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1	John S. Applegate
2	Nicholas A. Ashford, PhD, JD
3	Deborah H. Bennett
4	Christensen
5	William H. Farland, Ph.D., ATS
6	George M. Gray, Ph.D.
7	Dale Hattis, Ph.D.
8	Ortwin Renn
9	Jennifer Sass, Ph.D.

February 20, 2013

PEER REVIEW REPORT FOR
CALIFORNIA SAFER CONSUMER PRODUCT ALTERNATIVE REGULATION
***as revised* JANUARY 2013**

John S. Applegate
Walter W. Foskett Professor of Law
Indiana University Maurer School of Law
Bloomington, Indiana

Thank you for the opportunity to conduct a peer review of the California Safer Consumer Product Alternative Regulations (CCSPAR), as revised following hearings. My comments respond to the revised regulations dated January 29, 2013. The review follows the four specific Peer Review Topics identified in the attachment to the January 30, 2013, memorandum to peer reviewers from Dr. Jeff Wong.

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 Candidate Chemicals list.

(a) The revised regulations include no substantial changes in the criteria for selection of lists and chemicals, and they are appropriate.

(b) The two newly added lists are also appropriate for the purpose of identifying Candidate Chemicals.

(c) As I indicated in my previous comments, the approach of using existing lists makes a great deal of sense, because using lists rapidly generates a comprehensive list of chemicals and avoids duplication of effort. The lists are compiled by reliable and authoritative governmental organizations. The ability to add or subtract from the list is also important, as new information will develop and the CCSPAR process will undoubtedly develop over time.

The change in terminology from "Chemicals of Concern" to "Candidate Chemicals" provides a clarification and an adjustment of the CCSPAR structure, even though it does not appear to change the basic operation of the regulations. "Candidate Chemicals" is probably a more accurate name for chemicals derived from existing lists, because the lists are a preliminary step in the overall analysis. The Candidate Chemicals approach also emphasizes the risk-based nature of the overall CCSPAR process to the extent that it requires consideration of both hazard (toxicity) and exposure. AB 1879, which is the basis for the CCSPAR, clearly indicates that both hazard and exposure are to be considered in evaluating products. *See* §§ 25252(a), 25253(a). Within a risk-based structure, the list of

chemicals, without more, indicates a "candidate," and using the new nomenclature, it is clearer that chemicals only become Chemicals of Concern when they are associated with a product, and thus with *exposure* from a product. *See* § 69503.5(b)(2)(B) and article 3 generally.

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

(a) The memorandum to peer reviewers indicates that this topic is intended to raise the question whether the revised CCSPAR, having focused the regulations more sharply on the chemical-product combination, retains the breadth to cover the range of products and dangers envisioned by the AB 1879 legislation. The issue is not, it seems to me, definitions and exclusions from the meaning of "product" or "consumer product," though there has been some clarification of repair, replacement, and the like, which seem appropriate.

Rather, the topic focuses on the use of the term "potential" to modify both exposures and impacts/effects. As a preliminary matter, the idea of regulating potential harm, as opposed to actually realized harm, should not be controversial in this setting. It is the essence of preventive regulation, and prevention (as opposed to reparation or compensation) is the *raison d'etre* of most environmental, health, and safety regulation, including CCSPAR. The challenge confronting the rulemakers, therefore, is how to assure that the term "potential" means something more substantial than mere speculation, without depriving "potential" of the expansiveness necessary to fulfill the preventive legislative mandate.

The CCSPAR seems to address this in two ways. First, the revised CCSPAR adds a new definition of "potential" as "reasonably foreseeable based on reliable information." § 69501.1(a)(51)(A).[1] This is a relatively narrow definition, as it requires some degree of both [1] foreseeability and [2] quality of information. Both of these limitations carry legal baggage:

> [1] "Reasonably foreseeable" is not defined in the regulation, but it is the subject of an enormous amount of litigation and commentary in tort law, particularly in the famously knotty problem of proximate cause. The function of proximate cause in tort law is to narrow the hugely broad concept of cause in fact ("but-for" cause), so the use of the standard formula for proximate cause (reasonably foreseeable) is sensible enough here. It also makes structural sense, inasmuch as the regulations start with a broad term ("potential") and then narrow it through the definition.

[1] The definition of "potential" does not apply in two very specific cases, but this does not change the analysis here.

However, there is a danger that foreseeability will itself become a point of contention and legal wrangling. This could be quite disruptive to an already heavily burdened regulatory system.

[2] "Reliable information" is extensively defined in the regulations. § 69501.1(a)(58)-(59). The meaning of "reliable information" is perfectly sensible in its own terms. However, as with "reasonably foreseeable," there is a possibility that DTSC action will be delayed by challenges to "potential" based on this term. That is, a great deal of time could be spent resolving the scope issue, long before the heart of the CCSPAR – the alternatives analysis – comes into play.

Second, "potential" also seems to be limited by the way that it is used in article 3. The key section reads as follows:

> Key Prioritization Principles. Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria:
>
> (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
>
> (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse effects.

§§ 69503.2(a); *see also* §§ 69503.2(b), 69503.3(a)(1). In this language, potential exposure seems to be qualified by the capacity of the exposure to [1] "contribute to or cause" [2] "significant or widespread" impacts or effects.

[1] The term "contribute to or cause" (or vice versa) is common in federal environmental law statutes, and it is intended to be expansive. In particular, the phrase permits (or requires) regulatory action to go forward despite the existence of scientific uncertainty. *See, e.g., Massachusetts v. EPA*, 549 U.S. 497, 506 n.7, 534-35 (2007) (interpreting the Clean Air Act, 42 U.S.C. §§ 7521(a)(1)). *See also* 42 U.S.C. § 7408(a)(1)(A) (listing of air pollutants). In other words, "contribute to or cause" should not be interpreted to require a particular level of certainty in connecting the exposure and the effect or impact. Nevertheless, since "potential" is also used in this section, it might suggest that a particular impact or effect must also be "reasonably foreseeable" from the level of exposure caused by a product. I do not think that this interpretation was intended, but the section could be read to imply a level of certainty that would be difficult to demonstrate.

[2] Likewise, while the nature and scope of impacts and effects are very comprehensively defined (as in the initial proposed regulations), the term "significant or widespread" is undefined. Presumably it is meant to mean something like "more than de minimis," but *how much* more is left open to debate. This could add unproductive complexity to the department's analysis to justify the list of Priority Products.

The foregoing is admittedly a fairly laborious analysis of the language in the regulations – perhaps too laborious. I do not suggest that the regulations are misguided in

introducing "potential" to assure that the regulations are sufficiently preventive, and then trying to place some boundaries around the naturally expansive term "potential." There is also sense in using familiar terms like "reasonably foreseeable" and "reliable information." Nevertheless, the definitions and the way that "potential" is used in the regulations could be more limiting to the coverage of the CCSPAR than intended. Furthermore, both the terms themselves and the way that "potential" is used invite an affected party to bring in a large body of law and to parse the statutory language minutely at a very early stage in the proceedings, before the real work of the CCSPAR alternatives analysis has begun. Given the resource challenges that DTSC faces in implementing the CCSPAR, this must be considered carefully.

(b) Given the breadth of the CCSPAR, it is useful that the regulations repeatedly emphasize that other adequate regulatory regimes are an appropriate reason for DTSC *not* to act under CCSPAR. *See* §§ 69503.2(b)(2), 69501.1(b)(3). These anti-duplication provisions are good additions in the revised regulations.

(c) Section § 69503.2(b)(3) adds a new provision that permits DTSC to "consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible." Presumably the purpose of this new section is to allow the inclusion of a chemical-product combination as a Priority Product if there is such an alternative, or to allow exclusion if no such alternative exists. This makes sense, but within the structure of the CCSPAR it is not clear how this provision in article 3 is related to the formal Alternatives Analysis in article 5. Does it preempt or substitute for the Alternatives Analysis in some cases? Is it a preliminary alternatives analysis that will be repeated more fully later in the process?

It is possible that the answer is the unusually narrow meaning of "economically feasible." "Economically feasible" is defined as an alternative that "does not significantly reduce the manufacturer's operating margin." § 69501.1(a)(29). The more common understanding of "feasible" is much broader. For example, as described in the well known *Cotton Dust* case, "feasible" includes anything which is "capable of being done." *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 508-509 (1981). That is, a feasibility-based standard requires the manufacturer to stretch to the limits of what it can do, and so in the case of economically feasible, to the limits of what it can afford. The new CCSPAR definition would seem to treat as infeasible nearly anything that costs money (unless the whole cost can be passed along to the consumer, I suppose). So, given this narrow meaning, is § 69503.2(b)(3) to be understood to allow exclusion or inclusion only where the alternative or lack of alternative is extremely obvious and does not require the analysis in article 5? In any event, the relationship between the chapter 3 and chapter 5 provisions should be clarified.

3. The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products are scientifically understood and practical.

(a) The revised regulations limit the use of the Alternatives Analysis Threshold (AAT) – which is in effect the exception process for Priority Products – to the Practical Quantitation Limit (PQL) of a *contaminant* in a product. § 69501.1(a)(12). PQLs, in turn, refer to the lowest measurable quantity of the contaminant. § 69501.1(a)(52). The effect of this change is greatly to limit the scope of the prior AAT exceptions process. Assuming that limitation is intended, the rationale is presumably that, especially in such comprehensive regulatory regime, DTSC should be focusing its limited resources only on those contaminants which it can readily measure. This is sensible, just as it is sensible to treat intentionally added chemicals differently. § 69501.1(a)(26). As a practical matter, intentionally added chemicals are likely to be easier than contaminants to control, delete, or substitute in products.

(b) The fuller description of this question in the Scope of Work also notes the new requirement that the list of Priority Products is subject to the California APA. § 69503.4(a). It is not immediately obvious why the question to reviewers links the AAT-PQL process to the APA change, except that the narrowing of AAT-PQL means that little will be excluded from the Priority Product list, and so more Priority Products will be subject to APA procedures. (At least, that is how I read it.) It is hard to object to using a regular administrative process to promulgate and seek comment on administrative action, but – as above – the CCSPAR process will be an enormous undertaking at best, and this will require greater departmental resources.

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

(a) I observed in my report on the initial draft of the regulations that the term "adverse" is very broad, and it comprehensively covers the impacts and effects that AB 1879 and the CCSPAR seeks to prevent. For emissions and discharges, the adverse aspect is the emission itself, which has the potential to cause adverse effects or impacts (*e.g.,* § 69501.1(a)(9)(E) (water)). For adverse effects and impacts, the definitions focus on the harm that can be caused by exposure to the chemical in question (*e.g.,* § 69501.1(a)(7) (soil)). Between them, they cover the causes and effects comprehensively, and the recent changes in the definitions do not appear to change the broad scope at all.

(b) The question also states that a qualitative or quantitative determination of adverseness can be made, and that either is adequately protective if reliable information is available. I agree with this statement. Qualitative information must frequently be relied upon when quantitative information is absent, limited, or of questionable reliability – and this situation is common, if not typical, among toxics.

The acceptance of both quantitative and qualitative information is implied rather than expressly stated in the CCSPAR. (The actual words "quantitative" and "qualitative" are

only used in the regulations incidentally and in relation to Alternatives Analysis.) While the definition of "reliable information" as it relates to exposure mainly points to quantified information (such as monitoring data, § 69501.1(a)(58)), the general definition of "reliable information" is quite clearly *not* limited to quantitative information. § 69501.1(a)(57). Since the general definition is the one that would be used on the more uncertain toxicity side of the risk equation, this provides some assurance that quantification will not be a severe obstacle to protective regulation. Another indication of the validity of qualitative information is the acceptance of structural and mechanistic similarities as evidence of toxicity. § 69503.3(a)(3). Such similarities are indeed useful evidence, but one can rarely make a quantitative leap from one structure to another without data concerning both chemicals. Thus, to accept similarities *themselves* as evidence implies the acceptability of qualitative information.

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Thank you again for the opportunity to review the revised California Safer Consumer Product Alternative Regulations. I will be happy to clarify any of the foregoing comments or address other issues, should that be of assistance.

COMMENTARY ON THE REVISED CALIFORNIA SAFER CONSUMER PRODUCT REGULATIONS (and Summary of Significant Changes) (dated January 2013)

Nicholas A. Ashford, PhD, JD
President Ashford Associates, and
Professor, Massachusetts Institute of Technology

Evaluation of the Key Criteria:

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

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

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

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

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

General remarks: Being able to classify as a chemical of concern on the basis of the availability of a safer *chemical* substitute is extremely important and should be retained. This ties together risk assessment and alternatives assessment. However, the rule (and the summary of significant changes) is inappropriately structured and written in language that discusses only *chemical* substitution. More prominence needs to be given to substitutions or alternatives that include 'use of a safer technological or administrative approach that delivers a comparable functional purpose'.

In the four-page document entitled **Summary of Significant Changes**, bullet four on page 2 reads:

> "The regulations clarify that the required AA evaluation of chemical hazards and adverse impacts is limited in scope to the COCs, alternative replacement chemicals, and any other chemicals in the alternatives that differ from the chemicals in the Priority Product"

However, the rule itself obliquely, but specifically, requires that *non-chemical* alternatives are to be included in the alternatives analysis and the regulatory responses required of the manufacturer of the COCs. This is missing from the statement above.

The Definitions section 69501.1 (a)(10) clearly considers "alternative" to include changes in the "manufacturing process."

Article 5 Alternatives Analysis - Section 69505

Unfortunately, reference to this expansive and inclusive definition of alternatives is only obliquely referenced in the section dealing with 'identification of Alternatives' - Section 69505.5 (b)(1A) on page 62 reads:

> In addition to any alternative identified under section (a)(3)(B), the responsible entity shall identify and consider alternatives that meet the definition of 'alternative' under section 69501.1…

Fortunately, Section 60505.6 (a)(2)((B) on page 64 does consider non-chemical alternatives, but in general the rule is poorly written in bringing attention to these. The rule should be re-written.

In addition, under the discussion of Alternatives Analysis, bullet four on page 2 of the **Summary Document** should be amended to read:

> "The regulations clarify that the required AA evaluation of chemical hazards and adverse impacts is limited in scope to the COCs, alternative replacement chemicals, ~~and~~ any other chemicals in the alternatives that differ from the chemicals in the Priority Product, and safer technological or administrative approaches that deliver a comparable, but safer functional purpose as the COCs."

Article 6 Regulatory Responses - Section 69506

Section 69506.6(a): line 1 (page 83) [sentence continued from page 82, last line] delete the word "product" and substitute the words "technology or approach" so that it reads "a selected alternative technology or approach"

In addition, in the discussion Regulatory Responses in the four-page document entitled **Summary of Significant Changes**, add the following to the end of bullet two:

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

I question the limitation of bullet 7 on 'DTSC not being able to require a new Alternatives Assessment based on the receipt of new information' and in the text of the regulation itself to that effect. I recommend its elimination.

ADDITIONAL REMARKS REGARDING THE ECONOMIC IMPACT OF THE PROPOSED RULE

While not asked to comment upon the likely economic impact of the rule, I offer the following remarks.

1. The costs of additional tasks imposed upon the proposed rule should be balanced against (1) the public health and environmental consequences of not implementing the rule, and (2) the benefits of stimulating replacement of problematic chemicals (derived from the list of chemicals of concern) by more benign chemicals, changes in reformulated or substitute products, process technology, and other technological and administrative practices.

2. In general, much chemical production and usage has remain static for decades, while new products, synthetic pathways, ad approaches have been the focus of innovation that have insufficiently penetrated the market and general practice. Thus, the proposed rule can properly be interpreted as a 'modernization of the chemical industry' [1].

3. There will be winners and losers among industrial actors, but innovation and economic growth crucially depends on industry and product turnover and evolution. Otherwise the industrial sectors and nations in which they are embedded remain static and uncompetitive.

4. Europe and Asia are advancing in chemical innovation, and the chemical industry in the United States cannot afford to lag behind in the development and deployment of environmentally safer chemicals and processes.

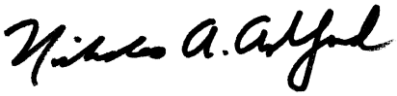
5. Finally, the proposed rule advances the regulation of chemicals from an exclusively risk-driven process towards a technology-based process which is less expensive by not requiring detailed and full-fledged risk analysis, and instead fostering *comparative* risk analysis and functional analysis -- and the identification of better technologies and approaches [2].

[1] "Using Regulation to Change the Market for Innovation," N.A. Ashford, C. Ayers, R.F. Stone, *Harvard Environmental Law Review*, Volume 9, Number 2, Summer 1985, pp. 419-466. Available at http://hdl.handle.net/1721.1/1555

[2] "Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH", Lars Koch and Nicholas A. Ashford, *Journal of Cleaner Production* 14(1): 31-46 2006. Available at http://hdl.handle.net/1721.1/38476 Revised version published in

Environmental Law Network International 2(2005):22-37. Available at http://hdl.handle.net/1721.1/55292

Respectfully submitted,



Nicholas A. Ashford, Ph.D., J.D.
President, Ashford Associates, and
Professor of Technology and Policy
Submitted 3 March 2013 in response to Service Authorization Number OSA 12-055

Peer Review of Revised Safer Consumer Products Regulations

Deborah H Bennett

Topic 1: Listing of Initial Candidate Chemicals

The revised regulation broadens the lists used to compile the initial candidate chemical list by adding respiratory sensitizers defined by the European Union and a more complete listing of chemicals considered under the federal Clean Water Act. I think that is very appropriate to broaden the list in this way as it will provide for a more complete listing of chemicals that cause potential harm.

Topic 2: Criteria for prioritizing product-chemical combinations

I am somewhat concerned with the language in 69503.2,a,2, specifically "potential for one or more exposures can contribute to or cause ***significant or widespread*** adverse impacts." There appears to be no definition for significant or widespread and I feel this criteria can be interpreted in a variable manner by the regulating body and the regulated entity.

I was very pleased with the additions of evaluating chemicals with structurally or mechanistically similar chemicals which there is a known toxicity profile, the addition of workplace presence of the chemical, and the inclusion of releases of the product in schools.

In section 69503.3,b,4, there is a list of factors to be considered. The items under A and D-H all appear to be factors related to quantifying the likely exposure to the public. In the prior version, items B and C, both related to chemicals that are basically never released in California, were an exemption. By placing them in this current list, it seems like one would be expected to evaluate exposures related to these compounds even though there is little chance for exposure. If the desire is do not have these as exemptions, but in some way have some sort of minimal evaluation, this intent should be made more clearly. Perhaps they could be listed together in their own subsection and it could be clearly stated that there is likely to be minimal exposure due to these scenarios.

In section 69503.4, the focus is on the process for identifying Priority Products. It is not clear from the regulation how broadly the product categories are defined. If a chemical is used in two very different product categories, which are not both being considered in the development of the priority product work plan, it is not inherently clear from the regulation that aggregate exposures from both product categories will be considered. There is some mention of aggregate exposures in the document, and the department may be planning on including aggregate exposures from multiple product categories, but it is not clearly stated. Aggregate exposure for

multiple use categories of products containing the same chemical of concern should be considered.

Topic 3: Alternative analysis threshold

I thought that the changes to the alternative analysis threshold were very clear and appropriate.

Topic 4: Use of the word “adverse”

With the exception of the statement “cause significant or widespread adverse impacts” in which significant and widespread were not defined, I thought that the uses of adverse in the document were clear and appropriate.

Department of Toxic Substances Control

Matthew Rodriquez
Secretary for
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Deborah O. Raphael, Director
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Edmund G. Brown Jr.
Governor

TO: Scientific Peer Reviewer

FROM: Jeff Wong, Ph.D.
Office of Pollution Prevention and Green Technology
Department of Toxic Substances Control

DATE: January 30, 2012

SUBJECT: NOTICE TO PROCEED WITH SCIENTIFIC PEER REVIEW FOR SAFER CONSUMER PRODUCT REGULATIONS

Thank you for your participation as a scientific peer reviewer for the California Safer Consumer Product Alternative Regulations. Attached you will find:

- Attachment 1: Summary of Proposed Regulations and Changes. Attachment 1 provides a brief background that has led the Department of Toxic Substances Control (DTSC) to propose regulations for Safer Consumer Products regulations and the revisions that were made.

- Attachment 2: Scientific Factors: Peer Review Topics. Attachment 2 contains the topics that DTSC is requesting the peer reviewers to comment on.

- Attachment 3: Revised Proposed Regulations for Safer Consumer Products. Attachment 3 contains the revised proposed regulations that are the subject of this peer review request, which can also be found at: http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf

  The unofficial version, without underline and strikeout, of the Revised Proposed Regulations can also be found at: http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text-NU.pdf

Please complete your review by **March 4, 2013** and send your written comments to Daphne Molin at daphne.molin@dtsc.ca.gov. If you require clarification of this communication, please contact Dr. Jeff Wong at jeff.wong@dtsc.ca.govor (916) 322-0504 or Daphne Molin at daphne.molin@dtsc.ca.gov or (916) 445-6130.

Attachment 1
Summary of Proposed and Revised Regulations

Background

On July 27, 2012, DTSC entered the rulemaking process for The Safer Consumer Products Regulations to fulfill the mandate of AB 1879, which became Chapter 559 (stats. of 2008). This law directs DTSC to adopt regulations to establish a process to reach an aspirational goal that encourages the manufacture of safer consumer products through innovation and the use of safer or less hazardous chemicals. DTSC is proposing a four step regulatory process that:

(1) Yields an informational list of chemicals that have been identified by an authoritative organization or reliable information to exhibit a hazard trait or shown by reliable information to demonstrate the occurrence of the chemical in the public or environment. These chemicals are referred to as Candidate Chemicals after they have been identified, subjected to stakeholder input, and finalized by DTSC.

(2) Allows DTSC to evaluate product-chemical combinations and nominate products for the proposed Priority Products list and finalize the list following public review and stakeholder input.

(3) Requires manufacturers to examine their Priority Products and their potential alternative products through an Alternatives Analysis and identify the selected alternative product, if any. Copies of the completed Alternatives Analysis Reports, excluding trade secret information, will be made publically available.

(4) Designates Regulatory Response options for DTSC to impose on to manufacturers based on their product selection in the Alternatives Analysis process.

In the July proposal, a product that would be listed as a Priority Product and that meets the criteria for an alternatives analysis threshold exemption was exempt from the requirement to perform an Alternatives Analysis if a responsible entity for the product submits an Alternatives Analysis Threshold Exemption Notification to DTSC. Peer reviewers were asked to review and provide comment on the scientific nature of four topics points. The previous request can be found at:
http://www.dtsc.ca.gov/LawsRegsPolicies/upload/Revised-Request-Memo.pdf

After considering public comments, Departmental resources, and various practical and policy issues, DTSC revised the proposed regulations and asks the reviewers to review the revised proposed regulation, and comment on the scientific nature of the same four points (Attachment 2). To provide the peer reviewer the context of these revised regulations, please refer to the Summary of Significant Changes in January 2013 Revised Proposed Regulations at:
http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Summary-of-Changes.pdf

Attachment 2
Scientific Factors: Peer Review Topics

The California statute for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

We request that you make this determination for each of the following topics that constitutes the scientific basis of the proposed regulatory action. An explanatory statement is provided for the topic to focus the review. Section 25252 of the Health and Safety Code provides the authority and basis for developing the proposed regulatory text that is the focus of this peer review.

Topics:

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 Candidate Chemicals list.

The list of chemicals is now called the "Candidate Chemicals" list. The regulations define "Candidate Chemical" as a chemical that is a candidate for designation as a "Chemical of Concern" (COC). A "Candidate Chemical" that is the basis for a product-chemical combination being listed as a Priority Product is designated as a "Chemical of Concern" with respect to that product. NOTE: This change in terminology does not affect the application of the regulations to the chemicals on the chemicals list.

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

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

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

Christensen response: These changes are consistent with our scientific understanding of the potential impacts of these chemicals on the human and ecosystem health.

Attachment 2
Scientific Factors: Peer Review Topics

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

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

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

Christensen response: These changes are important and founded in sound science. Replacing "a significant ability" with "potential" is especially important. "Significant ability" is an imprecise phrase open to a variety of interpretations. "Potential" is much clearer and consistent with the intent to protect human and ecosystem health.

3. The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products is scientifically understood and practical

In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California's Administrative Procedures Act (APA) for rulemaking. The APA requires proposals to be made public (public notice) with supporting documentation as to the necessity of the new requirements. Although the revised regulations are silent on this issue, the Department can use the APA rulemaking process in the future to allow for the establishment of an alternative analysis threshold for a product-chemical combination should the need arise.

Attachment 2
Scientific Factors: Peer Review Topics

Christensen response: The Practical Quantification Limit is scientifically sound. Furthermore, it is logical that that Alternative Analysis Threshold would apply only to contaminant chemicals and not to chemicals intentionally added to a product.

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

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

Christensen response: These changes seem appropriate. The terms "impact" and "effect" are often used as synonyms and the difference between them is subtle (impact perhaps being a generally negative effect).

To: Jeff Wong, Ph.D.
Office of the Chief Scientist
Department of Toxic Substances Control

From: William H. Farland, Ph.D., ATS
Scientific Peer Reviewer

Date: March 4, 2013

Subject: Scientific Peer Review for Safer Consumer Products Regulations

Thank you for the opportunity to serve as a scientific peer reviewer on the latest version of the Safer Consumer Products Regulations. I have completed my review which is structured around the scientific issues and peer review points that you provided. My detailed comments are attached.

My detailed comments notwithstanding, I am of the opinion that the proposed rule is based upon sound scientific knowledge, methods and practices. The Regulations continue to rely heavily on the work of others who have constructed lists of potentially hazardous substances which, for the most part, have relied on public processes and scientific peer review in their construction. The addition of lists from authoritative organizations will only strengthen the basis for State decision-making. The use of the term "candidate chemical" for the large number of chemicals that will comprise the "list of lists" is more scientifically defensible than call them "Chemicals of Concern" from the outset. "Concern" needs to be raised in the context of the product-chemical combination. The evaluation criteria for prioritizing the product-chemical combinations are robust and comprehensive. As such, they provide a reasonable basis for identifying all types of consumer products as potential Priority Products. The basis will still require significant scientific judgment but the clarification in the current version of the regulations to define "potential" effects or exposures as "reasonably foreseeable based on reliable information" will help in this context. I believe that the use of the "Practical Quantitation Limit (PQL)" is also an improvement for establishing an Alternatives Analysis Threshold. Finally, as discussed in my previous review, the discussion of what constitutes "adverse" continues to need further clarification. Slight changes to the use of "impact" versus "effect" in the proposed language of the regulation have done nothing to bring about this clarification.

Thank you again for the opportunity to participate in the scientific peer review of these proposed regulations. Feel free to contact me if you have questions regarding the attached detailed comments.

Review Topic: 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 Candidate Chemicals list.

Comment:

As indicated earlier, it is my opinion that the use of chemical lists developed by "authoritative bodies" in California as well as elsewhere in the US and internationally is a scientifically defensible approach to identifying "Candidate Chemicals". Each of the lists 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. This point was well made in the "Initial Statement of Reasons" (ISOR) document where individual lists, their processes and scientific integrity are described. While each list will have its own criteria and listing thresholds, in the aggregate, they produce a list of chemicals that embody the hazard traits or chemical characteristics described in the regulation. Originally, the chemicals identified in subsection (a)(2) were identified as Chemicals of Concern (COCs). I believe that the response to comments and the change to call these "Candidate Chemicals" is more consistent with the fact that additional analysis will be required in order to determine whether their presence in a product raises a "concern". Because these chemical lists were originally generated for a specific purpose (monitoring or reducing exposure/contamination), the Department is relying on the authoritative organization's determination regarding chemicals exhibiting a hazard trait to be listed. Further analysis will determine which of the traits may be exhibited under particular product chemical combinations and specific exposure scenarios and therefore, when a chemical may be of concern.

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

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

It has been determined that these lists of chemicals meet the same criteria that were used to identify the sources of chemicals that were in the July proposal. The lists are supported by an authoritative organization, used to limit exposure, and are consistent with similar programs in other states. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are reviewed and updated periodically. For these reasons, I see no problem with adding these lists to the list of lists. I do, however, question why the addition is limited to chemicals classified as Category 1 respiratory sensitizers when the same Regulation (EU Regulation 1272/2008) which has been in force since January, 2009 also includes a list of Category 1 skin sensitizers. Chemicals in this category meet the criteria of either having evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons or if there are positive results from appropriate animal testing. Chapter 54 (Section 69403.2) lists dermatotoxicity as one of the "Other Toxicological Hazard Traits" under Article 3. Sensitization is included as one of the toxicological endpoints in determining

dermatotoxicity. Therefore, it would seem prudent to not limit the addition to the list of respiratory sensitizers from the EU Regulation.

The regulation provides for the opportunity to add or remove chemicals from the list as new information relating to hazard traits becomes available. This opportunity includes a public notice and comment process which allows for broad based scientific input. This may be important for some future listing decisions because of the infrequency of updating of individual lists mentioned in the regulations and the evolution of the testing and assessment process.

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

Comment:

The regulation has provided a scientifically sound approach to prioritizing product-chemical combinations to identify consumer products containing Candidate Chemicals as potential Priority Products. To be considered a Priority Product, a product-chemical combination must meet both of the following criteria:
(1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
(2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts. In addition, it will consider waste and end-of-life effects in reaching this conclusion. The decision shall also consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. A further criterion to be considered is "the scope of other California State and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse impacts and potential exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product." In this way, if a product is regulated by another entity with respect to the same potential adverse impacts and potential exposure pathways, and potential adverse waste and end-of-life effects, a listing decision is made under the regulation only if there is a determination that the listing would "meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that are the basis for the listing." In addition, the regulation allows consideration as to whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

As stated above, the regulations require consideration of information from both candidate chemicals and consumer products in combination. Evaluating and examining the information

from both, based on the availability of information to inform such judgments, will allow for flexible decision-making regarding which of the products should be listed as Priority Products. Because the decision-making process to designate a product as "high priority" is based on a variety of information and a narrative approach, DTSC has continued to use a narrative approach to describing its priority setting decisions rather than a quantitative weighting scheme. This seems like a sound decision given the typical available information and the differences one would see from product to product. As indicated in section 69503.3, decision-makers will use a wide-range of available information to consider and evaluate the potential adverse impacts and widespread exposure. Given the broad range of characteristics related to adverse impact and exposure parameters specified for evaluation over the lifecycle of the product within the regulation, this approach seems comprehensive, scientifically-sound and should be applicable to a wide range of products.

In expressing its intent in the revised regulations to consider "potential" for adverse impacts or wide-spread exposure rather than using the term "ability to" cause, the DTSC is clearer in its position that the impacts and exposure are "reasonably foreseeable" rather than simply hypothetical, given available information. This is an important distinction in establishing the criteria for listing Priority Products.

Review topic: The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products are scientifically understood and practical.

Comment:

In the revised proposed regulations, the Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the listed chemicals solely as a contaminant chemical. There will not be an Alternatives Analysis Threshold provision for an intentionally added ingredient.
The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification, including the source of the contaminant COC(s). The notification must identify the PQL(s) for the COC(s) and the methods used to determine the PQL(s). The use of the PQL is standard practice in environmental regulations and laboratory analysis. This level is defined as a point where a signal can be quantified with statistical rigor. EPA has routinely used the PQL to estimate or evaluate the minimum concentration at which most laboratories can be expected to reliably measure a specific chemical contaminant during day-to-day analyses. This approach is scientifically defensible and understandable by the analytic community.

One issue that needs mention is that improved analytical performance (and hence, possible reduction of the PQL) may be suggested by lower detection limits from new methods. The existence of new methods with lower detection limits may not directly translate to improved analytical performance until sufficient experience is gained with the method and adoption is widespread. Since it will be incumbent on the submitter to justify the PQL selected for the COC(s) contained in the Priority Product, changes to PQL's in individual chemical candidates may be seen over time. These will need to be considered at the time of review of the notification.

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

Comment:

The regulation is clear in its intent to protect consumers from the hazardous components of consumer products. In this context, avoiding "adverse" impacts/effects is easily understandable. In the scientific or toxicological definition of adverse, it is less clear. I addressed this issue in detail in previous review comments. Certain endpoints from toxicological testing which are used to determine hazard based on animal studies or high level exposures need to be viewed carefully as to whether these constitute "adverse" effects in the context of human hazard. Issues discussed in this regard have to do with what constitutes an "adverse" versus an "adaptive" response to the exposure. While these issues will clearly need to be addressed in order to make a scientifically defensible case for the potential "adverse impacts" of product-chemical combinations, the closest statement I can find in the regulation is that "The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts…" While this statement may be reassuring to some, it is neither indicative of the difficulty nor explicit about role that scientific judgment will need to play in many of these decisions.

Of a less serious nature is the general use of impact and effect interchangeably. There appears to be no convention as to when one term is chosen over the other. In the current draft, impact has been changed to effect in a number of instances but there does not seem an obvious rationale for doing this. In general usage, "impact" is considered a weak alternative to "effect." The definition given for "impact" does not address a difference. Unless a rationale for the use is presented, it might be better to choose one or the other with "effect" being my preference.

Review

Safer Consumer Products

January, 2013 Revised Proposed Regulation

George M. Gray, Ph.D.

Professor, Department of Environmental and Occupational Health

Director, Center for Risk Science and Public Health

George Washington University

School of Public Health and Health Services

Washington, DC

March 4, 2013

I appreciate the opportunity to review the January 2013 Revised Safer Consumer Products Proposed Regulations. This iteration reflects continued thought and advice as the Department of Toxic Substances Control works to implement the requirements of Health and Safety Code section 25252.

My review is based on my understanding, developed through reading the materials supplied. My views come from my background as a risk analyst and toxicologist with a public health perspective. This review reflects my opinions and not necessarily those of George Washington University. I hope these comments will be considered along with my two previous sets of comments.

I begin with a few general comments about the revised regulations and then address the charge questions that were addressed to the peer reviewers.

My primary concern with the way the proposed regulations are structured is the very wide net that is cast in the beginning (the construction of the Candidate Chemicals list and the priority setting process) and the very narrow process of identifying priority products and conducting alternatives analyses (AAs). It is clear that the myriad of lists along with other criteria for identifying Candidate Chemicals will result in an initial list of hundreds or thousands of chemicals. Public concerns, and expectations, will be heightened when the presence of this large number of

potential chemicals of concern is identified. Yet the priority setting and listing process will begin with only five priority products. It seems to me that the potential for citizen frustration and dissatisfaction with the process will be very high.

In my view, a more targeted and risk-based approach to identifying candidate chemicals, which would result in a much smaller list, would be a more logical step. As I have noted in previous reviews, a list of candidate chemicals that is too long risks diluting effort, attention and resources. In addition, the presumably large Candidate Chemical list, based on many other lists, will doubtless cover the chemicals for which we have the greatest toxicological information. This will necessarily encourage the identification of new or less well-studied chemicals as potential alternatives in products or processes. Without a means to develop proxy hazard and dose-response information for these compounds we risk starting onto a "risk treadmill," moving from chemical to chemical as new information becomes available. The tools of structural or mechanistic similarity referred to in § 69503.3 would be useful in this situation.

The AA sections seem more reasoned and reflects the challenge of doing AA well. The idea of "potential" effects or exposures is dropped and replaced with "a material contribution to one or more adverse public health impacts" for example. In addition, the multi-criteria nature of AA decisions, with different possible outcomes to different populations is recognized. I would hope that guidance and examples for AA would include some of the very good work ongoing to demonstrate tools for these difficult decisions[1]. I am especially struck by the recognition of the importance of quantitative analysis tools, weighing and comparing multiple attributes and optimizing decisions in contrast to the very simplistic hazard-based approach taken in developing the Candidate Chemicals list.

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[1] I., Sinsheimer P, Malloy T. Integrating Safer Alternatives into Chemical Policy: Regulatory Framework for AB 1879. Los Angeles, CA: UCLA Law and Environmental Health Sustainable Technology & Policy Program; 2009 pages 1–13; Malloy T, Sinsheimer P, Blake A, Linkov I. Developing Regulatory Alternatives Analysis Methodologies for the California Green Chemistry Initiative. Los Angeles, CA: UCLA Sustainable Technology and Policy Program; 2011 pages 1–65.

Charge to Reviewers

The California statute for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

We request that you make this determination for each of the following topics that constitutes the scientific basis of the proposed regulatory action. An explanatory statement is provided for the topic to focus the review. Section 25252-25257.1 of the Health and Safety Code provide the authority and basis for developing the proposed regulatory text that is the focus of this peer review.

Topics:

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

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

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

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

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

As mentioned above, the hazard-based approach to list development is likely to lead to an unwieldy, unfocused and difficult to manage set of Candidate Chemicals

The focus on existing lists does not address the seeming contradiction of using certain hazard traits to develop the list while not acknowledging that many chemicals may not have been tested for the trait. This is a shortcoming that that I identified in a previous review:

> *"I am uncomfortable with the strong focus on specific hazard traits in both identifying COCs and in making de minimis determinations for two reasons. First, it is a well-established toxicologic fact that chemicals may have many different adverse effects. These effects may occur at different doses or be found in different test systems or species. Giving special consideration to carcinogens or compounds with "a reference dose or reference concentration has been developed based on neurotoxicity" in the EPA IRIS program, for example, misleads the public and, potentially, those conducting alternative assessments, about the specificity and accuracy of toxicologic values. For example, Xylenes; CASRN 1330-20-7, Toluene; CASRN 108-88-3 and 1,1,1-Trichloroethane all have oral RfD values in the IRIS database based on toxicologic outcomes other than neurotoxicity. Presumably, they would not be identified as having neurotoxicity as a hazard trait. But all three have positive results in toxicologic tests for neurotoxicity at some level of exposure.*
>
> *The second concern arises because of the unevenness of the database for many compounds. For example, in IRIS, Acetone (CASRN 67-64-1) has an oral RfD based on nephropathy yet the IRIS file points out "the database lacks chronic, developmental, developmental neurotoxicity, and multigenerational studies and adequate neurotoxicity studies." Here a compound can't even demonstrate one of the hazard traits of concern because it has not been tested. Even if we had complete data we know that the concordance of hazard traits between test species and humans is not very good, even for chemicals used at pharmaceutically active doses in humans[2].*
>
> *The potency and levels of human or environmental exposure would be a more focused means of identifying CoCs.*

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[2] Olson, H., *et al*. (2000) Concordance of the toxicity of pharmaceuticals in humans and in animals. *Regulatory Toxicology and Pharmacology* **32**(1):56-67

I continue to be concerned about the fundamental structure of the Candidate Chemical list. A list built from lists of chemicals with existing toxicologic or policy concerns will fundamentally encourage the use of new and less tested materials. If the AA process is robust enough, this may not be a problem. Making the AA process sufficiently robust will be a challenge.

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

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

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

Given the enormous number of chemicals likely to be on the Candidate Chemical list, the priority setting process must be rigorous and science-based to identify the right chemicals for further scrutiny. I have no confidence that the process in the revised proposed regulations will accomplish this. In my view, the change of the criterion from "ability to" to "potential" decreases the precision with which priority products can be identified. The change makes interpretation difficult (what does it mean to have "potential *exposures which must contribute to or cause significant or widespread adverse impacts"?)* and increases the possibility of arbitrary judgments about what evidence constitutes "potential" in both adverse effects and exposure contexts.

I would urge a return to the "ability to" language and, further, encourage development of guidance to clearly define how these judgments will be made. Some notion of causation along with criteria for evaluating both causation and attribution will be necessary.

I do not believe the use of biomonitoring data to as a prioritization factor can be scientifically supported (Section 69501.1 (a)(58)(B). Because biomonitoring data cannot apportion exposure to different sources and many Candidate Chemicals will have many sources of exposure (see Table) the identification of a chemical in biomonitoring studies does not indicate a product is a source of exposure.

Chemical	Candidate Chemical Hazard List	Non-Product Sources
Acetalehyde	Proposition 65 Carcinogen	Fruits Coffee Cigarette smoke
Benzene	Proposition 65 Carcinogen and Reproductive Toxicant	Eggs Bananas Cigarette smoke Gasoline

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

In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not be an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California's Administrative Procedure Act (APA) for rulemaking. The APA requires proposals to be made public (public notice) with supporting documentation as to the necessity of the new requirements. Although the revised regulations are silent on this issue, the Department can use the APA rulemaking process in the future to allow for the establishment of an

alternative analysis threshold for a product-chemical combination should the need arise.

The new approach to an Alternatives Analysis Threshold makes little sense to me. First, contrary to other regulations like those implementing Proposition 65, it is focused only on detection and has no role for the relative toxicity of a compound. In my view, an NSL-like approach, identifying a significant risk threshold, would be more scientifically sound. Second, it will be very difficult to administer. Constant advances in analytical chemistry mean the PQL will be a shifting target. The need to reexamine and update (and potentially revoke) threshold status will be constant, diverting effort and resources.

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

It is understandable and appropriate that the revised proposed regulations seek to identify and prioritize chemical uses that cause adverse effects on people or the environment. However, as defined in the 2013 Revised Proposed Regulations the term "adverse" is a confusing mix of qualitative, quantitative and theoretical effects with no concrete standard that must be met. For example, it is completely unclear who makes the designation, and which methods will be used, to identify "cumulative effects," "aggregate effects" or "potential to contribute to or cause adverse impacts" under § 69503.3. As noted above, the use of the term "potential" exacerbates this problem because the word has no generally agreed upon scientific meaning.

In my view the use of loose language in defining "adverse" will lead to either very little prioritization (because every product-chemical combination will have the "potential" for some exposure or adverse effect) or accusations of arbitrary behavior in prioritization because some assertions of "potential" put forward will be accepted and some will not.

Additional comment: § 69503.2 – How will DTSC know there is a "readily available safer alternative…."? This seems to open the potential for lobbying and strategic behavior on the part of competitors or vendors.

Responses to Peer Review Points

Dale Hattis, Ph.D.

Research Professor, Clark University

February 18, 2013

This document is my peer review of the updated "TEXT OF PROPOSED REGULATIONS – POST-HEARING CHANGES January 2013" for the DTSC regulations (Division 4.5, Title 22, California Code of Regulations. Below I have first provided my specific responses to the four points suggested in the inquiry to me. Then I provide comments on more general issues, and finally there is a section directed to specific parts of the text of the regulations and the statement of reasons document. The peer review points are given in normal type and my responses are provided in bold face.

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The California statute for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

We request that you make this determination for each of the following topics that constitutes the scientific basis of the proposed regulatory action.

Topics:

Review Issue 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 Candidate Chemicals

list.

The list of chemicals is now called the "Candidate Chemicals" list. The regulations define "Candidate Chemical" as a chemical that is a candidate for designation as a "Chemical of Concern" (COC). A "Candidate Chemical" that is the basis for a product- chemical combination being listed as a Priority Product is designated as a "Chemical of Concern" with respect to that product. NOTE: This change in terminology does not affect the application of the regulations to the chemicals on the chemicals list.

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

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

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

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

Response: The addition of these two new sources of candidate chemicals seems well founded. They each provide an additional useful perspective on additional chemicals for which there is some basis for concern to the extent they are used in consumer products.

This having been said, I have some residual concern with the definition of a "chemical" as used in the strike-through version of the new regulations:

““Chemical” means either of the following:

1. An organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity; or

2. A chemical ingredient, which means a substance comprising one or more substances described in subparagraph 1.”

Some pesticides, (e.g. toxaphene, now eliminated from use) have no single structure but are defined as the product of a chemical reaction (for toxaphene, the reaction of chlorine with camphene, which produces about 200 different individual chemical entities). I think that DTSC will want to be sure that it is clear that such a reaction product based on a mixture with no particular defined chemical structure is covered by the regulations as a “chemical”.

Review Issue 2

Evaluation criteria for prioritizing the product-chemical combinations in Article 3 are sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products. Revised regulations specify the key prioritization criteria as critical factors necessary to identify potential Priority

Products. The product-chemical combination identified and nominated for Priority Product listing must meet the key prioritization criteria.

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

phenomenon described is reasonably foreseeable based on reliable information.

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

Response: These clarifications are helpful, as far as they go. However there is still much to be defined in determining how DTSC will actually set its priorities in designating particular chemicals with particular hazard traits in particular products. It is clear from the choice to define the priority setting goal in the form of a narrative standard that DTSC does not want to lock itself in to a specific formula. However it seems clear that different formulae will be used for different hazard traits and that in at least in the cases of some hazard traits the formula will look something like:

Priority score = (potency) X (fraction used in a particular product type expected to reach people [or other type of vulnerable receptor, depending on the hazard trait] X (use volume)

In this equation

- **"potency" can be defined as the reciprocal of the dose found to cause a standardized response (e.g. 1/LD50 for an acutely lethal toxicant in a standard species; 1/ED10 for carcinogenesis over background)**
- **the second term is the "intake fraction" (fraction ingested, inhaled, or otherwise absorbed by people of that used for the purpose)**
- **"use volume" is the annual quantity estimated to be used in a particular product type in California**

Some variation of this type of scoring is likely to be needed among different hazard traits.

It should be emphasized that in an initial analysis, these relative priority scores should be calculated within sets of chemicals expected to exhibit specific hazard traits. Combining the information for different hazard traits is a step that can be left to later analysis. It is also important to understand that the DTSC need not have definitive evidence on the specific numerical values of each of the three components of this equation—the analysts will often need to develop estimates for specific chemicals based on analogies and utilizing adjustments to approximately put somewhat different types of data on comparable scales for ordering.

With this kind of elaboration, I think the priority-setting schema can be considered well founded in available risk assessment theory and available data.

Review Issue 3

The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products is scientifically understood and practical

In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California's Administrative Procedures Act (APA) for rulemaking. The APA requires proposals to be made public (public notice) with supporting documentation as to the necessity of the new requirements. Although the revised regulations are silent on this issue, the Department can use the APA rulemaking process in the future to allow for the establishment of an alternative analysis threshold for a product-chemical combination should the need arise.

Response: Defining the Alternatives Analysis Threshold in this way essentially removes the issue of the degree of hazard posed by analytically detectable amounts of a Chemical of Concern. This is probably reasonable and will cause no great difficulty if the basic formulae for prioritization are well structured and well implemented.

Some fairly serious priority-based weaning of candidates for attention is indicated by the new provision in the rules to limit the initial set of product-chemical combinations for attention to five. This is reasonable to focus the efforts of the department. However it does beg the question of how broad the definition of a "product" is. If the definition is as broad as, say, "paint" then it could include hundreds of different formulations made by different companies. Alternatively, is a "product" a specific paint formulation made by a particular manufacturer, perhaps limited to a specific color and place of intended use (e.g. "red indoor residential paint")?

In response to an inquiry for clarification, a DTSC worker directed attention to the following passages in the regulations and the "statement of reasons" document:

"1. Revised Regulations Section 69503.5 (b):
(b) List Contents. The Department shall specify in the proposed and final Priority Products lists the following for each listed product-chemical combination:
(1)(A) A description of the product-chemical combination that is sufficient for a responsible entity to determine whether one or more of its products is a Priority Product.
(B) If the product-chemical combination is a component of one or more assembled products, a description of the known assembled product(s) in which the component is used shall be included.

2. ISOR (keep in mind the ISOR may not entirely line up with the revised regulations)-
www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf

Section 69503.4(a)(2)(B)
DTSC intends to be as specific as possible when products with multiple parts or components are identified as Priority Products to name the specific component or homogeneous material that is basis for the listing, and, thus, subject to the Alternatives Analysis. DTSC may, of course, name an entire multi-component product as a Priority Product when it is appropriate to do so.

3. ISOR-
http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf
Section 69503.3(f) specifies that by January 1, 2014, DTSC must issue a Priority Product Work Plan covering next three years. This is intended to provide a level of certainty and predictability to responsible entities and other stakeholders regarding the types of products that will be considered for evaluation prior to releasing a proposed Priority Product List. The work plan will include product categories, which may illustrate for example a level of detail comparable to the Family (i.e., Cleaning Products) or Class (i.e., Laundry) hierarchy level identified using the Global Product Classification (GPC) Standards [http://www.gs1.org/gdsn/gpc] and a general explanation, which may include exposure concerns, such as access to sensitive subpopulations. The work plan will plot a course for DTSC for three years."

Response continued: Saying that DTSC will be "as specific as possible", it seems to me, still begs the question of how DTSC will balance the benefits and limitations of defining products relatively broadly or narrowly. A broad definition of a product type will increase the potential benefits of devoting one of the five precious initial chemical-product slots to a particular case. On the other hand the broader the definition of a product, the greater the complexity of the analysis needed to identify reasonably functionally equivalent "alternatives". The indoor paint example is illustrative. A manufacturer of a specific red pigment might argue that there is no practical alternative to its product if one wishes to achieve a very specific red hue. On the other hand, if one broadens the category to include a wide range of available colors and textures, then many paint formulations and even wallpaper in some cases could be considered as technically feasible alternatives if the "product" were defined as "indoor wall or ceiling covering". I would suggest that a couple of added paragraphs on this issue could usefully help guide DTSC staff to wiser choices in defining product categories.

Review Issue 4

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

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

Response: These minor clarifications do not seem to pose significant problems.

Other Issues Posed by the Current Draft

(Page numbers refer to the 106 page revised text of the regulations with strikeouts and additions).

***P 12 ,line 22--** (29) "Economically feasible" means that an alternative product or replacement chemical does not significantly reduce the manufacturer's operating margin.

Without further elaboration of what is meant by "significantly" this provision might be used to argue infeasibility for changes that decrease the manufacturer's operating

margin by 1-5%. This should be specified more clearly lest extensive litigation result.

"Functionally acceptable" means that an alternative product meets both of the following requirements:

(A) The product complies with all applicable legal requirements; and

(B) The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.

This definition seems good to me.

P. 13-- "Importer" means a person who imports a consumer product into the United States product that is subject to the requirements of this chapter. "Importer" does not include a person that imports a product solely for use in that person's workplace if that product is not sold or distributed by that person to others.

I am concerned that the last sentence in this definition could cause problems. Imagine that a maker of plywood or particle board imports an adhesive known to contain and emit formaldehyde. If "the product" is the adhesive, then the importer could argue that he just used the adhesive in his workplace to make the plywood or particle board but did not sell or distribute the adhesive itself. This would allow such a person/firm perhaps to get around the fact that consumers could be extensively exposed to emissions from the plywood or particle board manufactured with the adhesive. This, it seems to me, should be a prime candidate for regulation by DTSC, but may escape regulation unless the language is changed to make it clear that a product (e.g. plywood or particle board) that incorporates the imported material that causes such emissions and consumer exposures is subject to controls.

p. 65, line 1—" (C) Economic impacts.

1. The responsible entity shall evaluate, monetize, and compare for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives:

a. Public health and environmental costs; and

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

The suggestion that alternatives analyses include monetization of impacts might be qualified by some caveat like (where reasonably feasible) or some such. This is to avoid hanging up the process in very difficult issues such as how much a fish in the wild is worth, or how much an uncertain mild health response is worth.

STATEMENT

Ortwin Renn

March 3, 2013

Topics:

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

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

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

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

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

Statement:

According to my reading of the regulations for identifying and classifying chemicals, most of the reviewers' comments have been incorporated. There is a clear differentiation between the characterization of the hazardous properties of a chemical and the corresponding risks, which includes exposure and dose-response effects. As mentioned in my earlier statements, I strongly recommend to use two main criteria for characterizing hazards, such as pervasiveness and

ubiquity of exposure, to alert the regulators to chemicals that have a high loading of these two characteristics even if negative impacts have not yet been observed[1]. There is sufficient evidence that high persistency and ubiquitous exposure are normally highly correlated with some delayed environmental damage. Such damage could also affect human health.

With respect to the procedure of identifying and characterizing chemicals, the proposed legislation considers the potential identification pathways specified for the EU REACH regulation as well as for the existing Federal and state legislations in the United States. This appears sufficient in my view.

As a social scientist, I cannot comment the completeness or adequacy of the list of chemicals that have been attached to the existing documents. It is, however, essential that the list of chemicals is constantly monitored and updated. This can go in both directions: sometimes preliminary suspicions turn out to be unjustified, so that candidates on the list may be removed due to better evidence about their potential harm. Sometimes allegedly innocuous substances turn out to be more severe than estimated. Then they should be added to the list even if there were tested before. In particular in connection with nanoparticles, it is also mandatory to review from time to time some of the hazard criteria such as production volume, concentration in product and contamination pathways. As far as I can tell, I can see that such flexibility in changing the criteria and adapting them to new developments and innovative products is incorporated into the language of the proposed regulation.

In essence, I do not see any reasons for further changes.

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

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

[1] Mueller-Herold, U., Morosini, M. and Olivier Schucht, O. (2005): Choosing Chemicals for Precautionary Regulation: A Filter Series Approach. In: *Environmental Science and Technology* 39 (1): 683–69.

regulations define "potential" to mean that the phenomenon described is reasonably foreseeable based on reliable information.

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

Statement:

I totally agree with the change of the language from "ability to" to "potential of". Within a more precautionary understanding of risk management, regulation should not wait for a final proof of negative impact. If there is sufficient evidence that a chemical can cause negative impacts and if there is a reasonable cause to assume that these impacts are likely to affect the environment or human health within the context in which this chemical is being used, regulatory action may be justified. I think it would be beneficial to stress that the potential to do harm, i.e. the description of the hazardous properties of a chemical, is not sufficient for being placed on the chemical candidate list. In addition, it should be requested that there is a realistic option that this potential for harm is released into the environment within the context in which this chemical is used. This may include potential pathways of exposure, the potential volume that is being incorporated or released into the environment, and the knowledge about dose-effect relationships. A chemical that can never reach a human being or is not released into the environment at all should be treated differently than a chemical that will affect humans or the environment in course of its destined use.

This line of argumentation provides a middle ground between a fully precautionary and a fully evidence-based approach to risk management[2]. It does not require that harm is being confirmed either by animal studies or by epidemiological investigations. However, it is also not sufficient to list chemicals according to their potential of harmful effects, with the exception of high persistence and ubiquitous dispersion (see above). A chemical may enter the list if it contains specific hazards *and* if there is reasonable evidence to suggest that such a hazard can be released into the environment or incorporated by human beings.

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[2] Renn, O (2007): Precaution and Analysis: Two Sides of the Same Coin? In: *EMBO Reports*, 8: 303-305

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

In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not be an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California's Administrative Procedure Act (APA) for rulemaking. The APA requires proposals to be made public (public notice) with supporting documentation as to the necessity of the new requirements. Although the revised regulations are silent on this issue, the Department can use the APA rulemaking process in the future to allow for the establishment of an alternative analysis threshold for a product-chemical combination should the need arise.

Statement:

I fully agree with the changes that were made to the provisions on alternative analysis thresholds. In the first version this parallel route could have been interpreted as a loophole for reducing the amount of testing and for circumventing the more onerous procedure for being listed or removed from the list. I also go along with the narrow list of exemptions that is now being inserted into the language of the regulations.

I have two minor reservations: the first one refers to nanoparticles for which a volume-based threshold may be rather irrelevant[3]. Most of these nanoparticles impact on the environment or inflict harm on human health on the basis of surface exposure rather than on the overall dose. I'm not sure whether this specific hazard criterion has been included as an exemption to the list of exemption. Exemption rules that are purely based on volume may not be sufficient.

The second reservation concerns public scrutiny. It would be wise to allow for more public review if a chemical is pursuing the alternative analysis threshold route[4]. It may be beneficial to expand the time and intensity for public review if such a route is taken.

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[3] Pleus, R.C. (2013): The State of the Science: Human Health, Toxicology, and Nanotechnology Risks. In: J.A. Shatkin (ed.): *Nanotechnology. Health and Environmental Risks*, CRC Press, Taylor und Francis: Boca Raton, pp. 79-116

[4] Klinke, A. and Renn; O. (2012): Adaptive and Integrative Governance on Risk and Uncertainty. In: *Journal of Risk Research* , 15: 3 (2012), 273-292.

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

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

Statement

Since the term "adverse" has many meanings in the English language, it may be prudent to be more specific about its specific meaning within the context of this regulation. I feel now more comfortable with the explanations that have been inserted in the new version. However, there are still some weaknesses in the definitions and conceptualizations of the word "adverse". I would recommend specifying the term to denominate negative impacts on ecosystem services, landscape appearance and biodiversity in relation to environmental impacts and on human health and well-being in relation to life quality. I believe that these categories cover everything what needs to be included in this term.

In my view, impacts and effects are very difficult to distinguish. Effects may be more specifically connected to causal chains, while impacts may also include intervening variables that are not yet known. Impacts characterize sequential and associative consequences related to a system of preceding events. There is also the word "consequence", which means something similar. Yet I believe that the use of the two terms "impact" and "effect" are almost synonymous and therefore I do not recommend any changes in the latest version of the document.

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February 28, 2013

SCIENTIFIC PEER REVIEW FOR SAFER CONSUMER PRODUCT REGULATIONS

Thank you for this opportunity to provide external scientific peer review of specified issues of the Safer Consumer Products Proposed Regulations, as revised January 2013. I used the following two documents for my review:

The Revised Proposed Regulations for Safer Consumer Products (January 2013):
http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf

The unofficial version, without underline and strikeout, of the Revised Proposed Regulations:
http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text-NU.pdf

The Statement of Work described for the scientific peer review is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices for the following four topics. I have presented my responses to each of the four topics below. Overall I find the proposed regulations to be scientifically sound, with some significant improvements to strengthen them since the last draft.

Topic 1. Does the chemicals list developed by the sources named in the regulations accurately identify chemicals with hazardous traits that have public health and environmental concerns and so may be used to produce an initial Candidate Chemicals list? The revised regulations now include two additional lists: the chemicals classified as Category 1 respiratory sensitizers by the EU; and, chemicals identified as priority pollutants in CA under the federal CWA has been expanded to include section 303(d) (impaired waters list) chemicals in addition to 303 (c) chemicals.

The addition of the pollutants from the 303(d) list of the Clean Water Act is a significant improvement to the proposed regulations. This list includes any contaminant that contributes to an impaired water designation. It can include contaminants affecting California waters specifically, and those which have environmental impacts but may not necessarily affect human health. These can include metals, pesticides, and organics such as poly-chlorinated biphenyls (PCBs) and de-icing fluids. Metals such as copper from consumer products including marine antifouling paint, pool and spa algaecides, and vehicle brake pads may impair aquatic environments, but have no or limited human health effects. The incorporation of the 303(d) list into § 69502.2 (Candidate Chemicals Identification) will address

consumer product contaminants like copper that are recognized by the State of California a threat to environmental quality. For example, SB 346 requires that the use of copper in vehicle brake pads sold in California be reduced, and also includes a provision linking it with the Safer Consumer Products regulations.

Tri-TAC, representing California wastewater treatment facilities, submitted comments on the proposed safer consumer products regulations, recommending among other things that the 303(d) list of impaired waters be included as a means of identifying candidate chemicals. In their comments, Tri-TAC expressed great concern at the "growing tide" of chemical contaminants in the receiving waters that may compromise the ability of wastewater treatment technologies to operate effectively. We essentially have a toilet-to-tap water system, where wastewater from homes, industrial facilities, and land runoff can go through a wastewater treatment plant, be discharged into groundwater, lakes, or reservoirs, and eventually end up as well water or in a public water system and from there to kitchen tap water in homes around the country. Therefore, protecting all waterways is the best way to protect our source water for human consumption, bathing, and swimming, as well as protecting our environment.

The inclusion of this list into § 69502.2 (Candidate Chemicals Identification), along with the chemicals from the 303(c) list of the federal Clean Water Act is a significant improvement, and will provided a more comprehensive scientific listing of contaminants candidate chemicals of concern.

Topic 2: Are the evaluation criteria for prioritizing the product-chemical combinations in Article 3 sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products? Do the revised regulations specify the key prioritization criteria factors necessary to identify potential Priority Products? The revised proposed regulations define "potential" to mean that the phenomenon described is reasonably foreseeable based on reliable information. The revised proposed regulations require the Department to evaluate product-chemical combinations to determine potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures which must contribute to or cause significant or widespread adverse impacts.

After reviewing the text of the January 2013 proposed regulations for Article 3, as well as the changes from the earlier draft it is my opinion that the regulations as currently proposed provide fairly extensive and comprehensive adverse impact and exposure factors by which to identify potential Priority Products. The descriptions of adverse impacts [§ 69503.3(a)] and exposures [§ 69503.3(b)] are comprehensive and will be effective at identifying potential Priority Products. The inclusion of chemicals that are structurally or mechanistically similar to chemicals with known toxicity profiles [§ 69503.3(a)(3)] is an important factor that will allow the State to identify potential Priority Products even where little data is available.

Article 3 specifies that any product-chemical combination identified and listed as a Priority Product (slated for an Alternative Analysis) must meet both the criteria of having a potential for exposure to the Candidate Chemical(s), and the potential for exposure to contribute to or cause significant widespread adverse impacts [§ 69503.2(a)(2)]. While I support this requirement in principle, I have two concerns. First, what constitutes a "significant" or "widespread" adverse impact is not well-defined. Second, if the phrase "significant or widespread adverse impacts" is to be used to determine priority products, it should apply to the chemical, not the product-chemical combination, since the adverse environmental or health impacts attributable to a single product-chemical combination may be impossible to determine, although the chemical has documented significant and/or widespread adverse impacts.

Regarding the first concern, it is not clear to me what either "significant" or "widespread" mean in this context, who will decide, by what criteria, and for whom? Is impairment of one lake significant? Is two lakes? What about impairment of one river that is use for recreation, but not for drinking water? If the product-chemical combination only poses a risk (exposure plus hazard criteria are met) for people with severe asthma, is that significant or widespread? What if the product-chemical combination poses a risk to people with estrogen-sensitive cancer? Is that significant and/or widespread? What if the adverse effect is significant or widespread (or both), but not severe? What if a product-chemical combination causes a severe effect (such as permanent learning disabilities or severe asthma), but to a limited population so it is neither widespread nor statistically significant across the whole population of the state? I suggest either deleting the words, "significant or widespread" altogether, or adding severity, so that the potential for one or more exposures to contribute or cause severe adverse impacts be considered an additional principle for prioritization. Regarding the second concern, I recommend that the prioritization criteria be applied to the chemical, not the product-chemical combination.

I support the addition of the word "potential" at numerous places throughout this section, and the definition of "potential" to mean that the phenomenon described is reasonably foreseeable based on reliable information. This is both precautionary and reasonable, based on information that is "reasonably available" [§ 69503.2(b)]. In fact, without consideration of potential risks (exposures and adverse impacts), the Safer Consumer Products regulations would not serve its purpose of averting harm.

Topic 3: Are the principles that are outlined in the proposed regulations that will allow DTSC to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products scientifically understood and practical? In the revised regulations the Alternatives Analysis Threshold is now defined as a Practical Quantitation Limit (PQL). A threshold exemption will only apply if a Priority Product contains the COC solely as a contaminant (not for intentionally added ingredients) and the concentration of each Chemical of Concern does not exceed the Alternative Analysis Threshold. The DTSC believes it can use the APA rulemaking process in the future to allow for the establishment of an alternative analysis threshold for a product-chemical combination should the need arise.

Article 5 (Page 35) discusses the Alternative Analysis. The section on Threshold Notification in Lieu of Alternatives is discussed in § 69505.3 (Page 41) of the proposed regulations. The PQL is defined as the lowest concentration of a chemical that can reliably be measured within specified limits of precision and accuracy using routine laboratory operating procedures (§ 69501.1 Definitions, Page 13). I agree that the principles outlined in the proposed regulations that establish the Alternatives Analysis Threshold as a PQL for a COC that is present in a Priority Product solely as a contaminant, and not intentionally added, is scientifically understood. It may be practical in the majority of cases.

I am concerned about some cases, probably rare, where the contaminant COC may be at trace levels, even below the PQL, but is still potentially harmful. For example, there is evidence that asbestos is a contaminant of NY State talc powder, and is causally associated with mesothelioma, asbestosis, and excess lung cancer in miners of the talc, although it's hard to know how much of it is being used in consumer products. However, there are some cases in the courts today of plaintiffs/consumers with asbestos-related disease who claim that their only known exposure is from historical talc in consumer products. Further complicating matters, the company mining the NY State talc denies that its talc is contaminated with asbestos, although independent scientists have claimed to have detected it. The PQL may be inadequate to detect it at low but dangerous levels, since detection may depend on the extent

of effort expended using high-powered microscopic equipment. In another case, in Libby, Montana there is an epidemic of asbestos-related disease, and there is great concern about environmental exposures as the cause, although the asbestos has not been detected (i.e. levels of ambient exposures are likely below the PQL). This is likely because a bulk analysis of the mineral is very difficult, since trying to separate asbestos fibers from soil and rock samples is problematic even using rigorous analytical methods.

If there is reasonable grounds to believe that a COC may be present in a product, even as a contaminant, and if there is a potential that the product-chemical combination may present a risk even at levels below the PQL, than a threshold exemption should not be issued. DTSC needs to preserve its right to not issue a threshold exemption.

Topic 4: Can a qualitative or quantitative determination of adverse impact or effect be made? Will it be adequately protective of public health and the environment when reliable information is available?

I agree that the proposed regulations adequately describe measures of adverse impact so that a scientifically-defensible determination can be made. The section of Definitions (§ 69501.1) includes specific criteria to recognize adverse ecological impacts, adverse public health impacts, adverse soil quality impacts, adverse water quality impacts and others. In many cases the definitions include exceedances of an enforceable state or federal regulatory standard, descriptions of reduced function, altered properties, deterioration of quality, or endangerment. These determinations of adverse impact or effect should provide a significant measure of protection for health and the environment, when addressed and complied with.