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15-DAY PUBLIC NOTICE AND COMMENT PERIOD NOTICE OF PUBLIC AVAILABILITY OF POST-HEARING CHANGES AND AVAILABILITY OF DOCUMENTS ADDED TO THE RULEMAKING FILE

SAFER CONSUMER PRODUCT ALTERNATIVES

Department Reference Number: R-2010-05

Office of Administrative Law Notice File Number: Z-2010-0908-01

Pursuant to Government Code section 11346.8 subdivision (c), notice is hereby given:

- The Department of Toxic Substances Control (DTSC) has revised the text of the proposed regulations, which would add chapter 53 to division 4.5 of Title 22, California Code of Regulations, and to amend the Table of Contents (Attachment 1).
- DTSC has added the documents listed in Attachment 2 to the rulemaking file. The documents are scientific external peer reviewer comments and the Environmental Policy Council (EPC) Resolution.

AVAILABILITY OF THE ATTACHMENTS AND ADDITIONAL DOCUMENTS

The information upon which DTSC relied for revising text, revised text of the proposed regulations (Attachment 1) and the documents listed in Attachment 2 that are being added to the rulemaking file are available for public inspection between 8:00 a.m. and 5:00 p.m. at the Regulations Section, located on the 22nd Floor at 1001 I Street, Sacramento, California. Requests and inquiries concerning this matter may be directed to Jeff Woled, Regulations Coordinator, Regulations Section, at the address indicated above or by telephone at (916) 322-5225. If Mr. Woled is unavailable, please call Jon Cordova at (916) 324-7193.

COMMENTS

A public comment period for the submittal of written comments has been established commencing on November 16, 2010, and closing on December 3, 2010, at 5:00 p.m. for (1) the revised text, and (2) the documents added to the rulemaking file.

Notice is given that any interested person may submit comments regarding (1) these revisions and only these revisions of the text, and/or (2) the documents added to the rulemaking file by e-mail to gcregs@dtsc.ca.gov or by United States mail to:

Regulations Coordinator
Department of Toxic Substances Control
Regulations Section
PO Box 806
Sacramento, CA 95812-0806

Written comments must be RECEIVED no later than 5:00 p.m. on December 3, 2010, in order to be considered. Written comments received after that time will be added to the rulemaking file, but DTSC is not obligated to consider or respond to late comments. Written comments must clearly indicate whether they are in reference to the revised text of the proposed regulations (Attachment 1) or in reference to the documents listed in Attachment 2 being added to the rulemaking file.

Inquiries regarding technical aspects of the proposed regulations should be directed to Odette Madriago of DTSC at (916) 323-4927 or, if unavailable, Corey Yep of DTSC at (916) 445-3601. However, such oral inquiries are not part of the rulemaking record.

REVISIONS TO THE PROPOSED REGULATIONS

The proposed regulations to add Chapter 53 to division 4.5 of Title 22, California Code of Regulations, pertain to identification and prioritization of chemicals of concern in consumer products, evaluation of their alternatives, and regulatory responses for selected alternatives.

DTSC mailed the original proposed text and the notice of the 45-day public comment period and made both available for public review and comment on September 14, 2010. A copy of the notice was published in the California Regulatory Notice Register on September 17, 2010. A public hearing was held on November 1, 2010, during which written and oral testimony was accepted. In addition, written comments were accepted during the 45-day public comment period that ended on November 1, 2010. DTSC has now made post-hearing changes to the proposed text.

DTSC considers these new changes to the rulemaking to be sufficiently related changes, as defined by Title 1, California Code of Regulations, section 42.

Attachment 1 is the revised text to the originally proposed regulations shown with deletions as ~~strikeout~~ and new text as underline. Proposed modifications to the originally proposed regulations are summarized below and are set forth in detail in Attachment 1 to this notice. The following summary does not include modifications to correct typographical or grammatical errors, changes in numbering or formatting or reorganization of text; nor does it include all of the nonsubstantive revisions made to improve clarity. For a complete account of all modifications in the proposed regulations, please refer to the underline and strikeout sections in Attachment 1.

As a courtesy, the proposed regulation text, without underline or strikeout, is available at <http://www.dtsc.ca.gov/LawsRegsPolicies/index.cfm>

Partial Summary of Proposed Modifications

Some of the more significant modifications to the originally proposed regulations are summarized below. The proposed regulatory text, as modified, for all of the regulations is set forth in detail in Attachment 1 to this notice. All references to sections of regulation are to Title 22, California Code of Regulations. The following summary is not an exhaustive list of proposed changes. It does not include:

- modifications to correct typographical or grammatical errors, changes in numbering or formatting, reorganization of text;
- all of the nonsubstantive revisions made to improve the clarity of the proposed regulations; and
- changes that are less significant, for purposes of compliance with the Administrative Procedure Act, than those noted below.

For ease of readability, the section numbers set out below are from the previously proposed version of the regulations unless otherwise specified. For a complete account of all modifications in the proposed regulations, please refer to the underline and strikeout text in Attachment 1.

1. Modifications to Section 69301. Purpose and Applicability

Section 69301(b).

In response to public comments regarding the scope of the proposed regulations, the proposed regulation was modified to: (b)(3) eliminate the manufacturer having the burden of proof on the issue of whether or not a product is manufactured, stored in, or transported through California solely for use outside of California; (b)(4) eliminate the requirement that a manufacturer be unaware of an unintentionally added chemical or chemical ingredient in order to be outside the scope of these regulations (with one limited exception) and to eliminate the related due diligence requirements; (b)(5) move

and expand the reach of the exclusion from these regulations if another specified regulatory program already regulates the chemical of concern or priority product in a manner that addresses the public health and environmental threats that would otherwise be the basis for the chemical of concern or priority product being subject to these regulations; (b)(6) move and expand the reach of the exclusion from these regulations for a chemical of concern that DTSC determines has no exposure pathway that might pose a threat to public health or the environment during the product's useful life or end-of-life management; (b)(6)(A) and (B) and to further specify the standards and burden of proof for establishing the standard set forth in the immediately preceding text.

DTSC also notes the following in response to public comments received regarding Section 69301. The regulations do not expand the scope of "consumer products" as defined in the authorizing statute that are subject to these regulations. On the contrary, in the interest of clarity, DTSC imported the statutory definition of "consumer product" into the regulations. DTSC remains of the opinion that the incorporation by reference of the key statutory term is necessary to avoid confusion that could result from a different definition or usage of this term that is basic to the regulations. Nor do the regulations impermissibly expand the scope of consumer products subject to the regulations by failing to recognize the statutory non-duplication provision set out in Health & Safety Code Section 25257.1. As the above paragraph and proposed regulatory text demonstrates, DTSC has built this non-duplication standard into the regulations as a stand-alone exclusion. (See Section 69301(b)(5)). Furthermore, numerous other limitations and exclusions from the regulations have been brought into Section 69301 for clarity and in order for the scope of the regulations to conform to the scope established in the authorizing statute.

The proposed regulations are not inconsistent with Health & Safety Code Section 25252(b)(2), which requires DTSC to minimize costs and maximize benefits for the state's economy in enacting these regulations. Rather, the regulations build extensively on existing technical and scientific resources and standards. (See, for example, the definition of "carcinogen or reproductive toxin" in Section 69301.2(a)(9), moved to Section 69301.1(a)(11)). Finally, the proposed regulations do not apply to all consumer products placed into the stream of commerce in California, as some public comments assert. All statutory limitations and exclusions have been imported into the regulations as is, or otherwise clarified, interpreted, or made more specific.

Again, in response to public comments, DTSC notes that Section 69301(b)(2) is necessary to define and specify the scope of "consumer products" subject to the substantive requirements of the regulations. Section 69301(b)(2) is also necessary to recognize and clarify the applicability of the statutory limitations and exclusions from the applicability of these regulations. The regulatory text is entirely consistent with the statutory provisions, is well within DTSC's authority and does nothing to impermissibly shrink or expand the scope of activities described in the authorizing statute that are subject to these regulations. While there may be some limited duplication of statutory

provisions, this was done deliberately to achieve greater clarity and avoid confusion that may result from failure to specify that the terms and scope of the statute were the same being proposed in the regulations.

Section 69301(c).

In response to public comments regarding drafting and implementation concerns for proposed Section 69301(c), that provision has been moved and extensively rewritten. More specifically, the content of proposed Section 69301(c) has been moved to Section 69301(b)(4) for purposes of clarity. It is now more integrated into the specification of consumer products that are, or are not, subject to these regulations. More importantly, the proposed regulatory text has been significantly modified in response to public comments. That is, public comments pointed out that the requirement that a producer not know about an unintentionally added ingredient in order to be outside the scope of the regulations rendered the “unintentionally added” exception to the regulations virtually meaningless. In response to such public comments and to create greater clarity, DTSC has all but eliminated the requirement that a producer be unaware of unintentionally added ingredients in order to be eligible for the unintentionally added ingredient exclusion from the regulations. The only residual requirement is that a producer be unaware of an unintentionally added ingredient in order to be outside the regulations concerns a recycled feedstock, component, or processing agent, which can contain a “toxic along for the ride”. In the case of these materials there is a greater ability to be aware of such unintentionally added ingredients and to ferret them out by taking reasonably feasible steps to obtain knowledge regarding the chemicals they may contain.

2. Modifications to Section 69301.2. Definitions

In response to public comments, DTSC has proposed modifications to the definitions initially proposed in the regulations. The most critical modifications to the proposed definitions are discussed here to eliminate confusion and bring greater clarity to the proposed regulations. In response to additional public comments, DTSC also proposes to eliminate all of Section 69301.1 Guiding Principles. Accordingly, the definitions have been moved from Section 69301.2 to Section 69301.1.

Section 69301.2(a)(24)(A). “De Minimis Level”

As set forth above, the proposed definitions have been moved from Section 69301.2 to Section 69301.1. More specifically, the proposed definition of “de minimis level” has been moved from Section 69301.2(a)(24) to Section 69301.1(a)(26). More importantly, in response to public comments, DTSC proposes to significantly streamline and clarify the applicability of a “de minimis level” presence of a chemical of concern in a priority product. Initially, it should be noted that DTSC remains of the opinion that a de minimis level exclusion from the substantive requirements of the regulations is necessary in order for the identification and prioritization of chemicals of concern in priority products to be workable and focused on the highest risks posed and on risks that can actually be addressed through the alternatives assessment and regulatory response processes.

DTSC is also still convinced that 0.1% is the appropriate and necessary default value for a de minimis level cut-off. The 0.1% standard is not a universal value, but it is far and away the most commonly used level for various regulatory programs that, of necessity, recognize a level below which something is not subject to regulation. DTSC has retained a 0.1% concentration by weight as a necessary default value below which a chemical of concern is not subject to the substantive requirements of the regulations, more specifically the Alternatives Assessment requirements specified in Article 5 of the regulations. (See proposed Section 69303.2(d)(3))

In response to public comments, DTSC also proposes to eliminate all other regulatory program references and their respective de minimis values as not useful or necessary to effectively implement the regulations. In addition, this change results in much greater clarity regarding the requirements and implementation of the provision. But DTSC is proposing to add one additional alternative value for the controlling de minimis level. That alternative value is the applicable hazardous waste regulatory threshold under Health & Safety Code Section 25141. This change is necessary so that there is no inadvertent conflict between the hazardous waste requirements and these regulations as they may apply to the same product, particularly at the end of the useful life of a product.

Section 69301.2(a)(39). "Hazard Trait"

In response to public comments, DTSC is modifying the previously proposed definition of "hazard trait". The newly proposed definition of "hazard trait" may be found at Section 69301.1(a)(44)(A). The proposed definition has been revised to include: chemicals identified under Section 303(c) and Section 303(d) of the federal Clean Water Act and chemicals included on the United States Environmental Protection Agency Existing Chemicals Action Plan list.

The expansion of the term "hazard trait" responds to public comments indicating that the previously proposed definition was not reflective of all of the most significant threats to public health and the environment—particularly as to environmental endpoints. It is worth noting, though, that under both the previous proposed definition of "hazard trait" and the revised definition being proposed now it is virtually impossible at this point of adoption of the regulations for DTSC to engage in any meaningful evaluation of the potential environmental impacts from the implementation of the regulations.

As discussed above, the first activity triggered by the regulations is for the identification of chemicals of concern based on specified hazard traits and other enumerated factors. The list of hazard traits that may lead to a chemical being deemed a chemical of concern captures a vast array of chemicals. More specifically, it includes the yet-to-be adopted list of hazard traits that ultimately will be promulgated as regulations by the Office of Environmental Health Hazard Assessment (OEHHA), as required by statute. By definition, that list of hazard traits yet to be determined is not known or knowable. As such, it cannot now be studied or analyzed.

Until such time as OEHHA adopts a list of hazard traits in regulation, the regulations proposed here establish what hazard traits may lead to a chemical being evaluated for possible prioritization as a chemical of concern. These include chemicals that exhibit any of the following hazard traits: (a.) carcinogenicity or reproductive toxicity; (b.) mutagenicity; (c.) persistent bioaccumulative toxic chemicals; (d.) priority toxic pollutants under Section 303(c) of the federal Clean Water Act; (e.) chemicals listed pursuant to Section 303(d) of the federal Clean Water Act; and (f.) chemicals included on the United States Environmental Protection Agency's Existing Chemicals Action Plan list. Those designations are then further delineated in some cases by further specification within the same provisions and in others by cross-reference to other provisions in the proposed regulations.

For instance, carcinogenicity and reproductive toxicity are further defined by reference to proposed Section 69301.1(a)(11). That provision specifies that chemicals on any one or more of the following lists are carcinogens or reproductive toxins: (A) Health & Safety Code section 25249.8 (Proposition 65); (B) the National Toxicology Program Report on Carcinogens that lists chemicals known and reasonably anticipated to be human carcinogens; (C) United States Environmental Protection Agency chemicals classified as Known or Likely (Group A, B1, or B2), as maintained on its Integrated Risk Information System, or equivalent weigh-of-evidence classifications that result from subsequent revisions to its "Guidelines for Carcinogen Risk Assessment;" (D) the International Agency for Research on Cancer Group 1 and 2A Chemicals; (E) the International Agency for Research on Cancer Group 2B chemicals where there exists sufficient evidence of carcinogenicity in animals, even if evidence of carcinogenicity in humans is inadequate; and (F) the listings of Category 1A or 1B carcinogens and/or Category 1A or 1B reproduction toxicants in Annex VI to Regulation (EC) No. 1272/2008 of the European Parliament and Council. And "mutagenicity" is further specified within proposed Section 69301.1(a)(44)(A)(2)(b) to mean chemicals that are "listed as having mutagenic properties in the European Union Category 1A or 1B under Annex VI, part 3 of the Regulation (EC) No. 1272/2008."

Collectively, these listings and descriptions capture in excess of 1,000 chemicals. The Proposition 65 listings alone entail 521 chemicals listed as carcinogens and 302 chemicals listed as reproductive toxins. (Note, there is some overlap of the chemicals included on these various lists, so the precise number of distinct listings is not easily established.)

At this point, it is virtually impossible to know which of these 1,000-plus chemicals will be the subject of review under the regulations. That is, DTSC has made no commitment to act on any one of these potential pools of chemicals. Accordingly, it is also infeasible to conduct any meaningful evaluation of potential environmental effects that may result from the mere selection of one or more as-yet-unknown chemicals.

In addition, the proposed regulations call for further identification and prioritization of chemicals of concern in an unknown number of priority products. For the first five (5)

years in which the regulations are being implemented, the potential universe of priority products includes: children's products; personal care products; and household cleaning products. (Proposed Section 69303.3(c)(1)(A) through (C)).

These three categories of potential priority products are in turn defined elsewhere in the regulations proposed here. "Children's product" means a consumer product designed or intended primarily for children twelve (12) years of age or younger, as determined by one or more of the following factors:

- (A) A statement by a manufacturer about the intended use of the product;
- (B) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children twelve (12) years of age or younger; or
- (C) Whether the product is commonly recognized by consumers as being intended for use by a child twelve (12) years of age or younger. (See newly proposed Section 69301.1(a)(20))

"Personal care product" means a consumable product that is intended to be used in the topical care and/or grooming of the body and hair and that is rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to a body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions." (See newly proposed Section 69301.1(a)(58))

"Household cleaning products" means the following products intended or labeled for use in or around the home: glass cleaners, general purpose cleaners, degreasers, lime and scale removers, washroom cleaners, tub and shower cleaners, toilet cleaners, kitchen cleaners, sink and countertop cleaners, stove top and hood cleaners, oven and grill cleaners, carpet cleaners, metal cleaners and polishers, furniture polishers, floor care products, laundry detergents and stain removers, fabric softeners, drain cleaners, hard surface cleaners, dishwashing products, hand soaps, disinfectants, and odor abatement or enhancing products. "General purpose cleaners" are cleaners intended or labeled for more than one of the cleaning uses listed above." (See newly proposed Section 69303.1(a)(45))

It is immediately evident that, individually and collectively, these product categories encompass an incredibly vast array of consumer products. Again, these product categories reflect the application of the statutory criteria requiring DTSC to take into account: the volume of the chemical in commerce in California; the potential for exposure to the chemical in a consumer product; and potential effects on sensitive subpopulations, including infants and children. (Health & Safety Code Section 25252(a) (1) through (3)) In addition, the selection of these categories of products as potential priority products in the initial phases of implementation allows DTSC to consider important "every day" products in implementing the regulations.

After January 1, 2016, there is no limitation or specification of the types of products that may be identified as priority products. Even the initial restricted list of possible priority products captures tens of thousands of products. After that, the possible category of priority products grows exponentially. In light of this, DTSC cannot now reasonably foresee any environmental impacts from the adoption of the regulations and has no way of engaging in a meaningful analysis of the potential environmental effects, if any, from the implementation of the regulations. Evaluating the effects of potentially 1,000-plus chemicals that may be part of tens of thousands of products, and the possible environmental impact of alternative formulations, is both infeasible and unreasonably speculative. DTSC does not contemplate any physical changes to the environment resulting from the adoption of these regulations. It is important to note that there will be no physical change in the environment resulting from an action on the part of DTSC prior to the imposition of one or more Regulatory Responses, at the earliest, as the preceding activities being conducted by DTSC are intellectual evaluation and analysis only.

Section 69301.2(a)(53). “Place into the Stream of Commerce”

In response to public comments, DTSC proposes to modify the definition of “place into the stream of commerce”. The new proposed definition of “place into the stream of commerce” is in Section 69301.1(a)(61)(A). The revised definition addresses the concerns raised in public comments that the previous definition was difficult to understand and created the potential for applying the term to products that were not actually available for purchase in California. The revised definition of “place into the stream of commerce” also brings greater clarity to the term and allows for ease of implementation of the regulations. This term as modified is necessary in order for DTSC to exercise regulatory authority over not just those products sold directly to California consumers, but also over products that reach California customers indirectly—through distributors, suppliers and the like. The lack of such a provision would gut the scope of these regulations.

3. Modifications to Section 69301.6(c)(1). Chemical and Product Information

In response to public comments, DTSC is proposing to clarify and scale back the types and amount of information that parties are required to submit to DTSC as part of the information-gathering process that feeds into the identification and prioritization processes for chemicals and products. DTSC’s proposed revisions are set out in newly numbered Section 69301.5(c)(1)(A) through (G). The types of information deleted from the proposed regulation were information requirements that public comments identified as unnecessary and/or potentially damaging if handled in violation of trade secret protections.

Instead, DTSC is proposing to require much more general information about market presence, intended product use(s) and types of targeted customer base(s), as well as information about end-of-life management programs that may be in place. DTSC has proposed these new terms as necessary for DTSC to gather information about the

statutorily required criteria of volume in commerce of a chemical and potential for exposure to that chemical. Again, DTSC cannot run an effective and appropriate identification and prioritization process for chemicals of concern if it does not have information-gathering tools. This information is vital to the success of the statutorily established identification and prioritization processes. Absent such information, DTSC could overestimate or underestimate the public health threats posed by various chemicals due to a wide “data gap” for many chemicals. And manufacturers are often, if not always, in a better position than DTSC to know about a given chemical or product. Public comments also raised concerns about the burden of protecting information claimed as trade secret that might be required by the previous version of this provision. The revised text reduces the scope and sensitivity of the information sought; thus, at the same time greatly reduces burdens regarding assertions of trade secret privilege.

4. Modifications to Section 69302.1 & 69303.1. Applicability and Duplication

In response to public comments, DTSC is proposing to modify the scope of the exclusion from these regulations for chemicals of concern and consumer products that are adequately regulated by another State program and/or federal regulatory program. (See newly proposed Section 69301(b)(5)) The public comments questioned the scope of the authorizing legislation’s reach in order to qualify for exclusion from these regulations. More specifically, the public comments claimed DTSC was not satisfying the non-duplication provision in Health & Safety Code Section 25257.1 because the standard for qualifying for the exclusion was too stringent and not reasonably tailored. DTSC’s proposed modifications address the concerns raised in these public comments. The revised provision is necessary to satisfy the non-duplication provision in Section 25257.1 and is more narrowly tailored to get at the actual threat posed by a given chemical or product.

5. Chemical and Product Prioritization

Some commenters expressed concern that the regulations did not provide an understanding as to how the list of prioritization factors in Sections 69302.3 and 69303.3 would be used to prioritize Chemicals Under Consideration and Products Under Consideration. But many of these same commenters expressed support for the prioritization decision-making factors proposed for identifying Priority Chemicals and Priority Products in Sections 69302.4(b)(1) and 69303.4(b)(1). These commenters urged DTSC in setting priorities to apply these factors rigorously and through quantifiable methods to compare hazards of chemicals and potential exposures to these chemicals when contained in products.

Many of the factors previously listed in Sections 69302.3 and 69303.3 will still be considered to the extent pertinent and to the extent relevant reliable data and information is available. But ultimately the choice of chemicals and products to be placed on the lists will be based on the decision-making factors specified in Sections 69302.4 and 69303.4 (now in newly proposed Sections 69302.3 and 69303.3), which

will be applied using the quantifiable data specified in these sections. Language has been added to clarify the order in which DTSC will consider the factors specified in these sections to sequentially “screen” the chemicals and products being evaluated to ultimately select the proposed lists of Chemicals of Concern and Priority Products.

It is noted that some commenters have argued that DTSC should use a strict weighting and ranking system to list chemicals and products. However, DTSC believes that this type of rigid prioritization approach would ultimately lead to prioritization decisions that could not be fully scientifically supported for the following reasons:

1. Regulatory inflexibility.

The regulatory design of a prospective chemical and product prioritization scheme that would result in the strict weighting and ranking of the entire universe of chemicals and products in the marketplace cannot be derived at this point. While many inputs into such a prioritization system are scientific in origin, the development of this type of prioritization scheme does not reflect science alone. Informed decisions are made based on science. The immediate and specific integration of the prioritization factors into a generic static prioritization system for all chemicals and products in the marketplace would only reflect decisions based on current science and understanding. This would create the possibility of the process remaining ignorant to new science and understanding for future decisions, and, therefore, being inflexible if adopted into regulations. Historic attempts to modernize and update chemical regulatory schemes have met resistance (e.g. federal Toxic Substances Control Act and California’s Hazardous Waste Classification system) and remain largely unchanged since inception.

2. Science-based decisions are not “pure” science

The clear goal to identify Chemicals of Concern and Priority Products is based on the identification of actual and/or potential for harm to public health and the environment using the prioritization factors listed for chemicals and products in newly proposed Sections 69302.3 and 69303.3.

The comments expressing the need for a generic methodology to establish rank order from highest to the lowest order of concern for chemicals and products seem to assume that can be easily achieved through the development of a fully scientific process. The underlying assumption is that such a process can be designed that will be devoid of bias and provide “pure” scientific results to the decision maker.

A mathematical algorithm that generates a rank order or relative priority among chemicals and products would have its scientific origins, but the ultimate nature of its construction would reflect many decisions in at least three major ways:

(1) Prioritization Factors: Identifying and determining basis for scoring and weighting of the key prioritization factors to consider, while based upon scientific information, should also be based upon current regulatory goals. Decisions will be made by balancing science and regulatory goals.

(2) Accommodating Uncertainty: The expectation that a scientific process will provide “pure” scientific results for the decision making is based upon an underlying assumption that there is equal and complete scientific data available. Scientific data sets will be incomplete, dissimilar and unlikely equal. Accommodating such “uncertainty” in the diversity of information will be based on decisions not wholly based on science, but perhaps based on acceptable uses in the scientific community but still involve professional judgment rather than pure science. For example, risk assessment uses a range of uncertainty factors and risk *management* decisions are made based on one in 10,000 to one in a million risk factors.

(3) Coping with Dissimilar Hazards: The potential of causing chemical burns to all in the population versus the potential to cause birth defects in a developing fetus associated with any product and its chemical content will require careful consideration. Chemical hazards may be dissimilar, and products will have different patterns of exposure. Science-based and risk management decision making may be difficult in this instance.

Regulatory decisions need to be informed by the best scientific information available, not stifled by waiting for “perfect” information and not misled by the immature integration of chemical behavior, product design and life-cycle, and attendant exposures to the chemical(s) in the product that leads to misinformed policy tradeoffs. A balance needs to be reached between the science available and the regulatory decisions that are made. For that reason, DTSC is not specifying a weighting or ranking system for chemicals and products, but is proposing to use the best available scientific information and practices to determine the prioritization method. The data, method and process used to identify Chemicals of Concern and Priority Products will be explained by DTSC and will be available for public comment prior to finalizing the lists.

6. Modifications to Section 69302.3. Chemical Prioritization Modifications to Section 69303.3. Product Prioritization

In response to public comments, DTSC is proposing to eliminate the Chemical under Consideration and Product under Consideration lists. Some of these commenters questioned the need for two separate chemicals lists and two separate products lists. After considering these comments, DTSC has determined that having two sets of chemical and products lists is not necessary to the process and achievement toward developing safer alternatives to consumer products that contain chemicals of concern. Additionally, DTSC and interested party resources can be more efficiently utilized by focusing on a single list of Chemicals of Concern and a single list of Priority Products using the prioritization process set forth in revised Sections 69302.3 and 69303.3.

The factors that DTSC will utilize, to the extent pertinent, to develop the lists of Chemicals of Concern and Priority Products remain largely the same, with some streamlining. However, the proposed regulations have been made more specific as to

the process DTSC will use to evaluate chemicals and products based on the factors specified in newly proposed Sections 69302.3 and 69303.3. Additionally, in the interest of clarity, the factors specified are exhaustive and not subject to an open-ended “including but not limited to” qualifier.

7. Modifications to Alternatives Assessments

In response to public comments, DTSC has made several modifications to the proposed regulations that more explicitly recognize that Alternatives Assessments may range from relatively simple to highly complex assessments depending on the product that is the subject of the assessment. The proposed modifications to the Alternatives Assessment evaluation and comparison process bring greater clarity to the regulations. In addition, the proposed revisions create greater flexibility and tailor the chemical hazard/potential for exposure assessments and multimedia life cycle evaluations to the specific Priority Product being evaluated. Additionally, the evaluation factors relating to product function and performance and economic impacts are now proposed to be separated out from the multimedia life cycle evaluation, as suggested by several commenters.

Section 69305.1. Tier I Alternatives Assessment (AA) Notifications

In response to public comments, DTSC is proposing to eliminate the Tier I AA Notification in Section 69305.1. Numerous public comments expressed concerns that the Tier I AA Notification may inadvertently stifle innovation, impose stigma on a “safe” product and be otherwise counterproductive. In response to these public comments, DTSC is proposing to eliminate this requirement altogether. This should bring greater clarity to the burdens imposed by the regulations and on whom they are imposed and based on what triggering event(s). The elimination of this provision leaves DTSC with requiring an Alternatives Assessment only for products identified as Priority Products. This aligns the regulations more closely to the statutorily prescribed steps in the regulatory process, leaving only those steps essential to the effective administration of this process.

Other Changes to the Alternatives Assessment Process.

In response to public comments, DTSC is proposing to reduce the previously proposed two types of Alternatives Assessment Reports into a single AA Report. This change alone results in much greater clarity of what is required from the regulated community, in what form, and at what point in time. The terminology used in the proposed new text is much leaner, and, thus, much clearer than the previous iteration. The requirement of a single AA Report is the bare essential type of written assessment that DTSC must see in order for the regulated community and DTSC to perform their respective duties under the regulatory regime. Conforming changes to this major change have been made throughout various provisions in Article 5. (See, for example, newly proposed Sections 69303.3 and 69303.4.)

8. Modifications to Confidentiality of Information

Section 69310. Confidentiality of Information

This provision was originally intended to clarify the applicable statutory authorities, but in response to comments arguing that it essentially restates existing law, that provision has been removed as duplicative. The definition of “confidential information”, which is necessary for distinguishing between requirements for trade secret claims and all other confidentiality claims, has been moved to the newly proposed Section 69309(d) in order to consolidate the sections and simplify the article.

Section 69310.1. Assertion of a Claim of Confidential Information

Subsections (a)(1) and (a)(2) were revised to delete the mention of the claims index, which was itself deleted, and to make clear that the legal authority for a privilege claim must be communicated via separate correspondence at the time the submission is made. Language requiring a submitter to assert a claim with reference to the proper authority at the time of submission is necessary to ensure that DTSC is aware of the basis for why certain information has been redacted. Otherwise, DTSC will not know which statute or regulations will apply to each claim in the event of a request for disclosure, with the potential for delay and error as a result.

Subsection (b)(2) was revised to delete superfluous language and to better emphasize DTSC’s discretionary power in proactively disclosing the redacted copy to the public. The requirement for complete and redacted versions of a submission is necessary for DTSC to proactively and efficiently release non-confidential information to the public, which promotes greater transparency and faster and more efficient disclosure.

The requirement for conspicuous marking in the newly proposed Section 69309(c) of confidential information is necessary for appropriate handling of submitted information because it better informs DTSC staff as to how to handle the document in question, and reduces the chances of inadvertent disclosure.

The creation of a special definition of “confidential information” is necessary to ensure that certain provisions for the handling of trade secrets are consistent with those for handling other confidential information (such as the marking and submission of complete and redacted copies). Without such provisions, differences in handling between types of claims could lead to clerical errors, administrative delay, misapplication of the law, and/or reduced public disclosure.

Section 69310.2. Marking and Indexing of Documents

The requirement to mark confidential information and trade secret information was moved to a different section (the newly proposed Section 69309(c)) as part of a larger consolidation of sections. The requirement that persons submit a claims index at the time of submission was deleted as unnecessary and in response to comments that it was potentially in conflict with the statutory requirement for claim justification only upon request.

Section 69310.3. Safeguarding of Confidential Information

The prohibition on misuse of confidential information by employees was deleted as duplicative of existing law and Departmental practice. The requirement that employees take appropriate measures to safeguard confidential information was also deleted as duplicative of existing law and Departmental practice.

Section 69310.4. Support of a Claim of Trade Secret Protection

Language in Section 69310(a) regarding the timing of a justification submission was revised to more clearly reflect the “upon request” nature of the authorizing statute, while giving DTSC flexibility to negotiate a longer period so that responsible entities may have a reasonable period of time to submit their justification documentation as individual circumstances may require.

Certain content requirements for justification documentation in subparagraphs (a)(1) through (11) were removed in order to delete superfluous requests and to harmonize with the information categories already used in California case law and current DTSC guidelines. The certification requirement of subparagraph (a)(12) was removed as duplicative in favor of the existing certification provisions for submissions provided elsewhere in these regulations.

The modifications to the previous Section 69310.4 are now found in the newly proposed Section 69309.1. Section 69309.1(a) is necessary to operationalize the requirement that persons making a trade secret claim provide justification upon request of DTSC, while providing a default ten (10) day response time for planning purposes for submitters to supply trade secret claim justification when so requested. The explicit authority to negotiate a longer deadline is also necessary and appropriate to ensure that submitters are provided with a reasonable period of time to supply the justification requested in cases where substantial numbers of claims are made.

Subparagraph (a)(1) through (7) contains seven specified categories of information and is necessary to inform the submitter in advance of what kinds of information DTSC generally finds appropriate and useful when reviewing a PRA request for information claimed as a trade secret. These categories are directly relevant to a Departmental finding of trade secret justification as evidenced by the fact that the same criteria are referenced in the Restatement of Torts 2d §727, California case law (*see, e.g., Futurecraft Corp. v Clary Corp.* (1962), 205 Cal.App.2d 279, 289), and requested under current Departmental practice. Without this specific guidance, submitters might omit relevant justification evidence which could, in turn, delay Departmental review or lead to unduly adverse findings.

Subparagraph (b)'s incorporation-by-reference language is necessary for streamlining the justification documentation and reducing the regulatory compliance burden for submitters.

Subparagraph (c) ensures that justification information is treated properly and with minimal administrative burden. Furthermore, it is necessary that the substantiation requirement not be applied to the justification documents themselves in order to avoid an infinite substantiation loop.

Section 69310.5. Departmental Review of Trade Secrets

This section, which contained provisions for independent review of trade secret claims, has been deleted in conformance with the provisions of HSC Section 25257(a), which requires that information claimed as a trade secret may only be released according to the provisions of that section.

This section also contained clarifying procedures for the review of trade secret claims after a request for release, which were deleted as essentially duplicative of existing law.

Section 69310.6. Hazard Trait Submissions

This section is modified to remove certain provisions that further define the term “hazardous trait submissions” as used in HSC 25257(f) as unnecessary and in response to comments that it was potentially unwarranted. The provision in revised Section 69309.2(a) is necessary to avoid potential confusion by reconciling an inadvertent terminological difference between the statute and the regulations. It is also necessary to clarify that the language of HSC Section 25257(f) operates to prohibit trade secret protection for such submissions, in order to avoid a too literal reading that might suggest silence on the question, which could leave open the alternative of seeking trade secret protection under the PRA, thereby contravening the clear intent of the section.

Revised Section 69309.2(b) is necessary to further interpret the given term to avoid potential confusion by clarifying that the term properly pertains to all submissions – including those related to alternatives. The relevant statute, HSC Section 25257(f), denies trade secret protection to submissions made “pursuant to this article [14]” and DTSC interprets those submissions to include information about alternatives because that article explicitly calls for “...a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives...” (See HSC Section 25253(a)(2)). Without this clarification, the intent of HSC Section 25257(f) to make hazard trait information available to consumers could be substantially frustrated if the term was later construed to apply only to a smaller range of chemicals or chemical substances.

DOCUMENTS ADDED TO THE RULEMAKING FILE

1. External Scientific Peer Reviewer Comments

DTSC is adding comments from seven (7) external scientific peer reviewers to the rulemaking file. Health and Safety Code section 57004 requires that the scientific basis of proposed regulations being proposed by entities within Cal/EPA undergo an external scientific peer review. DTSC has complied with Health and Safety Code section 57004

and had the science-based portions of the regulations with the accompanying Initial Statement of Reasons undergo seven (7) independent external scientific peer reviews. The subsequent seven (7) sets of written peer reviewer comments contain an evaluation of the scientific basis of the regulations and have been added to the rulemaking file.

2. Environmental Policy Council Resolution

DTSC is adding the EPC resolution adopted on October 27, 2010. Existing law (Section 25252.5 of the Health and Safety Code) requires, subject to a specified exception, DTSC to prepare, and submit to the California Environmental Policy Council (CEPC) for review, a multimedia evaluation prior to adopting these regulations. However, the law provides an exception to this requirement if the CEPC conclusively determines that the regulation will not have any significant adverse impact on public health or the environment. During the October 27, 2010, meeting of the CEPC, written and oral testimony was accepted on the issue described here. The CEPC unanimously made a conclusive determination that the adoption of these regulations would not have a significant adverse impact on public health or the environment. Thus, DTSC is not required to prepare a multimedia life cycle evaluation of the regulations.

OTHER STATUTORY REQUIREMENTS

California Environmental Quality Act

DTSC notes that its compliance with overarching or separate legal requirements apart from its compliance with the Administrative Procedure Act is not within the ambit of the review of the proposed regulations made by the Office of Administrative Law. DTSC is well aware that review by the Office of Administrative Law is confined to the statutory criteria set out in Government Code Section 11349.1 as made more specific by implementing regulations in Title 1, California Code of Regulations and ancillary provisions within the Administrative Procedure Act that directly bear on the proposed regulations' validity. DTSC received numerous public comments related to the California Environmental Quality Act ("CEQA", Public Resources Code Section 21000 et seq.). DTSC reiterates its position that a Notice of Exemption is the appropriate compliance with CEQA at this time. The modifications to the proposed regulations do not change DTSC's analysis.

DTSC acknowledges that there will be a point in the implementation of the regulations that the DTSC may have to do additional analysis to comply with its obligations under CEQA. When DTSC has winnowed down the potential pool of chemicals and products and moved further into implementation of the later regulatory steps, it will be in a position to conduct a rational, meaningful evaluation of potential significant effects on the environment, if any.

Attachments (2)