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Overview and Organization

This document summarizes and responds to public comments submitted to the Department of Toxic Substances Control (DTSC) on the Revised Initial Statement of Reasons (ISOR) for the *proposed Rulemaking titled Safer Consumer Products Alternatives*, which was released to the public on December 21, 2012.

- The Revised ISOR was available for comment for 30 days, with the public comment period closing on January 22, 2013.

DTSC received a total of 12 letters commenting on the Revised ISOR. The docket number for this project is R-2011-02. An alphabetical list of commenters and the number assigned to their correspondence is included in Table 1. The designation “1-1” means comment letter 1, comment 1 and so forth.

For the purpose of orderly presentation, the comments have been categorized in the order and by the Article in the regulations that they address. Comments that are miscellaneous or general in nature have been addressed under the most appropriate headings under Procedural, Legal, and Overarching Issues at the end of the document. 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.

Table 1		
List of Commenters		
#	Name of Entity	Number of comments
1	Alliance of Automobile Manufacturers	15
2	American Chemistry Council	1
3	American Coatings Association	6
4	Complex Durable Goods Coalition	3
5	Consumer Specialty Products Association	15
6	Direct Selling Association	4
7	Electronics Industry: ITIC Tech America, CEA, SIC	3
8	Food Packaging Coalition	2

Table 1		
List of Commenters		
#	Name of Entity	Number of comments
9	North American Insulation Manufacturers Association	1
10	Quint, Julia	1
11	Rubber Manufacturers Association	15
12	Shaw Industries, Inc.	1
13	Toy Industry Association	6

§69501.1 Definitions

Comments: 1-2, 1-5, 1-15

Comments Summary:

Some definitions do not conform to existing definitions of same term in other federal and state statutes and regulations. A comment strongly urges revisions to Article 1 definitions incorporating by reference existing definitions and uses of these terms in other regulatory schemes. No specific definitions are named.

Response:

The comment relates to various provisions that have text changes, but the expressed concern is not related to, or is unaffected by the revisions in the Revised ISOR. However, as a courtesy, DTSC provides the following information: DTSC is not required to have all of its definitions conform to existing definitions of the same terms. DTSC has chosen to do so when it made sense for this regulatory program and not to do so when there is a different or better approach needed to attain the goals of the regulations. Accordingly, DTSC is making no change to the regulations in response to these comments.

§69501.1(a) (Add contaminant)

Comment: 13-3

Comment Summary:

The term "contaminant" is a recurring concept in the ISOR; so, it needs a definition. It is unclear how DTSC will consider contaminants in the regulations.

Response:

DTSC amended the proposed regulations (January 2013 version) to include a definition for "contaminant," which is generally any unintentionally added chemicals. DTSC is making no other changes to the regulations in response to this comment.

§69501.1(a)(4) Adverse Ecological Impacts

Comment: 1-11

Comment Summary:

The definition of "adverse ecological impacts" is inconsistent with existing regulatory schemes and renders other existing definitions irrelevant, including federal and state Endangered Species Acts. It is also inconsistent with the California Environmental Quality Act's (CEQA) definition. The commenter urged revision of this definition to align with other usages.

Response:

The comment relates to a provision that has text changes, but the expressed concern is not related to, or is unaffected by the revisions in the Revised ISOR. However, as a courtesy, DTSC provides the following information: The definition of "adverse ecological impacts" has been revised to change the term "adverse impacts" to "adverse effects." The regulations do not use "effects" and "impacts" synonymously. "Adverse impacts" in the regulations is a defined term, which encompasses both adverse public health and adverse environmental impacts; both of these terms are then defined further. The definition of "adverse ecological impacts" is a listing of various factors that may be affected negatively by a Chemical of Concern. "Adverse impacts" is used throughout the regulations with qualifying phrases, such as "the ability to contribute to or cause."

In the revised draft (January 2013 version), the regulatory text has been amended to provide additional clarity. The qualifying phrase used to modify adverse impacts has been changed to "potential" which is defined to mean "reasonably foreseeable based on reliable information." DTSC is making no other changes to the regulations in response to this comment.

§69501.1(a)(9) Adverse waste and end-of-life impacts

Comment: 11-1

Comment Summary:

The comment supports the additional language in the ISOR under this definition which clarifies that the evaluation of Chemicals of Concern in products and their alternatives include “waste and end-of-life disposal,” as is required by Health and Safety Code 25253(a)(2)(J)

Response:

Comment noted.

Comment: 3-1**Comment Summary:**

Comment did not suggest any changes to the language.

Response:

Comment noted.

§69501.1(a)(13) Alternatives Analysis Threshold**Comment: 11-3****Comment Summary:**

The comment supports the Alternatives Analysis (AA) Threshold concept, which provides an exemption for products that contain a Chemical of Concern below a specified concentration by weight. The comment requests a default AA Threshold for all chemicals at 0.1%, and to allow the default value to be raised or lowered on a chemical-product specific basis.

Response:

The comment relates to a provision that has text changes, but the expressed concern is not related to, or is unaffected by the revisions made in the Revised ISOR. However, as a courtesy, DTSC provides the following information: The revised Draft (January 2013) has been amended to include a default AA Threshold for Chemicals of Concern that are present in the Priority Product solely as a contaminant. There is no longer an AA Threshold concentration for intentionally added ingredients. DTSC is making no additional changes to the regulations in response to this comment.

§69501.1(a)(21) Component**Comment: 1-9**

Comment Summary:

Commenter supports deletion of catalytic converter example from ISOR.

Response:

DTSC appreciates the support for this change.

Comment: 13-2**Comment Summary:**

This comment refers to section 69503.2(a)(1)(B)4.d. of revised ISOR, and the previous draft of the ISOR. The commenter agrees with the statement that there is little to no exposure to a “Chemical of Concern” (COC) from inaccessible components (This provision has been revised. COC is now Candidate Chemical, and the term “potential accessibility is now used. Inaccessible components or accessible components have not been included in recent versions of the drafts.), but expresses concern that the regulations are not specific enough to understand DTSC’s approach.

Response:

As stated in the Revised ISOR, this provision is “another factor for DTSC to consider as part of prioritization. How the Chemical of Concern is contained or bound during the use of the product determines, in part, the amount of exposure that may occur. For instance, the Chemical of Concern may be a component inside a product and may not be accessible to the user, in which case, there is little to no exposure as a result of use of the product.”

Section 69503.2(a)(1)(B)4.d. in the July 2012 version of the regulations refers only to the containment of the COC within the product and does not use the term “inaccessible” or “accessible.” DTSC has revised this provision to provide greater clarity and has renumbered this provision as section 69503.3(a)(3)(F). This criterion for exposure now states, “Containment of the Candidate Chemical(s) within the product, including potential accessibility to the Candidate Chemical(s) during the useful life of the product and the potential for releases of the Candidate Chemical(s) during the useful life and at the end-of-life.”

Although the example given in the ISOR refers to little or no exposure during use, there may be other exposure pathways (e.g. inhalation) that may need to be assessed that are unaffected by a component simply because it is out of reach. There may also be potential human or environmental exposure or consequences during other phases of the product’s life cycle other than use (e.g., manufacturing, transportation, waste, and end-of-life.). DTSC will evaluate product-chemical combinations for possible listing as a Priority Product

by considering this criterion and others to assess exposure to the Candidate Chemicals in products. The containment, likelihood, frequency, duration of exposure to the Candidate Chemical across all phases of the life cycle of the product will remain one of the prioritization factors that DTSC will assess.

§69501.1(a)(38) Legal requirements

Comment: 11-5

Comment Summary:

Comment supports language in Revised ISOR that states that an alternative should comply with other binding requirements applicable to the product.

Response:

Comment noted.

§69501.1(a)(40) Manufacture

Comment: 5-5

Comment Summary:

There is a concern with the addition of the word "unnecessary" as part of the Revised ISOR explanation of "manufacture."

Response:

The ISOR was revised to clarify exclusions for activities to repair, refurbish, service, or alter an existing product as being outside the definition of "manufacture." The term "unnecessary" was added to explain that maintenance of existing products could continue without the involvement of the Safer Consumer Product (SCP) regulations by excluding these activities. DTSC is making no further changes to the regulations in response to this comment.

Comment: 4-2

Comment Summary:

Comment agrees that activities of repair, parts replacement, refurbishment, installation of replacement parts, and alterations do not constitute "manufacture." In the July 2012 version, however, the definition of "manufacture" carves out these same activities as being included in the definition, creating a conflict with the Revised ISOR.

Response:

DTSC respectfully disagrees. The July 2012 version of the regulations and the Revised ISOR are not in conflict. The term “manufacture” does have a carve-out for activities that are not included in the definition. The Revised ISOR only clarified that it was the *installation* of replacement parts that is excluded from the term “manufacture.” Further, the example provided supported the concept that repair and maintenance of existing products should be excluded to the point that the replacement parts should also be excluded. Replacement parts are not excluded from these regulations; so, the examples that may have led one to conclude they were excluded have been deleted from the Revised ISOR. DTSC is making no changes to the regulations in response to this comment.

§69501.1(a)(42)(A) Materials and resource consumption

Comment: 1-12

Comment Summary:

Definition of "water conservation" is inconsistent with other uses of the term. The definition in the Revised ISOR is overly broad, as well.

Response:

DTSC revised the text as part of the Revised ISOR, but did not provide a definition for “water conservation.” Instead, the Revised ISOR clarifies that water conservation is included within the term “materials and resource consumption” because the Health and Safety Code section 25253(a)(2)(D) requires water conservation be included in the AA.

Comment: 1-13

Comment Summary:

Definition of "energy efficiency" is overly broad and provides no clear guidance for energy groups to achieve energy efficiency.

Response:

DTSC revised the ISOR regarding this term, but did not provide a definition for “energy efficiency.” The Revised ISOR clarifies that “energy efficiency” is included in the term “materials and resource consumption,” as Health and Safety Code section 25253(a)(2)(H) requires energy efficiency be included in the AA. DTSC is making no changes to the regulations in response to this comment.

Comment: 11-6

Comment Summary:

The requirement to assess "energy efficiency" and "energy inputs" is beyond DTSC's authority, since these requirements apply to out-of-state responsible entities.

Response:

The comment relates to a provision that has text changes, but the expressed concern is not related to, or is unaffected by the changes to the ISOR reflected in the Revised ISOR. However, as a courtesy, DTSC provides the following information: Health and Safety Code sections 25253(a)(2)(G) and (H) mandate that energy efficiency, as well as, production, in-use, and transportation energy inputs are included in the process that evaluates potential alternatives, which is called the AA in the regulations.

The requirements of the regulations apply to the Priority Products if the product enters into the stream of commerce in California, regardless of the point of manufacture. In the case of the many product manufacturers that have no presence in California, DTSC has no practical, and in most cases no legal ability to compel such manufacturers to comply with these requirements. For this reason, the duty to comply with the requirements falls to other responsible entities to compel and enforce compliance with the proposed regulations. This is similar to the duty to comply approach embodied in other California statutes and regulations that impose requirements on products sold in California that are produced 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).

DTSC is making no change to the regulations in response to this comment.

§69501.1(a)(51) Release

Comment: 1-14

Comment Summary:

Definition of "release" in Revised ISOR is entirely inconsistent with the meaning of "release" in other statutes, including Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and Title 22 of the California Code of Regulations.

Response:

This comment does not relate to any revised text change. However, as a courtesy, DTSC provides the following information. DTSC agrees that "release" is defined differently from other uses for purposes of the regulations. The definitions found in Title 22 of the California Code of Regulations and in CERCLA are not suitable to evaluate exposures to chemicals in consumer products. The definition of "release" crafted by DTSC in these regulations is

geared to application in the context of consumer products. Accordingly, DTSC is making no changes to the regulations in response to this comment.

§69501.1(a)(52) Reliable information

Comment: 5-6

Comment Summary:

There is significant variability in the quality, purpose, and applicability of "reliable information," and there is no means or criteria with which to evaluate the information. The comment requests a change to a "weight of evidence" approach.

Response:

DTSC respectfully disagrees that there is no means or criteria for determining what is "reliable information." The criteria are specified in section 69501.1(a)(52)(A) through (D) to qualify the data sources that will be acceptable to inform various parts of the prioritization and AA processes. The Revised ISOR provides lists sources of data, studies, and information that is widely accepted by the scientific community. Data, studies, and information that come from these sources is acceptable, and will be used by DTSC to evaluate chemicals, products, alternatives assessments, and regulatory responses. DTSC is making no change to the regulations in response to this comment.

§69501.2(b)(2) Priority Product Replacement Notification

Comment: 3-2

Comment Summary:

Commenter is very pleased with regulatory off ramp options for not having to complete the AA process for reformulation.

Response:

Comment noted.

§69501.2(d)(4) Failure to Comply

Comment: 5-7

Comment Summary:

The comment requests revision to section 69501.2(d)(4)(C) and (D) to clarify that Failure to Comply posting applies only to identified products containing Chemical(s) of Concern.

Response:

The section previously numbered 69501.2(d)(4) provides that the Failure to Comply List is based on "each product covered by a notice of non-compliance". In addition, notices of non-compliance may only be issued by DTSC regarding Priority Products; and Priority Products must, by definition, contain one or more Chemicals of Concern. Therefore, no clarification is needed that the Failure to Comply List applies only to products containing a Chemical(s) of Concern. Accordingly, DTSC is making no change to the regulations in response to this comment.

Article 2. Chemicals of Concern Identification

§69502.2(a)

Comment: 13-5

Comment Summary:

DTSC has not explained why each of the included lists is necessary to fulfill the statutory mandates.

Response:

DTSC respectfully disagrees with the assertion. Section 69502.2 of the first ISOR and Revised ISOR discusses the list of lists approach, and specifies the criteria used to identify the initial list of chemicals, followed by discussion on each of the enumerated lists in this section.

The principal criterion that placed the chemical lists together in Section 69502.2(a) is that DTSC is accepting the chemical's hazard trait identification by each authoritative organization that is responsible for the chemicals list. The chemicals on these chemical lists exhibit strong evidence for toxicological hazard traits and evidence for the exposure potential hazard traits according to the regulations set out in Title 22, California Code of Regulations, Chapter 54. Also, each of these chemicals lists was evaluated and analyzed for conformance with the important scientific and policy principles. Each of them is included as necessary to effectuate the statutory mandate to advance the search for safer chemicals in consumer products. Please refer to Section 69505.2 of the revised ISOR issued in December 2012 for details on each of the source lists.

§69502.2(a) & (b)

Comment: 3-3

Comment Summary:

Commenter supports language in Revised ISOR that "each of the chemicals lists incorporated in Article 2 is necessary to have a robust, scientifically rigorous, and significant suite of Chemicals of Concern subject to these regulations."

Response:

Comment noted.

§69502.2(b)(2)

Comment: 5-8

Comment Summary:

Commenter supports clarification of the above provision.

Response:

Comment noted.

Article 3 Process for Identifying and Prioritizing Product-Chemical Combinations

§69503.2 Priority Products Prioritization Factors

§69503.2(a)(1)(B)

Comment: 11-7

Comment Summary:

Comment objects to use of market presence information as a surrogate for exposure.

Response:

DTSC wishes it had access to more direct data regarding exposures to chemicals and products. Unfortunately, that data is limited, uneven, and hard to come by. Thus, DTSC has used market data as a surrogate for exposure. In addition, Health & Safety Code section 25252(a)(1) expressly requires that DTSC take the volume of the chemical in commerce in this state into account in identifying and prioritizing chemicals in products. Therefore, DTSC has determined that market presence information is necessary as the only practical way in which DTSC can satisfy this statutory mandate. As a result, DTSC is making no change to the regulations in response to this comment.

§69503.2(a)(1)(B)(2)

Comment: 3-4

Comment Summary:

DTSC uses the term "grounded in science" in the ISOR. DTSC should define this term, and give examples.

Response:

DTSC respectfully disagrees that a regulatory definition is necessary. This is not a term of art with a meaning specific to these regulations. Rather, "grounded in science" means based on science, which is the common understanding of this term. The regulations include a specific listing of what is considered "reliable information demonstrating the occurrence of exposure to a chemical" under section 69501.1(a)(53).

§69503.3(g) Initial Priority Product Listing**Comment:** 10-1**Comment Summary:**

This comment refers to the provisions for DTSC to prioritize only product-chemical combinations that meet the criteria in sections 69502.2(a)(1) and 69502.2(a)(2). The commenter expresses concern that this restrictive requirement for identifying the initial list of Priority Products will result in failure to identify some unregulated solvents, which will have a disproportionate negative effect on California workers.

Response:

The comment relates to a provision that has text changes, but the expressed concern is not related to, or is unaffected by the revisions to the ISOR. However, as a courtesy, DTSC provides the following information. The Revised ISOR notes that this provision is necessary for DTSC to winnow down the approximately 1,200 Candidate Chemicals (previously known as Chemicals of Concern) identified in the regulations. This will send a better signal to the marketplace as to which chemicals may be identified as Chemicals of Concern (new definition) during the early days of implementation.

It is important to note that the initial number of Priority Products has been limited to no more than five, while there are approximately 1,200 Candidate Chemicals (previously known as Chemicals of Concern) identified in the regulations, as mentioned earlier. Besides, implementation will largely depend on the information available and DTSC must start somewhere. Additionally, the proposed regulations provide a number of opportunities for the regulated community and other stakeholders to provide information on chemicals and products to DTSC throughout implementation of the regulations. There is the opportunity to petition DTSC to add a chemical or product for listing as a Priority Product,

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

§69503.5(d) Alternatives Analysis Threshold Exemption

Comment: 11-4

Comment Summary:

The comment requests a default AA Threshold of 0.1% that should apply to a single chemical only, and not a group of chemicals.

Response:

The comment relates to a provision that has text changes, but the expressed concern is not related to, or is unaffected by the revisions in the ISOR. However, as a courtesy, DTSC provides the following information: All of the text previously in section 69503.5—*Alternatives Analysis Threshold Exemptions*—has been eliminated in the revised Draft (January 2013 version) in response to the public comments revised on the Draft (July 21012) regulatory text. DTSC is making no further changes to the regulations in response to this comment.

§69503.6 Alternatives Analysis Threshold Exemption Notification

Comment: 13-4

Comment Summary:

There is no need for an AAT Notification, and there is no description of why it is needed.

Response:

DTSC respectfully disagrees with this statement. The Revised ISOR notes that, overall, this requirement is necessary because DTSC needs to have a means of knowing which responsible entities are subject to the requirement to conduct an AA, and which are not. It is also necessary for DTSC to plan its work and maximize its limited resources in reviewing AA Reports. Each of the particular content pieces is necessary in order for: the responsible entity to be confident in its determination; DTSC to have an ability to monitor and follow-up on claims of exemption from the AA requirement; and to engender confidence in this largely self-implementing piece of the program.

§69503.6(a)(5) Laboratory analytical testing protocols**Comment:** 11-8

Comment Summary:

Supplier certifications should be sufficient basis for an AAT. A manufacturer should be able to rely on certification from its supplier(s). The language in the Revised ISOR is confusing, and should be clarified.

Response:

The comment relates to a provision that has text changes, but the expressed concern is not related to, or is unaffected by the revisions in the ISOR. However, as a courtesy, DTSC provides the following information: As stated in the Revised ISOR, even if the manufacturers rely on supplier certifications regarding purchased material content, many manufacturers supplement the information provided by suppliers with further analytical testing. The knowledge of materials and processes are only adequate as substantiation of the presence or absence and concentration of all Chemicals of Concern as long as the entire manufacturing process is under the direct control of the responsible entity. Responsible entities should have a high degree of assurance about the content of their products to qualify for this exemption. Reliance on supplier certifications is not an appropriate standard for meeting this largely self-implementing exemption from these regulations. Therefore, DTSC is making no change to the regulations in response to this comment.

§69503.6(c) Revised AA Threshold Exemption Notification**Comment:** 11-9

Comment Summary:

The commenter objects that the term "significantly modified" is not clear.

Response:

Section 69503.6(c) requires that a new AA Threshold Notification be submitted when any of the information submitted in the original submittal changes significantly. It is necessary for DTSC to have an ability to monitor and follow-up on claims of exemption from the AA requirement. The other option considered would have been to require periodic submittals of the AA Threshold Exemption Notifications, which would have been more burdensome for the responsible entities.

Significant changes may include, for example, changes to the contact information for the responsible entities to be able to reach the responsible entity, a new source for the Chemical of Concern to be able to confirm that the AA Threshold is still being met, or changes to a new analytical testing protocol being implemented for auditing purposes. DTSC is making no change to the regulations in response to this comment.

Article 4. Petition Process for Identification and Prioritization of Chemicals and Products

§69504.1 Merits of Petitions

Comment: 11-11

Comment summary:

This comment expresses concerns about the timing of the petition process. Specifically, the commenter is concerned that because the Priority Products list will only be updated at least once every three years, there could be a situation where a manufacturer would be required to complete a Preliminary and Final AA before a determination to grant or deny a delisting petition has been made.

Response:

DTSC respectfully disagrees. The timing for petition determinations reflects the time DTSC needs to conduct a merits review, and to set petition-review priorities, in light of resource constraints. Further, as outlined in section 69504(b)(3), a person may not petition DTSC to remove a product-chemical combination from the Priority Products lists until three years after the date the product-chemical combination was placed on the Priority Products list. Section 69505.1(b) contains the timeframes for compliance with the AA process, which provides that a Final AA Report is due no later than twelve (12) months after the date DTSC issues a notice of compliance for the Preliminary AA Report, which is due no later than 180 days after the product is listed on the Priority Products list. As a result, there will never be a situation in which a responsible entity required to conduct an AA could have been relieved of this obligation by virtue of a petition being granted. DTSC is making no change to the regulation in response to these comments.

Article 5 Alternatives Analysis

§69505.1 Alternatives Analysis General Provisions

Comment: 9-1

Comment Summary:

The regulations evidence a bias in favor of untested products and substances. An untested product is not synonymous with a safe product.

Response:

DTSC respectfully disagrees with the assertion that the regulations evidence a bias in favor for untested products and substances. The AA process and criteria seek to have a broad array of potential alternatives to the Chemical of Concern in the Priority Product evaluated regardless of how well characterized or not the potential alternative is. DTSC agrees that an untested product is not synonymous with a safe product. That is why all potential alternatives to a Chemical of Concern are subject to the same AA criteria and requirements. DTSC is not making any changes to the regulations in response to this comment.

§69505.1(c)(2)

Comment: 3-5

Comment Summary:

The commenter infers that DTSC's preferred approach is removal of a product from the market. The commenter disagrees with this as the preferred approach, and claims that DTSC's main priority should be to encourage reformulation, not removal of product from market.

Response:

The commenter is incorrect in inferring DTSC prefers product removal to product reformulation. The overarching goal of the program is developing safer consumer products; that goal is achieved either by removal of the product or undergoing an AA to seek a safer product, followed by Regulatory Response(s), if necessary. It is up to each responsible entity to determine which path of compliance it will take. All options under the regulations are equally valid. DTSC is not making any changes to the regulations in response to this comment.

Comment: 11-10

Comment Summary:

The above comment recommends that the granting of a petition be used as the basis for exemption from the Alternatives Analysis requirement.

Response:

As stated in the ISOR, the petition process contained in Article 4 is to be used to urge DTSC to include a chemical or product or delist a chemical or product from the prioritization process(es). If a chemical or product is delisted, then the chemical and/or product is no longer on the Priority Product list under Article 3, and is not subject to the requirements of preparing an AA. Hence, the requirements of Article 5 are not applicable, and an exemption from Article 5 is unnecessary. DTSC is not making any changes to the regulations in response to this comment.

§69505.1(g)(1)

Comment: 5-9

Comment Summary:

The discussion of removal of a Chemical of Concern for which there is "no need" implies that non-essential ingredients are commonly included in products. Commenter seeks basis for this conclusion.

Response:

DTSC makes no presumption about how frequently chemical ingredients are included in products that turn out not to be necessary. The staging of the AA, including making an early decision regarding the necessity of the Chemical(s) of Concern, is an efficient way of determining the necessity of the chemical(s) used in the Priority Product.

The first step of stage one of the AA requires that the responsible entity identify the product requirements and function of the Chemical(s) of Concern. In doing so, the responsible entity must identify the function, performance, and legal requirements, if any, associated with the Priority Product and the role and function that the Chemical(s) of Concern play in meeting those requirements. If Chemical(s) of Concern are present as contaminants and not intentionally added, it is plausible that the Priority Product can meet all of its product requirements and functions without the presence of the Chemical(s) of Concern. DTSC is not making any change to the regulations in response to this comment.

§69505.2 Analysis of Priority Product and Alternatives

§69505.2(a)(2)

Comment: 5-10

Comment Summary:

It is unclear what the nexus is between “market signals” based on public comment and the more conventional view of “market signals” via consumer response to a product based on efficacy, performance, etc. Clarification is sought.

Response:

The public has conventionally provided consumer input by expressing opinions about the products and services that matter most to them through surveys or through their purchasing decisions. While consumers may still be able to provide market signals through their purchasing decisions, the proposed regulations allow for more formal input and require that the responsible entities consider and explain the in Final AA Report why or how a comment was or was not addressed in their selection of an alternative or retention of the Priority Product. DTSC is making no change to the regulations in response to this comment.

§69505.2(b)(2)

Comment: 11-12

Comment Summary:

DTSC should not be allowed to select an alternate chemical.

Response:

DTSC believes that the manufacturers of the priority products are in the best position to determine the most appropriate alternative, if any, to the use of the Chemical of Concern in a Priority Product. Given that DTSC does not mandate an outcome, the manufacturer elects the alternative. For this reason, it is the manufacturer or other responsible entity that the regulations require to perform an AA. The regulatory responses will be priority product-specific and alternative-specific. That is, the responsible entity may elect to continue using the Chemical of Concern. However, this may result in a different/additional regulatory response(s) being imposed by DTSC. Nevertheless, DTSC does not select an alternate chemical for a product. DTSC is not making any change to the regulations in response to this comment.

§69505.5 Alternatives Analysis Report

§69505.5

Comment: 5-11

Comment Summary:

This provision was significantly revised. How much additional time will be provided should DTSC require additional data to fill informational gaps as part of the final AA Report?

Response:

It is unclear what provisions the commenter is referring to that were significantly revised. The periods for submitting the Preliminary and Final AA Report, Abridged AA Report, and/or Alternate process Work Plan have not been revised. The Final AA Report must include an implementation schedule for implementing the selected alternative and regulatory responses, if applicable. A regulatory response may include, among other possibilities, the filling of data gaps. DTSC will craft the time for complying with the Regulatory Response according to the nature and complexity of the Regulatory Response being imposed. DTSC is not making any change to the regulations in response to this comment.

§69505.6 Department Review and Determination for Alternatives Analysis Reports

§69505.6(a)(2)

Comment: 5-12

Comment Summary:

It is unclear how DTSC will make call as to what deserves "legitimate" Trade Secret protection.

Response:

DTSC respectfully disagrees. All trade secret determinations will be made based on the criteria, timelines, and processes spelled out in previously numbered Article 10, that is now Article 9. For a detailed explanation of how trade secret determinations will be made, please see the ISOR and Revised ISOR for the Trade Secret Article, as well as the responses to comments for that Article (previously 10, now 9) in DTSC's other Responses to Comments documents. DTSC is not making any changes to the regulations in response to this comment.

§69505.6(a)(3)

Comment: 11-13

Comment Summary:

The commenter wants the petition process to be available to seek additional time to perform an AA. There would be additional time beyond the current maximum in the regulations.

Response:

DTSC is still of the opinion that it is not necessary or appropriate to make the petition process available for seeking additional time to perform an AA. DTSC will specify in a notice of compliance for the Preliminary AA Report the date for submitting the Final AA Report. While the default time period is twelve (12) months from the date the notice of compliance is issued for the Preliminary AA Report, DTSC may specify a later date—if specified conditions are met. If the responsible entity proposes to undertake a more comprehensive second stage AA in which regulatory safety and/or performance testing is necessary, a due date of thirty-six (36) months after the Preliminary AA may be specified per section 69505.5(k)(1)(C).

§69505.6(a)(6)(A)

Comment: 5-13

Comment Summary:

We disagree that public's protection is enhanced through the general availability of AA reports. We ask for clarification of this conclusion.

Response:

Public health and the environment receive more protection when responsible entities study their products to determine if they can be made with fewer harmful ingredients or a lower concentration of such ingredients. Public health and the environment are more protected when consumers can make informed decisions about the composition of the products they buy and alternatives to those products. DTSC is not making any change to the regulations in response to this comment.

Article 6. Regulatory Responses

§69506.8 End of Life Management Requirements

Comment: 3-1

Comment Summary:

Proposed Extended Producer Responsibility/End-of-Life (E-O-L) program is too burdensome. It does not conform to the existing statutory E-O-L program for paint. This

provision violates Health & Safety Code section 25257.1's prohibition against duplicative or conflicting regulation under this program. In particular, the commenter felt that the "maximum extent feasible" language and "written approval" requirements are unduly burdensome.

Response:

The fact that DTSC's E-O-L program is not identical to another E-O-L program for paint does not mean that it conflicts with that other program; nor does it mean that it duplicates this program, since this program has different requirements that are unique to this program. DTSC respectfully disagrees that the "maximum extent feasible" and "written approval" requirements are unduly burdensome. These provisions are necessary to ensure that the E-O-L program is effective and efficient.

Comment: 5-14

Comment Summary:

How will DTSC enforce and/or evaluate the effectiveness of the E-O-L programs?

Response:

Under the requirements in section 69506.8(a)(2)(A)3, responsible entities must coordinate their efforts with stakeholders, including DTSC; and submit the product stewardship plan for review and approval as specified in section 69506.8(a)(2)(C). In addition, responsible entities, namely the manufacturers, are required to submit an annual report under section 69506.8(a)(2)(D) detailing by total tonnage the quantity of products placed into the stream of commerce in California over the previous one-year period; and the quantity of products recovered over the same one-year period.

Comment: 11-2

Comment Summary:

The comment requests that the ISOR be revised to clarify the E-O-L requirements are limited to products that are required to be managed as hazardous waste in California at the end of the useful life of the product(s).

Response:

DTSC respectfully disagrees that this point needs further clarification in the ISOR. The regulation text is quite clear. This response confirms that the commenter correctly understands the provision. Again, only those products that must be managed as hazardous wastes in California at the end of the products' useful lives are subject to the E-

O-L requirements in Article 6 of the regulations. DTSC is not making any change to the regulations in response to this comment.

§69506.9 Advancement of Green Chemistry and Green Engineering

Comment: 11-14

Comment Summary:

The comment objects to being subject to a Research & Development Project as a Regulatory Response.

Response:

When a manufacturer concludes that no safer alternative to its Priority Product is functionally acceptable, as well as technically and economically feasible; or a manufacturer selects an alternative that reduces but does not eliminate the use of Candidate Chemicals in the product, DTSC may (as authorized by Health and Safety Code section 25253(b)(8) of the authorizing legislation) require the manufacturer to initiate a Research and Development project or fund a challenge grant pertinent to the Priority Product that uses green chemistry and/or green engineering principles to:

- (i) design a safer alternative;
- (ii) improve the performance of a safer alternative;
- (iii) decrease the cost of a safer alternative; and/or,
- (iv) increase the market penetration of a safer alternative.

Quite simply, this Regulatory Response is expressly enumerated in the authorizing legislation as one of the Regulatory Responses that DTSC may impose upon the completion of the AA. Therefore, DTSC is not making any change to the regulations in response to this comment.

§69506.11 Exemption from Regulatory Responses

Comment: 5-15

Comment Summary:

This provision appears to shift the burden of determining the Regulatory Response requirements to the responsible entity and is diametrically opposed by the authorizing statutes. It would also be more useful to make this determination earlier. The commenter asks for clarification regarding DTSC's intent.

Response:

DTSC respectfully disagrees that the regulations impermissibly shift the burden of determining a Regulatory Response to the responsible entity in a manner that is in conflict with the authorizing legislation. Section 69506.11 deals with exemptions from the requirement to comply with any Regulatory Response(s) imposed by DTSC. It does not shift the burden of who may determine what is the appropriate Regulatory Response and who may impose that Regulatory Response; those rights and duties are still with DTSC. DTSC is not making any change to the regulations in response to this comment.

Comment: 8-1

Comment Summary:

"This rationale reflects the legal flaw encompassed in SCPA [Safer Consumer Products Alternatives] Section 69506.11, in which DTSC improperly shifts the burden of preventing regulatory duplication from the Agency to industry in violation of GCI [the Green Chemistry Initiative]."

Response:

DTSC respectfully disagrees that Section 69506.11 or the rationales for it articulated in the Revised ISOR violate the non-duplication provision in Health & Safety Code section 25257.1. In fact, DTSC included this provision and numerous others to ensure DTSC does not violate this non-duplication provision. There is no legal burden shifting as to that provision. DTSC has the ability to require information from responsible entities to determine their exempt status from various requirements, including performing a Regulatory Response, in order to avoid duplication or conflict with other programs. Therefore, DTSC is making no change to the regulations in response to this comment.

Comment: 11-15

Comment Summary:

Comment expresses support for section 69506.11.

Response:

Comment noted.

Article 9. Trade Secret

Comments: 5-12, 3-6

Comments Summary:

The above comments expressed the following concerns:

- It is unclear how DTSC will make a call as to what deserves "legitimate" Trade Secret protection; and,
- DTSC has unfettered discretion to review and approve or disapprove a claim of Trade Secret. In addition, Trade Secret provisions are not easy to follow, which is contrary to requirements of Health & Safety Code section 25253(c).

Response:

DTSC notes that this comment is outside the scope of topics subject to comment as part of its issuance of a Revised ISOR. Nonetheless, DTSC offers the following responses as a courtesy to the commenter:

- All trade secret determinations will be made based on the criteria, timelines, and processes spelled out in detail in Article 9 of the regulations (Note: this was previously numbered Article 10 in the July 2012 version of the regulations.); and,
- DTSC does not have unfettered discretion to review and approve or disapprove a Trade Secret claim. On the contrary, review is governed by the criteria in Sections 69509 and 69509.1. DTSC disagrees that the process, timelines, and criteria for making and reviewing Trade Secret claims and decisions violates Health & Safety Code section 25253. Section 25253 is concerned with tools related to conducting an AA. It has no applicability to the Trade Secret provisions in these regulations. In addition, DTSC notes that it has made the Trade Secret provisions as simple and easy to follow as is feasible, while maintaining program effectiveness and conformity with the authorizing legislation.

Procedural, Legal, and Overarching Issues

Administrative Procedure Act

Comments: 1-1, 1-4, 1-6, 1-7, 1-8, 1-9, 2-1, 4-1, 4-3, 5-1, 5-2, 5-3, 13-1

Comments Summary:

The above comments expressed concern with the timing of the issuance of the Revised ISOR. In summary, the following concerns were expressed:

- An objection was raised that piecemeal release of components of rulemaking violates purposes of the Administrative Procedure Act (APA);
- A Revised ISOR released as an "orphan" document (i.e., not in conjunction with regulations text) violates Government Code section 11346.2. The first ISOR was released as a false pretense. The public could not tell what DTSC intended with the original regulations text since the Revised ISOR was released after the initial regulations text. A Revised ISOR must be accompanied by regulation text that the

Revised ISOR is explaining. Government Code section 11346.4 requires a 45-day public comment period for the Revised ISOR;

- Commenter requests withdrawal of Revised ISOR or extension of public comment period. The segmenting of regulations text, External Scientific Peer Review Reports, and the Revised ISOR deprived the public of meaningful opportunity for input; and,
- Commenter supports deletion of catalytic converter example from the Revised ISOR.

Response:

DTSC notes the following in response to the above comments.

- The “piecemeal” release of documents is expressly authorized under the APA. More specifically, it is authorized by Government Code section 11347.1(b). That provision authorizes the agency adopting regulations to supplement the rulemaking file with additional reports or documents so long as the agency provides a 15-day public comment period for the additional material placed in the rulemaking file. DTSC complied with Government Code section 11347.1(b) in the release of the Revised ISOR;
- The release of the Revised ISOR does not violate Government Code section 11346.2(b). DTSC fully complied with Government Code section 11346.2(b) at the time it released the first version of the regulations in July 2012. Nonetheless, in response to comments DTSC received on the first version of the ISOR, DTSC decided the public would benefit from a fuller explanation of some of the provisions in the draft regulations. In addition, DTSC determined that the public would benefit from a fuller explication of certain statements of necessity in the first version of the ISOR. The Revised ISOR was not released under Government Code section 11346.2(b). As discussed above, it was released under Government Code section 11347.1(b). Because the first version of the ISOR that accompanied the public notice and proposed regulations text in July 2012 satisfied Government Code section 11346.2(b), DTSC fully complied with that section. Government Code section 11347.1(b) does not require the re-release of proposed regulations text with each addition of material into the rulemaking file. Government Code section 11346.4 applies to proposed regulations text only; it does not apply to ancillary documents in the rulemaking file, including the Revised ISOR;
- As described in the above two responses to comments, a Revised ISOR was allowed under Government Code section 11347.1(b). It did not need to be accompanied by revised regulation text. Accordingly, DTSC is not going to withdraw the Revised ISOR or extend the public comment period for commenting on it. The issuance of various documents at different dates as they are made part of the rulemaking file is not a violation of the APA; it is expressly allowed under Government Code section 11347.1(b). Moreover, the public was given additional

opportunities for meaningful public comment by providing distinct public comment periods on the myriad documents that DTSC has circulated for public comment. Any attempt to run one concurrent public comment period for the External Scientific Peer Review reports and the Revised ISOR would undoubtedly have been met with objections that DTSC was depriving the public of the opportunity for meaningful public comment because the concurrent public comment periods provide too little time for review of information and submittal of comments. In addition, the public had the opportunity to comment on additional versions of the regulations as well. There was no error in DTSC's issuance of a Revised ISOR. Even assuming for the sake of discussion that this was somehow in error, that error would be harmless in light of the modest non-substantive nature of virtually all of the changes DTSC made in the Revised ISOR;

- The first ISOR was not circulated as a false pretense. It well described what DTSC intended with the version of the regulations proposed in July 2012; it fully complied with the APA as well. DTSC issued a Revised ISOR in response to comments from one of these commenters that it could be made more clear and specific, and more obviously conform to APA requirements, especially the necessity standard. Therefore, DTSC issued the Revised ISOR to go above and beyond APA requirements to give the public a fuller understanding of its initial proposed regulations; and,
- DTSC notes the fact that the commenter appreciated the removal of catalytic converters as an example of a product that might be regulated under these regulations.

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

Regulations are Too Burdensome

Comments: 6-1, 6-3, 7-3

Comments Summary:

The above comments expressed the view that the regulations are too burdensome and expensive. They further claimed that it is wrong to put burden of reporting specific chemicals contained in products on the individual distributor given that the proposed regulations cover over 1,200 explicit chemicals with the potential to trigger a duty to disclose.

Response:

DTSC considered all public comments received during the extensive pre-APA outreach and input activities, as well as during the APA public comment periods in order to reduce

burdens on regulated entities to the extent feasible. DTSC has made significant changes from the pre-APA draft regulations to the initially noticed regulations and from the proposed regulations in July 2012 to the January 2013 proposed regulations in response to public comments received. Many of these changes reduce the burdens that would have been placed on the regulated community when compared to earlier drafts. DTSC did not accept all of the commenters' suggestions because DTSC concluded that the rejected suggestions would not accomplish the required program in a manner that was as efficient, effective, and scientifically sound.

Just a few of the many changes DTSC made to lessen the burdens placed on the regulated community are:

- the elimination of the accreditation body and certified assessor programs;
- the streamlined and step-wise AA process; and,
- the introduction of numerous "off-ramps" from the AA process.

In addition, DTSC notes that the very nature of the authorizing legislation is to impose burdens on manufacturers and other responsible entities. That is, the authorizing legislation creates new broad authority in DTSC to regulate consumer products, and for the manufacturers of those products to be responsible for analyzing the content of their products to see if the risk posed by them due to the presence of harmful chemicals may be reduced or eliminated. Again, there is no way that such a program could exist without the imposition of burdens on those affected.

DTSC is convinced that the changes discussed above, as well as others, and the overall approach it is taking, will result in the regulations being workable. In addition, the regulations do not impose any "reporting duties" on "distributors" of consumer products. More specifically, distributors are not subject to the regulations at all. Also, not all manufacturers who use any of the Candidate Chemicals must report this to DTSC. Rather, the duty to self-identify the use of a chemical in a product is triggered only if the chemical product pairing is identified as a Priority Product. Accordingly, DTSC declines to make any changes to the proposed regulations in response to these comments.

Request for Exemption

Comment: 6-4

Comment Summary:

DTSC should amend the regulations to exempt independent distributors selling products on behalf of direct selling companies from any overly burdensome disclosure requirements.

Response:

See Response to Comments 6-1, 6-3, and 7-3 above.

Comment: 3-1

Comment Summary:

Health and Safety section 25257.1 is a clear mandate that DTSC cannot supersede another agency's regulatory program. Manufacturers should receive an explicit exemption from the end-of-life management regulatory response if the manufacturer is participating in an end-of-life management or product responsibility program mandated by a California statute. The comment also claimed that the "maximum extent feasible" and "written approval" elements were unduly burdensome.

Response:

This standard for determining that one or more regulatory programs duplicates the program is in Health & Safety Code section 25257.1(c), which provides: "The department [DTSC] shall not duplicate or adopt conflicting regulations for product categories already regulated for subject to pending regulation consistent with this Article [14]." As discussed in response to earlier comments, this language in section 25257.1(c) is noteworthy here for two reasons. First, it does not prohibit all duplicative or conflicting regulations. Rather, it prohibits such regulation if a product is already regulated, or subject to pending regulation "consistent with the purposes" of Article 14—the entire statutory "Green Chemistry" (Safer Consumer Products) program. It consists, in part, of life cycle thinking, and the overall quest for safer products. Thus, it is concerned with the regulation of a product *throughout its entire life cycle*. Secondly, the prohibition in section 25257.1(c) extends only to "product categories." DTSC has not proposed any specific product categories for regulation under this program. It has instead left the determination of products specifically subject to regulation to later implementation stages.

The fact that DTSC's end-of-life program is not identical to another program for paint (for example) does not mean that it conflicts with that other program; nor does it mean that it duplicates this program, since it has additional and different requirements. A conflict will arise, if at all, if DTSC (as part of implementing these regulations) imposes requirements on responsible entities under an end-of-life program that conflict with its existing regulatory obligations. These regulations do not do that. In addition, DTSC respectfully disagrees that the "maximum extent feasible" and "written approval" requirements are unduly burdensome. DTSC believes these elements of the end-of-life program are necessary to ensure an efficient and effective end-of-life program.

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

Miscellaneous**Comments:** 5-4, 6-2, 13-6

Comments Summary:

The above comments expressed general concerns with the regulations and the Revised ISOR. In summary, the comments expressed the following:

- "Tone" in Revised ISOR is different. DTSC gets benefit of "may" while regulated community is saddled with mandatory language;
- Regulations could require distributors to report to consumers specific chemicals contained in the products they contract to sell on behalf of direct selling companies. This could result in reduced sales and a negative economic impact on California; and,
- Commenter asserts that narrative approach can be a problem, and hopes DTSC will be able to achieve its goals despite this approach.

Response:

- DTSC did not intend to change its tone in the Revised ISOR. Without knowing which provisions are being referred to here, it is extremely difficult to respond to these comments. DTSC has used "may" and "shall" throughout the regulations to refer to both its role and that of the regulated community. Whether or not a provision is discretionary or compulsory was decided on a case-by-case basis depending on what the provision does. It is also unsurprising that the regulated entities subject to these regulations have more duties imposed upon them than DTSC does as the regulator;
- The regulations do not impose any burdens on distributors of products. The entities in the supply chain for products subject to the regulations are manufacturers, importers, assemblers, and retailers. The regulations apply to products entered into the California stream of commerce irrespective of point of manufacture;

As discussed at some length in the first ISOR, and in responses to comments on the July 2012 version of the regulations, the narrative approach was the result of much careful consideration by DTSC of this approach and various alternative approaches—including the "weight of evidence" approach. DTSC continues to think this approach offers the best basis for DTSC achieving the goals of this program. DTSC is making no change to the regulations in response to these comments.

Comment: 1-3

Comment Summary:

The commenter reiterates all of its previous comments to the July 2012 version of the proposed regulations.

Response:

This comment is outside the scope of issues subject to public comment on the Revised ISOR issued by DTSC. Therefore, DTSC respectfully declines to respond to this comment.

Comment: 8-2

Comment Summary:

The federal Food and Drug Administration extensively regulates food contact materials. As such, they should be exempt from this program based on Health & Safety Code section 25257.1.

Response:

The comment is outside the scope of the issues open to comment on the Revised ISOR. The commenter is referred to the discussion of Regulatory Duplication/Conflict in the Response to Comments for the July 2012 version of the regulations. Those responses are applicable here as well. DTSC is making no change to the regulations in response to these comments.

Comment: 12-1

Comment Summary:

Commenter feels that formaldehyde in carpet adhesives is not a significant source of formaldehyde emissions.

Response:

DTSC did not mean to imply that all carpet adhesives contain formaldehyde, or that it was a likely candidate for being a Priority Product. DTSC has offered numerous examples of consumer products that contain various chemicals. However, DTSC has not pre-selected any chemicals or products for inclusion in this program during later stages of implementation. DTSC has further specified the chemicals that may be considered for prioritization as a Priority Product in the initial stages of implementation as part of the January 2013 version of the regulations. Other than that, any of these ~200 chemicals in untold number of products may be selected during Priority Products listing. DTSC is not making any change to the regulations in response to these comments.

Necessity**Comments:** 1-10, 7-1, 7-2

Comments Summary:

- Certain unspecified definitions still do not meet Necessity standard.
- Commenters are concerned that the revised Necessity statements support provisions with which the industry disagrees; and,
- Commenter is worried that beefed up Necessity statements means that DTSC will not be open to comments on those provisions.

Response:

- Without identifying which definitions are alleged to be deficient, DTSC cannot address this comment on the merits. Nevertheless, DTSC notes that it believes it has satisfied the necessity standard for all definitions and other provisions of the regulations;
- It is impossible to know which provisions the commenter is describing because no sections were identified. The fact that the commenter disagrees with an unspecified provision has no effect on the requirement in the APA for DTSC to include a statement of Necessity for every provision. DTSC has done that—in part, in response to comments that the first ISOR was deficient in this respect in certain places. Again, DTSC believes its first ISOR fully complied with the APA, but released a Revised ISOR to provide even further information about and support for the proposed regulations—even though it was not required; and,
- DTSC has, and will continue to be open to suggestions for improving the regulations. The January 2013 version of the regulations demonstrates DTSC's willingness to listen and to make changes in response to comments. The revised Necessity statements in no way prevent DTSC from taking in and responding to comments.

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

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