

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.

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.

(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?

There should be no default *de minimis* level initially; as more chemicals and products of concern are evaluated, a *de minimis* could be set for some chemicals and products for purposes of prioritizing regulatory action to protect public health and the environment.

• If the level is set chemical-by-chemical --- what should be the basis for the determination?

-- Hazard threat (based on what information)? **Inherent hazard traits (e.g., OEHHA SB 509 traits)**

-- Exposure threat (based on what information)? **Likely consumer use, as well as possible sensitive subpopulations**

-- Should / how should cumulative exposures to the same chemical used in multiple products be considered? **Yes, based on best available data and likely consumer exposure to multiple sources (e.g. phthalates in both personal care products and cleaning products, and, for children, toys.)**

-- Lowest current regulatory level for the chemical or product? **This should be a starting point only; some current regulatory levels are inadequate (e.g. CPSIA regulations for lead in children's toys.)**

-- Non-detect at arbitrary detection limit?

-- Other ideas?

All of these factors should be considered in establishing a chemical-by-chemical (or chemical class by chemical class) de minimis exemption.

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

The de minimis level should be applied to the product as a whole for a formulated chemical product, and to each reasonably separable component for an assembled product or article.

(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?

The de minimis level should be applied individually for each chemical, except in cases where multiple chemicals may exhibit a cumulative or synergistic effect on a particular biological pathway (e.g., thyroid hormone control of development, or immune system trigger/ asthma) or health endpoint (e.g., skin irritation, central nervous system effects) where an aggregate assessment may be appropriate for adequate human health and/or environmental protection.

(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?

There should be no *de minimis* exemption allowed for carcinogens, mutagens, reproductive toxins (CMRs), persistent, bioaccumulative or toxic substances (PBTs), and endocrine disruptors. These are classes of chemicals for which there is no “safe” *de minimis* dose. If a manufacturer believes that a chemical in one of these classes is present in essentially *de minimis* concentrations, or cannot be reasonably removed from the product, the manufacturer should submit information supporting this assertion for DTSC’s review.

- How should presence or non-presence be determined?

The presence of intentionally added chemicals (e.g. process raw materials, solvents, intermediates, catalysts, reaction by-products, etc.) should be known by the manufacturer.

(vi) Which of the following should the de minimis exemption apply to?

- Unintentional additives --- if so, which ones?

Any chemical that is not part of a recipe or is a known/ expected contaminant or residual of a manufacturing process *may* be allowed under a *de minimis* exemption.

- Chemicals contained in naturally-occurring content? Other not-recycled content?

Chemicals of concern of “natural” origin that occur in a product at “background” levels (with the complication that this may vary from location to location, per DTSC’s experience with cleanup levels) may be allowed under a *de minimis* exemption.

- Chemicals contained in recycled content?

Chemicals of concern reasonably expected to be present in recycled content (e.g. flame retardants in plastic from recycled electronics) should be treated as “recipe” ingredients (see (v)) and be permitted a *de minimis* exemption unless they are in one of the classes (PBTs, CMRs, EDRs) for which there is no “safe” dose.

- Chemicals introduced from the air, or from water used as a processing aid or as an ingredient?

Exempt only if they occur at levels equivalent to background (see response under “naturally-occurring content” sub-question) *plus* what was intentionally added by the manufacturer (see response under “unintentional additives” above.)

-- Other ideas?

- Intentionally-added chemical ingredients?

No blanket exemption should apply to intentionally-added ingredients.

- Residual reagents & other chemicals from chemical transformations?

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, unreacted 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.

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*

Self-implementation: No.

(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?
- Other ideas?

In order to obtain an exemption, the manufacturer should be required to submit notification of the chemicals present at or below the *de minimis* level, provide documentation (analytical work, recipe, etc.), and a request for DTSC approval. My only hesitation about requiring DTSC to approve exemptions is that this could potentially become burdensome to DTSC if and when more than a handful of *de minimis* requests are filed. Allowing non-CBI portions of the notification to be revealed publically would allow for third-parties to vet the *de minimis* exemption claims in this latter situation.

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

Yes, if “unintentional” is defined as in detailed responses under Question #3A (v) where the definition of “intentional” and “unintentional” are clarified.

(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?

See detailed responses under Question #3A (vi)

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

A manufacturer should be aware of/ 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?

Yes, the exemption should apply if the manufacturer has knowledge of the unintentionally-added chemical's presence, unless the chemical is present above any *de minimis* level set for the chemical as a Chemical of Concern, or if it is a member of the three classes of chemicals for which no *de minimis* level is acceptable.

Comments from Bill Carroll

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?

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.

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 Global 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 (1000 ppm) unless a different level is identified based on a health risk assessment <http://ecb.jrc.ec.europa.eu/classification-labelling/> . For the over 3000 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 1300 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.

Exposure through products that are not ingested, inhaled or bathed in are usually pretty small exposures. Focus first on the doughnut and not the hole.

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

For simplicity, at least initially, to the product as a whole, but there is an entirely different set of complexity with articles. Is the CoC isolated inside—say for example, as a permanent Ni-Cd battery—or is it on the surface where it could come into contact with skin? Imagine electronics, with a number of case colors and variations if a CoC is embedded within and out of common exposure. The complexity of reporting increases geometrically.

Now, it may be that in choosing products of concern some of that complexity can be engineered out of the regulation by practical application. My advice remains to start simple.

- (iv) Should the de minimis level be applied individually for each chemical

Once again, for simplicity, individually

- (v) Should there be any chemical or category of chemicals for which no de minimis exemption is allowed?

No. Exceptional cases can be handled by exceptions to concentration. Consider carcinogens. Most monomers used in making the commodity plastics have greater or lesser concerns about carcinogenesis. On the other hand, parts per billion of such a monomer, bound in its plastic, seems like a truly de minimis hazard compared to high ppms of a material with a palpable exposure route. In many cases, such materials with low ppb of a carcinogen are allowed for food contact by FDA on the basis of negligible migration.

And remember for CMRs under Prop 65 there is an effective de minimis apparatus.

- (vi) Which of the following should the de minimis exemption apply to?

- Unintentional additives --- if so, which ones?
- Intentionally-added chemical ingredients?
- Residual reagents & other chemicals from chemical transformations?

Same answer, really. Allow for all cases with the opportunity for special consideration based on the combination of product and chemical

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?

- Self-implementing with the requirement that the state has the right to ask for documentation of the de minimis determination

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

I'm really quite uncomfortable with the concept of intentional and unintentional additives. This probably fits with my overall feelings about de minimis, but if I could summarize:

I believe that every CoC in a PoC should have a de minimis level, regardless of the chemical, even if that level is the analytical limit of detection, although that is, first, a moving target and second, much too stringent for real treatment of the hazard posed by most materials in most applications. I use it only as an example.

For virtually all CoCs, including (and perhaps especially) CMRs, etc, effective de minimis levels have been set in other areas of regulation, for a number of practical reasons:

- Background levels of the chemical are ubiquitous in the environment (dioxin, lead)
- Isolation of the material with limited or undetected migration, even in food contact (vinyl chloride in PVC; styrene in polystyrene)
- Safety factors for exposure to CMRs in California Prop 65, as well as the other regulatory approaches mentioned previously

For this reason, I prefer the idea of knowledge of the presence of the material as a criterion. Reiterating and refining comments from the call: de minimis levels should be set as though the CoC were an ingredient in the recipe—whether a pure chemical or a commercial mixture (e.g. technical grade or commercial grade) used to make the PoC. This takes into account—as it should—not just the hazard of the CoC, but the nature of

the PoC. Traces of tributyl tin, trapped in a matrix, isolated on the inside of a multi-component article are different than tributyl tin painted on a ship's hull.

As an aside, I continue to work under the assumption that the goal of this program is to work on the chemicals and products that present the highest potential for human or environmental exposure, based on a reasonably foreseeable use of the product. And I'm not ruling out that a de minimis level for a CoC might be different in different PoCs—use the TBT case above as one example.

For all instances where a CoC may be present in the PoC by virtue of any method other than specific inclusion in the recipe—that is, all the means noted in (ii) above—the question becomes whether the manufacturer has credible information that the CoC is in the PoC at a level above the ingredient de minimis level. Credible information could be known from testing, calculation, public information provided by third party analysis or information provided by another manufacturer, among others, including a reasonable analytical and statistical error factor. If there is no credible reason to believe the CoC is present above the de minimis level, no action should be needed, based on the idea that the manufacturer, knowing about the regulations, has offered the product for sale. Maintaining documentation of the reasoning leading to that belief might be prudent. If there is a reasonable probability or fair certainty that the CoC is present in the PoC above the de minimis level, notification should be required and action taken according to the regulatory process.

Comments from Richard Denison

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.

There should not be a blanket or one-size-fits-all de minimis exemption. Any such exemption should apply only to unintentionally added chemicals.

(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?

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?

All of these factors are relevant in setting a chemical-by-chemical de minimis level.

Because these chemicals will be relatively few in number and data-rich, de minimis levels for each should be developed based on a pre-set agreed-upon risk level. OEHHA is well-suited to and should assist DTSC in setting these levels.

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

They should be applied to: a) formulations as a whole, and b) each readily separable component of non-formulated products.

(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?

Levels should generally be set individually, but where multiple chemicals are linked to the same or very similar adverse effects, an aggregate level would likely be more appropriate.

(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?

De minimis exemptions should not be allowed for intentionally-added chemicals.

- How should presence or non-presence be determined?

The amount of intentionally added chemicals will by definition be known. For unintentionally added chemicals, testing using practical limits of detection should be required.

(vi) Which of the following should the de minimis exemption apply to?

- Unintentional additives --- if so, which ones?

Yes, where the chemical:

- **does not serve or contribute functionally or performance-wise to the product or an associated production process, and**
- **is integrally associated with the acquisition or production of an intentionally-added chemical and cannot reasonably be removed prior to addition to the product.**

-- Chemicals contained in naturally-occurring content?

Only if present in the product or component at the same levels found in nature and meeting the other requirements re: serving no function and unable to be removed.

Other not-recycled content?

What would this material be? Unclear.

-- Chemicals contained in recycled content?

Only if present in the product or component at the same levels found in the recycled material and meeting the other requirements re: serving no function and unable to be removed.

-- Chemicals introduced from the air, or from water used as a processing aid or as an ingredient?

Only if present in the product or component at the same levels found in nature and meeting the other requirements re: serving no function and unable to be removed.

-- Other ideas?

- Intentionally-added chemical ingredients?

No.

- Residual reagents & other chemicals from chemical transformations?

These 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).

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*

No.

(ii) Should the manufacturer be required to submit one of the following?

- Notification of the chemicals present below the de minimis level?

Insufficient.

- Notification, plus other information (e.g., analytical work, recipe, other)?

Insufficient.

- Notification, plus request for DTSC approval of the exemption?

This process – notification plus documentation plus DTSC approval – should generally be required.

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.

- Other ideas?

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

Yes, per the above.

(ii) Which of the following should the exemption apply to?
-- Chemicals contained in naturally-occurring content?

Only if present in the product or component at the same levels found in nature and meeting the other requirements re: serving no function and unable to be removed.

-- Chemicals contained in other non-recycled content?

What would this material be? Unclear.

-- Chemicals contained in recycled content?

Only if present in the product or component at the same levels found in the recycled material and meeting the other requirements re: serving no function and unable to be removed.

-- Chemicals introduced from the air, or from water used as a processing aid or as an ingredient?

Only if present in the product or component at the same levels found in nature and meeting the other requirements re: serving no function and unable to be removed.

-- Only chemicals present below the de minimis level?

Yes.

-- Other ideas?

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

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.

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

Yes, where other requirements for eligibility are met.

MEMORANDUM

From: Joseph H. Guth, J.D., Ph.D.
Berkeley Center For Green Chemistry
Science & Environmental Health Network

To: Green Ribbon Science Panel, Subcommittee 3

Re: *De minimis* Chemicals and Unintentionally-Added Chemicals

Date: April 17, 2011

This is in response to the request for written statements made during the April 6, 2011 public meeting by telephone conference of Subcommittee 3 of the Green Ribbon Science Panel.

SUMMARY

Question #3A(i): Should there be a *de minimis* exemption, or not?

There should be no blanket *de minimis* exemption that would apply to all potential chemicals of concern and all potential products of concern. Instead, DTSC should establish narrower *de minimis* exemptions as part of the regulatory process of identifying particular chemicals and products of concern.

Question #3A(ii) – (vi): Guidelines for establishing a *de minimis* exemption.

1. Since DTSC will be starting out with a fairly small number of chemicals and products of concern, any *de minimis* level should be set individually product by product and chemical by chemical. If DTSC begins to designate larger numbers of chemicals and products of concern, then it can consider at that time whether to establish default levels that apply broadly to those chemicals and products.
2. Hazard, exposure threat, cumulative exposures, lowest current regulatory levels for a chemical and detection limits are all relevant to setting a *de minimis* exemption.
3. No *de minimis* exemption should be set for the following categories of chemicals: CMR's, PBT's or endocrine disruptors.
4. No *de minimis* exemption should be permitted for chemicals of concern that are intentionally added to a product of concern by a

manufacturer for a functional or industrial purpose.

5. A manufacturer should be required to demonstrate that it can meet any criteria, assumptions and conditions that are used to justify obtaining the exemption, and that they will be maintained in the future as a condition for obtaining the exemption.

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?

Since at this time there will be a small number of chemicals and products of concern, DTSC should require notification, information and DTSC approval of each exemption. It seems very likely that such information will be designated as CBI, but if it is not, then perhaps public disclosure and some sort of petition process could substitute for DTSC approvals.

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)?

A narrowly-defined exemption may be appropriate when a product of concern contains a chemical of concern that is not intentionally added (criteria are specified below).

RESPONSES TO QUESTIONS

Question #3A(i): Should there be a *de minimis* exemption, or not?

There should be no blanket *de minimis* exemption that would apply to all potential Chemicals of Concern and all potential Products of Concern. AB 1879 is of much broader potential scope than many other statutes containing *de minimis* exemptions. Interposing a *de minimis* exemption at a point in the regulations that would make it available to *all* potential chemicals of concern and *all* potential products of concern, even before those are identified by DTSC, would create simply too many inappropriate safe harbors that are insufficiently tailored to the various rationales for establishing a *de minimis* exemption.

Instead, DTSC should establish narrower *de minimis* exemptions as part of the public process of identifying chemicals of concern and, especially, products of concern. For example, when DTSC identifies a product of concern, it should consider whether a *de minimis* exemption for such a product would be appropriate for one or more particular chemicals of concern. This would permit a much more

reasoned and calibrated consideration of this issue than would a blanket exemption applicable to all products and chemicals of concern.

Question #3A(ii) – (vi): Guidelines for establishing a *de minimis* exemption.

1. Since DTSC will be starting out with a fairly small number of chemicals of concern and products of concern, any *de minimis* level should be set individually product by product and chemical by chemical. If DTSC begins to designate larger numbers of chemicals and products of concern, then it can consider at that time whether to establish default levels that apply broadly to those chemicals and products.

2. Hazard, exposure threat, cumulative exposures, lowest current regulatory levels for a chemical and detection limits are all relevant to setting a *de minimis* exemption. Essentially, such an exemption should only be allowed when the exposures to a chemical of concern in a product of concern will be safe enough for human health and the environment that no alternatives analysis would be appropriate. For products of concern containing chemicals of concern, this should be a high bar and the burden of proof should rest with manufacturers.

3. No *de minimis* exemption should be set for the following categories of chemicals: CMR's or PBT's or endocrine disruptors. These chemicals have impacts on human health and the environment at very low concentrations and in low amounts so that the presumed rationale for this exemption simply does not apply to these chemicals. If DTSC believes that industry can show that these kinds of chemicals can be used in certain products of concern in some circumstances without creating a threat to human health and the environment, then it might establish a limited *de minimis* exemption with criteria reflecting those circumstances. The burden of proof on this issue should be placed on manufacturers.

4. No *de minimis* exemption should be permitted for chemicals of concern that are intentionally added to a product of concern by a manufacturer for a functional or industrial purpose. Requiring alternatives analyses for intentionally added chemicals of concern does not present the same burden as requiring alternatives analyses for potentially numerous adventitious contaminants. The point of AB 1879 is to drive development of safer alternatives, and if a chemical of concern is intentionally added to a product of concern for a functional or industrial purpose, then it should be subject to the alternatives analysis process, which should not be avoidable by simply being diluted to below a *de minimis* threshold.

5. When various assumptions and criteria are used to establish a *de minimis* exemption, a manufacturer should be required to demonstrate that it can meet the criteria, assumptions and conditions that are used to justify obtaining the exemption, and that they will be maintained in the future as a condition for obtaining the exemption.

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?

At this point in the development of the regulations, since there will be a small number of chemicals of concern and products of concern, DTSC should require notification, information and DTSC approval of each exemption. It seems very likely that such information will be designated as CBI, but if it is not, then perhaps public disclosure and some sort of petition process could substitute for DTSC approvals.

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)?

A narrowly-defined exemption may be appropriate when a product of concern contains a chemical of concern that is not intentionally added. The criteria should be as follows:

- a. The chemical of concern is not a CMR, PBT or ED (see above).
- b. It is adventitiously and unintentionally included in a product of concern as a trace contaminant of a manufacturing process.
- c. It does not serve a functional purpose that the manufacturer desires.
- d. 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.
- e. At the *de minimis* level, the chemical of concern will cause no threat to human health and the environment, taking into account cumulative exposures to the chemical. The burden of proof on this issue should be on the manufacturer.
- f. The 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.

During the April 6, 2011 meeting of this subcommittee, Richard Denison raised for consideration an example in which a chemical of concern is accompanied by modified forms of that chemical that are also of concern but are "unintentionally" added as contaminants of the manufacturing process (such as various forms of PDBE's). 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 PDBE's in Richard Denison's 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 chemical variants that accompany a chemical of concern are not themselves chemicals of concern, then they would not be subject to the further provisions of the regulation (which apply to chemicals of concern only) whether they are intentionally added or not; they really are no different than any other chemical in a product of concern that has not been designated a chemical of concern.

From: Dale Johnson <dalejohnson@sbcglobal.net>
To: Kathy Barwick <KBarwick@dtsc.ca.gov>
Date: 4/21/2011 2:00 PM
Subject: Responses to Topic #3 De Minimis Chemicals and Unintentionally-added Chemicals

Kathy

My comments and suggestions follow. In the text I use the term "Authoritative Bodies" as an all inclusive term, to include nations, governments, and specific regional regulatory efforts or bodies including EPA, REACH, Prop 65 and the like. I use AB to represent Authoritative Bodies. I also use the term "manufacturer" to represent the product producer, supplier, etc.

Question #3A.

(i) Should there be a de minimis exemption or not?

My answer is yes, and the level to be chosen that triggers an exemption should be one that has AB precedence developed through a scientific review process.

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

My answer is a combination. The baseline default level should be set at 0.1% because of the AB precedence for that level. Chemicals that should have a lower level can and should be based on current lower levels accepted by ABs. This can be done reasonably and there is sufficient scientific evidence to accept lower levels for certain chemicals. In the future, if the levels should be lowered further - which would automatically occur if AB levels are lowered, or new risk information emerges with scientific review, the "new" lower level would be initiated with public notice. Once the chemical lists and de minimis levels are set, exemptions would be in force for chemical levels below the de minimis level.

Chemicals that are to be considered for de minimis levels higher than the baseline 0.1%, should be proposed by petition from the manufacturer. Relevant information supporting the petition would include but not be limited to information on higher levels accepted by ABs.

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

My answer is to the product as a whole and to components that can be easily removed or replaced within the product. Under this opinion, I view a component as such to be a "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?

My answer is that it should be applied individually and only used (considered) in aggregate when there is clear scientific evidence that additivity, synergism, or antagonism will occur under the intended use or life. 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?

My answer is yes and the chemicals fall into the high potency carcinogens, compounds where linearized low-dose calculation methods are not appropriate, or compounds known to bioaccumulate and thereby presenting exposure levels above accepted de minimis levels. If these compounds are previously adjusted to lower de minimis levels via AB determinations, and the lower levels are 2 logs below the baseline 0.1% level, then manufacturers should file an exemption notification to DTSC.

(vi) Which of the following should the de minimis exemption apply to: unintentional, intentional, residuals.

My answer is that all intentionally added chemicals should be included in the de minimis regulations. It is my opinion 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". If an unintentionally added chemical, not known to be present by the manufacturer or previously considered to have been removed, is determined to be in the product by further testing - either by the manufacturer or a second party - and its presence becomes "known" to DTSC or to the manufacturer, it would therefore fall under the de minimis regulations.

#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?

My answer is yes, with a notification that 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.

#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)?
My answer was included in #3A (vi) above.

Thank you

Dale Johnson