

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

CRITERIA AND PROCESS FOR PROVIDING AN EXEMPTION FROM THE ALTERNATIVES ASSESSMENT REQUIREMENTS FOR PRIORITY PRODUCTS THAT CONTAIN A PRIORITY CHEMICAL (PC) THAT IS: (I) ONLY PRESENT AT OR BELOW A "DE MINIMIS" LEVEL; AND/OR (II) IS AN "UNINTENTIONALLY-ADDED" OR "UNKNOWN" CHEMICAL.

Five Decision Points

- (1) De minimis level
- (2) Calculation of the concentration of a PC in a Priority Product
- (3) Limitation on allowance of exemption --- based on type of PC
- (4) Limitation on allowance of exemption --- based on source of PC
- (5) Exemption process

NOTE: The options presented on the following pages are intended to present DTSC's understanding of the primary suggestions offered by one or more members of GRSP Subcommittee #3. Members of the subcommittee or the GRSP may wish to offer variations on these options. These options do not represent DTSC's proposals or perspective on these issues.

1 --- DE MINIMIS LEVEL

Option 1A

- Default de minimis level = 0.1%
- DTSC may set a de minimis lower level (but no lower than the detection limit) --- based on levels specified or accepted by Authoritative Bodies (level would be subject to change, with public notice, based on new information)
- DTSC may set a higher de minimis level after receipt and consideration of a manufacturer's petition that includes supporting information

Option 1B

- DTSC shall specify the de minimis level (if any) for each Priority chemical/product combination when listing Priority Products, based on agreed upon risk levels and consideration of the following factors:
 - Inherent hazard traits
 - Exposures based on likely consumer uses
 - Exposure potential for sensitive subpopulations
 - Potential for cumulative exposures from multiple consumer products
 - Existing relevant regulatory thresholds
 - Detection limits
- DTSC shall consult with OEHHA in determining de minimis levels
- No default de minimis level

2 --- CALCULATION OF CONCENTRATION OF PC IN PRIORITY PRODUCT

Option 2A

PRODUCT

- Apply the de minimis concentration calculation to the product as a whole (unless the PC is in an externally-exposed component so as to present the potential for direct contact)

CHEMICALS

- Apply the de minimis concentration calculation separately to each individual PC in the Priority Product

Option 2B

PRODUCT

- *Formulated products* --- apply the de minimis concentration calculation to the product as a whole
- *Assembled products* --- apply the de minimis concentration calculation separately to each reasonably separable component

CHEMICALS

- Apply the de minimis concentration calculation separately to each individual PC in the Priority Product, **EXCEPT** apply to aggregate concentration of multiple PCs in the Priority Product where:
 - A relevant endpoint in an assay or test system is changed showing that additivity, synergism, or antagonism occurs when the PCs are in the test system together
 - Multiple PCs exhibit cumulative or synergist effects on a particular biological pathway or health endpoint
 - Multiple PCs are linked to the same of very similar adverse effects

3 --- LIMITATION ON ALLOWANCE OF EXEMPTION --- BASED ON TYPE OF PC

Option 3A

- De minimis exemption allowed for all PCs

Option 3B

- No de minimis exemption, or alternatively a DTSC-specified lower de minimis level if that level is at least 2 logarithms below 0.1%, for:
 - High potency carcinogens
 - Compounds for which linearized low-dose calculation methods are not appropriate
 - Compounds known to bioaccumulate, thus presenting cumulative exposure levels above the established de minimis level

Option 3C

- No de minimis exemption for CMRs, PBTs and endocrine disruptors, **EXCEPT** manufacturers may submit for DTSC consideration documentation that the PC is present below a “safe” de minimis level AND cannot reasonably be removed from the Priority Product
- The manufacturer bears the burden of proof

4 --- LIMITATION ON ALLOWANCE OF EXEMPTION --- BASED ON SOURCE OF PC

Option 4A

- No alternatives assessment is required if the PC is not known by the manufacturer to be present in the Priority Product above the de minimis level
- Presence of the PC in the Priority Product above the de minimis level is considered to be “known” if EITHER of the following apply:
 - 1) The PC is included as an ingredient above the de minimis level in the Priority Product recipe; OR
 - 2) The manufacturer has other “credible information” (e.g., testing, calculations, public third-party analysis, information from other manufacturers) that the PC is present in the Priority Product above the de minimis level
- If a PC is not known to be present in the Priority Product above the de minimis level, or was previously considered to have been removed from the Priority Product, an alternatives assessment will be required if the PC is later determined by testing to be present above the de minimis level and this information becomes known to the manufacturer

4 --- LIMITATION ON ALLOWANCE OF EXEMPTION --- BASED ON SOURCE OF PC (con't)

Option 4B

- No alternatives assessment is required, if a de minimis level has been set for the PC / Priority Product, and BOTH of the following apply:
 - 1) The PC is not present in the Priority Product above the de minimis level;
AND
 - 2) The PC does not contribute functionally or performance-wise to the Priority Product, but one of the following applies:
 - The PC is a known / expected contaminant and cannot reasonably be removed,
 - The PC is a residual reagent or other chemical (e.g., process solvents, catalysts, intermediates, unreacted monomers, byproducts) that cannot reasonably be removed, but that is critical to the acquisition or production of another PC that does serve a functional or performance purpose in the Priority Product,
 - The source of the PC is recycled content (if the PC concentration in the Priority Product does not exceed the concentration in the recycled content), or
 - The source of the PC is a naturally-occurring material or the source is air or water used as a processing aid or an ingredient (if the PC concentration in the Priority Product does not exceed background)
- The manufacturer has a “duty of reasonable investigation”:
 - Chemical analysis if there is any basis to expect the PC, or
 - The Priority Product may be presumed (subject to rebuttable by DTSC or another party) to not contain the PC above the de minimis level if there are strong arguments for why this would be very unlikely

5 --- EXEMPTION PROCESS

Option 5A

- Exemption is self-implementing by the manufacturer, but the manufacturer must provide documentation to DTSC upon request

Option 5B

- The manufacturer must provide a notification to DTSC identifying those PCs present in the Priority Product at or below the de minimis level
- No DTSC approval required, **UNLESS** DTSC has specified a de minimis level below 0.1% --- in this case, the notification to DTSC must include supporting documentation **AND** DTSC approval is required

Option 5C

- Manufacturer must notification and supporting documentation to DTSC
- Manufacturer must demonstrate that they can (and will continue to) meet the criteria, assumptions, and conditions that are the bases for the exemption
- Manufacturer bears the burden of proof to demonstrate that the PC is below the specified de minimis level, and will cause no potential threat to human health or the environment, taking into account cumulative / aggregate exposures
- DTSC approval required **UNLESS** the manufacturer's notification and all supporting documentation is made publicly available by the manufacturer and/or DTSC (if there is no CBI claim) **AND** DTSC does not take action disapproving the exemption --- Any person may submit a petition (with supporting documentation) to DTSC asking DTSC to disapprove the exemption