-13, DB-14, DB-15, DB-16, NC-5, NC-6, WF-8, WF-9, WF-10, WF-11, GG-3, GG-8, DH-6, DH-8, PL-5, PL-6, OR-6, OR-7, JS-12

Findings Summary:

The above Findings expressed support or areas of concern related to Topic 3. In summary, the following views were expressed:

- The fundamental standard is protective of public health and the environment , and technically feasible;
- DTSC uses its judgment to evaluate the seriousness of the risk and to weigh it

against the practicality and reasonableness of making changes;

- Section 69503.5(c) and (d) are sensible to balance the benefits of recycling and the danger of contaminants;
- The considerations are thorough, reasonable, and avoid duplication of others' efforts;
- The regulations should look more to potency and levels of exposure than hazard traits;
- The principles for the Alternatives Analysis Threshold (AA Threshold) exemption are "scientifically understood," and the use of the concepts is also logical in the context of the overall structure of the threshold exemption provision;
- The principles underpinning the AA Thresholds are clear and will ensure approval of alternative chemicals is based on the best available science and technologies;
- If a chemical poses a serious threat to human health or the environment, it may not be sufficient to grant an AA Threshold exemption;
- Supports the reasonable accommodation to consider whether or not it is technically or economically feasible to remove the contaminants which are unavoidable and beyond the control of the responsible entity;
- While DTSC is explicit about its intent to separate the AA Threshold from a determination of *de minimis* risk, it is likely to find that stakeholders will not see this distinction when providing their comments during public workshops;
- The emphasis on "detection" rather than "quantitation" is consistent with our understanding that chemicals may have adverse impacts below levels of quantitative measurement;
- The AA Threshold does not factor in how sensitive subpopulations are affected;
- Evaluating the considerations in section 69503.5(c)(3) is easier said than done, and potential difficulties with applying these principles are not, but should be, discussed in the Statement of Reasons;
- The approach to setting the AA Threshold is a reasonable approach to take, but it is essentially a policy-based, rather than a science-based decision;
- The regulations should have flexibility to accommodate a non-additive way of combining the multiple Chemical(s) of Concern whose joint effects are multiplicative, or have different potencies, and should address Priority Products that have two or more Chemical(s) of Concern that do not exhibit the same hazard trait or endpoint;
- More guidance should be provided to understand how DTSC will weigh technical difficulties of removing unintended contamination against the criteria in section

69503.5(c);

- This section is scientifically understood, is robust and is comprehensive. However, whether or not the science is available to be able to develop a threshold for each chemical will depend on the chemical, or class of chemicals, and it is hard to predict how flexible this will be for future chemicals;
- DTSC should be wary of manufacturers "diluting" the concentration of chemicals in their products and increasing "serving size" to fall below AA Threshold levels;
- The provisions incorrectly assume that there is a single threshold that may be relevant in comparison for potential alternative chemicals;
- The AA Threshold is important to focus effort and resources. However, the definition of cumulative exposure is congruent with the definition in one recent National Academy of Sciences report, but at odds with that in another. These attributes need more specificity to ensure consistency and fairness in their application;
- DTSC should not set the detection level as the AA Threshold if laboratory analytical methods are not available or are not sensitive enough to detect Chemical(s) of Concern at or below the levels that have the potential to create public health or environmental risk; and
- The regulations should consider the expected intake fraction for the use of Chemical(s) of Concern in the types of application expected for the product under analysis.

Response:

DTSC acknowledges these findings, and the AA Threshold exemption was revised. The AA Threshold will no longer be determined for a specific Priority Product, so all the criteria for setting a threshold have been deleted from the proposed regulations. The AA Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the Chemical of Concern solely as a contaminant chemical. If during the product prioritization process DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product this can be addressed in the rulemaking for that Priority Product listing.

DTSC considered in its earlier regulations proposal, dated September 2010, the use and concept of the term "de minimis" to harmonize the proposed regulations with the application of de minimis level concepts with numerous state, federal, and global regulations. It was crafted to serve as an "administrative convenience." That is, the "de

minimis" levels and concepts contemplated in earlier drafts of these regulations were never intended to define a level at which risks were negligible or unimportant. The term "de minimis" as used in the EU's Restriction of Hazardous Substances Directive, REACH and other programs is a reporting limit based on volume, not risk. The overlapping and potentially conflicting uses of the term caused DTSC to reconsider the use of the term, and to instead create an independent term to minimize the mistaken assumption that the concentration equates to an acceptable level of risk. The proposed regulations dated July 2012 appropriately introduced the use of the term "Alternatives Analysis Threshold" and related Exemption Notification—that is an exemption from the requirement to conduct an AA. In response to comments on the proposed regulations dated July 2012, the term was amended to "Alternatives Analysis Threshold Notification."

An AA Threshold is 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). If during the product prioritization process, DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product, this can 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 reserved the right 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.

DTSC is cognizant that the PQL is media- and product- specific and that it will ultimately require that manufacturers account for any concentration of intentionally added Chemical(s) of Concern in the products that they manufacture. Despite the potential variability in the concentrations detected, the proposed regulations are aligned with and consistent with the goal and intent of AB 1879, in which continuous improvement is sought for safer alternatives in lieu of establishing safe harbors for chemicals that have been demonstrated to be of concern. As technological advances are made and the concentrations of chemicals are detected, assessments on whether they are of concern can be made. DTSC believes that this approach strikes the proper balance between innovation and safer consumer products.

At the onset, DTSC will develop guidance materials to address the preparation of the AA and examples of how to demonstrate compliance with threshold requirements, if

applicable. Responsible entities may use supply chain declarations, third party chemical management certifications and internal process controls to obtain data; however, the data demonstrating compliance with any threshold must be provided with the appropriate notifications and/or AA Reports. As the program matures, DTSC may recommend product- specific testing to demonstrate compliance. 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.

**Public Comments on ESPR Findings Topic 3**

**Comments:** 1-9, 2-8, 3-1, 3-2, 4-6, 7-5, 7-10, 7-19, 7-27, 7-28, 7-38, 7-45, 8-8, 8-11, 8-14, 8-30, 8-35, 8-39, 8-41, 8-49, 8-51, 8-61, 8-65, 8-66, 8-71, 10-23, 10-24, 10-25, 11-1, 11-2, 11-5, 11-6, 11-11, 11-12, 11-13, 11-19, 11-20, 11-21, 13-1, 13-2, 13-8, 14-11, 14-12, 14-13, 14-14

Comments Summary:

The above comments expressed support or noted areas of concern related to the ESPR Findings on Topic 3. Specifically, commenters found:

- Mr. Applegate –
    - Support for the finding commending DTSC for recognizing that the benefits of recycling may outweigh the danger of contaminants;
    - Support for the finding that the principles for threshold exemptions are “scientifically understood” in that they deploy frequently used terms and concepts in a rational way;
    - Support for the finding that "In sum, the principles for the threshold exemption are "scientifically understood" in that they deploy frequently used terms and concepts in a rational way…"; and
    - Some comments agree and some disagree with the finding that the process for establishing the AA Threshold serves to focus the regulation and compliance efforts on the chemicals and products that are most likely to pose risk. One comment stated that given the scope of the Chemical(s) of Concern, it seems to argue the contrary. In addition, details of the AA Threshold process have not been published, and making a scientific judgment does not seem possible.

- Dr. Ashford –

  - Support for the finding that the AA Threshold exemption should not be available for chemicals that are carcinogens, mutagens, teratogens or endocrine disruptors; and
  - Support and disagreement for the finding that excluding carcinogens, mutagens, teratogens and endocrine disruptors from the AA Threshold exemption is at odds with all global regulatory systems, which do employ a *de minimis* for such substances.

- Dr. Bennett –
  - Support for the finding that it is important to consider the economic and technological feasibility of removing contaminants when setting the AA Threshold ;
  - Support for the finding that it is unclear how DTSC would weigh the technical difficulties related to removing contaminants with the criteria in section 69503.5(c)(3).

- Dr. Christensen –
  - Support for the finding that regarding AA Thresholds, the principles here are clear and will ensure that approval of alternative chemical is based on best available science and technologies; and
  - Comment that emphasis on detection rather than quantification is consistent with understanding of chemicals is an opinion, and does not represent a scientific consensus.

- Dr. Farland –
  - Support for the finding that there are a variety of difficulties with this endeavor. For example, the minimum concentration of the Chemical(s) of Concern that can be detected in the Priority Product with available laboratory analytical methodology may be difficult;
  - Support for the finding that presence or absence of a threshold dose response is rather simplistic; the regulations must include a more rigorous discussion of dose response and thresholds;
  - Support for the finding that background concentrations of both exogenous and endogenous concentrations of Chemical(s) of Concern must be considered;
  - Support for the finding that cumulative exposures to other Chemical(s) of Concern that exhibit the same hazard traits leaves much scientific complexity unstated;

  - Support for the finding that "the inherent potency of the Chemical of Concern" is a valid scientific concern and the need for discussion of available test data and an evaluation of the statistical treatment of the toxicological data;
  - Support for the finding that setting the default AA Threshold to the limit of detection is a policy-based decision rather than a science-based decision; and
  - Support for the finding that there should be consideration of situations where it is not technically or economically feasible to remove contaminants.

- Dr. Gray –
  - Support for the finding that AA Threshold exemption is an important administrative tool for focusing effort and resources, while noting a significant number of scientific and technical issues requiring "more specificity to ensure consistency and fairness in their application"; and
  - Support for the finding that establishing AA Threshold s may prove difficult.

- Dr. Hattis –
  - Support for the suggestion that DTSC consider indoor air pollutants more carefully than outdoor ones, specifically in determining AA Threshold exemptions, to be more protective;
  - Support for the finding that the AA Threshold may not factor in critical exposure pathway information; and
  - Commenters note or disagree with the finding that manufacturers will dilute their products in order for the Chemical(s) of Concern in the product to be below the AA Threshold, as there are significant benefits to providing products in concentrated forms into the marketplace.

- Dr. Locke –
  - Support for the finding that it is unclear if there are suitable laboratory analytical methodologies for numerous Chemical(s) of Concern in many Priority Products, and this approach could be counterproductive and actually defeat the incorporation of the best science;
  - Support for the finding that the AA Threshold should be determined from public health and/or environmental health level rather than detection limit of a chemical; and

  - Support for the finding that combinations of chemicals can have both additive and/or multiplicative effects and this should be accounted for in AA Threshold determinations. Commenter states that this is oversimplification.
- Dr. Renn –
  - Support for the finding that the proposed regulations seem to assume that there is a single threshold relevant for comparison purposes among alternative chemicals whether it relates to endpoints or priority of other desirable environmental outcomes; and
  - Support for the finding that establishing AA Thresholds may prove difficult. Because all chemicals can cause harm, dose rather than presence should be taken into account.

- Dr. Sass –
  - Support for the finding that AA Thresholds set on a case-by-case basis is scientifically understood, robust, and comprehensive enough to allow DTSC to develop scientifically defensible AA Thresholds;
  - Support for the finding that this AA Thresholds process may be challenging for some chemicals or classes of chemicals; and
  - Support for the finding that DTSC is wise to identify critical properties like inherent potency, the ability to bioaccumulate, the unintended presence body tissues, and the disproportionate impact on sensitive populations or habitats. These critical properties provide guideposts for meaningful assessments of the impacts of chemicals, even when little is known of their toxicity.
- Comment noted that only two of the ESPR entities recognized the significant analytical challenges;
- Comment noted that none of the ESPR entities acknowledged or suggested the use of international *de minimis* standards, as a starting point;
  - Comment that Dr. Gray's finding regarding lack of available information would support a de minimis threshold approach to refine the scope to greatest hazards.
- Comment noted that the default AA Threshold is driven by policy and administrative decisions, rather than a broad scientific foundation;
- Comment noted that a de minimis AA Threshold would be consistent with other regulatory programs run by US EPA and the European Union (EU);
- Comment noted that the regulations should only apply to intentionally added chemicals and a default AA Threshold should be used;

- Comment noted that question failed to require ESPR entities to address the practicality of the proposal; and
- Comment noted that reviewer expressed an opinion that does not reflect an established scientific consensus.

Response:

DTSC appreciates the public feedback on the ESPR Topic 3 findings. For a more detailed discussion on the rationale for accepting or rejecting the ESPR Findings please the responses to the ESPR Topic 3, above. Those responses are equally applicable here as well. Thus, further responses to these same issues would be redundant.

DTSC is mindful of the concerns raised by the ESPR entities and the public, and has revised the AA Threshold exemption. Please refer to the ESPR Reviewer's Reports on the revised regulations (dated January 2013), and the corresponding Response to Findings for the revisions to the proposed regulations. More detailed discussion of DTSC's rationale for the revised AA Threshold exemption may also be found in the Response to Comments for the January 2013 version of the regulations.

**TOPIC 4**

THE DEFINITIONS OF THE VARIOUS "ADVERSE" IMPACTS AND GENERAL USAGE OF THE TERM "ADVERSE" IMPACTS IS USED THROUGHOUT THE REGULATIONS. WITHIN THE CONTEXT OF THE DEFINITIONAL AND GENERAL USE OF THE TERM "ADVERSE" IMPACTS IN THE REGULATIONS AND WHEN SCIENTIFIC INFORMATION IS AVAILABLE, A QUALITATIVE OR QUANTITATIVE DETERMINATION OF ADVERSE IMPACT CAN BE MADE, AND IS ADEQUATELY PROTECTIVE OF PUBLIC HEALTH AND THE ENVIRONMENT.

**ESPR Findings on Topic 4**

**Findings:** JA-11, DB-17, DB-19, NC-8, WF-12, GG-9, DH-7, PL-7, OR-8, JS-13, JS-14

Findings Summary:

The above Findings expressed support or areas of concern related to Topic 4. In summary, the following statements of support were expressed:

- The term "adverse impacts" as used in the regulations is adequate to protect public health and the environment;
- "Adverse" is carefully defined and applied consistently throughout the proposed regulations to adequately protect public health and the environment;

- Furthermore, when scientific information is available, a qualitative or quantitative determination of adverse impact can generally be made. While scientific information may be in short supply with regard to some criteria, the proposed regulations provide sufficient latitude in such situation to protect the interests of both the public and responsible entities;
- The definitions and goals of the various adverse impacts are very appropriate;
- The scientific portions of the proposed rule is based upon sound scientific knowledge, methods, and practices;
- The descriptions of adverse ecological, public health, and waste and end-of-life impacts are comprehensive and appropriate;
- The definition of "adverse effect" from the Office of Environmental Health Hazard Assessment's (OEHHA) Green Chemistry Hazard Traits (22 CCR 69401.2(a)) is scientifically valuable, and should be added into the definitions of adverse impacts;
- The use of the term "adverse impacts" in Article 5 does not appear to limit the breadth or utility of the term; and
- The approach of more specifically defining "adverse" in the context of different analyses will cause little difficulty.

In summary, the following statements of concern were expressed:

- DTSC will need a great deal of data to determine the risk of adverse impacts quantitatively;
- The scientific definition of "adverse" is not very clear. This topic is the subject of scientific debate, and there are issues regarding what constitutes an "adverse" versus an "adaptive" response to the exposure (see National Research Council report and various publications);
- Adverse air quality impacts included are not adverse impacts; they may result in adverse impacts;
- Bioaccumulation without consequences is not an adverse impact;
- Public health impacts are reasonably defined subject to concerns about the concordance of hazard traits between test species and humans.
- Exceedance of a standard is not an adverse effect. The values used in setting standards have some degree of conservatism embedded. There may be public health consequences above a standard, but it is not certain; and
- The definition of what is called "adverse" is still quite controversial in the regulatory literature and suggest providing clearer statements to include potential

for harm not only experienced harm, and to limit the adverse effects to those that are officially recognized by the respective medical or ecological authorities.

- Chemicals on the EPA Contaminant Candidate List (CCL) for drinking water contaminants shall also be included in the definition of "adverse water quality impacts."

Response:

DTSC agrees with the findings that adverse public health impacts are appropriately covered and are addressed in a scientifically appropriate manner. One ESPR entity further recommended incorporating the definition of "adverse effect" from the Office of Environmental Health Hazard Assessment's (OEHHA) Green Chemistry Hazard Traits (22 CCR 69401.2(a)) into the definitions of adverse impacts. DTSC believes that the concept of this definition had already been incorporated into the definitions of adverse impacts in the proposed regulations. The definition of "adverse public health impacts" included a reference to OEHHA's article 2 or article 3 of chapter 54 (22 CCR). These articles refer to the hazard traits and toxicological endpoints, and which are subsequently defined as having an adverse effect (defined in 22 CCR 69401.2(a)). "Adverse ecological impacts" also already referenced adverse effect as defined in section 69401.2(a) of Chapter 54.

DTSC agrees with the ESPR entities' findings that the term "adverse" is scientifically debated, and toxicological testing may lead to different endpoints, because testing protocols change and traditional endpoints that were recognized as "adverse" will change. These regulations are designed to take into account current scientific data 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.

Adaptive response to exposure would augment traditional weight of evidence approaches to include an effect that is potentially adverse or potentially indicative of adaptability. 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.

Section 69501.1(a)(3) through (10) provides a number of definitions for "adverse impacts." 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 of 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.

DTSC agrees that the term "potential for harm" needed clarification, and the proposed regulations dated July 2012 were revised in January 2013 to more clearly align with the authorizing legislation. The revised language is found in section 69503.2(a), and the definition of "potential" is in section 69501.1(a)(51). DTSC respectfully disagrees with the suggestion to limit the universe of adverse effects to those that are officially recognized by the respective medical or ecological authorities. This is because the definitions need to be comprehensive enough to be applicable to the toxicological effects on public health specified in Articles 2 and/or 3. These effects clarify life cycle considerations consistent with the statutory requirements in Health and Safety Code section 25253(a)(2).

DTSC agrees with the comment that value judgments and trade-offs may be needed to determine if impacts are beneficial, neutral, or adverse. Since responsible entities must evaluate adverse impacts in the Alternatives Analysis, DTSC does not determine if the impacts are adverse. The responsible entity selects the alternative, and DTSC may impose an appropriate regulatory response(s) based on the selection made by the responsible entity to retain the Priority Product or to choose an alternative.

DTSC disagrees with the ESPR entities' finding that the definitions of "adverse air quality impacts" are not adverse impacts, but they may result in adverse impacts. This definition is written in a slightly different manner than the other adverse definitions, in that, instead of listing specific impacts, this definition of "adverse air quality impacts" means any impacts caused by air emissions of the contaminants listed. The definition by reference also includes any potential "adverse public health impacts", "adverse ecological impacts", "adverse soils quality impact", or "adverse water quality impacts". Each of these specific "adverse impacts" is then in turn defined. For purposes of implementing these regulations, DTSC defined this term to be as specific as possible to be practical and to provide clarity in the selection of Priority Products and for the purposes of their evaluation during the AA.

DTSC agrees with the ESPR entities' finding and noted in the ISOR that bioaccumulation may not cause consequences in the lower trophic organisms, but may adversely impact higher trophic organisms. In addition, pursuant to Health and Safety Code section 25256.1, OEHHA adopted hazard traits in chapter 54 of Title 22, California Code of Regulations, which include bioaccumulation. Pursuant to Health and Safety Code section 25252(b), these hazard traits must be included as criteria to evaluate chemicals and their criteria for the purposes of this regulation. Therefore, the regulations were not revised in response to this finding.

DTSC agrees in part with the ESPR entity's finding that there may be concerns about the concordance of hazard traits between test species and humans. As indicated in section 69502.2, "hazard traits" are only one of the factors used by the DTSC to determine if a chemical should be included on the Candidate Chemicals list. More specifically, section 69502.2(a) provides in pertinent part, *"*a chemical is identified as a Candidate Chemical, if it exhibits a hazard trait and/or an environmental or toxicological endpoint, and meets one or both of the following criteria: [.]*"* Accordingly, if and when there might be limitations in using "hazard traits" for the selection of Candidate Chemicals, as was expressed by the ESPR entity, the regulations indicate that other elements such as toxicological or environmental endpoints will be used in the evaluation process. Therefore, the regulations were not revised in response to this finding.

DTSC agrees in part with the ESPR entity's finding that exceedance of a standard in the scientific sense is not an adverse effect. However, exceedance of a standard is enforceable, and action must be taken to limit exposure, as for example, with drinking water standards. Furthermore, for the purposes of this regulation, this approach provides an indication of adverse outcome, is a practical use of DTSCs resources, and is consistent with Health and Safety Code section 25252(b)(2), which provides: "the department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy." Therefore, the regulations were not revised in response to this finding.

DTSC disagrees with the peer reviewer's finding/recommendation to include the Contaminant Candidate List (CCL) in the definition of "adverse water quality impacts."

Safe Drinking Water Act directs that US EPA to periodically publish a Contaminant Candidate List (CCL). The contaminants on this list are not regulated by existing national primary drinking water regulations, but they are known or anticipated to occur in public water systems, and may require regulation. The CCL alone does not impose any requirements on public water systems, however; EPA may regulate contaminants on the list in the future. After the listing process, CCL contaminants are evaluated further to determine if a contaminant has sufficient data to meet the regulatory determination. If the data are sufficient for a particular contaminant, then a regulatory determination is made on whether EPA should issue a national primary drinking water regulation for a specific contaminant, considering three areas:

- projected adverse health effects from the contaminant;
- the extent of occurrence of the contaminant in drinking water; and
- regulation of the contaminant would present a "meaningful opportunity" for reducing risks to health.

DTSC recognizes that the CCL list is developed by EPA, an authoritative organization, and is intended for the protection of public health and/or the environment. CCL does not require compliance and has no enforcement consequences. Listing is the first step in determining if the contaminant exhibits a hazard trait by the authoritative organization. CCL list is used by EPA as a "screening list" for making regulatory determinations on contaminants found in drinking water. Also, it is important to note that EPA is not limited to making regulatory determinations for only those contaminants on the CCL. EPA can also decide to regulate other unregulated contaminants if information becomes available showing that a specific contaminant presents a public health risk.

**Public Comments on ESPR Findings Topic 4**
**Comments:** 2-9, 7-11, 8-52, 8-72, 10-26, 12-1, 14-15, 14-16, 14-17, 14-18

Comments Summary:

The above comments expressed support or areas of concern related to the ESPR Findings on Topic 4. Specifically, commenters noted:

- Mr. Applegate –
    - Support for the finding that the term "adverse impacts" is comprehensive and will ensure that AAs essentially consider any human health or environmental impact that might be of concern; and

  - Support for the finding that the proposed regulations do not sufficiently distinguish between differing degrees of harm via adverse impact and definitions are broad and not parallel.

- Dr. Gray –
  - Support for the finding that "adverse effects" are outcomes and an impact without an outcome is not "adverse;"
  - Support for the finding that bioaccumulation without consequences is not an adverse effect;
  - Support for the finding that the definition of "adverse air quality impacts" lists specific chemicals, instead of defining the adverse impacts in air that might result in specific chemical identification; and
  - Support for the finding that exceedance of a standard is not an adverse effect. The values used in setting standards have some degree of conservatism embedded. There may be public health consequences above a standard but it is not certain.

- Dr. Farland –
  - Support for the finding that DTSC should adopt a more nuanced approach that distinguishes between "adverse" versus "adaptive" responses to exposure, and the concept of "relevant responses for regulation" should be incorporated into the regulations; and
  - Support for the finding that DTSC should review his report about approaches to identifying adverse effects in the context of the NRC report *Toxicity Testing in the 20$^{th}$ Century*.

- Dr. Locke –
  - Support for the finding that DTSC should incorporate National Research Council's 2007 definition of "adverse effect," which was adopted by OEHHA in Chapter 54 into the definitions of adverse public health impacts, adverse environmental impacts, and adverse ecological effects.

- Dr. Renn –
  - Support for the finding that DTSC should improve the definition of adverse impacts to better clarify the term.

**Response:**

DTSC appreciates the public feedback on the ESPR Topic 4 findings. For a detailed discussion on the rationale for accepting or rejecting the ESPR Findings please review the responses to the ESPR Topic 4, above. Since those responses are applicable here as well, further responses here would be redundant. DTSC also notes that there are detailed discussions of the rationale for all of the definitions in the regulations in the Initial Statement of Reasons for the regulations. In addition, the Response to Comments documents for the July 2012, January 2013, and April 2013 versions of the regulations also has further explanation regarding the defined terms in the regulations.

**ESPR on other Non-Specified Big Picture Scientific Issues**

To ensure that the ESPR entities commented on all aspects of the scientific basis of the proposed regulations, the ESPR entities were instructed to review other aspects of the proposed regulations that may include the "scientific basis" and/or "scientific portions" of the regulations that were not specifically called for under the four topic areas above. The ESPR entities were asked to contemplate the following questions:

(a) In reading the supporting documentation and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above?

(b) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

**Findings:** JA-1, JA-12, JA-13, JA-14, JA-15, JA-16, JA-22, JA-23, NA-1, NA-2, NA-3, DB-5, DB-18, DB-20, DB-21, DB-22, DB-23, NC-7, NC-9, WF-1, GG-10, GG-11, GG-12, GG-13, GG-14, DH-9, DH-10, DH-12, DH-13, DH-14, DH-15, DH-16, DH-17, DH-18, DH-19, DH-20, PL-8, PL-9, OR-9

Findings Summary:
In summary, the following statements of support or concern were expressed:

- The proposed regulation is based upon sound scientific knowledge, methods, and practices;
- An issue with the Alternatives Analysis(AA) is the absence of an explicit standard for a responsible entity to choose or reject an alternative, or for DTSC to accept or reject the responsible entity’s choice;
- The proposed regulations address the “gaps” that drove the enactment of the safer consumer products regulations: the data gap, the safety gap, and the technology gap;

- Using existing data makes a great deal of sense and lets the program rely on established reliable information;
- The proposed regulations represent a well thought out regulatory structure for addressing a lingering environmental and public health problem - the use of untested chemicals in consumer products - and for taking on such a large problem with very limited governmental resources for doing so;
- Use of AA encourages continuous improvement, and allows manufacturers to see areas where innovations can yield benefits;
- The scientific portions of the proposed regulations are clearly based on sound scientific knowledge, methods, and practices;
- Flexibility in the AA process is appropriate and necessary;
- The professional ethics consideration of certified assessors is a good criterion;
- The petition process will prove to be a useful tool to engage non-governmental organizations (NGOs);
- The regulations appropriately place emphasis on exposure factors;
- Reliable information should include journal papers by academic researchers;
- The AA process needs to better consider exposure from personal care products and indoor exposures;
- The life cycle assessment does not necessarily comport with the goals of the regulations;
- It is unclear how the regulations avoid regrettable substitutes;
- The regulations will not reduce the overall use of a chemical, only use of a chemical in a specific product;
- Retailers may be problematic as responsible entities;
- Use of biomonitoring data may be problematic with respect to consumer products;
- DTSC must consider how risk values are calculated, over time or at one specific time;
- DTSC should provide guidance on how “safer alternatives” and their effects should be compared;
- DTSC should clarify what “no appreciable risk to human health” means;
- In the ISOR, on page 13 in Definitions
    - Include “industrial and agricultural workplaces” after “offices” in the section on definitions;
    - Include emissions from office equipment and machines, industrial processes, and the use of chemically-formulated products by workers;

- The regulatory responses represent a good array of options; but could go further in cases where imminent danger is detected; and
- Definition of sensitive subpopulations should be rewritten with a more scientific basis.
    - DTSC should use more precise scientific terms in definitions, for example: "women of childbearing age" is a more accurate descriptor than "pregnant women"; and
    - DTSC should include environmental justice communities as a sensitive subpopulation.

Response:

DTSC appreciates and accepts the general statements of support expressed by ESPR entities on the big picture question. In an effort to reduce redundancy and improve readability, DTSC has grouped the above big picture findings by the article in which the concept or topic is presented in the proposed regulations.

DTSC is not making any changes to the regulations or the ISOR to acknowledge "industrial and agricultural workplaces" locations impacted by adverse air quality and include "emissions from office equipment and machines, industrial processes, and the use of chemically-formulated products by workers." DTSC will add these clarifications to the Final Statement of Reasons, which is the appropriate place in which they should be made.

**ARTICLE 1**

- Definition of sensitive subpopulations should be rewritten with a more scientific basis.
    - DTSC should use more precise scientific terms in definitions, for example: "women of childbearing age" is a more accurate descriptor than "pregnant women"; and
    - DTSC should include environmental justice communities as a sensitive subpopulation.

DTSC respectfully disagrees. The term "sensitive subpopulations," as defined in section 695051.1(a )(64) meets the need and goals of the proposed regulations without adding "women of childbearing age" and/or "environmental justice communities."

The prioritization processes in Articles 2 and 3 focus on Candidate Chemicals that have adverse impacts on human health and the environment. Consumer products identified

as a source of exposure to the Candidate Chemicals may be listed as Priority Products containing Chemical(s) of Concern. They must be prioritized by use of the following statutory factors, at a minimum:

- the volume of a chemical in commerce in California;
- the potential for exposure to a chemical in a consumer product; and,
- potential effects on "sensitive subpopulations," including infants and children. (Health & Safety Code section 25252(a) (1)-(3).)

"Sensitive subpopulations" as defined in section 69501.1(a )(64), of the proposed regulations, means "*subgroups that comprise a meaningful portion of the general population* that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait and/or toxicological endpoint, including, but not limited to, infants, children, pregnant women, and elderly individuals. *'Sensitive subpopulations'* also include persons at greater risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to the nature of their occupation." (Emphases added)

Expansion of the term "sensitive subpopulations to include women of childbearing age would capture females from adolescence until menopause, but would ignore males in this same age group. This would be despite evidence that demonstrates exposure to males also affects male reproductive health and the health of offspring. This expansion would be so broad as to render the term "sensitive subpopulations" so expansive as to not make meaningful distinctions in the regulations.

Similarly inclusion of "environmental justice communities" in the definition of sensitive subpopulations is not necessary, as they *are* already implicitly included in the definition. The regulatory text that provides "subgroups that comprise a meaningful portion of the general population" and "also include persons at greater risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals" captures "environmental justice communities" that are identified as such because they meet these narrative criteria.

- Retailers may be problematic as responsible entities

As stated in the ISOR discussing section 69501.2, Duty to Comply and Consequences of Non-Compliance, the primary responsibility to comply falls on the manufacturer of a Priority Product. However, if a manufacturer fails to comply, the responsibility falls on

the importer. Only if both the manufacturer and importer fail to comply, does the responsibility to comply fall on the assembler or retailer of the consumer product. A "responsible entity," as defined, means any manufacturer, importer, assembler or retailer of the consumer product. For a more detailed discussion on the hierarchy of these responsibilities refer to the ISOR for Article 1, the Response to Comments for Article 1 and the Final Statement of Reasons.

Given that a vast number of the consumer products placed into the stream of commerce in California are done so by someone other than the actual manufacturer of the product, the duty to comply in the proposed regulations is not placed solely on the manufacturer. DTSC's ability to implement the directives of Health and Safety Code sections 25252 and 25253 requires that DTSC be able to compel and enforce compliance with the requirements of these regulations in California. As such, the proposed regulations are similar to the duty to comply approach embodied in other California statutes and regulations that impose requirements on products that are sold in California, but manufactured both in-state and out-of-state (for example, California's Toxics in Packaging Prevention Act, Article 10.4 of Chapter 6.5 of Division 20 of the Health and Safety Code).

If a responsible entity for a Priority Product fails to comply with the requirements of Article 5, the Priority Product may not be offered for sale or distributed in California commerce.

- Reliable information should include journal papers by academic researchers

Although journal papers by academic researchers are not explicitly listed in the definition of reliable information, DTSC agrees with the finding that journal papers by academic researchers are often at the forefront of identifying new chemicals that may be of concern. DTSC has listed "scientifically peer reviewed reports and other literature" among the types of information that constitute "reliable information." This could include journal papers by academics. In implementing the proposed regulations, DTSC will not limit the use of available data, which, as many have said, is limited.

- A point concentration at a single location or point in time is not necessarily "associated with adverse public health or environmental impacts."

This finding pertains to section 69501.1(a )(58) (April 2013 version) that defines "Reliable information demonstrating the occurrence of exposures to a chemical." During

implementation, DTSC shall assess exposure to a chemical based on reliable information from:

- monitoring data that shows the chemical to be present in the home or places employment;
- biomonitoring data that meets the test of reliable information;
- information that is predictive of exposure based on calculations that are described in Article 5 of Chapter 54 of the California Code of Regulations adopted by OEHHA;
- modeling results for exposure assessments and exposure or modeled point concentrations associated with adverse public health impacts; and
- monitoring data related to wastewater or storm water collection and treatment system;

When modeling is to be used to determine exposure to a chemical of interest, modeling will include the chemical's exposure point concentration(s) associated with adverse public health or environmental impacts, as well as environmental accumulation of a chemical.

DTSC acknowledges that an exposure point concentration at a single location or point in time is not necessarily "associated with adverse public health or environmental impacts." DTSC will also rely on information that is predictive of exposure based on calculations that are described in Article 5 of Chapter 54 regulations.

**ARTICLE 2**

- Use of biomonitoring data may be problematic with respect to consumer products.

DTSC acknowledges that establishing a connection between biomonitoring data with consumer products may be difficult. However, while the mere presence of a chemical in an organism or environmental medium cannot be directly linked to a chemical in a product, the presence of this chemical is indicative of releases from at least one source. This is comparable to the exposure demonstrated through various other monitoring programs, such as chemical presence in an indoor setting may be considered reliable information showing exposure. Also, monitoring data related to wastewater or storm water collection and treatment systems presents evidence of exposure to the public and/or the environment. Biomonitoring data used in conjunction with other data and other methods, such as information that is predictive of exposure based on calculations

that are described in Article 5 of Chapter 54 or exposure modeling that may be used to determine exposure to a chemical of interest, will show if exposure is occurring.

**ARTICLE 3**

- DTSC should clarify what "no appreciable risk to human health" means and at what level of confidence should this be judged.

The above referenced phrase "no appreciable risk to human health" is used in the ISOR to explain the provisions in section 69503.5(c )(3 )(D) of the proposed regulations dated July 2012, regarding the presence or absence of a threshold dose response. In response to comments on the July 2012 version of the proposed regulations, section 69503.5 was revised in the January 2013 and April 2013 versions. The provisions that were the subject of the comment were deleted. The revised provisions, in section 69503.5(c), however, still allow DTSC to establish an AA Threshold if during the product prioritization process, it determines that an AA Threshold is needed for a particular intentionally added chemical-product combination, and must be addressed in the rulemaking for that Priority Product listing.

While the term "appreciable" was used in the ISOR accompanying the proposed regulations dated July 2012, given that those provisions have been deleted from the January and April 2013 version, this term will also be deleted from the FSOR.

DTSC will not include in the proposed regulations any benchmark, such as is suggested by the comment urging the inclusion of 1/100,000 risk of mild adverse effects with 95% confidence level. However, the proposed regulations have been amended to remove the provisions that require DTSC to set the AA Threshold on a case-by-case basis for each Chemical of Concern in a Priority Product based on the criteria specified in previously numbered section 69503.5.

An AA Threshold is now generally specified for a Priority Product only if the Chemical(s) of Concern that led to identification as a Priority Product is/are present in the product solely as contaminants. In those cases, the An AA Threshold is the Practical Quantitation Limit (PQL) for each of the chemical(s). If DTSC determines during the product prioritization process that an AA Threshold is appropriate for a particular intentionally added Chemical of Concern in a particular product, this can be addressed in the rulemaking for that Priority Product listing. That is, DTSC has reserved the right to establish specific An AA Threshold on a case-by-case basis for intentionally added chemicals or for contaminants at a concentration higher than the PQL.

**ARTICLE 5**

- An issue with the AA is the absence of an explicit standard for a responsible entity to choose or reject an alternative, or for DTSC to accept or reject the entity's choice.
- DTSC should provide guidance on how "safer alternatives" and their effects should be compared.

DTSC agrees that the proposed regulations do not contain prescriptive standards; however, given the breadth and scope of the proposed regulations, it would be simply unthinkable that DTSC would know all the varying types and pieces of information to make the regulations prescriptive and protective at the same time. The use of narrative standards offers significant advantages over other approaches because they establish the standards or goals and objectives that must be achieved and allow for varying methods and/or criteria that can be used to demonstrate whether the goals and objectives have been met. In contrast, a prescriptive standard would prescribe concentrations, methods of detection, intended uses of the products etc., without stating goals and objectives and would limit the options the regulated entities and DTSC would have at their disposal.

Article 5 of the proposed regulations specifies the minimum threshold for what must be done as part of the AA. As stated in the ISOR, the First and Second Stage AA, and the corresponding Preliminary and Final AA Reports, respectively, comprise the process for an evaluation of the availability of potential alternatives, and address the impacts through a multimedia lifecycle evaluation. During the first stage, the goal, scope, and range of alternatives being considered in the AA must be identified. In the second stage, the relevant factors are refined, compared, and assessed. Collectively, these processes—along with the accompanying reports—establish the basis for identifying the most suitable alternative to the Priority Product, if any, and lay the foundation for imposition of any appropriate regulatory response(s) under Article 6.

DTSC does not select or mandate that a specific alternative be selected; it is a decision reserved for the responsible entity. The responsible entity has the ultimate decision regarding what alternatives are further evaluated and implemented as a safer alternative. Section 69501.1(a)(62), of the proposed regulations, defines "safer alternative" as "an alternative that, in comparison with another product or product manufacturing process, has reduced potential adverse impacts and/or potential

exposures associated with one or more Candidate Chemical(s), Chemical(s) of Concern, and/or replacement chemicals, whichever is/are applicable." A responsible entity may elect to carry forward more than one alternative for additional research and development; however, it is not required. Further, responsible entities may continue to evaluate as many alternatives as they choose that do not pose greater or more adverse impacts than the Priority Product. However, DTSC believes that by narrowing the number of alternatives that are moved forward, costs incurred by the responsible entity may be significantly reduced. As such, the scenarios envisioning that DTSC may impose inappropriate or sub-optimal solutions and thus create prevent environmentally preferable alternatives from being adopted, is unfounded. Again, this is because DTSC is not selecting the alternative, the responsible entity is. DTSC will then impose an appropriate regulatory response in light of the selected alternative.

If a responsible entity submits a Final AA Report selecting an alternative, and later reconsiders another alternative, the Final AA Report must be amended to include the new alternative. DTSC does not "approve" the new alternative, but rather ensures that the appropriate regulatory responses are put in place to address any impact from the selected alternative.

As stated in the proposed regulations at section 69505, in the ISOR, and as required by AB 1879, DTSC has always envisioned the development of guidance materials to assist manufacturers, distributors, retailers, and consumers make consumer product manufacturing, sales and purchasing decisions, as specified in Health and Safety Code section 25253(c). Guidance materials may be developed to be product-specific if DTSC determines that is appropriate and useful. Similarly, if DTSC determines it is appropriate to develop guidance materials that balance different human health and environmental impacts, it will do so during implementation.

- The AA process needs to better consider exposure from personal care products and indoor exposures.

DTSC respectfully disagrees that the AA process should be amended to better consider exposure from personal care products and indoor exposure, as the proposed regulations already address these sorts of exposures. The First and Second Stage AA, and the corresponding Preliminary and Final AA Reports, respectively, comprise the process for an evaluation of the availability of potential alternatives, and address the impacts through a multimedia lifecycle evaluation. During the first stage, the goal, scope, and range of alternatives being considered in the AA must be identified. In the

subsequent second stage, the relevant factors are refined, compared, and assessed. The thirteen criteria in Health and Safety Code section 25253(a)(2) comprise the general contents of an AA, which requires the evaluation of Chemicals of Concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of Concern during the life cycle impacts (i.e., from raw material extraction through materials processing, manufacture, distribution, use, repair and maintenance, to disposal or recycling). To the extent that exposure from personal care products and indoor exposure are identified as relevant factors in the AA, they will be addressed. It is not necessary to explicitly call out "exposure from personal care products and indoor exposure" in the proposed regulations.

The requirements in section 69505.7(g)(1) require that the information be presented in a matrix or other summary format that provides a clear visual comparison among the chemical alternatives being considered and their associated adverse impacts. If the Priority Product is a personal care product that results in indoor exposure, that must be summarized in the Preliminary AA Report and further evaluated in the Final AA Report. The summary may include a conceptual model that illustrates the routes of exposure being contemplated and evaluated and/or being dismissed if the information and analytical tools being used demonstrates that a particular route of exposure may be dismissed. The tools and information used must be included in the Preliminary AA Report that is submitted to DTSC.

- The life cycle assessment does not necessarily comport with the goals of the regulations.

DTSC respectfully disagrees that life cycle assessments do not comport with the goals of the regulations. As indicated in the ISOR, the proposed regulations contain requirements that are not new. The requirements parallel popular life cycle assessment tools for evaluating and/or taking inventory of the impacts of products or services. Manufacturers who are faced with balancing choices commonly take the criteria included in the proposed regulations into account and making tradeoffs when re-manufacturing a product to address a market need or demand. The AA process in the regulations is consistent with commonly used life cycle assessment tools. While manufacturers may have traditionally focused on economic impacts, the proposed regulations require that a responsible entity take into account the life cycle impacts associated with a Priority Product and the alternatives that are considered.

- It is unclear how the regulations avoid regrettable substitutes.

It is important to note that regrettable substitutes have been created in large part due to the lack of an infrastructure to address chemical replacement, which has historically been done piecemeal without addressing multimedia impacts. The proposed regulations establish a process to identify and prioritize chemicals and chemical ingredients in consumer products that may be of concern, based on science. And perhaps more importantly here, the regulations establish a process to evaluate the Chemical(s) of Concern in consumer products *and their potential alternatives* to determine how best to limit exposure or reduce the level of hazard posed by the Chemical(s) of Concern. The evaluation called for in the AA to address life cycle impacts inherently addresses multimedia impacts, thus addressing or preventing regrettable substitutes.

The provisions allow reformulations, redesigns, or replacements to occur without unnecessary DTSC oversight when the reformulated product does not contain any Chemical(s) of Concern or a substitute chemical and hence does not pose a risk of a regrettable substitute. A responsible entity may substitute for Chemical(s) of Concern with either a replacement chemical that is not on the Candidate Chemicals list or a Candidate Chemical that is already in use in lieu of the Chemical(s) of Concern to manufacture the same Priority Product and not be required to conduct an AA.

The notifications and options afforded to responsible entities, especially manufacturers, are not only an improvement from the status quo but also ensure that the appropriate factors are being considered. One key to the success of the program created under the proposed regulations is that the manufacturers may take the initiative to seek safer alternatives and not wait until their products are prioritized. The goal of the proposed regulations is not to prioritize every product and ensure that an AA is conducted for each product, but instead to promote incremental improvements. As such, the notifications allowed create an incentive for manufacturers to begin considering reformulations of their own volition before a product is prioritized. A manufacturer who takes the initiative to remove the Chemical(s) of Concern in its product is afforded opportunities to minimize the amount of DTSC oversight and/or avoid the requirement of conducting an AA under Article 5. The specified activities must be carried out by no later than the due date for the applicable AA Report and one of the following Intent Notifications followed by the Confirmation Notification must be submitted.

- A Chemical Removal Intent and/or Confirmation Notification, certifying that the Chemical(s) of Concern will be/have been removed from the product without the use of any replacement chemical(s);

- A Product Removal Intent and/or Confirmation Notification, certifying that the manufacturer will cease or has ceased fulfilling orders for the product from persons selling or distributing the Priority Product in California.

- A Product-Chemical Replacement Intent and/or Confirmation Notification, certifying that the Chemicals(s) of Concern will be or have been removed from the product and any replacement chemical meets one of the following criteria:
    - The replacement chemical is not on the list of Candidate Chemicals; or
    - The replacement chemical is a Candidate Chemical that is already in use, in lieu of the Chemical(s) of Concern, to manufacture the same product by the same or a different manufacturer.

The notification requirements apply to all replacement chemicals whether on the Candidate Chemicals list or not. DTSC is cognizant that replacement chemicals not on the Candidate Chemical list may have health and environmental effects; however, to the extent that replacement chemicals exhibit hazard traits, those chemicals must be addressed through a subsequent Priority Product prioritization process. This is the only practical and logical means to allow entities to switch to safer alternatives or run the risk of being re-prioritized. Also, consumers may provide the necessary feedback in the marketplace through their buying preferences.

- The regulations will not reduce the overall use of a chemical, only use of a chemical in a specific product.

DTSC respectfully disagrees with the contention that the regulations will not lead to an overall reduction in the use of a chemical. While DTSC cannot predict the future, it anticipates that the regulations will increase awareness of the hazards created by the presence of certain chemicals in products. Responsible entities, namely manufacturers actively engaged in conducting research and development, may reduce the use of those chemicals or determine that the levels being used are unnecessary for the function and performance of the product. In order to avoid regulatory oversight, these entities will look to implement alternatives to the use of Candidate Chemicals and/or Chemicals of Concern in their products.

**ARTICLE 6**

- The regulatory responses represent a good array of options, but could go further in cases where imminent danger is detected.

DTSC agrees with the above recommendation. In response to the above recommendation and other related comments submitted on the July 2012 version of the proposed regulations, section 69506.5(b) was amended. The proposed regulations dated January and April 2013, require that in making a determination that a product containing a Chemical of Concern may no longer be placed in the stream of commerce in California, notwithstanding that there are no alternatives, DTSC must consider the exposure pathways and the ability to contribute to or cause adverse public health impacts and/or environmental impacts associated with an alternative product or the Priority Product. The provisions in section 69506.5(a) have been amended, the term "ability to" has been deleted, and "potential" inserted in its place.

**Public Comments on ESPR Big Picture Issues**

Comments: 2-10, 2-11, 3-3, 3-5, 6-1, 6-4, 7-1, 7-3, 7-11, 7-12, 7-22, 7-25, 7-29, 7-30, 7-31, 7-32, 7-33, 7-39, 7-40, 8-10, 8-12, 8-15, 8-16, 8-17, 8-18, 8-19, 8-20, 8-21, 8-31, 8-32, 8-33, 8-42, 8-44, 8-47, 8-53, 8-54, 8-55, 8-67, 8-68, 10-5, 10-6, 10-7, 10-8, 10-9, 10-10, 11-4, 11-18, 11-23, 13-9, 14-19, 14-20, 14-21

The above comments addressed the ESPR Big Picture findings, and specifically commented:

- The responses to the Big Picture question were largely unfocused, reflecting the lack of direction in the question;
- Many ESPR entities noted that there is work left to be done by DTSC to make the regulation practical, meaningful, and defensible—especially as related to the prioritization process and AA Threshold ;
- Comments noted that some entities expressed opinions not necessarily supported by existing scientific understanding or consensus;
- Despite differences of opinion on some issues, there is substantial agreement among the ESPR entities that DTSC has proposed in its draft regulations a science-based program;
- Support for the finding that DTSC should aim to focus the regulations on consumer products that pose true risks for human health and the environment, and avoid regrettable substitutes; and

- Comments commending multiple ESPR entities' finding that the "scientific portion of the draft regulations is "based on sound scientific knowledge, methods and practices."

- Mr. Applegate
    - Support for the finding that DTSC needs to find the most efficient way to regulate and must be careful to avoid duplicating prior regulatory efforts;
    - Support for the finding that the regulations address the three gaps;
    - Support for the finding that there is a lack of mandatory data gathering mechanisms;
    - Support for the finding that there is a lack of resources to implement the law;
    - Support for the finding that the overall regulation is an efficient effort to promote a culture of iteration and continuous improvement;
    - Support for the concern regarding lack of explicit standard for a responsible entity to choose an alternative is valid, but commenter believes the regulations reflect the express language and intent of AB 1879 in allowing entities to choose the alternative;
    - Disagree with reviewer's contention that chemicals in consumer products are untested; and
    - Disagree with reviewer's belief that the regulated and the regulator will collaborate.

- Dr. Ashford
    - Commenter notes that the ability to substitute with safer technological or administrative approaches is already incorporated as an option in the AA process; and
    - Commenter disagrees that DTSC could expand the program to include industrial and agricultural workplaces.

- Dr. Bennett
    - Commenter notes that reviewer's comments appear to be driven more by policy considerations than scientific ones;
    - Support for the finding that traditional life cycle assessments do not adequately address all factors that are critical to quantifying all public health impacts;

  - Support for the finding that not all life cycle impacts focus on the goal of reducing the level of hazard posed by chemicals in products; and
  - Support for the finding that the regulations do not address the concern of consumer vulnerability from "off-brand" items.

- Dr. Farland
  - Support for the finding that DTSC should use the best available science and judgments in its decision-making. Although, DTSC should not employ every new theory that arises, but rather adopt advances as they become settled science.

- Dr. Gray
  - Support for the finding that DTSC should allow as much flexibility as possible in the AA process;
  - Support for the finding that the regulations should establish a system that truly leads to good choices that result in reduced risk;
  - Support for the finding that the AA process will involve value judgments; commenter noted that DTSC should place more emphasis on the decision- making process that must evaluate such judgments;
  - Support for the finding that the AA process must be transparent as to how options are weighed, but commenter notes that this transparency must not threaten confidential business information;
  - Support for the finding that the AA process can be easily confused by a traditional approach to chemical assessment, and that choosing between alternatives means weighing incommensurate outcomes;
  - Support for the finding that a data-poor chemical could be substituted for a data-rich chemical inviting regrettable substitutes;
  - Support for the finding that there is a lack of specificity, guidance, and transparency in the process for weighing and choosing alternatives; and
  - Support for the finding that life-cycle thinking is appropriate and can help avoid unintended consequences when choosing alternatives.

- Dr. Hattis
  - Support for the finding that the petition process will leverage the resources of NGOs;
  - Support for the finding that non-chemical alternatives such as technology substitution should be explicitly welcomed;

  - Support and disagreement for the finding that DTSC should consider an imminent hazard options for regulatory responses to recall products already in market; and
  - Support for the finding that there should be professional ethics requirements for AA assessor certification.

- Dr. Locke
  - Support for the finding that DTSC should use more precise scientific terms in definitions, for example: “women of childbearing age” is a more accurate descriptor than “pregnant women;” and
  - Support for the finding that DTSC should include environmental justice communities as a sensitive subpopulation.

- Dr. Renn
  - Comment found reviewer’s findings to be fairly balanced and recognize complexity of chemical management.

Response:

DTSC appreciates the public feedback on the ESPR Big Picture findings. For a more detailed discussion on the rationale for accepting or rejecting the ESPR Findings, please see the responses to the ESPR Big Picture findings, above. Because those responses are equally applicable here, additional responses on these same issues would be redundant.

Without more specific details regarding which opinions by the ESPR are not necessarily supported by existing scientific understanding or consensus, DTSC cannot respond to this vague concern.

DTSC respectfully disagrees that the responses to the big picture questions were unfocused. The question was broad in nature in order to allow ESPR entities to comment on any scientific aspect of the regulations they felt warranted a response. DTSC finds the comments elicited by the question were appropriate and helpful in guiding the regulation drafting process.

**ESPR comments Out of Scope**
Comments: NA-9, NA-11, NA-17, NA-18, NA-19, NA-20, NA-21, NA-22, DH-11

The above comments expressed concerns that fell outside of the scope of this ESPR, and were not related to any scientific concerns. They are summarized below.

- In the ISOR:
  - DTSC should state that information will be gathered through federal and state right-to-know authorities, and should use subpoenas and other legal instruments where appropriate;
  - "The most suitable alternative" should be replaced with "the three most suitable alternatives"; and
  - The ISOR provides no analysis of expected cost or benefit of the regulations.
- The costs of the tasks imposed on entities should be weighed against the protection to public health and safety;
- The proposed rule can be seen as a modernization of the chemical industry, as it will bring new innovation to chemical production and usage;
- Innovation will lead to winners and losers among industrial actors, but economic growth depends on product turnover and evolution;
- Europe and Asia are leading chemical innovation with the United States lagging behind, which we cannot afford; and
- The proposed rule takes us from a risk-based process to a technology-based process.

Response:

The above ESPR comments expressed concerns with the proposed regulations that were outside the scope the questions and issues for review put to the ESPR entities and do not relate to the scientific portions of the proposed regulations.

DTSC does not feel that the ISOR must state that information will be gathered through federal and state right-to-know authorities, and should use subpoenas and other legal instruments where appropriate. At the outset, DTSC feels that information gathering techniques included in the proposed regulations will be sufficient to allow the program to function effectively. If enhanced information gathering proves necessary in the future, DTSC may expand upon those methods at that time.

DTSC disagrees that in the ISOR, "[t]he most suitable alternative" should be replaced with "the three most suitable alternatives," as the aim of these regulations is to allow responsible entities to choose the alternative which is most preferable to their operation. DTSC will respond to this choice with an appropriate regulatory response where necessary.

DTSC appreciates the reviewer's insight that regards the proposed rule as a modernization of the chemical industry, and agrees that innovation may lead to winners and losers among industrial actors. DTSC further acknowledges the reviewer's opinion that Europe and Asia are leading chemical innovation with the United States lagging behind and that the proposed rule takes us from a risk-based process to a technology-based process.

For a discussion of the analysis of economic impacts related to the proposed regulations, please refer to Economic and Fiscal Impact Analysis (Std. 399) portion of the Response to Comments for the July 2012 and January 2013 versions of the proposed regulations and the Economic and Fiscal Impact Analysis (Std. 399) and attachments that were subject to public notice and comment commencing on May 22, 2013.

**Public Comments Out of Scope**

Comments: 7-6, 8-62, 9-1, 10-6, 10-11, 11-7, 11-8, 11-23, 12-1, 14-1

The above comments expressed concerns about the ESPR's comments or point of view that are not scientifically based, and are therefore outside of the scope of issues subject to public comment as part of the ESPR process.

- There is a potential for unequal treatment of economic operators under the regulations;
- The extreme complexity of the AA process and high administrative burdens of implementation raise concerns about compatibility with the Technical Barriers to Trade Agreement;
- Creation of an accreditation and certification system raises concerns about compatibility with the Technical Barriers to Trade Agreement and potential hardships for manufacturers in third world countries;
- Where products are regulated by other agencies for safety and performance, DTSC should not be empowered to determine/require that a safer alternative chemical should be used;
- DTSC should respond to petitions to delist a Priority Product before an entity must comply with the requirement to do an AA;
- DTSC should allow tire manufacturers to demonstrate the need for more time to complete AAs; and
- DTSC should exempt ingredients in tires from the regulation.
- Dr. Ashford

  - Support for the comment that economic impacts should include positive impacts of green chemistry and other external costs and benefits;
  - Commenter disagrees that responsible entities should put forward three alternatives for the department to choose from at the end of the AA process.
- Dr. Hattis
  - Support for comment that ISOR provides no analysis of expected cost or benefit of the regulations pending identification of Priority Product categories, and notes the need for such analysis.

Response:

To the extent that these comments do not relate to the scientific portions of the proposed regulations, they are outside the scope of topics subject to public comments. Comments identical to or similar to these comments were responded to in the Response to Comments for the July 2012 version of the proposed regulations. See those responses to comments for a detailed discussion of these topics.

**External Scientific Peer Review Process**

**Comments:** 1-8, 1-12, 2-1, 4-1, 5-1, 8-1, 8-2, 8-77, 8-78, 8-79, 8-80, 8-81, 8-82, 8-83, 10-2

**Comments Summary:**

The above comments expressed concern with the ESPR process and stated DTSC did not meet the requirements of California Health & Safety Code section 57004. Specifically:

- Because ESPR entities were only asked to consider specific portions of the regulations, they lack familiarity with the entirety of the proposed rule and do not understand the interconnections of each provision;
- There was a lack of supplemental direction for the Big Picture question;
- Public input on the topics for the ESPR was not solicited;

- The scientific issues raised in our comments or in the ESPR may not be addressed prior to release of the next draft release and were not addressed in the recently updated Initial Statement of Reasons (ISOR) for the regulations;
- The ESPR entities efforts have not been utilized in a practical and meaningful manner;
- DTSC should consider the ESPR entities' findings; and explain why when DTSC disagrees as required by Health & Safety Code section 57004;
- The public did not have an opportunity to review the ESPR Reports (Reports) during the public comment period for the proposed regulations that ended on October 11, 2012;
- DTSC provided inadequate guidance to the ESPR entities for appropriate consideration of the "scientific basis" and scientific portions" of regulations per Health & Safety Code section 57004;
- DTSC waited three months from August 30, 2012 to November 30, 2012, to release the ESPR Reports for public comment;
- These Reports focus on policy rather than scientific rigor of the regulation;
- DTSC should empanel and complete an additional ESPR review in the event of any "significant" revision to the regulation; and
- DTSC needs to address the comments from ESPR entities and the public.

**Response:**

DTSC respectfully disagrees with the comments asserting that the ESPR process undertaken by DTSC has not adhered to the requirements of Health and Safety Code section 57004, and that the process was inadequate. As is required by Health & Safety Code section 57004(b), DTSC submitted the scientific portions of the proposed regulations, along with a statement of the scientific topics for the ESPR entities to comment on (referred to as "Topics 1-4") and supporting documents (Initial Statement of Reasons) to the ESPR entities for their evaluation. Each ESPR reviewer submitted a written Report containing his or her Findings on the scientific basis of the proposed regulations to DTSC.

Per the requirements of Health and Safety Code section 57004(a)(2), the four topics provided to the ESPR entities represent the provisions of the proposed regulations that are the "scientific basis" and/or "scientific portions" of the proposed rule that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment. While the ESPR reviewer may review

the provisions that are not scientifically based, those comments are not subject to the same requirements under Health and Safety Code section 570004. As such, not all provisions of the regulations required review by the ESPR entities.

Further, Health and Safety Code section 57004(d)(2) specifies, "a board, department, or office may accept the finding of the external scientific peer review entity, in whole, or in part, and *may* revise the scientific portions of the proposed rule accordingly*".* It further specifies that if the agency adopting regulations "disagrees with any aspect of the finding of the external scientific peer review entity, it shall explain, and include as part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices." This is precisely what DTSC has done in this document.

The ESPR process (Health and Safety Code section 57004) is a separate requirement from the Administrative Procedure Act (APA), Government Code, section 11340 et seq. The ESPR process acknowledges the APA process, and requires that the findings and the explanation for agreeing or disagreeing with an ESPR Finding is included as part of the final rulemaking record under the APA. It is important to note that neither law requires DTSC to take the action sought in these comments, namely, for DTSC to:

- Host the public comment periods for the ESPR Findings concurrently with the those for the proposed regulation;
- Seek stakeholder input on the ESPR process prior to soliciting input from the ESPR entities; or
- Respond to the ESPR Findings and public comments prior to release of the next draft or be sure they were addressed in a Revised Initial Statement of Reasons (ISOR) for the regulation.

DTSC has made every feasible effort to provide documents related to the proposed regulations on a timely basis so as not to delay the review and finalization of the proposed regulations. As stated earlier, on July 18, 2012, DTSC requested the ESPR entities to begin their reviews and to submit their reviews by August 30, 2012. Simultaneously, DTSC received comments from July 27, 2012 until October 11, 2012 on the proposed regulations dated July 2012. This included a thirty (30) day extension that moved the last day of the comment period from September 11, 2012 to October 11, 2012. As such , the deadline for providing the ESPR Findings was extended to October 11, 2012, to provide the ESPR entities the same extension that was provided to

other stakeholders. The ESPR Reports were posted for public comment as soon as was practical. DTSC received comments on the ESPR Reports from November 30, 2012 to January 4, 2013.

DTSC will continue to meet its ESPR obligations under Health & Safety Code section 57004. If DTSC makes any changes to the scientific bases for the regulations or the scientific portions of the regulations that triggers further ESPR under the statute for those changes, DTSC will comply with that duty.

DTSC respectfully disagrees that it has not used the ESPR entities in a meaningful way. DTSC reviewed the ESPR Findings, and revised the proposed regulations where appropriate. DTSC also disagrees that appropriate direction was not provided for the big picture question, as it was designed to elicit a broad array of responses at a necessarily high conceptual level.

**Selection of External Scientific Peer Review Entities**

**Comments:** 1-6, 1-7, 1-13, 2-2, 4-2, 8-1, 8-3, 8-4, 8-5, 8-6, 8-11, 8-34, 10-1, 14-2

Comments Summary:

The above comments expressed support or concern with the selection of ESPR entities. In summary, the following was expressed:

- The criteria used to select ESPR entities should be disclosed in an effort to provide more transparency regarding the process and to assure a balance of expertise and perspectives;
- The ESPR selection process falls short of the best practices used by the National Academy of Sciences, especially in terms of the need for a balance of scientific perspectives in committee composition;
- ESPR entities who have more practical experience implementing regulations or complying with them as a regulated entity would have better served this endeavor;
- ESPR entities have sufficient and appropriate expertise;
- Selection process is flawed – California Water Board indicated that University of California had identified six ESPR entities. However, four additional ESPR entities were selected, which is not consistent with the ESPR process;

- ESPR entities must be unbiased and conflict of interest must be disclosed or appropriately counter-balanced by other ESPR entities;
- The ESPR entities should have had balanced representation like the make-up of the Green Ribbon Science Panel with multi-sector representation;
- All of the ESPR entities are currently affiliated with academia and the tone of their reports lacks sensitivity to economic and market pressures;
- The ESPR entities should have included entities affiliated with unaffected industries and government entities;
- The European Union's REACH program is the only true ESPR for these regulations and recommend that in future, DTSC provide sufficient time for stakeholders to provide comments;
- It is unclear if some ESPR entities' previous involvement with these regulations is consistent with ESPR Guidelines; and
- The process should have ensured that the selected ESPR entities had sufficient and appropriate expertise.

**Response:**

Health and Safety Code section 57004(b), not DTSC, specifies the criteria that must be met in the selection of the ESPR entities. In addition, DTSC must comply with an Interagency Agreement between California EPA and the University of California, Berkeley Institute of the Environment. Through this arrangement, Berkeley Institute of the Environment identifies reviewer candidates. The reviewer candidates are required to complete a 15-page Conflict of Interest Disclosure form and submit it for review. (For a copy of the Interagency Agreement, including the Conflict of Interest Disclosure form, please visit this linked site.)[2]

For example, candidate entities must disclose "any relevant aspect of your background …that might be reasonably construed by others as affecting your judgment." The Berkeley Institute of the Environment then, in concert with an unofficial panel, identifies reviewer candidates from the information provided in the request letter provided by DTSC. In this case, DTSC requested that the ESPR entities have expertise in general toxicology, including chemical hazard assessments tools, such as Green Screen, USEPA's Design for the Environment; materials science, product design, manufacturing practices, and familiarization with material properties involved in common consumer products; and Alternatives Assessments and related tools, including life cycle analysis,

[2] http://www.dtsc.ca.gov/LawsRegsPolicies/upload/Interagency-Agreement.pdf

life cycle thinking, with emphasis on consumer products. Based on the information provided, Berkeley Institute of the Environment decided if the reviewer candidates were appropriate for the assignment. While members of European Union's REACH program may have been suitable candidates, there was no requirement that an exhaustive evaluation of *all* potential candidates be conducted.

Therefore, DTSC respectfully disagrees that any of the ESPR entities had bias or conflicts that would impair them from an objective scientific evaluation. Additionally, instructing the Berkeley Institute of the Environment to select entities based on multi-sector representation, as opposed to the scientific expertise specified above, would detract from the point of having an impartial body, such as the Berkeley Institute of the Environment, objectively reviewing candidate reviewer credentials to ensure a lack of bias or perceived bias. Furthermore, there are no requirements that an exhaustive evaluation of *all* potential candidates be conducted.

Health and Safety Code section 57004(b) establishes the criteria limiting the entities that may serve as external scientific peer reviewers to "the National Academy of Sciences, the University of California, the California State University, or any similar scientific institution of higher learning, any combination of those entities, or with a scientist or group of scientists of comparable stature and qualifications that is recommended by the President of the University of California."

Given that the process related to the Interagency Agreement between DTSC and Berkeley Institute of the Environment is a lengthy one, DTSC solicited additional ESPR entities to ensure the proposed regulations underwent a thorough scientific review prior to taking further action on the proposed regulations.

The complexity of the proposed regulations and essential expertise identified for its review dictate the number of reviewers identified for a proposal. The number assigned, and their expertise is determined by the UC Project Director after careful consideration of the information provided in the request letter and its attachments. For other proposals, the number of ESPR entities has ranged from one to eight. In this case, Cal/EPA solicited input from four entities and DTSC independently sought input from another six entities to ensure adequate coverage of the topics. The selected ESPR entities confirmed that they were able to serve as an unbiased ESPR entity, and did not have financial interests in these proposed regulations.

In regard to the comments regarding Dr. Christensen's previous involvement, DTSC had Drs. Christensen, Locke, Gray, Renn, and Farland review an earlier version of the

proposed regulations (dated September 2010). Health and Safety Code section 57004(c) specifies that no person may serve as an ESPR reviewer for the scientific portion of a rule if that person participated *in the development* of the scientific basis or scientific portion of the rule. Performing a scientific review is a very different process from participating in the development of the scientific portions of the rule. ESPR entities provide feedback regarding the scientific appropriateness, as opposed to being involved in the scientific and policy decision-making to determine how the regulations should be written. The scientific review process is more similar to the work provided by the GRSP, in which DTSC was not required to adopt the approaches provided by any of the GRSP committees or members. Given that none of the ESPR entities served or participated in the development of the proposed regulations, DTSC is in compliance with the statutory parameters.

In regards to the expertise of specific ESPR entities, there is significant value in having a variety of individuals with a wide range of subject matter knowledge provide DTSC with robust, diverse perspectives on the regulations. As such, several ESPR entities were selected to ensure the topics were evaluated from a variety of points of view. While any one of the ESPR entities may not have all of the scientific knowledge and expertise necessary to provide comprehensive findings for all of the topics, each reviewer provided input is valued by DTSC.

DTSC notes that the ESPR is limited to the “scientific basis" and/or "scientific portions" of the proposed rule. Economic and market pressures of the proposed regulation do not fall into the category of scientific basis.

**Scope of External Scientific Peer Review Topics**

**Comments:** 1-1, 1-2, 1-3, 1-4, 1-5, 1-14, 2-3, 2-4, 2-5, 4-2, 4-3, 8-7, 10-3, 10-4, 14-3, 14-4
Comments Summary:

The above comments expressed concern with the scope of the topic areas in which the ESPR were allowed to comment on. While commenters agreed with the four portions selected by DTSC, some felt that more topics could have been covered. Specifically, commenters felt there could have been discussion of:

- A comprehensive view of the entire regulatory program;
- Data reliability, study quality, and evaluation of aggregate and cumulative risk;
- The processes for integrating results across studies;

- Scientific process for evaluating multiple studies to determine overall weight-of-evidence for a particular metric, effect or outcome;
- Definitions such as “reliable information,” “sensitive subpopulations,” and “reliable information demonstrating the occurrence of exposure;”
- Criteria used to select the lists from which Chemical(s) of Concern will be identified;
- Process in Article 3 for all potentially regulated products;
- Criteria used to compare alternatives;
- Role of certified assessors in development of Alternatives Analysis;
- Alternatives Analysis demands in-depth scientific rigor and the proposed approaches;
- Use of weight-of-evidence in decision-making;
- Relationship between the conclusions of an Alternatives Analysis and the Regulatory Response;
- Guidance on prioritization of the listed Chemical(s) of Concern;
- Conditions under which entities might expect variation in the AA Threshold ;
- Scientific procedures such as those employed by US EPA, US Food and Drug Administration or the European Chemicals Agency to evaluate weight of evidence;
- The economic impacts of the proposed regulations and cost effectiveness of the proposed regulations with product review process; and
- Practical considerations of this regulatory approach.

Response**:**

The focus of the ESPR request was on the scientific basis and scientific portions of the proposed regulations and is consistent with the Health & Safety Code Section 57004. Beyond the specific topics, the ESPR entities were asked to comment on any “Big Picture considerations” they had, and specifically to contemplate:

- If there are any additional issues that are part of the scientific basis of the proposed rule; and
- Considering the whole package, if the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices.

DTSC respectfully disagrees that the scope the ESPR was inappropriately limited, and believes that many of these above listed concerns were addressed by the ESPR entities’ comments. Specifically, ESPR entities commented on:

- A comprehensive view of the entire regulatory program;
- Data reliability, study quality, and evaluation of aggregate and cumulative risk;
- The processes for integrating results across studies;
- Scientific process for evaluating multiple studies to determine overall weight-of-the- evidence for a particular metric, effect or outcome;
- Definitions such as “reliable information,” “sensitive subpopulations,” and “reliable information demonstrating the occurrence of exposure;”
- Criteria used to select the lists from which Chemical(s) of Concern will be identified;
- Process in Article 3 for all potentially regulated products;
- Criteria used to compare alternatives;
- Alternatives Analysis demands in-depth scientific rigor and the proposed approaches;
- Use of weight-of-evidence in decision-making;
- Prioritization of the listed Chemical(s) of Concern; and
- Practical considerations of this regulatory approach.

DTSC notes that the relationship between the conclusions of an Alternatives Analysis and the regulatory response is more of a scientific policy decision than a “purely” scientific one, and notes that the ESPR entities did in fact comment on this relationship. Additionally, ESPR entities commented on the economic impacts of the proposed regulations and cost effectiveness of the proposed regulations, though this was certainty outside the scope of their review of the scientific portions of the regulations. DTSC does not agree that the scientific procedures such as those employed by US EPA, US Food and Drug Administration or the European Chemicals Agency to evaluate weight of evidence needed to be specifically addressed in this document since they do not form the scientific basis for these proposed regulations.

As the process for establishing an AA Threshold changed significantly from the July 2012 version of the regulations to the January 2013 version of the regulations, a more robust discussion of that topic may be seen in the ESPR for the January 2013 proposed regulations. Lastly, there was not a discussion of the role of certified assessors in development of Alternatives Analysis because that program was eliminated from the July 2012 version of the regulations (as of the January 2013 version).

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