July 27, 2023

RE: Comments on the DTSC Proposed Addition of Microplastics to the Candidate Chemicals List, *ID No. #12767*

Submitted via CalSAFER, https://calsafer.dtsc.ca.gov/workflows/comment/

We welcome the opportunity to comment on the proposal[1] by the Department of Toxic Substances Control (DTSC) to add microplastics to the Candidate Chemicals List under the Safer Consumer Products Program (SCPP). We offer comments on all elements of the report, including (1) whether microplastics meet the definition of a "chemical"; (2) the potential hazard, toxicological, or environmental endpoints that are the basis for listing, and (3) the definition of microplastics. We note several general comments followed by specific comments on the report.

General Comments

We believe additional research is needed to improve our understanding of microplastic sources, pathways, fates, and impacts in the environment. Microplastic research is challenging due to a lack of standardized definitions and research methods used by the scientific community and the complex nature of microplastics in the environment. Industry scientists are committed to

[1] The proposal is available at https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/04/Background-Document-Proposal-to-Add-Microplastics-to-the-Candidate-Chemical-List_May272023.pdf. Information about the proposal is available at https://dtsc.ca.gov/scp/candidate-chemical-list_microplastics/.

increasing science-based knowledge on microplastics and are delivering on this commitment by leading key research on microplastics. For example, the American Chemistry Council (ACC)[2] Microplastics Research Consortium is coordinating global microplastic research with the International Council of Chemical Associations (ICCA). Through ICCA, the chemical industry is reaching out to researchers all over the globe to advance discussions and move fundamental science and research forward.

Specific Comments

1. **Microplastics Do Not Meet the Definition of "Chemical" Under the Safer Consumer Products ('SCP') Regulation of Priority Products and Are Not Eligible for Listing on The Candidate Chemicals List ('CCL') Chemicals**

On April 27, the California Department of Toxic Substances Control (DTSC) proposed adding microplastics to its Candidate Chemicals List (CCL).[3]

The proposal would define "microplastics" to mean:

> solid polymeric materials to which chemical additives or other substances may have been added, which are particles having at least three dimensions that are less than 5,000 micrometers (μm). Polymers derived in nature that have not been chemically modified (other than by hydrolysis) are excluded.[4]

That definition encompasses all plastics that have a particle size of 5 mm or less. A listing of "all plastics" having a particular particle size does meet the definition of "chemical" in the SCPP regulations.

"Microplastics," however, are not a chemical, or even a group of chemicals. It is well known that microplastics are not a discrete well-defined substance but rather a variable mixture of particles and fibers that is context dependent. The World Health Organization WHO (2022) describes microplastics as "a heterogeneous mixture of particles and fibres of various shapes, sizes, polymer composition, surface chemistry and associated chemicals." They also report that this the "properties and composition of NMP change during their life cycle in the environment."[5]

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[2] ACC represents the leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health, safety, and security performance through Responsible Care®; common sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes, and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.

[3] Candidate Chemical List. https://dtsc.ca.gov/scp/candidate-chemicals-list/

[4] DTSC Proposal at 2.

[5] World Health Organization. (2022). Dietary and inhalation exposure to nano- and microplastic particles and potential implications for human health. https://www.who.int/publications/i/item/9789240054608.

DTSC's Green Ribbon Science Panel takes the position that, "[to] add microplastics as a "chemical" for the purposes of SCP's regulatory framework, it would be necessary to develop a definition around the particle size, polymer type, shape, and/or other properties and to identify one or more hazard traits and endpoints shared by all particles that meet this definition."[6] It acknowledges, however, that "pure polymers" or polymetric chemical substances, while meeting the definition of "chemical" under the SCP, might not satisfy hazard criteria: "[w]hile it may be possible to identify a plastic polymer as a Chemical of Concern, based on its potential to degrade and subsequently form microplastics, defining the polymer as a Candidate Chemical based solely on the hazard traits of its degradants could pose challenges."[7]

Importantly, the enacting statute requires two important threshold elements that are not met: a covered chemical in a covered consumer product.

Microplastics Are Not Discrete Chemical Substance And Cannot Be Listed As A Candidate Chemical under the SCPP

In 2008, the State of California passed two new laws to begin implementation of a green chemistry program. The first, AB 1879 (Feuer, Chapter 559, Statutes of 2008) mandates that a regulatory process be established for identifying and prioritizing **chemicals of concern in consumer products** and to create methods for analyzing alternatives to existing hazardous chemicals. Out of this, DTSC's Safer Consumer Products program was developed.[8] [emphasis added]

The recital to AB 1879 says "This bill would require the department by January 1, 2011, to adopt regulations to establish a process by which chemicals or chemical ingredients in products may be identified and prioritized for consideration as being chemicals of concern." [emphasis added][9]

Those regulations that implement the SCPP, codified at Cal. Health & Safety Code § 25251 et seq. Section 25252(a) directs DTSC to "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 statute does not define the term "chemical," but DTSC has defined it in 22 Cal. Code Regs. § 69501.1(a)(20)(A) as follows:

> "Chemical" means either of the following:
> 1. An organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any

[6] Green Ribbon Science Panel Background Document: Microplastics, November 2021, available at https://dtsc.ca.gov/wp-content/uploads/sites/31/2021/10/Fall-2021_GRSP-Background-Document_accessible.pdf
[7] *Id.*
[8] Green Chemistry | Department of Toxic Substances Control (ca.gov). https://dtsc.ca.gov/dtsc-website-archive/green-chemistry/
[9] https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/01/ab_1879_GCI.pdf

> degradate, metabolite, or reaction product of a substance with a particular molecular identity; or
> 2. A chemical ingredient, which means a substance comprising one or more substances described in subparagraph 1.

Most of paragraph 1 of DTSC's definition of "chemical" is derived from the definition of "chemical substance" in section 3(2)(A) of the federal Toxic Substances Control Act (TSCA), which provides in part:

> Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—
> (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
> (ii) any element or uncombined radical.[10]

Notably, the TSCA definition expressly excludes mixtures.[11] TSCA § 3(2)(B) provides that the term "chemical substance" "does not include – (i) any mixture …." TSCA § 3(10) defines "mixture" to mean:

> any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.[12]

The references in TSCA § 3(2) and in the SCPP definition of "chemical" to "substances occurring in whole or in part as a result of a chemical reaction or occurring in nature" is to what EPA characterizes as UVCBs, i.e., Unknown or Variable compositions, Complex reaction products and Biological materials.[13]

By contrast, "solid polymeric materials" having a particular particle size are not UVCBs. They are mixtures, i.e., combinations of two or more chemicals (specific polymers, additives, impurities, and byproducts). They are not the result of a chemical reaction, as plastics are made by compounding additives into polymer resins. Thus, they qualify as mixtures, not chemicals for purposes of the SCPP regulations. As mixtures, they are not eligible for addition to the

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[10] 15 U.S.C. § 2602(2)(A).
[11] *Id.* § 2602(2)(B)(i).
[12] *Id.* § 2602(10).
[13] EPA, Toxic Substances Control Act Inventory Representation for Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials: UVCB Substances (1995), https://www.epa.gov/sites/default/files/2015-05/documents/uvcb.pdf.

Candidate Chemicals List.

Nevertheless, DTSC has asserted that solid plastics of a particular particle size are "chemicals" by saying:

> The regulations specify that "molecular identity" may be described in terms of a substance's particle size, size distribution, and surface area. DTSC is basing its proposed definition for MPs (see below) on the polymeric structure and size distribution (< 5,000 microns) of MPs.

Certainly, any particular chemical does have a molecular identity. But plastics of a certain particle size lack a molecular identity, as they are a loosely-defined category of materials which may differ from each other in many respects. DTSC is not proposing to add any particular chemical to the Candidate Chemicals List. Instead, it is proposing to add potentially tens of thousands of different combinations of individual chemicals (such as polymers, additives, impurities, and byproducts) when they form plastic which at some point breaks down or degrades to a particular particle size. The concept of molecular identity has no application to microplastics.

DTSC's definition of "molecular identity" in § 69501.1(a)(20)(B) provides:

"Molecular identity" means the substance's properties listed below:

1. Agglomeration state;
2. Bulk density;
3. Chemical composition, including surface coating;
4. Crystal structure;
5. Dispersability;
6. Molecular structure;
7. Particle density;
8. Particle size, size distribution, and surface area;
9. Physical form and shape, at room temperature and pressure;
10. Physiochemical properties;
11. Porosity;
12. Solubility in water and biologically relevant fluids;
13. Surface charge; and
14. Surface reactivity.

DTSC asserts that plastics of a particular particle size have a "molecular identity" due to their "polymeric structure" and "size distribution."[14] Polymeric structure, however, is not one of the listed properties in DTSC's regulation that defines chemical's "molecular identity." It is not part of "chemical composition" (property 3), which specifies the identity, arrangement, and ratio of

[14] DTSC Proposal at 1.

the chemical elements making up a compound by way of chemical and atomic bonds.[15] Chemical composition, which is often described using molecular formulas (e.g., H_20), is unique to particular compounds; it is inapplicable to broad categories such as plastics of a particular particle size. "Polymeric structure" is not covered by "molecular structure" (property 6) either. Molecular structure refers to the location of the atoms, groups or ions relative to one another in a molecule, as well as the number and location of chemical bonds.[16] Like chemical composition, molecular structure, too, is specific to individual substances; it does not apply to broad descriptions such as "polymeric."

Only materials meeting the definition of "chemical" in § 69501.1(a)(20)(A) are eligible for listing as candidate chemicals. The SCPP regulations in § 69501.1(a)(19) define "candidate chemical" to mean "a **chemical** that is a candidate for designation as a Chemical of Concern, and that is identified as a Candidate Chemical under section 69502.2" (emphasis added). Section 69502.2(a) provides:

> a **chemical** is identified as a Candidate Chemical if it exhibits a hazard trait and/or an environmental or toxicological endpoint, and meets one or both of the following criteria…

(Emphasis added.) Since plastic materials of a particular particle size do not qualify as "chemicals," DTSC may not add "microplastics" to the Candidate Chemicals List.

"Microplastics Are Not A Covered "Consumer Product"

"Microplastics" are also not a covered "consumer product" under the governing statute. Under the statute, "consumer product" is defined to mean "a product or part of the product that is used, bought, or leased for use by a person for any purposes." (Health & Saf. Code, § 25251, subd. (e).) The definition then excludes any "dangerous drug or dangerous device" under section 4022 of the Business and Professions Code, "[d]ental restorative materials" under section 1648.20, subdivision (b) of the same code, any "device" as defined in section 4023 of the same code, any "food" as defined in section 109935, subdivision (a) of the Health and Safety Code, the packaging associated with several of these products, and any "pesticide" as defined under a certain federal law. (Health & Saf. Code, § 25251, subd. (e)(1)–(6).)

Under Health & Saf. Code § 109935. "Food" means either of the following: (a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.

DTSC's Green Ribbon Science Panel report observes that, at least with respect to secondary

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[15] See, e.g., https://chem.libretexts.org/Courses/College_of_Marin/CHEM_114%3A_Introductory_Chemistry/06%3A_Chemical_Composition; https://byjus.com/chemistry/chemical-and-its-composition/; https://www.reagent.co.uk/blog/what-is-chemical-composition-in-chemistry/.

[16] See, e.g., http://www.chem.ucla.edu/~harding/IGOC/M/molecular_structure.html.

microplastics, "[b]y definition, secondary microplastics are not present in consumer products when they are sold or distributed in California."[17]

2.0 Microplastics Have Not Be Demonstrated to Cause Unreasonable Harm To Health or the Environment

Candidate Chemicals to our knowledge have exclusively been identified based upon hazard properties of chemicals through an authoritative body mechanism. These include chemicals with one or more of the following properties: carcinogenicity, reproductive toxicity, developmental toxicity, mutagenicity, endocrine disruption, neurotoxicity, PBT, vPvB, respiratory sensitization. No authoritative body to date has concluded that microplastics pose a health hazard to consumers. In fact WHO (2022) concluded that "the limited data provide little evidence that microplastics have adverse effects in humans."[18] Other groups have communicated a lack of human health risk.

Peer reviewed literature and media reports have reported that microplastic particles appear to be ubiquitous in the environment. However, the mere presence of microplastics does not necessarily mean they are intrinsically hazardous or that they present an unacceptable risk to the environment or to human health at current concentrations. Microplastic complexity (e.g., heterogeneity of size, shape, chemical composition, etc.) has led to some unsubstantiated statements that are refuted by the current data. For example, ECHA alleged:

> "…that human and ecological exceedances of risk "may be considered in terms of when, rather than if" and recommends microplastics be treated as "non-threshold substances" for the purposes of risk assessment – with any released to the environment assumed to result in risk."[19]

Current scientific information on potential microplastics hazards and our understanding of biological mechanisms do not support this type of allegation.[20] For example, two recent studies reported no adverse effects to fish growth or reproduction when exposed to microfiber concentrations up to three times those typically seen in the environment.[21,22] Two studies are

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[17] *Id.*
[18] WHO (2022).
[19] ECHA. (2020). Committee for Risk Assessment (RAC) & Committee for Socio-economic Analysis (SEAC): Opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics. https://echa.europa.eu/documents/10162/23665416/rest_microplastics_opinion_rac_16339_en.pdf/b4d383cd-24fc-82e9-cccf-6d9f66ee9089
[20] Koelmans, AA et al. (2022). Risk assessment of microplastic particles. *Nat Rev Mater*. 7:138–152. https://doi.org/10.1038/s41578-021-00411-y
[21]Bunge et al. (2021). Exposure to microplastic fibers does not change fish early life stage development of three-spined sticklebacks (*Gasterosteus aculeatus*). *Microplastics and Nanoplastics*. 1:15. https://doi.org/10.1186/s43591-021-00015-x
[22] Bunge et al. (2022). Less impact than suspected: Dietary exposure of three-spined sticklebacks to microplastic fibers does not affect their body condition and immune parameters. *Science of the Total Environment*. 819: 153077. https://www.sciencedirect.com/science/article/abs/pii/S004896972200167X?via%3Dihub

insufficient to draw conclusions on potential risks from microplastics and likewise so is ECHA's unsupported assumptions and general statements about microplastic toxicity.

Physical Hazard Characteristics

The study of microplastics is a relatively new field and offers several unique challenges to researchers and risk assessors. Interactions with the surrounding environment may result in the formation of secondary microplastics in a process referred to as "weathering." The modifications produced by these interactions are complex, and may impact fate, transport, uptake, and responses. These environmentally relevant microplastics may have different physical and chemical (e.g., physicochemical) properties that can influence both hazards and risks. Therefore, it is imperative that primary (e.g., virgin) and secondary (i.e., weathered) microplastics be appropriately defined and characterized. A risk assessment framework proposed by Koelmans et al. (2022), illustrates that there are several factors that should be considered when determining the potential hazards and ultimately risks of microplastics. To assess for these physicochemical variables without making artificial categories, it is critical to determine what propert(ies) may pose a risk to health or the environment.[23]

Microplastics have a number of physical properties that may exert toxicity in the environment or to human health. The size, shape, density, surface characteristics, and quantity may all play a role in potential toxicity. This is especially true for aquatic organisms, which have been more extensively studied than other organisms.

Ecotoxicology studies on microplastics report conflicting observations, even for the same endpoint in the same species.[24] Potential effect mechanisms, include food dilution (inhibited food assimilation or decreased nutritional value); internal physical damage; external physical damage; and with much lower certainty, oxidative stress.[25,26,27] However, the quality of ecological effects studies and the weight of evidence for ecological effects are limited.[28] This conclusion was also reached by the Science Advice for Policy by European Academies (SAPEA) in 2019, which noted "The working group concludes from this evidence that, while ecological risks are very rare at present for NMPs (plastics of sizes below 5mm), there are at least some locations in coastal waters and sediments where ecological risks might currently exist."[29]

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[23] Koelmans, et al. (2022).
[24] Environment and Climate Change Canada and Health Canada. (2020). Science assessment of plastic pollution. https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/science-assessment-plastic-pollution.html
[25] de Ruijter VN et al. (2020). Quality criteria for microplastic effect studies in the context of risk assessment: a critical review. *Environ. Sci. Technol*. 54: 11692–11705.
[26] Bucci, K et al. (2020). What is known and unknown about the effects of plastic pollution: a meta- analysis and systematic review. *Ecol. Appl*. 30: e02044.
[27] de Ruijter VN et al. (2020). Quality criteria for microplastic effect studies in the context of risk assessment: a critical review. *Environ. Sci. Technol*. 54: 11692–11705.
[28] Id.
[29] Science Advice for Policy by European Academies (SAPEA). (2019). A Scientific Perspective on Microplastics in Nature and Society. Berlin: SAPEA. https://doi.org/10.26356/microplastics.

Most recently the California State Water Resources Control Board's (State Water Board) published its draft California Integrated Report on Surface Water Quality Assessment ('Report'). The Report that proposes to classify a number of waterbodies as Category 2 or Category 3 to meet the US Clean Water Act section 305(b) requirement of reporting on water quality conditions.[30] Critical to note is this categorization does not result in the listing of these waterbodies as impaired but does require additional information to be develop *because there is insufficient data available to make a determination whether an impairment is present*. As with many other regulatory bodies, California is unable to make a determination on the hazards and risks of microplastics to the environment with the available data because of its poor quality.

The data regarding the potential risks of microplastic exposure to human health is even more uncertain. In Gouin et al. (2022), the authors used a microplastic toxicity screening assessment tool they developed to compare and evaluated 74 studies *in vivo* and *in vitro* studies against quality assurance and quality control (QA/QC) criteria.[31] The majority of these studies primarily used spherical, monodisperse particles (~60% or 43/74) comprised of polystyrene (~46% or 34/74); very few studies examined microplastic fibers. The median particle size tested was 2.2 μm and 0.5 μm for both *in vivo* and *in vitro* effect studies, respectively. After comparing these studies to the QA/QC criteria, only 10 ingestion and 2 inhalation studies met the inclusion criteria to be deemed suitable for use in a risk assessment. Given most of these studies used materials (i.e., a single type, size, and shape) that are not representative of the heterogenous mixtures found in the environment, it is challenging to extrapolate the experimental results into a measurement for potential human health risks.

The World Health Organization used independent experts to systematically review the potential human toxicity of microplastics in drinking water and through dietary and inhalation exposure.[32,33] For drinking water, the WHO concluded:

> "Based on the limited evidence available, chemicals and biofilms associated with microplastics in drinking-water pose a low concern for human health. Although there is insufficient information to draw firm conclusions on the toxicity related to the physical hazard of plastic particles, particularly for the nano-size particles, no reliable information suggests it is a concern."

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[30] California State Water Resources Control Board. (2023). Draft Staff Report for the 2024 California Integrated Report: Surface Water Quality Assessments to comply with Clean Water Act 303(d) List and 305(b) Report. https://www.waterboards.ca.gov/water_issues/programs/water_quality_assessment/2024_integrated_report/draft-2024-IR-staff-report.pdf

[31] Gouin, T et al. (2022). Screening and prioritization of nano- and microplastic particle toxicity studies for evaluating human health risks – development and application of a toxicity study assessment tool. *Micropl. & Nanopl*. 2:2. https://doi.org/10.1186/s43591-021-00023-x

[32] World Health Organization (WHO). (2022). Dietary and inhalation exposure to nano- and microplastic particles and potential implications for human health. 30 August 2022. ISBN: 978-92-4-005460-8. https://www.who.int/publications/i/item/9789240054608

[33] World Health Organization (WHO). (2019). Microplastics in drinking-water. ISBN: 978-92-4-151619-8. https://www.who.int/publications/i/item/9789241516198

Similarly, the WHO concluded for exposure to microplastics through dietary ingestion or through inhalation exposure:

> "The weight of the scientific evidence provided by current data on adverse effects of NMP on human health is low, because of substantial limitations of the available information."
>
> and
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> "The assessment scores indicated that the available data are of only very limited use for assessing the risk of NMP to human health."

It is important to note that a number of systematic reviews conducted by regulatory agencies all reached similar conclusions; the current data on microplastic toxicity is highly uncertain and further information is necessary to conclude on the potential hazards and risks of microplastics to the environment and human health.[34,35,36,37]

Using Persistence as the Basis for the Proposed Listing of "Microplastics" is Arbitrary and Ignores the (Bio)Degradation Differences in Polymers

California defines persistence as, "the propensity for *a chemical substance* to remain in the environment for a long time period subsequent to its release by resisting chemical and biological degradation."[38] The statute goes on to list potential lines of evidence that demonstrate "persistence." Some of these are based in science with numerical values that could be tested (i.e., half-lives in various environmental compartments, although no testing protocols are specified) and some of these are arbitrary and open to interpretation (i.e., identified by an "authoritative organization" and "resistance to degradation in wastewater treatment processes").However, this definition ignores the point that whether a microplastic will be persistent is based on its structure.[39] Regardless, typical methods to assess persistence cannot be used because they were not developed for polymetric materials and "microplastics" as defined by DTSC, encompasses so many polymers and natural materials where some will be classified as persistent while other will

[34] U.S. Interagency Marine Debris Coordinating Committee (US IMDCC). (2022). Draft Report on Microfiber Pollution. https://marinedebris.noaa.gov/interagency-marine-debris-coordinating-committee-reports/report-microfiber-pollution.
[35] European Food Safety Authority (2016). EFSA Journal. 14(6):4501. DOI: https://doi.org/10.2903/j.efsa.2016.450.
[36] European Food Safety Authority (2021). EFSA Journal 2021;18(8):EN-6815. DOI: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2021.EN-6815.
[37] Environment and Climate Change Canada and Health Canada. (2020). ISBN 978-0-660-35897-0. Cat. No.: En14-424/2020E-PDF. https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/science-assessment-plastic-pollution.html.
[38] See Cal. Code Regs. tit. 22, section 69405.3.
[39] Kim JR, et al. (2023). Exploring structure-activity relationships for polymer biodegradability by microorganisms. Sci Total Environ. Sep 10;890:164338. doi: 10.1016/j.scitotenv.2023.164338. Epub 2023 May 19. PMID: 37211122.

not.[40]

The criteria to determine persistence are not appropriate (i.e., "out of the domain of applicability of an assay or a model") for microplastics.[41] These criteria were developed using a set of discrete bioavailable substances, mainly organochlorine chemistry. Since polymer chemistries were not used in their initial development, it is scientifically inappropriate to use the proposed criteria in this instance. In addition to being out of domain, there are a number of practical considerations unique to microplastics and polymers. The (bio)degradation criteria that are used to define persistence must be technically feasible, focus on the most relevant compartment pathways for degradation, and adapted to polymers. Persistence in one compartment does not mean a substance will accumulate in the environment overall; a holistic assessment should be used to determine whether there is accumulation.[42,43]

In a research project initiated by CEFIC LRI and conducted at Fraunhofer, scientists evaluated the persistence assessment of polymeric and other materials.[44] The project investigated aims to offer practical guidance that will improve robustness, consistency and predictability of persistence assessments in chemical regulation. One investigation pieced together similarities and differences in degradation behavior of natural and synthetic polymers.[45] Natural polymers like natural rubber, cellulose, hemicellulose, etc. are part of any natural environment, and the release or occurrence of these substances is not regarded as problematic. However, applying regulatory persistence criteria, e.g. from REACH Annex XIII would flag many of these natural polymers as persistent or even very persistent. While polymers derived in nature that have not been chemically modified (other than by hydrolysis) are excluded from the DTSC definition, it is clear that the guidance from using metrics of measuring persistence alone would not include or exclude the appropriate polymers. Persistency in nature can reflect the need of biological organisms for resilient material, for example protecting the organism from external influences.

Biodegradable materials will be an important, if not the substitute for many applications of intentionally added microplastics. Innovation in this area must therefore be safeguarded. With their versatility, polymers offer functionalities enabling many aspects of our modern life. Synthetic polymers can be tailored to the needs of individual applications. Any criteria for

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[40] As an example, poly(3-hydroxybutyrate-co-3-hydroxyvalerate (PHBV) was found to biodegrade in freshwater, marine and activated sludge using a modified OECD 301/310 protocol. McDonough, KNR, et al. (2017). Assessing the biodegradability of microparticles disposed down the drain', Chemosphere, 175: 452-58.
[41] Albright III, V and Y. Chai. (2021). Knowledge Gaps in Polymer Biodegradation Research. Environ. Sci. Technol. 55, 17, 11476–11488. https://pubs.acs.org/doi/10.1021/acs.est.1c00994
[42] Redman, A, et al. Moving persistence assessments into the 21st century: A role for weight-of-evidence and overall persistence. Integr Environ Assess Manag. 2022 Jun;18(4):868-887. doi: 10.1002/ieam.4548.
[43] Moshood TD, et al. (2022). Sustainability of biodegradable plastics: New problem or solution to solve the global plastic pollution? Current Research in Green and Sustainable Chemistry. 5:100273. https://doi.org/10.1016/j.crgsc.2022.100273.
[44] Project ECO52 – Bioavailability, complex substances and overall persistence (BCOP): three themes to deliver a step-change in persistence assessments. http://cefic-lri.org/projects/eco52-bioavailability-complex-substances-and-overall-persistence-bcop-three-themes-to-deliver-a-step-change-in-persistence-assessments/.
[45] See Work Package 4 – Comparison between natural and synthetic polymers - http://cefic-lri.org/wp-content/uploads/2022/07/ECO52-WP4-Report-polymer-Final.pdf.

biodegradability must take the material, use, and remediation steps into account. To do otherwise, it will not only lead to increased prices or even the loss of certain products but also hinder the development of new, innovative products.

3.0 The Definition of Microplastics Proposed by DTSC is Arbitrary and is Internally Inconsistent

The Definition of Microplastics Should Distinguish Between Primary and Secondary Sources of Microplastics

It is critically important to separate primary versus secondary microparticles, particularly as they have different physical-chemical characteristics (i.e., particle size, size distribution, and surface area used in the justification for the proposed definition) and will require different mitigation strategies.

The DTSC acknowledges that there are two broad categories of microplastics in the environment. Primary microplastics include preproduction plastic pellets and intentionally added microplastics. Pre-production pellets are typically 1-5mm in size and comprised of raw polymer (e.g., resin) from the manufacturer and often lack the additives found in plastic articles. Intentionally added microplastics are tiny plastic particles manufactured and intentionally added to some products to perform a concrete function, like abrasion.[46] Some intentional microplastics (e.g., consumer products) are washed into wastewater and are treated in wastewater treatment plant and are removed before the wastewater enters the environment. Reformulation and improved manufacturing and shipping protocols will likely be the main mitigation strategies for primary microplastics. A common property of both types of primary microplastics is that they have not experienced environmental weathering like secondary microplastics.[47] This lack of weathering affects a microplastic size, size distribution, shape, and surface characteristics. In fact, researchers can easily distinguish between primary and secondary microplastics.[48] This further supports our assertion that the DTSC justification for a distinct chemical identity for microplastics lacks the necessary specificity.

Secondary microplastics are created from the chemical, biological, or mechanical breakdown of larger (plastic) items in the environment. Secondary microplastics, as a sub-category, are more complex than primary microplastics.[49] Secondary microplastics are created from the chemical, biological, or mechanical breakdown of larger (plastic) items in the environment. This means that there is no uniform shape, size, or chemical composition of secondary microplastics because they start from various sources and encounter different degradative factors while in the

[46] https://cefic.org/policy-matters/chemical-safety/intentionally-added-microplastic-particles
[47] Andrady, AL. (2011). Microplastics in the marine environment. Mar Pollut Bull. 2011 Aug;62(8):1596-605. doi: 10.1016/j.marpolbul.2011.05.030.
[48] Kefer, S. et al. (2021). Environmental Microplastic Particles vs. Engineered Plastic Microparticles—A Comparative Review. Polymers (Basel). 13(17): 2881. doi: 10.3390/polym13172881.
[49] Waldman WR, Rillig MC. (2020). Microplastic Research Should Embrace the Complexity of Secondary Particles. Environ Sci Technol. 54(13):7751-7753. doi: 10.1021/acs.est.0c02194.

environment. Mitigation strategies will likely involve solid waste management and/or improved design requirement.

Adoption of a Technically Feasible Lower Size Limit to Demonstrate Actual Presence

DTSC proposes a broad definition for "microplastics" be adopted to allow the agency to the greatest latitude in future actions.[50] The current definition has an upper size limit of 5,000 micrometers but does not include a lower bound. While such a broad definition may make sense in a field that is new and is rapidly advancing, scientific and technical limitations should be acknowledged and addressed in the definition. Current detection methodologies do not allow for the detection of all materials covered in the DSTC proposal due to the wide range of materials (e.g., sizes, forms, composition and other properties), sample types/matrices, and the potentially very small amounts (e.g. in the case of coating). The ability to detect and measure microplastics is especially important as DTSC will need to demonstrate presence in the environment and actual exposure for any future listing.

There are a number of scientific issues regarding measuring microplastics at lower sizes (e.g., 1nm). Scientifically, when a polymer's size is in the 1nm range, it raises the question of "molecular particles." Since a carbon-to-carbon bond is approximately 0.15 nm long, a chain of ~7 carbon atoms (~1 nm) could be considered a microplastic under the proposed definition. Molecular molecules of this size are unlikely to behave in a chemically, environmentally (e.g., (bio)degradation), or toxicologically similar manner as larger particles. This poses an issue for any regulatory decision predicated on these other properties. Exposure and concentration measurements may also be confounded by a definition that lacks necessary specificity.

Accurately measuring and detecting microplastics smaller than 100nm represents a technological challenge with today's technology. EPA[51] recently cited a publication[52] whose authors note today's technologies can only reliably detect microplastic particles down to 5 µm in limited circumstances. ECHA also acknowledged this limitation in its regulation restricting intentionally added microplastic particles and resulted in a practical lower limit of 100nm.[53] The technological limitations of microplastic quantification can lead to inaccuracies when researchers attempt to quantify smaller particles to demonstrate presence in the environment or for the purpose of conducting an exposure assessment.

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[50] "Microplastics" are defined as solid polymeric materials to which chemical additives or other substances may have been added, which are particles having at least three dimensions that are less than 5,000 micrometers (µm). Polymers derived in nature that have not been chemically modified (other than by hydrolysis) are excluded.
[51] U.S. EPA. (2022). Memorandum: Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law. https://www.epa.gov/dwsrf/bipartisan-infrastructure-law-srf-memorandum. Last Accessed: 10.15.22.
[52] Frias JPGL, Roisin Nash. (2019). Microplastics: Finding a consensus on the definition. *Marine Pollution Bulletin*.138:145-147. https://doi.org/10.1016/j.marpolbul.2018.11.022.
[53] Commission Regulation (EU) amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles. https://ec.europa.eu/transparency/comitology-register/screen/documents/083921/1/consult?lang=en. Last Accessed 10.09.22.

DTSC should recognize a technically feasible lower size limit based on current high-throughput technologies. Currently, reliable methods are incapable of reliably detecting microplastics smaller than 5-10 μm, a limitation acknowledged by the broader scientific community.[54,55] Similar to the concept of Best Available Technology (BAT), DTSC could define the requirements necessary for a technology or method to be considered a BAT. The DTSC stated[56] that a lower limit is not necessary in its microplastic definition because listing microplastics on the CCL does not create any new regulatory obligations; size limitations would be discussed when microplastics are listed with a priority product. The ability to arbitrarily restrict/include different sized microplastics in a future regulation with no pre-defined criteria creates a situation where manufactures are left to guess what preemptive actions they may take to reformulate or improve the circularity of their formulas or products.

The microplastic definition proposed by DTSC is arbitrary, ignores key technological limitations, and disregards clear differences that are globally recognized.

Conclusion

In summary, DTSC may not add broad and poorly defined categories of mixtures to the Candidate Chemicals List simply on the basis of their polymeric structure and particle size. This is clear from the substances included on the Candidate Chemicals List. Virtually all entries are for specific substances with specific chemical compositions and molecular structures (and, typically, CAS numbers). In a handful of cases, narrow categories of chemically related substances are listed, such as "dioxins." Never before has DTSC added an amorphous class such as "microplastics." It should not do so now.

We thank you for considering these comments.

Sincerely,

American Chemistry Council
American Composites Manufacturers Association
California Chamber of Commerce
California Manufacturers & Technology Association
Flexible Packaging Association
Plastics Industry Association
Styrene Information and Research Center

[54] Frias JPGL, Roisin Nash. (2019).
[55] Draft ASTM WK72349. "Realistically, the lower limit of a microplastic is 5-10 μm when determined by this test method."
[56] Virtual Public Workshop: June 27, 2023, from 9:00 AM to Noon, Pacific Standard Time.