



QUESTIONS and CONCERNS RAISED IN PUBLIC WORKSHOPS REGARDING AB1879 REGULATORY PACKAGE DEVELOPMENT

INTRODUCTION

The California Department of Toxic Substances Control is developing Rules for Safer Alternatives to Chemicals of Concern in Consumer Products, pursuant to AB 1879 (Chapter 559, Statutes of 2008).

Great efforts have been taken to initiate an in-depth and thoughtful discussion of options, to seek widespread input, and to involve all interested parties, stakeholders and the public in this process. A Wiki was used to gather initial thoughts and suggestions online. Several public workshops were held. A draft Straw Proposal was developed and posted on the DTSC website and discussed at several more public workshops. Guidance was sought from the Green Ribbon Science Panel at two day-long meetings followed by yet another public workshop. The multitude of comments received have been compiled and considered as DTSC staff weigh the various options for promulgating rules that achieve the ultimate goal of decreasing toxics in consumer products to protect public health and the environment.

The following synopsis of major issues raised during the past several months is provided to highlight questions that must be addressed as the final draft rules are completed. DTSC is sharing this synopsis of the wide range of questions, concerns and options raised in the public workshops so that all interested parties are aware of the areas DTSC will focus on in developing these rules, and to continue seeking examples from knowledgeable parties of *specific* processes and language that can be included in the final draft rules.

DTSC urges and welcomes a more focused response from interested parties of actual language and specific processes to be considered in this next phase of decision-making. As staff work toward completing the final rule package that will ultimately be subject to the state's formal Administrative Procedures Act (APA) process, DTSC welcomes continued and focused reaction to these various issues. DTSC will have additional public review of the draft proposed rules prior to beginning the formal APA process.

QUESTIONS and CONCERNS RAISED

1. Scope, Applicability, and Starting Point

Scope of the program must be better defined and narrowed to allow for a pragmatic, implementable, and realistic program.

Questions:

Chemicals

- 1.1. Should *chemicals* be the entry point for determining which *consumer products* are regulated?
- 1.2. Which chemicals should be addressed first? What objective criteria should be applied to make that determination?
- 1.3. Should chemicals be grouped, or phased, by sub-type or class (such as surfactant, preservative, insulator, plasticizer, etc. or some other grouping scheme)? If so, what are those groups, phases, or sub-types?
- 1.4. How many chemicals would be included in the first collection (suite) of chemicals in the initial rule? In the second rule? In subsequent rules?

- 1.5. What is the process to move from a *chemical* to a particular *consumer product* for alternatives analysis? How is that done and by whom? How long does that process take?
- 1.6. How many *consumer products* would result from that first suite of chemicals? From subsequent suites?

Lists of lists

- 1.7. Should "lists of lists" of chemicals be the entry point for determining which consumer products are regulated?
- 1.8. Which government lists should be used? For what purpose(s)?
- 1.9. Which authoritative bodies' lists should be used? For what purpose(s)?
- 1.10. What is the process to move from a chemical on a list to a particular consumer product for alternatives analysis? How is that done and by whom? How long does that process take?

Product categories

- 1.11. Should *product categories* be the entry point for determining which consumer products are regulated?
- 1.12. What are the highest priority categories? Why?
- 1.13. How are product categories defined—consistently across industry? What objective criteria define each category?
- 1.14. Should products be grouped, or phased, by sub-type? If so, what are those groups, phases, or sub-types?
- 1.15. How many discrete products are included in each category, group, or sub-type?

Integrated entry pathway

- 1.16. How should *chemicals* and *products* be combined as an integrated entry point?
- 1.17. Which specific chemicals and specific consumer products should be in the first rulemaking? In subsequent rules?
- 1.18. What is the "intersection" between *chemical* and *product*? How is that intersection determined? By whom? How would an integrated mechanism work?
- 1.19. How many *consumer products* would be included?
- 1.20. What information is required so the mechanism would function effectively and efficiently?
- 1.21. Who has such information?

2. Exemption

Many stakeholders commented that certain uses of specific chemicals should be exempt from the regulation when it can be shown that a specific use of a chemical does not pose a threat to human health, safety, or the environment.

Questions:

- 2.1. What are the pros and cons of including a possible exemption for a chemical or chemical ingredient in a consumer product which presents:
 - 2.1.1. an insignificant level of hazard?
 - 2.1.2. for which exposure is adequately controlled through product design and manufacture?
- 2.2. Should "de minimis" quantities of a chemical be a consideration for an exemption? If so how? How much (what quantity)?
- 2.3. Should "de minimis" instead be used in the prioritization process? If so, how?

3. Hazard Traits

Some stakeholders have commented that the list of categories is too broad. Others say the initial end-points reflect chronic human health effects and minimize or ignore ecological and other effects. Stakeholders commented that fewer hazard end-points should be used initially and others phased-in via subsequent rulemaking.

Questions:

- 3.1. Which hazard end-points should be the initial priority? Why?

- 3.2. How and when should other end-points be considered?
- 3.3. Which end-points should be added, deleted, or changed? Why?
- 3.4. Should end-points be grouped—such as chronic and acute human health, ecological effects, lethal and sub-lethal, sensitivity, etc.? What are those groups?
- 3.5. Who should decide? OEHHA? A particular authoritative body for a respective end-point (such as IARC for cancer)?
- 3.6. How should hazard trait information be used in prioritization? In alternatives assessment? In regulatory response?
- 3.7. How much time should allowed for hazard characterization?
- 3.8. Does this time period differ by product category (i.e., chemical formulation versus manufactured article, relative to product cycle, etc.)?
- 3.9. If so, how should those time differences be addressed in the rule?
- 3.10. Should the Toxics Information Clearinghouse be linked to the required processes? If so, how and when? In what way?
- 3.11. Once the hazard end-points for chemical ingredients in a consumer product are determined, what information should be provided to the supply chain for that product? How and when should that information be shared?

4. Data Requirements

How should data requirements be defined to avoid broad, unclear, or should specify particular test methods.

Questions:

- 4.1. How could the data requirements be made more specific to improve the hazard characterization step?
- 4.2. What types of data should not be allowed or used in characterizing a hazard end-point of a chemical ingredient in a consumer product?
- 4.3. Should specific test methods be required? If so, which ones?
- 4.4. How much time should be allowed to conduct testing and generate required data—where no data now exists?

5. Prioritization

Should DTSC consider other criteria for prioritization than the ones listed below?

- Priority 1: Anticipated to be released during use or disposal, or to which humans are being exposed.
- Priority 2: Will not be released during use, but may be released after disposal.
- Priority 3: Will not be released during use or disposal.

Questions:

- 5.1. What criteria should be used to prioritize and determine *which consumer products* must conduct alternatives analysis and the resulting regulatory response?
- 5.2. Should “de minimis” quantities of chemicals be included in a prioritization process? If so, how?
- 5.3. Should tiers be included in prioritization? What are those tiers?
- 5.4. Should phasing be part of prioritization? What are those phases?
- 5.5. Should risk considerations be included in a prioritization scheme? If so, which risk considerations? How and by whom?
- 5.6. Should exposure considerations be included in a prioritization scheme? If so, which exposure considerations? How and by whom?
- 5.7. Should market share and unit volume be included in prioritization (i.e., target most widely used consumer products)?
- 5.8. Who should determine priorities?

- 5.9. Should the priorities be set forth directly in the rule? Alternatively, should a recurring public process to set priorities be prescribed in the rule?
- 5.10. Once the hazard end-points and prioritization of chemical ingredients, as chemicals of concern, in a consumer product is completed, what information should be shared with the supply chain for that consumer product?
- 5.11. How and when should this information be provided? To whom in the supply chain?

6. Alternatives Assessment

Because a wide variety of products would potentially contain a variety of chemicals of concern, a one-size-fits-all analysis likely would not be very informative. Instead, a more useful alternatives analysis will likely be process- and product-specific; or should a tiered approach to alternative assessments be used?

Questions:

- 6.1. Should the alternatives analysis process consider different factors for different types of products? If so, what differences would you suggest and for what types of products?
- 6.2. Should the alternatives analysis process provide a special process or special provisions for products that have existing ongoing programs for evaluating and comparing alternatives? If so, what would you suggest this process or provisions would be and what would be the conditions for allowing them?

A potentially huge number of products may be identified that contain a potentially huge number of chemicals of concern.

- 6.3. Should the number of consumer products required to complete an alternatives assessment be managed in some way in the alternatives analysis process? If so, in what way?
- 6.4. If DTSC selected a process that includes various levels or types of alternatives analysis requirements for various situations, what should those situations be and what should be included in the alternatives analysis process for each of the different levels?
- 6.5. Are there situations when an alternatives analysis should be expedited or eliminated? If so, what are the conditions of such situations? What would be included in an expedited alternatives analysis?
- 6.6. If an alternatives analysis is not required for certain products or alternatives, how will potentially regrettable or unforeseen impacts of alternatives be identified? Should they be identified?
- 6.7. How should potential alternatives be defined? What types of alternatives should be required to be considered in the alternatives analysis? What should be done if no potential alternatives exist?

The alternatives analysis process is likely to include a comparison step in which dissimilar impacts are compared for the consumer product and potential alternatives. In this step impacts associated with hazard, exposure, environmental, economic and other life cycle factors will need to be compared so that a determination of the preferred option(s) can be identified.

- 6.8. How should dissimilar impacts associated with the consumer product and potential alternatives be compared after the impacts of each have been characterized? What format should be used? Would there be decision rules, and if so, what would they be? Are some factors more important than others?
- 6.9. If DTSC creates heuristic decision rules for comparing the impacts associated with the consumer product and the alternatives, what should these rules be? What values should these rules reflect?
- 6.10. Should the comparison step in the alternatives analysis result in an identification of a "preferred" alternative? Which is most appropriate? How would you suggest defining "preferred" alternative?
- 6.11. Should the process require that a "preferred" alternative be adopted in lieu of that original consumer product? Who should decide if an alternative should be implemented and how should it be required?

If it is assumed that a manufacturer of a consumer product that contains a chemical of concern is in the best position to know or to obtain the information needed to evaluate the product and its potential alternatives, the manufacturer

could perform the analysis. However, several stakeholders assert that manufacturers may not conduct the evaluation objectively or may not seriously consider all potential alternatives.

- 6.12. Who should be required to perform the alternatives analysis for a particular consumer product and why?
- 6.13. How much discretion should the person performing the analysis have in making determinations in the analysis, including but not limited to the type and magnitude of the impacts and the selection of an alternative or other course of action? Should there be standards governing these determinations, and if so, what should they be?
- 6.14. How should DTSC verify that an alternatives analysis is adequate and complete?
- 6.15. If DTSC creates a third party system for performing alternatives assessment, what requirements should be specified for the third party and for the alternatives analysis? Should this system be mandatory? Should the third party requirements specify any standards for the analysis or the third party? If so, would these standards be?
- 6.16. Should the alternatives analysis require the same alternatives to be considered for products containing the same chemical of concern that may be produced by different manufacturers and different processes?
- 6.17. Should the alternatives analysis process include provisions that allow transparency and public comment with regard to the alternatives analysis? If so, how much of the analysis should be made public and how should the public comments be incorporated into the process?
- 6.18. Should a provision be included in the alternatives analysis process that will allow others in the marketplace to benefit from alternatives analyses that have already been completed for similar products? If so, what would this provision be?

Although a full life-cycle analysis is known to be a highly resource-intensive exercise, the statute requires the alternatives analysis process to be developed using life cycle tools and that the process should be simplified and accessible.

- 6.19. How much time should be allowed to complete an alternatives assessment? Should the timeframe be different depending on the type of product, such as a chemical formulation, like a cleaning product, or a manufactured item that is comprised of assembled parts, like a toy? If so, what types of differences should be allowed, and what types of products should they apply to?
- 6.20. Should a "beta" test of the alternatives analysis process be included in the regulations? If so, what would the provisions of such a test be? How would the results of the test be incorporated into the required alternatives analysis process?

7. Regulatory Responses

The statute requires that the regulations specify response actions which include:

- Not requiring any action.
- Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.
- Imposing requirements on the labeling or other type of consumer product information.
- Imposing a restriction on the use of the chemical of concern in the consumer product.
- Prohibiting the use of the chemical of concern in the consumer product.
- Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product.
- Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.
- Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.
- Any other outcome the department determines accomplishes the requirements of this article.

Questions:

The law requires a response action following the completion of an alternative analysis. Criteria for actuating a response action and appropriate time frames for implementation are needed for each of these response actions.

- 7.1. What criteria should be used to impose each of the above listed response actions? Why?
- 7.2. What are appropriate timeframes for implementing each of these response actions? Are there circumstances or situations that should be considered to provide additional time for implementation?
- 7.3. What, if any, other specific outcomes would you recommend that DTSC consider?

The conclusion of the alternative analysis should provide the basis for the response actions. Criteria can be developed in regulation that would prescribe the specific response actions that a manufacturer must implement to appropriately address their specific alternative analysis findings (self-implementing). Some commenters object to the self-implementing approach because it allows the manufacturers to evaluate which response action would be most appropriate without DTSC or third party review.

- 7.4. If DTSC prescribes in regulation the response action that must be taken for a particular alternative analysis outcome, which response actions lend themselves to be implemented in this manner? Which response actions should be subject to DTSC discretion on a case by case basis? Why?
- 7.5. Should DTSC review an implementation plan which details how and when a response action will be conducted before a response action is implemented? Are there instances when review would not be necessary?

The statute allows prohibiting the use of a *chemical of concern in a consumer product*. Many commenters object to banning a chemical or chemicals given tremendous economic consequences to industry and consumers when no other response action is available when there are no potential alternatives. Conversely, many commenters are concerned that hazardous chemicals continued to be used in consumer products and should be banned more quickly.

- 7.6. What should be the criteria for prohibiting the use of a specific chemical in consumer products?
- 7.7. Should there be a separate regulatory process for imposing such a prohibition? If so, what should it be?

The conceptual outline identifies significant impacts as a trigger for response actions.

- 7.8. If a safer alternative does not exist, should response actions be used to reduce hazards, or reduce exposures? Why?
- 7.9. Should we have a response action to address significant life cycle impacts, or accelerate the development of safer alternatives?
- 7.10. How should we define "significant impact" for the purpose of requiring a response action?
- 7.11. If we can not define a significant impact, how can we link a specific response action to the findings in the alternative analysis?

The statute provides a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.

- 7.12. What mechanisms are available to fund green chemistry challenge grants? What would these mechanisms entail?
- 7.13. How and by whom would these be funded?
- 7.14. How can we best use an option for research and development proposals? How could this be implemented?
- 7.15. Should a certification program be used to acknowledge innovation that results in safer product substitutions or other advances that promote green chemistry? How would we develop this type of program?

A variance procedure would allow for modifications of provisions that address issues that have not been anticipated. Many commenters feel that this will be a way for manufacturers to defer the implementation of the regulations while creating an overwhelming workload for DTSC.

- 7.16. In an effort to accommodate very different situations, does a variance adequately allow DTSC to accommodate extensions of a deadline, exclusions based on a de minimis threshold, or modifications of a response action? What should the criteria be?

8. Terms and Definitions

Clear and meaningful definitions of key terms are necessary to ensure the success of the regulation.

Questions:

- 8.1. How should the following terms be defined?
- 8.1.1. "Authoritative body"
 - 8.1.2. "Chemical"
 - 8.1.3. "Chemical ingredient:"
 - 8.1.4. "Chemical of concern"
 - 8.1.5. "Consumer product"
 - 8.1.6. "Manufacturer"

9. Role of State Government

How broad a role should state government have in implementing this rule?

Questions:

- 9.1. What is the proper role for state government for this rule?
- 9.2. Should DTSC set rules for required processes?
- 9.3. Should DTSC conduct those processes directly?
- 9.4. Should DTSC mandate standards, protocols, and methodologies for those processes? If so, what should be included in the initial rule? Which of these must be developed further (by the public or private sector, or both) before it can be applied as a general rule of applicability?
- 9.5. Should DTSC test consumer products?
- 9.6. How should DTSC monitor the overall system?
- 9.7. Should the initial rule be expanded or revised periodically—to add chemicals or products, to revise procedures, to set performance or professional standards, etc.?
- 9.8. If so, what should be part of the first rulemaking? What should be part of the second and third rulemakings?
- 9.9. How should the subject(s) of those subsequent rulemakings be determined?
- 9.10. Which *consumer products* are also regulated by other governmental agencies?
- 9.11. Should a fee or assessment be levied by state government?
- 9.12. If so, how high should the fee be set?
- 9.13. Who should be assessed that fee?