

Topic #3 --- De Minimis Chemicals and Unintentionally-Added Chemicals

Statute:

- DTSC shall adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.
- The regulations shall establish an identification and prioritization process that includes, but is not limited to, all of the following considerations: (1) the volume of the chemical in commerce in this state; (2) the potential for exposure to the chemical in a consumer product; and (3) potential effects on sensitive subpopulations, including infants and children.
- DTSC shall develop criteria by which chemicals and their alternatives may be evaluated. These criteria shall include, but not be limited to, the traits, characteristics, and endpoints that are included in the clearinghouse data.
- DTSC shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes --- DTSC is not required to reference and use only the available information from these sources.
- DTSC shall adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.

See Attachment 3-1 for complete statutes that provide the mandate, authorities and scope for these regulations.

LIST OF ATTACHMENTS:

3-1 Statutes

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.
- (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?
 - 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?
- (iii) Should the de minimis level be applied to the product as a whole, or to each component of the 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?
- (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?
- (vi) Which of the following should the de minimis exemption apply to?
- Unintentional 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?

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?
 - 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.
- (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?