

June 23, 2017

Kerri Malinowski
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333

Via Electronic Message

Re: Petition requesting revision of Maine's Chemicals of Concern List

Dear Ms. Malinowski:

The undersigned organizations are writing in opposition to the American Chemistry Council's petition to revise Maine's chemicals of concern list created under Department of Environmental Protection Regulations, Chapter 880 "REGULATION OF CHEMICAL USE IN CHILDREN'S PRODUCTS," to remove the listings for decamethylcyclopentasiloxane (D5), dodecamethylcyclohexasiloxane (D6), and octamethyltrisiloxane (L3).

The Environmental Health Strategy Center is a Maine-based public interest organization with offices in both Bangor and Portland, working to ensure that all people are healthy and thriving in a healthy economy, through affordable access to safer food, water, and products; and investments that create and retain good, green jobs.

The eleven additional organizations joining this comment, identified under the signature line, represent a diverse range of public health and environmental organizations from across our state.

Statutory and Regulatory Requirements

38 M.R.S. § 1693(1) establishes the criteria for a chemical to be included on the state's list of chemicals of concern:

...A chemical may be included on the list only if it has been identified by an authoritative governmental entity on the basis of credible scientific evidence as being:

A. A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;

B. Persistent, bioaccumulative and toxic; or

C. Very persistent and very bioaccumulative.

The statute as quoted above plainly provides three criteria to be met for inclusion on the list: 1) Identification by an authoritative governmental entity, 2) use of credible scientific evidence as the basis of the decision by the authoritative governmental entity, and 3) classification in one of the three listed hazard types.

“Authoritative governmental entity” and the meaning of the various classifications of hazards is defined neither in the statute nor in the Department’s implementing regulations.¹ The second factor, “Credible scientific evidence” is further defined at 38 M.R.S. § 1691(8a):

“Credible scientific evidence” means the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency, including but not limited to the United States Department of Health and Human Services, National Toxicology Program, Food and Drug Administration and Centers for Disease Control and Prevention; the United States Environmental Protection Agency; the World Health Organization; and the European Union, European Chemicals Agency.

It therefore must be assumed that the first criteria of being listed by an authoritative governmental entity is unrestricted, meaning that the findings of both state and national governments should be considered, so long as they meet the second criteria of being based on credible evidence. The fact that the statutory definition of “authoritative governmental entity” includes state or other non-federal and non-international governments is supported in the statute’s definition of “credible scientific evidence.” This definition modifies the generic “authoritative governmental agency” with additional descriptors of “federal or international” for the purposes of that definition. If “authoritative governmental agency” already excluded state agencies, then the addition of “federal or international” would not be necessary. Further, it must be presumed that the definition of the specific classification of hazards must follow those as determined by the “authoritative governmental agency.” This reading is also consistent with the clear statutory construct of creating a broad list of chemicals of concern, which will be further narrowed to a list of high concern and ultimately priority chemicals.

In order to be removed from the list of chemicals of concern, under 38 M.R.S. § 1693, a petitioner must demonstrate that the chemical should not be listed under the §1693(1) criteria cited above, or that the chemical is not used in covered consumer products in accordance with §1693(2). In their petition requesting the delisting, the American Chemistry Council (ACC) makes no claim that D5, D6, or L3 are exempt under the §1693(2) criteria. Indeed, they specifically note that all three chemicals are used in consumer products.² Therefore, the only question before the Department is whether or not these three chemicals meet the criteria of §1693(1).

¹ Chapter 880: REGULATION OF CHEMICAL USE IN CHILDREN’S PRODUCTS. At <http://www.maine.gov/sos/cec/rules/06/096/096c880.doc>

² “D5, D6 and L3 are used in a variety of consumer and industrial products... including automotive, health care, aerospace, personal care, electronics, and construction.” ACC. “Petition to Remove Silicone Substances D5, D6 and L3 from the Maine Kid’s Safe Products Act Chemicals of Concern List.” P. 8 at <http://www.maine.gov/tools/whatsnew/attach.php?id=754702&an=1>

Inclusion on State of California's Chemicals of Concern List

The State of California's Department of Toxic Substances Control's (DTSC) maintains a "Candidate Chemical List" on the basis of "authoritative lists" created by others.³ D5,⁴ D6,⁵ and L3⁶ are all included on the DTSC Candidate Chemical List.

DTSC has identified all three chemicals as having persistent, bioaccumulative and toxic (PBT) traits on the basis of the same Canadian list as Maine. However, DTSC **additionally** identifies D5 and D6 as having traits as of "[a] carcinogen, a reproductive or developmental toxicant or an endocrine disruptor." In the case of D5, DTSC has identified it as having traits of carcinogenicity and reproductive toxicity.⁴ In the case of D6, DTSC has identified it as having endocrine and reproductive toxicities.⁵

Therefore, it is clear that D5 and D6 meet the first and third hurdles of the Maine statute – a governmental entity in the form of the State of California has identified them as having carcinogenic, reproductive and/or endocrine impacts. Therefore, the remaining question is whether or not DTSC's inclusion of D5 and D6 are based on credible scientific evidence.

The authoritative list cited by DTSC for these traits of D5 and D6 is the California Environmental Contaminant Biomonitoring Program's (CECBP) list of Priority Chemicals. The specific rationale for inclusion of D5 and D6 in this program is outlined in a CECBP report.⁷ This report references other governmental studies of the health impacts of D5⁸ and D6⁹, which in turn are based upon findings from peer-reviewed papers published in peer-reviewed journals. This meets the Maine statute criteria that the evaluation must include "...the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal."

³ See <http://www.dtsc.ca.gov/SCP/CandidateChemicalsList.cfm> for general information on the DTSC Candidate Chemicals List and <http://www.dtsc.ca.gov/SCP/SourceLists.cfm> for details on the specific authoritative lists.

⁴ "Decamethylcyclopentasiloxane" at <https://calsafer.dtsc.ca.gov/chemical/ChemicalDetail.aspx?chemid=21353>

⁵ "Dodecamethylcyclohexasiloxane (D6)" at <https://calsafer.dtsc.ca.gov/chemical/ChemicalDetail.aspx?chemid=21352>

⁶ "Trisiloxane, octamethyl-" at <https://calsafer.dtsc.ca.gov/chemical/ChemicalDetail.aspx?chemid=20536>

⁷ CECBP 2008. "Cyclosiloxanes." Available at <http://biomonitoring.ca.gov/sites/default/files/downloads/1208cyclosiloxanes.pdf>

⁸ OEHHA (2007). Toxicity Data Review: Decamethylcyclopentasiloxane (D5). September 13, 2007. Available at <http://www.arb.ca.gov/toxics/dryclean/oehhad5review.pdf>

⁹ Environment Canada. 2008. Draft Screening Assessment for the Challenge Dodecamethylcyclohexasiloxane (D6). Chemical Abstracts Service Registry Number 540-97-6. Available at: https://www.ec.gc.ca/ese-ees/FC0D11E7-DB34-41AA-B1B3-E66EFD8813F1/batch2_540-97-6_en.pdf

European Regulation

The European Chemicals Agency (ECHA) oversees the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) legislation in the EU.

In a 2016 report recommending the restriction of D5 under REACH, and relying on a number of previous reports, ECHA identified D5 as very persistent and very bioaccumulative (vPvB).¹⁰ This report is based on studies meeting the criteria for credible scientific evidence. Although the regulatory restrictions are still in the process of being implemented, that element is not required under Maine statute for a chemical to be included on the chemicals of concern list.

In a recent 2017 report, ECHA is requesting that the registrant for the chemical L3 update the chemical safety report for the chemical due to concerns that L3 is PBT and vPvB.¹¹ The United Kingdom, as the Member State Competent Authority, determined the L3 meets the criteria for T as well as for vB or B, and is seeking additional information to determine if it can be classified as vP or P. Specifically, the report notes that, "Overall, ECHA concludes that the available evidence suggests that L3 screens as P and vP, but there is insufficient evidence to show conclusively that the substance is not P/vP in any compartment."

Conclusions

Although the petition to delist D5, D6, and L3 documents that the original Canadian classifications Maine based their inclusion on may have been changed, this alone is insufficient reason under statute for the chemicals to be removed from the chemicals of concern list. The Department must determine that the statutory criteria for inclusion are no longer met, namely that the chemicals have not been identified as having one of the three hazardous traits by another governmental entity using credible scientific evidence.

D5 has been determined on credible scientific evidence as being a carcinogen and having reproductive toxicity by the State of California. It has also been identified as very persistent and very bioaccumulative by the European Union. The Department should also consider the State of Oregon's finding of D5 as a Tier 1 "Priority Persistent Pollutant."¹²

D6 has been determined on credible scientific evidence as having reproductive and endocrine toxicity by the State of California.

¹⁰ European Chemicals Agency. (2016). *Background Document for the Committee for Risk Assessment and Committee for Socio-economic Analysis*. Retrieved from

<https://echa.europa.eu/documents/10162/23cd6eda-688d-44ea-99b0-a254a8f83ba5>

¹¹ European Chemicals Agency. (2017). *Decision on Substance Evaluation: Octamethyltrisiloxane*.

Retrieved from <https://echa.europa.eu/documents/10162/ba74ee45-9c32-f2ee-4bea-7b0b6e6a52f9>

¹² List available at <http://www.deq.state.or.us/wq/SB737/docs/LegRpAtt20100601.pdf>

L3 has been determined by the EU as being toxic, bioaccumulative, and that it screens as persistent. While it is waiting additional information before making a final determination of very persistent or persistent status, this finding should be adequate evidence, along with the continued presence of L3 on California's Candidate Chemical List, to maintain L3 on Maine's list.

Thank you for your time and attention to this matter. If you have any questions as to the information we have provided, please contact Patrick MacRoy of the Environmental Health Strategy Center at 207-699-5796 or pmacroy@ourhealthyfuture.org

Sincerely,



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