Technical Document for the Proposal to Add Microplastics to the Candidate Chemicals List

INTRODUCTION

The mission of the California Department of Toxic Substances Control's (DTSC's) Safer Consumer Products (SCP) Program is to advance the design, development, and use of products that are chemically safer for people and the environment. The SCP Program accomplishes this mission by identifying product-chemical combinations as "Priority Products" containing a "Chemical of Concern". Manufacturers of Priority Products must do an Alternatives Analysis to evaluate possible safer alternatives to the Chemical(s) of Concern contained in the Priority Product. While the SCP Program may evaluate nearly any consumer product that is placed in commerce in California, the chemical ingredients we can evaluate as Chemical(s) of Concern in Priority Products are limited. Only chemical ingredients that are included on DTSC's Candidate Chemicals (CC) List can be considered as potential Chemicals of Concern in Priority Products.

DTSC is concerned over the potential adverse impacts of microplastics (MPs) (Koelmans et al. 2019; Suaria et al. 2020; Wong et al. 2020; Brahney et al. 2021). MPs are ubiquitous in the environment, and both humans and animals are chronically exposed to MPs. Further, there is an emerging body of evidence suggesting that some of these exposures have the potential to be harmful.

On June 27, 2023, DTSC hosted a virtual workshop and public comment period for our proposal to add microplastics to the CC List. While many of the public comments supported our proposal, some commenters felt our definition of microplastics lacked specificity. As required by law for rulemaking packages based in science, DTSC then submitted the proposal for External Scientific Peer Review (ESPR). The reviewers generally supported the proposal and recommend additional references. We incorporated some of those references. We did not make changes to the proposed definition in response to public comments or ESPR. However, we made changes to simplify the definition and remove redundancies. We also removed the exclusion for polymers derived in nature because we may narrow our microplastics definition when adopting priority products, as appropriate. The proposed definition was adapted from and is consistent with the California State Water Resources Control Board's definition for MPs in drinking water.

DTSC'S PROPOSAL

Adding MPs to the CC List would allow the SCP Program to evaluate potential Priority Products that may contain or release MPs. DTSC proposes the following definition for microplastics:

"Microplastics" are plastics that are less than 5 millimeters (mm) in their longest dimension, inclusive of those materials that are intentionally manufactured at those dimensions or are generated by the fragmentation of larger plastics.

AUTHORITY TO ADD CHEMICALS TO THE CC LIST

Title 22, section 69502.2, subdivision (b) allows for revisions to the CC List. DTSC may identify as CCs those chemicals that DTSC determines may contribute to or cause adverse impacts and exposures. A variety of factors may be considered in making these determinations, including, but not limited to, the chemical's hazard trait(s) and/or environmental or toxicological endpoint(s); the chemical's physicochemical properties; the potential for the chemical to adversely impact sensitive subpopulations; and the chemical's environmental fate.

Plastics are comprised of a variety of polymers that may or may not contain additives. Some common types include, but are not limited to:

- Low-density polyethylene
- High-density polyethylene
- Polypropylene
- Polystyrene

- Polyvinyl Chloride
- Polyethylene terephthalate
- Polyurethane

Despite the structural heterogeneity and complexity of different plastic polymers, microplastics collectively meet the definition of “chemical”, because they are “organic or inorganic substances of a particular molecular identity”. [1]

MICROPLASTIC HAZARD TRAITS AND/OR TOXICOLOGICAL AND ENVIRONMENTAL ENDPOINTS

Environmental Persistence

The exposure potential hazard trait of environmental persistence is defined as “the propensity for a chemical substance to remain in the environment for a long time subsequent to its release by resisting chemical and biological degradation.” [2] Evidence for the hazard trait includes, but is not limited to:

- The substance having been identified as persistent by an authoritative organization;
- Resistance to degradation in wastewater treatment processes;
- A half-life in marine, fresh or estuary water of greater than 40 to 60 days, in sediment of greater than 2 months, in ambient air of greater than 2 days, or in soil of greater than 2 months; and/or,
- Structural similarity to other persistent chemicals.

A recent study summarizing the environmental persistence of plastic reviewed six types of plastic polymers (Chamas et al. 2020). The results of that study suggest that in the marine environment, estimated half-lives for five of the six materials ranged from 53 – 1,200 years. The results also suggested that when buried in terrestrial environments, half-lives for five of the six materials increased, and ranged from 250 – 5,000 years. Only one material of the six tested,

[1] See Cal. Code Regs. tit. 22, section 69501.1, subdivision (a)(20).
[2] See Cal. Code Regs. tit. 22, section 69405.3.

low-density polyethylene, exhibited an estimated half-life of less than 5 years in terrestrial and marine environments.

Differences in the physicochemical properties of MPs compared to bulk plastic, and different degradation pathways, may lead to variation in MP persistence. Bulk plastic in the environment degrades into MPs, essentially creating a constant source of MPs (Chamas et al. 2020; MacLeod 2021). One study found that different types of MP materials persist in the environment for up to 11 years (Zhu et al. 2020).

DTSC has determined that the available, reliable information suggests that MPs exhibit the exposure potential hazard trait of environmental persistence.

Mobility in Environmental Media

The exposure potential hazard trait of mobility in environmental media is defined as the capacity for rapid movement of a chemical substance in the environment.[3] Evidence for the environmental mobility of a chemical substance includes, but is not limited to:

- Reports in the scientific literature of environmental mobility,
- Evidence of the widespread contamination of the food chain, or for global distribution, or ubiquitousness in the environment; and/or,
- Physicochemical characteristics predisposing to ease of movement through environmental compartments such as air, water, or soil.

DTSC has determined that the available, reliable information suggests that MPs exhibit the mobility in environmental media hazard trait. They are readily carried by wind and water currents, and they are distributed globally (Hale et al. 2020; Suaria et al. 2020; MacLeod 2021; United Nations Environment Program 2021; Goeppert and Goldscheider 2021).

Particle Size or Fiber Dimension

The exposure potential hazard trait of particle size or fiber dimension is defined as the

[3] See Cal. Code Regs. tit. 22, section 69405.6.

existence of a chemical substance in the form of small particles or fibers or the propensity to form into such small-sized particles or fibers with use or environmental release.[4] Evidence for the exposure potential hazard trait of particle size or fiber dimension includes, but is not limited to measures of particle size less than or equal to 10 micrometers in mass median aerodynamic diameter for inhalation exposure, or less than 10 micrometers in any dimension for dermal or ingestion exposure, or fibers with a 3:1 aspect ratio and a width less than or equal to 3 micrometers. It is well established that plastics and microplastics have the propensity to degrade into such small sized-particles in the environment (Lambert and Wagner 2016; Pfohl et al. 2022; Cardenas-Alcaide et al. 2022).

RELIABLE INFORMATION

DTSC must consider potential exposures to the chemical based on:[5]

- Reliable information regarding potential exposures to the chemical, and
- Reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical.

Reliable information is defined as a scientific study or other scientific information that meets the criteria in subparagraphs (A) and (B) below:[6]

(A) The study or other scientific information was:

1. Published in a scientifically peer-reviewed report or other literature;
2. Published in a report of the United States National Academies;
3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or,
4. Conducted, developed, submitted, prepared for, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.

[4] See Cal. Code Regs. tit. 22, section 69405.7

[5] See Cal. Code Regs. tit. 22, section 69502.2(b)(2).

[6] See Cal. Code Regs. tit. 22, section 69501.1(a)(57).

(B) With respect to a scientific study, the study design was appropriate to the hypothesis being tested, and sufficient to support the proposition(s) for which the study is presented to the Department.

Exposures to Microplastics

Reliable information demonstrating the occurrence, or potential occurrence, of exposures to MPs include:[7]

- Monitoring data that shows MPs to be present in household dust, indoor air, or drinking water.[8]
    - Various reports found MPs in drinking water, household dust, and/or indoor and outdoor air (Gasperi et al. 2018; Eerles-Medrano et al. 2019; Koelmans et al. 2019; Zhang et al. 2020; Soltani et al. 2021; Sheng et al. 2023; Eberhard et al. 2024; Hashemihedeshi et al. 2024).
- Monitoring data that shows MPs to be present in, or released from, products used in or present in homes, schools, or places of employment.[9]
    - MPs are found in a variety of consumer products, including personal care products, cosmetics, household and industrial detergents, medical devices and medications, food products, paints and industrial coatings, waxes, polishes, decorative glitters, and textiles (European Chemicals Agency 2019; European Chemicals Agency 2021; Yang et al. 2021; Yang et al. 2023a). MPs that may be present in personal care products include, but are not limited to, toothpaste, lipstick, mascara, eye shadow, eyeliner, make-up preparations, bathing products, nail extenders, hair fixers and sprays, bulking agents, fragrance products, body and hand sprays, powders, shaving cream, baby products, and skin conditioning agents (Becker et al. 2014; United Nations Environment Program 2015). MPs may be released from clothing and textiles during clothes washing and wearing

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[7] See Cal. Code Regs. tit. 22, section 69501.1(a)(57).
[8] See Cal. Code Regs. tit. 22, section 69501.1(a)(58)(A)(1).
[9] See Cal. Code Regs. tit. 22, section 69501.1(a)(58)(A)(2).

(Hartline et al. 2016; Galafassi et al. 2019; Suaria et al. 2020; Cai et al. 2021). MPs are also released from tires during use (Sommer et al. 2018) and from cigarette butts discarded into the environment (Sommer et al. 2018; Moran et al. 2021).

- Data that shows that MPs are present in stormwater and wastewater, and that a fraction of MPs are discharged to receiving waters, even after treatment in stormwater and wastewater treatment systems.[10]
    - MPs end up in stormwater collection systems during rainfall and runoff events, and they directly discharge into receiving waters without treatment in most urban environments in California (Moran et al. 2021). Wastewater treatment plants receive municipal sewage that contains high levels of MPs, and a fraction of MPs are not removed during treatment and are released back into the environment (Prata 2018; Conley et al. 2019). It is estimated that 95% of the synthetic microfibers released during apparel washing enter California waterbodies, and eventually end up in the biosolids from wastewater treatment that are applied back to land (Geyer et al. 2022).
- Data that shows that MPs are accumulative or persistent in the environment[11], and evidence that MPs exhibit the exposure hazard traits of persistence and environmental mobility.[12]
    - MPs have become widely distributed in aquatic and terrestrial ecosystems throughout the world, suggesting that they are highly mobile in the environment (Cozar et al. 2017; Ryan et al. 2023). MPs are even found in the food supply. There are three main pathways for how MPs enter food: contamination of the environment in which the food was grown; industrial food packaging; and atmospheric deposition (Ramsperger et al. 2022).
- Microplastics have been detected in human placenta and infant feces, suggesting that unborn children are exposed to MPs in the womb (Ragusa et al. 2020; Zhang et al.

[10] See Cal. Code Regs. tit. 22, section 69501.1(a)(58)(E)(4).
[11] See Cal. Code Regs. tit. 22, section 69501.1(a)(58)(A)(3).
[12] See Cal. Code Regs. tit. 22, section 69501.1(a)(58)(C)(2).

2021). MPs have been detected in the cardiac tissues collected from patients undergoing cardiac surgery (Yang et al. 2023b). Exposure routes may include ingestion, inhalation, and/or dermal (Duis and Coors 2016; Dris et al. 2017; Gasperi et al. 2018; Eerles-Medrano et al. 2019; Koelmans et al. 2019; Hale et al. 2020; Zhang et al. 2020; Kutralam-Muniasamy et al. 2020; Wong et al. 2020; MacLeod 2021; United Nations Environment Program 2021; Mohamed Nor et al. 2021; Soltani et al. 2021; Li and Liu 2024). It has been suggested that humans are exposed to MPs predominantly via diet and inhalation (Cox et al. 2019; Mohamed Nor et al. 2021; World Health Organization 2022).

- Over 4,000 species of microbes, plants and animals have been shown to ingest plastic debris (Tekman et al.).

The SCP Program has determined that the reliable information available regarding the global distribution and persistence of MPs in the environment and the exposure of terrestrial and aquatic organisms to MPs, demonstrates that there is a significant potential for human and animal exposure to MPs. The references regarding potential exposures to MPs cited in this document are not exhaustive, and there is a large volume of information available in the scientific literature showing that MPs are distributed throughout virtually every ecosystem on Earth. The environmental persistence of MPs, their mobility in environmental media, and their global distribution in the environment, all contribute to increased potential for human and animal exposure to MPs.

NO NEW REGULATORY REQUIREMENTS

Adding MPs to the CC List will not create any new regulatory requirements or any new regulated entities. Adding MPs to the CC List will allow DTSC to evaluate product-chemical combinations that contain MPs or that may release MPs for the purpose of identifying potential Priority Products.

REFERENCES

Becker LC et al. (2014). Safety assessment of modified terephthalate polymers as used in cosmetics. International Journal of Toxicology. 33:pp 365–475.

Brahney J et al. (2021). Constraining the atmospheric limb of the plastic cycle. Proceedings of the National Academy of Sciences. 118:pp e2020719118.

Cai et al. (2021). Formation of Fiber Fragments during Abrasion of Polyester Textiles. Environmental Science & Technology. 55:pp 80001–88009.

Cardenas-Alcaide MF et al. (2022). Environmental impact and mitigation of micro(nano)plastics pollution using green catalytic tools and green analytical methods. Green Analytical Chemistry. 3:pp 100031. doi: 10.1016/j.greeac.2022.100031.

Chamas A et al. (2020). Degradation rates of plastics in the environment. ACS Sustainable Chemistry & Engineering. 8:pp 3494–3511. doi: 10.1021/acssuschemeng.9b06635.

Conley K et al. (2019). Wastewater treatment plants as a source of microplastics to an urban estuary: Removal efficiencies and loading per capita over one year. Water Research X. 3:pp 100030. doi: 10.1016/j.wroa.2019.100030.

Cox KD et al. (2019). Human consumption of microplastics. Environmental Science & Technology. 53:pp 7068–7074. doi: 10.1021/acs.est.9b01517.

Cozar et al. (2017). The Arctic Ocean as a dead end for floating plastics in the North Atlantic branch of the Thermohaline Circulation. Science Advances.

Dris R et al. (2017). A first overview of textile fibers, including microplastics, in indoor and outdoor environments. Environmental Pollution. 221:pp 453–458. doi: 10.1016/j.envpol.2016.12.013.

Duis K and Coors A. (2016). Microplastics in the aquatic and terrestrial environment: sources (with a specific focus on personal care products), fate and effects. Environmental Sciences Europe. 28:pp 2. doi: 10.1186/s12302-015-0069-y.

Eberhard et al. (2024). Systematic review of microplastics and nanoplastics in indoor and outdoor air: identifying a framework and data needs for quantifying human inhalation exposures. Journal of Exposure Science & Environmental Epidemiology.

Eerles-Medrano D, Heather A. Leslie and Brian Quinn. (2019). Microplastics in drinking water: A review and assessment - ScienceDirect. Current Opinion in Environmental Science Health. 7:pp 69–75.

European Chemicals Agency. (2019). Annex to the Annex XV Restriction Report: Proposal for a Restriction, Intentionally Added Microplastics. Available at: https://echa.europa.eu/documents/10162/db081bde-ea3e-ab53-3135-8aaffe66d0cb.

European Chemicals Agency. (2021). Microplastics - ECHA. Available at:

https://echa.europa.eu/hot-topics/microplastics. Accessed 9 Jun 2021.

Galafassi S, Nizzetto L and Volta P. (2019). Plastic sources: A survey across scientific and grey literature for their inventory and relative contribution to microplastics pollution in natural environments, with an emphasis on surface water. Science of The Total Environment. 693:pp 133499. doi: 10.1016/j.scitotenv.2019.07.305.

Gasperi J et al. (2018). Microplastics in air: Are we breathing it in? Current Opinion in Environmental Science & Health. 1:pp 1–5. doi: 10.1016/j.coesh.2017.10.002.

Geyer R et al. (2022). Quantity and fate of synthetic microfiber emissions from apparel washing in California and strategies for their reduction. Environmental Pollution. 298:pp 118835. doi: 10.1016/j.envpol.2022.118835.

Goeppert N and Goldscheider N. (2021). Experimental field evidence for transport of microplastic tracers over large distances in an alluvial aquifer. Journal of Hazardous Materials. 408:pp 124844. doi: 10.1016/j.jhazmat.2020.124844.

Hale RC et al. (2020). A global perspective on microplastics - Hale - 2020 - Journal of Geophysical Research: Oceans - Wiley Online Library. Journal of Geophysical Research: Oceans. 125:pp e2018JC014719.

Hartline NL et al. (2016). Microfiber masses recovered from conventional machine washing of new or aged garments. Environmental Science & Technology. 50:pp 11532–11538.

Hashemihedeshi et al. (2024). Size-Resolved Identification and Quantification of Micro/Nanoplastics in Indoor Air Using Pyrolysis Gas Chromatography−Ion Mobility Mass Spectrometry. Journal of American Soceity for Mass Spectrometry. 35:pp 275–284.

Koelmans AA et al. (2019). Microplastics in freshwaters and drinking water: Critical review and assessment of data quality. Water Research. 155:pp 410–422. doi: 10.1016/j.watres.2019.02.054.

Kutralam-Muniasamy G et al. (2020). Branded milks - Are they immune from microplastics contamination? The Science of the Total Environment. 714:pp 136823. doi: 10.1016/j.scitotenv.2020.136823.

Lambert S and Wagner M. (2016). Characterisation of nanoplastics during the degradation of polystyrene. Chemosphere. 145:pp 265–268. doi: 10.1016/j.chemosphere.2015.11.078.

Li and Liu. (2024). Micro(nano)plastics in the Human Body: Sources, Occurrences, Fates, and Health Risks. Environmental Science & Technology. 58:pp 3065–3078.

MacLeod. (2021). The global threat from plastic pollution. Science. 373:pp 61–65.

Mohamed Nor NH et al. (2021). Lifetime accumulation of microplastic in children and adults.

Environmental Science & Technology. 55:pp 5084–5096. doi: 10.1021/acs.est.0c07384.

Moran K et al. (2021). San Francisco Estuary Institute: A Synthesis of Microplastic Sources and Pathways to Urban Runoff.

Pfohl P et al. (2022). Environmental Degradation of Microplastics: How to Measure Fragmentation Rates to Secondary Micro- and Nanoplastic Fragments and Dissociation into Dissolved Organics. Environmental Science & Technology. 56:pp 11323–11334. doi: 10.1021/acs.est.2c01228.

Prata JC. (2018). Microplastics in wastewater: State of the knowledge on sources, fate and solutions. Marine Pollution Bulletin. 129:pp 262–265. doi: 10.1016/j.marpolbul.2018.02.046.

Ragusa A et al. (2020). Plasticenta: First evidence of microplastics in human placenta. Available at: https://pubmed.ncbi.nlm.nih.gov/33395930/. Accessed 15 Dec 2021.

Ramsperger AFRM et al. (2022). Nano- and microplastics: a comprehensive review on their exposure routes, translocation, and fate in humans. NanoImpact. 29:pp 100441. doi: 10.1016/j.impact.2022.100441.

Ryan et al. (2023). Transport and deposition of ocean-sourced microplastic particles by a North Atlantic hurricane. Communications Earth & Environment.

Sheng et al. (2023). Quantitation of Atmospheric Suspended Polystyrene Nanoplastics by Active Sampling Prior to Pyrolysis−Gas Chromatography−Mass Spectrometry. 57:pp 10754–10762.

Soltani NS, Taylor MP and Wilson SP. (2021). Quantification and exposure assessment of microplastics in Australian indoor house dust. Environmental Pollution. 283:pp 117064. doi: 10.1016/j.envpol.2021.117064.

Sommer F et al. (2018). Tire abrasion as a major source of microplastics in the environment. Aerosol and Air Quality Research. 18:pp 2014–2028. doi: 10.4209/aaqr.2018.03.0099.

Suaria G et al. (2020). Microfibers in oceanic surface waters: A global characterization. Science Advances. 6:pp eaay8493.

Tekman et al. 4,076 species are affected by litter (1,956 publications). in: Alfred Wegener Institute Helmholtz Centre for Polar and Marine Research. Available at: https://litterbase.awi.de/interaction. Accessed 11 Jun 2024.

United Nations Environment Program. (2015). United Nations Environment Programme: Plastic in Cosmetics: Are We Polluting the Environment through our Personal Care? Available at: https://wedocs.unep.org/xmlui/handle/20.500.11822/9664.

United Nations Environment Program UNE. (2021). From pollution to solution: a global assessment of marine litter and plastic pollution. Available at: http://www.unep.org/resources/pollution-solution-global-assessment-marine-litter-and-plastic-pollution.

Wong SL et al. (2020). Microplastics and nanoplastics in global food webs: A bibliometric analysis (2009–2019). Marine Pollution Bulletin. 158:pp 111432. doi: 10.1016/j.marpolbul.2020.111432.

World Health Organization. (2022). Dietary and inhalation exposure to nano- and microplastic particles and potential implications for human health. World Health Organization, ISBN: 978-92-4-005460-8.

Yang T, Gao and Nowack. (2023a). Formation of microplastic fibers and fibrils during abrasion of a representative set of 12 polyester textiles. Science of The Total Environment. 862:.

Yang T, Luo and Nowack. (2021). Characterization of Nanoplastics, Fibrils, and Microplastics Released during Washing and Abrasion of Polyester Textiles. Environmental Science & Technology. pp 15873–15881.

Yang Y et al. (2023b). Detection of Various Microplastics in Patients Undergoing Cardiac Surgery. Environmental Science & Technology. 57:pp 10911–10918. doi: 10.1021/acs.est.2c07179.

Zhang J et al. (2021). Occurrence of polyethylene terephthalate and polycarbonate microplastics in infant and adult feces. Environmental Science & Technology Letters. 8:pp 989–994. doi: 10.1021/acs.estlett.1c00559.

Zhang J, Wang L and Kannan K. (2020). Microplastics in house dust from 12 countries and associated human exposure. Environment International. 134:pp 105314. doi: 10.1016/j.envint.2019.105314.

Zhu L et al. (2020). Photochemical dissolution of buoyant microplastics to dissolved organic carbon: Rates and microbial impacts. Journal of Hazardous Materials. 383:pp 121065. doi: 10.1016/j.jhazmat.2019.121065.