

Green Ribbon Science Panel

Report-Out of Subcommittee #3

De Minimis and Unintentionally-Added / Unknown Chemicals

(Teleconferences held: April 6 and 18, 2011)

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NOTE: In general, the notes set forth in this report-out are presented in the sequence of the subcommittee's discussions rather than strictly by topic. Repeated comments that applied to multiple topics are generally only presented once in these notes.

Question #3A: WHAT SHOULD BE THE DE MINIMIS LEVEL / CRITERIA (TO EXEMPT A PRIORITY PRODUCT FROM THE ALTERNATIVES ASSESSMENT PROCESS)?

- (i) Should there be a de minimis exemption, or not? *The remaining questions below assume that there will be a de minimis exemption.*

Comment Summary: De minimis Exemption

Some subcommittee members expressed that a de minimis exemption default level is necessary, because it would be impractical to require manufacturers to prove there is zero chemical in the product (due to impurities in the manufacturing process and knowledge gaps in the supply chain). Other subcommittee members expressed that there should not be a blanket de minimis exemption, but that it should be set based on the chemicals and products of concern once they are chosen. Another type of staged approach was also suggested such that a level is not set at the outset, but the process includes an ability to introduce an exemption later on. It was also noted that the exemption should only apply to unintentionally added chemicals, given that manufacturers would know how much of a chemical is intentionally added to a product.

Specific Comments: Include a de minimis level exemption

- Yes, there should be a de minimis exemption, given practical constraints.
- Yes, and the level that DTSC chooses should have Authoritative Body precedence, developed through a scientific review process.

- Proving the negative will be difficult and impractical with advances in science and analytical detection limits. If we don't set a de minimis level (default level is zero), that requires that people prove there is none of this chemical in a product, which is often impossible to guarantee given impurities in the manufacturing process and supply chain.

Specific Comments: Do not include a de minimis level exemption

- No blanket de minimis exemption. Instead, determine if it is appropriate to establish narrower de minimis exemptions when department identifies chemicals and products of concern.
- There should not be a blanket default de minimis exemption. De minimis exemptions may be established by DTSC for some chemicals of concern in some products of concern as implementation of the Safer Product regulations proceeds.
- There should not be a blanket or one-size-fits-all de minimis exemption. Any such exemption should apply only to unintentionally added chemicals.
- If de minimis is set on unintentionally added materials, an alternatives analysis may be difficult to conduct.
 - In an AA, could develop processes where you aren't looking at alternative for *chemical*, but you are looking at alternative for the manufacturing *process*. Subcommittee member is okay with making a distinction of unintentionally versus intentionally added chemicals, and then look at processes that lead to chemicals being incorporated.
- At the onset of the process, consider not setting have a de minimis level, but allow within the process to introduce or establish a chemical/product specific de minimis exemption

(ii) Should there be a set default de minimis level, or should the de minimis level be determined chemical-by-chemical, or a combination?

➤ If a default level is set --- what should it be?

Comment Summary: Default De Minimis Level

Two subcommittee member comments urged setting a default de minimis level at 0.1% for intentionally added ingredients (because of Authoritative Body precedence for that level), with the option to increase or reduce that level depending on the chemicals and products that DTSC prioritizes. The member also provided examples of several international models, some of which have mechanisms to adjust thresholds. This is described as an appealable, modifiable, adjustable threshold. Other subcommittee members thought that there should be no default de minimis level, but rather that it should be set on a chemical-by-chemical or chemical class basis.

Specific Comments: Default de minimis level

- Yes. 0.1% should be the default with the option to evaluate by exception higher or lower. The overarching goal of the Green Chemistry Initiative is to reduce significant adverse impact to public health and the environment. So, the process should try to keep the focus on key contributors to exposure that are of "real concern" to human

health or the environment. This can be done by looking primarily at “intentionally-added” ingredients above the 0.1% de minimis threshold. Other international systems that have set default de minimis levels, many with thresholds that vary by chemical.¹

- The baseline default level should be set at 0.1%, as set by Authoritative Body precedence. Higher and lower thresholds will be addressed on a chemical-by-chemical basis:
 - Chemicals that should have *lower* levels than 0.1% will make that determination based on sufficient scientific evidence. *Currently*, these lower thresholds will be based on Authoritative Body levels, and *in the future*, it will be based on responding to changing levels from Authoritative Bodies, or if new risk information emerges with scientific review. A “new” lower threshold would be initiated with public notice.
 - Chemicals that are to be considered for de minimis levels *higher* than the baseline 0.1%, should be proposed by petition from the manufacturer, including (by not limited to) information on higher levels accepted by ABs
- Another Subcommittee member expressed concern that 0.1 % is too high for some chemicals
- Set a default level as a starting point that is modulated by kinds of products that we prioritize. This can be appealed or on action of the department.
- Could start with straw de minimis, then apply it to the chemical and the chemical in the product and consider the exposure of the chemical in the product to make a decision whether to proceed with an alternatives analysis.

Specific Comments: No default de minimis level

- Since DTSC is starting with fairly small number of chemicals and products, it should be set individually chemical by chemical and product by product. If its scope broadens, then it can consider establishing default levels that apply broadly to those chemicals and products.
- Since chemicals of concern will by definition be data-rich chemicals, any de minimis level can and should be set on a chemical-by-chemical basis.

¹ **International Guidance for Establishing Different De minimis Levels:** There are other resources that could be considered in this context:

Endpoint-specific cutoff values articulated in the GHS guidance materials (which explicitly discuss adjusting thresholds) or those used by other countries in their GHS-based classification and labeling programs. Under the EU's GHS Classification and Labeling program the de minimis trigger level is 0.1% in a product (1,000 ppm) unless a different level is identified based on a health risk assessment <http://ecb.jrc.ec.europa.eu/classification-labelling/> . For the over 3,000 chemicals addressed in this regulation, 15% have thresholds adjusted to lower or higher levels, and 85% operate at 0.1%.

The EU Cosmetic Directive addresses over 1,300 hazardous chemicals with a default de minimis of 0.1% in product, but also contains specific threshold levels for over 300 chemicals that range between 0.001% and 25% (w/w)

http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index_en.htm

In Proposition 65, California has developed chemical- specific exposure limits. No Significant Risk exposure limits require consideration of how, regardless of the presence or total content of a substance in a consumer product, exposure to the environment and to users may occur.

In the European Union's REACH regulation, hazardous chemicals contained in articles are limited to 0.1% in product. There is no de minimis adjustment mechanism.

- There should be no default de minimis level initially; as more chemicals and products of concern are evaluated, a de minimis level could be set for some chemicals and products for purposes of prioritizing regulatory action to protect public health and the environment.
- There should not be a default de minimis level.

- If the level is set chemical-by-chemical --- what should be the basis for the determination?
- Hazard threat (based on what information)?
 - Exposure threat (based on what information)?
 - Should / how should cumulative exposures to the same chemical used in multiple products be considered?
 - Lowest current regulatory level for the chemical or product?
 - Non-detect at arbitrary detection limit?
 - Other ideas?

Comment Summary: Chemical-by Chemical De Minimis Level

In setting the de minimis level by chemical or chemical class, all listed factors (hazard, exposure, cumulative exposures and lowest current regulatory level) should be considered. Specifically, hazard threat should be based on inherent hazard traits (per OEHHA, SB 509), and risk analysis over a period of time (dose-response), with adjustments for those chemicals that do not follow a normal dose response curve (proteins, heavy metals, bioaccumulative). Exposure should be based on likely consumer use (including ingested, inhaled, bathed in), and sensitive subpopulations. Cumulative exposure should be based on multiple source exposures (e.g. phthalates in both personal care products and cleaning products, and, for children, toys.). A de minimis level should be developed based on a pre-set agreed-upon risk level, which would be uniform (e.g., 1 in 1 million) but would then translate into a chemical-specific concentration limit. Evaluating based on lowest current regulatory level should only be a starting point, given limitations of other regulatory bodies' levels. The issue of "Non-detect at arbitrary detection limit" was not explicitly addressed.

- (iii) Should the de minimis level be applied to the product as a whole, or to each component of the product?

Comment Summary: De Minimis Applicability to Components or Entire Product

One subcommittee member thought that the de minimis should be set for the product as a whole for simplicity sake. Other subcommittee members felt that de minimis levels should be applied to the whole product if formulated, and to each component in the case of an assembled product. Another committee member argued that levels should be applied to the product as a whole and to components that can be easily removed or replaced within the product (such that each of the "components" is in fact its own separate "product").

- (iv) Should the de minimis level be applied individually for each chemical, or to the aggregate concentration of all chemicals in the product/component meeting a specified criterion?
- If the aggregate approach is used, what criterion should be used to group chemicals:
 - Hazard trait?
 - Mode of action?
 - Other ideas?

Comment Summary: De Minimis Applicability to Individual or Aggregate Chemical

Subcommittee members had different opinions regarding an individual or aggregate approach to setting the de minimis level. Some subcommittee members felt that the de minimis level should apply to each chemical. Other members felt that an individual chemical approach should be taken, *unless* multiple chemicals were linked to the same adverse effects, exhibited a cumulative effect on a particular biological pathway or health endpoint, or had the same mode of action. In these cases, a cumulative approach was suggested (based on mode of action, “similar adverse effects”, biological pathway, health endpoint). Specifically, one member outlined the necessary evidence for such an aggregate determination, noting the evidence for using the aggregate approach would be when a relevant endpoint in an assay or test system is changed showing that additivity, synergism, or antagonism does occur when the chemicals are in the test system together. The scientific review of these data must be rigorous.

- (v) Should there be any chemical or category of chemicals for which no de minimis exemption is allowed? If so:
- What chemical(s) or category(ies) of chemicals?
 - How should presence or non-presence be determined?

Comment Summary: No De Minimis for Chemicals/Chemical Category

Some subcommittee members felt that there should be no de minimis exemption allowed for certain categories of chemicals, including carcinogens, mutagens and reproductive toxins (CMRs), PBTs, endocrine disrupters, and other compounds where no threshold can be identified or assumed below which there would be no effect (i.e., those with a linear dose-response curve and hence effects even at low doses). Another subcommittee member opined that there should not be certain classes for which no de minimis exemption is allowed. This member suggested looking at how the regulations for foods and pharmaceuticals approach the issue, and noted that exceptional cases can be handled by exceptions to concentration (rather than chemical class).

One specific evaluation method was suggested such that if these compounds are previously adjusted to lower de minimis levels via Authoritative Body determinations, and the lower levels are 2 logs below the baseline 0.1% level, then manufacturers should file an exemption notification to DTSC.

Subcommittee members felt that the manufacturer should have the burden of proof for showing that a de minimis level is acceptable, including testing using practical limits of

detection for unintentionally added chemicals), and analytical chemistry tests to determine concentrations of intentionally added chemicals. [See also later discussion of intent vs. knowledge]

- (vi) Which of the following should the de minimis exemption apply to?
- Unintentionally Added additives --- if so, which ones?
 - Chemicals contained in naturally-occurring content? Other not-recycled content?
 - Chemicals contained in recycled content?
 - Chemicals introduced from the air, or from water used as a processing aid or as an ingredient?
 - Other ideas?
 - Intentionally-added chemical ingredients?
 - Residual reagents & other chemicals from chemical transformations?

Comment Summary: De Minimis and Unintentional, Intentional and Residuals

One subcommittee member suggested allowing the exemption to be applied to all cases with special consideration, given the products and chemicals that are prioritized. One subcommittee member suggested applying the de minimis exemption only to unintentional additives where the chemical 1) does not serve a functional or performance purpose for the product or an associated production process, and 2) is “integrally associated with the acquisition or production of an intentionally-added chemical and cannot be removed prior to addition to the product”. Another member similarly expressed that an exemption *may* be applied to a chemical that is not part of a recipe or is not a known/expected contaminant or residual of the manufacturing process. Another member suggested that DTSC should have a process for bringing products under the de minimis regulations that may have been previously exempted, if the presence of a chemical becomes known through product testing (by the manufacturer or another party).

Chemicals that are present in the product at the same levels as those that occur naturally in nature or as those found in recycled content may be allowed under the exemption, as long as they meet the above functionality criteria. Another member noted that these “background levels” may vary by location (like cleanup levels), which must be addressed. For chemicals contained in recycled content that are used as feedstock for a product, these should be treated as “recipe” ingredients (intentionally added), and therefore should adhere to associated de minimis level thresholds.

Several subcommittee members were in agreement that no de minimis exemption should apply to intentionally added chemicals. One member specifically noted that if a chemical is known by the manufacturer to be in the product, regardless of its source of entry or whether it has a function in the intended use - then it falls under the “intentional rule”.

With regard to the issue of “Residual reagents & other chemicals from chemical transformations,” Some of this conversation focused on the issue of “toxics along for the ride” in manufacturing.

Specific Comments: Residual reagents and chemicals

- Residual reagents would not be eligible if they serve or contribute to the function of the ingredient they contaminate (e.g., a congener co-produced along with the desired congener), or could reasonably be removed from the intentionally added chemical prior to introduction into the product (e.g., unreacted monomer in a polymer).
- A de minimis exemption may be allowed for residual reagents and other chemicals otherwise critical to the production of the chemical of concern in the product of concern (e.g. process solvents, catalysts, intermediates, un reacted monomer, known/ expected byproducts or contaminants) with the caveats above for classes of chemicals for which no de minimis should be allowed because of low-dose effects
- To address the “toxics along for the ride,” consider the “otherwise regulated” language in the regulations: if there is an allowed residual set for some particular chemical by the federal government, go with that.

Specific Comments: “intentional” versus “knowledge”

- Difficulty with the idea of “intent” because it is hard for DTSC to write a rule about intent. Consider distinguishing between intent to remove the chemical (and inability to do so (or completely do so) given manufacturing process limitations), versus intent to include in process/product (CoC is specifically added to the recipe). It may wind up being cleaner to talk about de minimis levels and levels of exposure, regardless of intent.
- Consider not addressing the idea of “intent” at all in the regulations because it is too difficult to come up with a working definition.
- Are residual materials that are a product of a series of reactions considered intentional, or unintentional?
 - Intentional. Chemicals are identified at the end of the process through analytical chemistry techniques...even if you didn’t want them to be there, they are. By definition of the process, they become intentional.
- Consider making the criteria a distinction between it being added to the recipe as part of the normal process *versus* having things “ride along” in the manufacturing process—other language that unintentional? Inadvertent? How do you address that in a way that doesn’t create a regulation that focuses on concentrations way below where you want? Comes down to concentration, rather than intent. The criteria should be whether it is part of normal recipe for making a product or not.
- *Written comment:* During 4/6 meeting, one subcommittee member raised for consideration an example in which a chemical of concern is accompanied by related forms of that chemical that are also of concern, asking whether the related forms are “unintentionally” added as contaminants of the manufacturing process (such as various forms of PBDEs). It would seem inappropriate for such chemicals to be granted a safe harbor de minimis exemption. I would propose that one solution would be to define chemicals of concern so as to include all such variants of chemicals of concern where they actually are of concern. Thus, the various forms of PBDE’s in the given example should all be chemicals of concern, and any de minimis exemption in such a case ought to apply to the total cumulative concentration of such variants. If the chemical variants that accompany a chemical of concern are not themselves CoCs, then they would not be subject to the further

provisions of the regulation (which apply to CoCs only), whether they are really no different than any other chemical in a product of concern that has not been designated a CoC.

Question #3B: WHAT PROCESS SHOULD BE USED TO ALLOW AN EXEMPTION FOR A PRIORITY PRODUCT THAT CONTAINS THE CHEMICAL AT OR BELOW THE DE MINIMIS LEVEL?

- (i) Should the exemption be self-implementing (i.e., the manufacturer self determines if their product qualifies for the exemption, and no notification to DTSC is required)? *or*
- (ii) Should the manufacturer be required to submit one of the following?
 - Notification of the chemicals present below the de minimis level?
 - Notification, plus other information (e.g., analytical work, recipe, other)?
 - Notification, plus request for DTSC approval of the exemption?

Comment Summary: De Minimis Self Implementing or Notification

There were several suggestions for whether the exemption should be self-implementing, or require various levels of notice and approval. One member noted specifically for chemicals that require a lower de minimis threshold than the 0.1%, DTSC should approve those exemptions.

A subcommittee member expressed a tension between making sure that companies were held accountable, but realizing that the notification/review/approval process could not be too resource intensive for the department. Some subcommittee members did not want the exemptions to be self implementing.

Another subcommittee member expressed that a notification identifying certain priority chemical(s) are present in the product and that the de minimis regulation is satisfied. In the specific case where a lower level has been set (such as 2 logs below the 0.1% level) then a notification plus supporting information should be submitted. The manufacturer should have the option to designate certain information as proprietary if necessary, but this option should not be construed as an avenue to bypass disclosure of information to DTSC. In this specific category, which could include highly potent compounds of concern, DTSC should approve the exemption.

Specific Comments: De minimis notification and certification

- Have manufacturers provide a certification that the chemical of concern is below the de minimis
- Potential “certification mechanisms” include:
 - Require DTSC review and approval for all exemption requests
 - Requirement manufacturers keep specified information, available upon request from DTSC and/or public
 - An executive should sign the notification.
 - Post notification for external review (if CBI is not an issue) so that if DTSC does not have the resources then others can provide input even if after the fact.

- One possible alternative would be where full public access is provided by the manufacturer to the request and the basis and documentation for it; in which case that might suffice and not require DTSC review and approval.

Question #3C: WHAT SHOULD BE THE CRITERIA FOR ALLOWING AN EXEMPTION WHEN THE PRODUCT CONTAINS THE CHEMICAL ONLY AS AN UNINTENTIONALLY-ADDED CHEMICAL (TO EXEMPT A PRIORITY PRODUCT FROM THE ALTERNATIVES ASSESSMENT PROCESS)?

(i) Should there be an exemption for unintentionally-added chemicals, or not?

Comment Summary: De Minimis Exemption for Unintentionally Added Chemical

Several subcommittee members felt that there should be an exemption for unintentionally added chemicals; however, some felt it was important to clarify the definition of “intentional” and “unintentional.”

The remaining questions below assume that there will be an exemption.

(ii) Which of the following should the exemption apply to?

- Chemicals contained in naturally-occurring content?
- Chemicals contained in other non-recycled content?
- Chemicals contained in recycled content?
- Chemicals introduced from the air, or from water used as a processing aid or as an ingredient?
- Only chemicals present below the de minimis level?
- Other ideas?

(iii) What steps, if any, should a manufacturer be required to take to obtain knowledge about the presence of unintentionally-added chemicals?

Specific Comments: Knowledge of unintentionally-added chemicals in products

- If there is any basis for expecting a chemical of concern may be present, chemical analysis should generally be required to determine its presence and level.
- Alternatively, strong arguments for why the chemical is very unlikely to be present above the de minimis level could be provided, e.g., none of the starting materials in aggregate include the chemical above such level.
- Any such presumption needs to be “readily rebuttable” – that is, the basis for it needs to be either actively reviewed by DTSC, or be made accessible such that any available information challenging the presumption can be provided by competitors, members of the public, etc.
- A manufacturer should be aware of and notify DTSC of recipe ingredients (see #3A(v) and #3C (i) and known, expected contaminants (e.g., 1,4-dioxane in the manufacture of ethoxylated surfactants, heavy metals utilized to stabilize plastics, unreacted monomers, residual solvents, formaldehyde-donor preservatives, and mixtures such as deca/octa/hexa-PBDE.)

(iv) Should the exemption apply if the manufacturer has knowledge of the unintentionally-added chemical's presence?

Specific Comments and Framework Suggestions for “Intent” and “Knowledge”

- If there is a chemical of concern that is present *in the recipe* [intentionally added] for making a product, call that ingredient. Need to establish a de minimis level for ingredients. If you have presence or potential presence in recycled material, naturally occurring, monomer [shows knowledge, credible evidence that it is present as an ancillary to the process] call that a component (find other word). You as the manufacturer would have that evidence available for review, either from public, government, or other manufacturers disclosure.
 - Credible evidence: evidence from an approved source, i.e. public interest groups, government, another manufacturer has reported it. Manufacturer either knows that its process results in the CoC being present, or should know to look for it, and initiate testing.
 - Reporting/Knowledge: Explicit versus implicit reporting. Different burden for the 2 approaches, consider liability aspects
 - Alternative 1: Manufacturer should have to report in a public statement that it has no knowledge of the CoC in their product (explicit, affirmative statement on lack of knowledge).
 - Alternative 2: By offering for sale, and not offering to do AA, manufacturer has effectively said that the CoC is not in the product (Implicit, assumed statement, implied marketability). Have no reason to report/notify unless someone comes forward saying you might have more than that in your product. (takes burden off DTSC)
 - Affirmative statement requires an investigation into the supply chain, and there is currently a lack of information about what goes into a product.
- Knowledge may be a better concept is better than intent, especially if DTSC has a de minimis level set (or even if it just practically set at the detection limit).
 - Manufacturer could say it had no knowledge that there was an unintentionally added chemical, and that no knowledge exists (from other parties)
 - Good faith knowledge rests on the process itself, (how much of the chemical is added in the process, and QC on accuracy of the product) rather than the analytical testing on the product at the end

Other Comments:

De minimis exemptions for already reformulated products:

- Two ways to address the de minimis issue for products (i.e. products that have already reformulated, and will be looking for an exemption):
 - Define product category such that it reflects that difference (i.e. different product sub-category those with low or no concern) OR
 - Set de minimis level for category as a whole

Summary of Exemption Criteria (written comment):

A narrowly defined exemption may be appropriate when a product of concern contains a chemical of concern that is not intentionally added. One subcommittee member thought the criteria should be:

1. CoC is not a CMR, PBT, or ED
2. It is adventitiously and unintentionally included in a product of concern as a trace contaminant of a manufacturing process
3. It does not serve a functional purpose that the manufacturer desires
4. The exemption should be set at an appropriate trace contaminant level that is reasonably attainable and reflects the circumstances by which the product unintentionally contains the chemical
5. At the de minimis level, the CoC will cause no threat to human health and the environment, taking into account cumulative exposures to the chemical. The burden of proof should be on the manufacturer
6. Exemption levels should apply regardless of manufacturer's knowledge of the presence of the chemical. Manufacturers should have a duty of reasonable investigation to ensure their products contain no chemicals of concern over any de minimis levels, and must act promptly upon discovering that such is not the case.