

July 27, 2023

## Comments on the DTSC Proposal to add Microplastics to the Candidate Chemicals List

*Comments submitted via [calsafer.dtsc.ca.gov](https://calsafer.dtsc.ca.gov)*

These comments are submitted on behalf of the undersigned scientists and academics. We declare collectively that we have no direct or indirect financial or fiduciary interest in the subject of these comments. The co-signers' institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support unless indicated otherwise.

We strongly support the Department of Toxic Substances Control's ("DTSC") proposal to add microplastics to its Candidate Chemicals List ("Proposed Listing"), a crucial first step that would allow DTSC to "evaluate product-chemical combinations" that contain or release microplastics "for future consideration as potential Priority Products" and potentially trigger downstream alternatives analyses.<sup>1</sup>

The Proposed Listing provides a critical opportunity for the State of California to lead efforts in reducing microplastics exposure, which presents a major threat to planetary and human health.

Multiple lines of scientific evidence underscore the potential for microplastics to "contribute to or cause adverse impacts"<sup>2</sup> in humans and wildlife.<sup>3,4</sup> Microplastics are ubiquitous, highly mobile, persistent and bio-accumulative, and exert serious harms to human health.<sup>5</sup> Microplastics have been located everywhere they have been studied, including in the human body<sup>6,7,8,9</sup> and in environmental media like surface water, coastal beaches, sediment, fresh water, air, and food.<sup>10</sup> As a result, human exposure to microplastics is widespread; scientists estimate we ingest a credit card worth of them each week<sup>11,12</sup> Microplastics can also persist and bioaccumulate in living organisms, increasing the risk for long-term exposures.<sup>13</sup>

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<sup>1</sup> Department of Toxic Substances Control (2023). Proposal to add microplastics to the candidate chemicals list. Available: [https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/04/Background-Documents-Proposal-to-Add-Microplastics-to-the-Candidate-Chemical-List\\_May272023.pdf](https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/04/Background-Documents-Proposal-to-Add-Microplastics-to-the-Candidate-Chemical-List_May272023.pdf)  
<sup>2</sup> 22 CCR § 69502.2(b)(1)(A).

<sup>3</sup> Landrigan, P. J., Raps, H., Cropper, M., Bald, C., Brunner, M., Canonizado, E. M., ... Dunlop, S. (2023). The Minderoo-Monaco Commission on Plastics and Human Health. *Annals of Global Health*, 89(1), 23. DOI: <https://doi.org/10.5334/aogh.4056>

<sup>4</sup> California State Policy Evidence Consortium (CalSPEC). Microplastics occurrence, health effects, and mitigation policies: An evidence review for the California state legislature. January 2023. Sacramento, CA. Available: <https://uccs.ucdavis.edu/calspec/2022-research-topic>

<sup>5</sup> *Id.*

<sup>6</sup> Jenner, L. C., Rotchell, J. M., Bennett, R. T., Cowen, M., Tentzeris, V., & Sadofsky, L. R. (2022). Detection of microplastics in human lung tissue using  $\mu$ FTIR spectroscopy. *Science of the Total Environment*, 831, 154907. <https://doi.org/https://doi.org/10.1016/j.scitotenv.2022.154907>

<sup>7</sup> Ragusa, A., Svelato, A., Santacroce, C., Catalano, P., Notarstefano, V., Carnevali, O., Papa, F., Rongioletti, M. C. A., Baiocco, F., Draghi, S., D'Amore, E., Rinaldo, D., Matta, M., & Giorgini, E. (2021). Plasticenta: First evidence of microplastics in human placenta. *Environment International*, 146, 106274. <https://doi.org/https://doi.org/10.1016/j.envint.2020.106274>

<sup>8</sup> Ragusa A, Notarstefano V, Svelato A, Belloni A, Gioacchini G, Blondeel C, Zucchelli E, De Luca C, D'Avino S, Gulotta A, Carnevali O, Giorgini E. Raman Microspectroscopy Detection and Characterisation of Microplastics in Human Breastmilk. *Polymers (Basel)*. 2022 Jun 30;14(13):2700. doi: 10.3390/polym14132700. PMID: 35808745; PMCID: PMC9269371.

<sup>9</sup> Leslie, H. A., van Velzen, M. J. M., Brandsma, S. H., Vethaak, A. D., Garcia-Vallejo, J. J., & Lamoree, M. H. (2022). Discovery and quantification of plastic particle pollution in human blood. *Environment International*, 163, 107199. <https://doi.org/https://doi.org/10.1016/j.envint.2022.107199>

<sup>10</sup> Hale RC, et al. A Global Perspective on Microplastics. *Journal of Geophysical Research: Oceans*. 2020;125(1):e2018JC014719. <https://doi.org/10.1029/2018JC014719>.

<sup>11</sup> Senathirajah K, Attwood S, Bhagwat G, Carbery M, Wilson S, Palanisami T. Estimation of the mass of microplastics ingested - A pivotal first step towards human health risk assessment. *J Hazard Mater*. 2021 Feb 15;404(Pt B):124004. doi: 10.1016/j.jhazmat.2020.124004. Epub 2020 Oct 6. PMID: 33130380.

<sup>12</sup> Dalberg Advisors et al. (2019). No plastic in nature: Assessing plastic ingestion from nature to people. Available: [https://d2ouvy59p0dg6k.cloudfront.net/downloads/plastic\\_ingestion\\_web\\_spreads.pdf](https://d2ouvy59p0dg6k.cloudfront.net/downloads/plastic_ingestion_web_spreads.pdf)

<sup>13</sup> Browne MA, et al. Ingested Microscopic Plastic Translocates to the Circulatory System of the Mussel, *Mytilus edulis* (L.). *Environ Sci Technol*. 2008;42(13):5026-5031. doi:10.1021/es800249a.

Recent comprehensive reports have identified the health hazards associated with microplastics exposure, including a report conducted for the California Legislature that found exposure to microplastics is suspected to be a digestive and reproductive hazard to humans.<sup>14</sup> An additional report summarizes animal and *in vitro* studies demonstrating the gastrointestinal, pulmonary, dermal, placental, and systemic toxicity of microplastics.<sup>15</sup> The adverse health impacts associated with certain microplastics are in part due to chemical additives, including PFAS, phthalates, and BPA, which are linked to serious and irreversible health harms<sup>16, 17, 18, 19, 20</sup> and can easily leach from microplastics into the surrounding environment.<sup>21</sup>

While the scientific information included in the Proposed Listing satisfies the criteria for listing microplastics as Candidate Chemicals and accurately reflects the growing concern over the ubiquity and health effects of microplastics exposure, we have also identified several critical respects in which DTSC could strengthen its definitions of “microplastics” and “polymeric materials,” and its identification of the full array of reliable information on microplastics in the Proposed Listing.

We urge DTSC to make these additional changes to the Proposed Listing. We also recommend that DTSC expeditiously identify Priority Products that contain or release microplastics so that microplastics can be appropriately categorized as a Chemical of Concern.<sup>22</sup>

Our comments address the following:

- 1. Commenters strongly support DTSC’s proposal to add microplastics to the Candidate Chemicals List.**
- 2. DTSC should expand its proposed definitions of "microplastics" and "polymeric material" to reflect the best available science.**
- 3. DTSC should consider additional scientific evidence demonstrating the health harms of microplastics to further support the Proposed Listing.**
- 4. DTSC should account for industry sponsorship and author conflicts of interest when considering reliable information to support the Proposed Listing.**

We appreciate the opportunity to provide public input. If you have any questions regarding these comments, please feel free to contact Courtney Cooper ([courtney.cooper@ucsf.edu](mailto:courtney.cooper@ucsf.edu)) or Rashmi Joglekar ([rashmi.joglekar@ucsf.edu](mailto:rashmi.joglekar@ucsf.edu)).

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<sup>14</sup> California State Policy Evidence Consortium (CalSPEC). Microplastics occurrence, health effects, and mitigation policies: An evidence review for the California state legislature. January 2023. Sacramento, CA. Available: <https://ucsc.ucdavis.edu/calspec/2022-research-topic>

<sup>15</sup> Landrigan, P. J., Raps, H., Cropper, M., Bald, C., Brunner, M., Canonizado, E. M., ... Dunlop, S. (2023). The Minderoo-Monaco Commission on Plastics and Human Health. *Annals of Global Health*, 89(1), 23. DOI: <https://doi.org/10.5334/aogh.4056>

<sup>16</sup> Rogers, R. D., Reh, C. M., & Breysse, P. (2021). Advancing per- and polyfluoroalkyl substances (PFAS) research: an overview of ATSDR and NCEH activities and recommendations. *Journal of Exposure Science & Environmental Epidemiology*, 31(6), 961-971. <https://doi.org/10.1038/s41370-021-00316-6>

<sup>17</sup> National Academies of Sciences, Engineering, and Medicine. (2022). Guidance on PFAS exposure, testing, and clinical follow-up. <https://doi.org/10.17226/26156>

<sup>18</sup> Welch BM, Keil AP, Buckley JP, et al. Associations Between Prenatal Urinary Biomarkers of Phthalate Exposure and Preterm Birth: A Pooled Study of 16 US Cohorts. *JAMA Pediatr*. 2022;176(9):895–905. doi:10.1001/jamapediatrics.2022.2252

<sup>19</sup> Radke, E. G., Braun, J. M., Meeker, J. D., & Cooper, G. S. (2018). Phthalate exposure and male reproductive outcomes: A systematic review of the human epidemiological evidence. *Environment International*, 121, 764-793. <https://doi.org/https://doi.org/10.1016/j.envint.2018.07.029>

<sup>20</sup> Bisphenol A | EFSA n.d. Available: <https://www.efsa.europa.eu/en/topics/topic/bisphenol>

<sup>21</sup> Landrigan, P. J., Raps, H., Cropper, M., Bald, C., Brunner, M., Canonizado, E. M., ... Dunlop, S. (2023). The Minderoo-Monaco Commission on Plastics and Human Health. *Annals of Global Health*, 89(1), 23. DOI: <https://doi.org/10.5334/aogh.4056>

<sup>22</sup> 22 CCR § 69503.5(b)(2)(B).

Sincerely,

Courtney Cooper, MPH  
Science Associate  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco

Rashmi Joglekar, PhD  
Associate Director, Science and Policy  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco

Swati Rayasam, MSc  
Science Associate  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco

Jessica Trowbridge, PhD, MPH  
Associate Research Scientist  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco

Tracey Woodruff, PhD, MPH  
Professor and Director  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences

Dimitri Abrahamsson, PhD  
Assistant Professor  
New York University

Daniel Axelrad, MPP  
Independent Consultant

Nicholas Chartres, PhD  
Senior Research Fellow  
Faculty of Medicine & Health  
The University of Sydney

Jeanne Ann Conry, MD, PhD  
President  
The International Federation of Gynecology and Obstetrics

Robert Gould, MD  
Associate Adjunct Professor  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
President, San Francisco Bay Physicians for Social Responsibility\*

Philip J. Landrigan, MD, MSc  
Professor and Director  
Program for Global Public Health and the Common Good  
Boston College

Emily Lasher  
Graduate Student Intern  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco

Ted Schettler MD, MPH  
Science Director  
Science and Environmental Health Network

Patrice Sutton, MPH  
Research Collaborator  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco

Julia Varshavsky, PhD, MPH  
Assistant Professor  
Departments of Health Sciences and Civil and Environmental Engineering  
Northeastern University

Bhawani Venkataraman, PhD  
Associate Professor of Chemistry  
Department of Natural Sciences and Mathematics  
The New School

Marya Zlatnik, MD  
Professor of OBGYN and MFM  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco

*\*Denotes signature on behalf of organization or institution*

## DETAILED COMMENTS

### 1. Commenters strongly support DTSC's proposal to add microplastics to the Candidate Chemicals List.

We strongly support DTSC's Proposed Listing,<sup>23</sup> which is a crucial first step that will ultimately allow for the identification of Priority Products that contain microplastics or release microplastics into the environment. The Proposed Listing also accurately reflects the growing concern over the ubiquity of microplastics and their associated human health harms.

In the Proposed Listing, DTSC has correctly identified microplastics as a "chemical," consistent with the State of California's definition of chemicals: "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 degradate, metabolite, or reaction product of a substance with a particular molecular identity";<sup>24</sup> where "molecular identity" can be defined based upon a substance's "particle size, size distribution, and surface area".<sup>25</sup>

Finally, we strongly support DTSC's proposal to consider persistence and mobility as hazard traits and listing criteria in the Proposed Listing. This consideration is consistent with DTSC's 2021 decision to regulate PFAS as a class in certain consumer products based on persistence alone, becoming the first regulatory body to do so.<sup>26</sup> Scientific evidence demonstrates that microplastics can take decades to completely break down, underscoring their strong persistence in the environment.<sup>27</sup> Evidence has also demonstrated microplastics' capacity for environmental mobility and "long range" transport, given their size and environmental persistence.<sup>28, 29</sup>

### 2. DTSC should expand its proposed definitions of "microplastics" and "polymeric material" to reflect the best available science.

We generally support DTSC's proposed broad definition of microplastics. This definition, which does not include a lower limit on the size of microplastics,<sup>30</sup> allows for a greater inclusion of scientific evidence on microplastics, including evidence demonstrating that even smaller sizes of microplastics (as well as those on the nano-scale) can contribute to adverse health impacts.<sup>31</sup> We further support DTSC's inclusion of both primary and secondary microplastics in the proposed definition, especially since secondary

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<sup>23</sup> Department of Toxic Substances Control (2023). Proposal to add microplastics to the candidate chemicals list. Available: [https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/04/Background-Documents-Proposal-to-Add-Microplastics-to-the-Candidate-Chemical-List\\_May272023.pdf](https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/04/Background-Documents-Proposal-to-Add-Microplastics-to-the-Candidate-Chemical-List_May272023.pdf)

<sup>24</sup> 22 CCR § 69501.1(a)(20)(A)(1).

<sup>25</sup> 22 CCR § 69501.1(a)(20)(B)(8).

<sup>26</sup> Bălan SA, Mathrani VC, Guo DF, Algazi AM. Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program. *Environ Health Perspect*. 2021 Feb;129(2):25001. doi: 10.1289/EHP7431. Epub 2021 Feb 17. PMID: 33595352; PMCID: PMC7888260.

<sup>27</sup> Lebreton, L., Egger, M. & Slat, B. A global mass budget for positively buoyant macroplastic debris in the ocean. *Sci Rep* 9, 12922 (2019). <https://doi.org/10.1038/s41598-019-49413-5>

<sup>28</sup> California State Policy Evidence Consortium (CalSPEC). Microplastics occurrence, health effects, and mitigation policies: An evidence review for the California state legislature. January 2023. Sacramento, CA. Available: <https://uccs.ucdavis.edu/calspec/2022-research-topic>

<sup>29</sup> Evangelidou, N., Grythe, H., Klimont, Z. et al. Atmospheric transport is a major pathway of microplastics to remote regions. *Nat Commun* 11, 3381 (2020). <https://doi.org/10.1038/s41467-020-17201-9>

<sup>30</sup> DTSC uses the size definition of particles less than 5,000 micrometers rather than the California State Water Resources Control Board definition of particles greater than 1 nanometer and less than 5,000 micrometers. See State Water Resources Control Board. (2020). Resolution No. 2020-0021: Adoption of definition of 'microplastics in drinking water'. Retrieved 30 June from [https://www.waterboards.ca.gov/board\\_decisions/adopted\\_orders/resolutions/2020/rs2020\\_0021.pdf](https://www.waterboards.ca.gov/board_decisions/adopted_orders/resolutions/2020/rs2020_0021.pdf).

<sup>31</sup> Yang, Q., Dai, H., Cheng, Y., Wang, B., Xu, J., Zhang, Y., Chen, Y., Xu, F., Ma, Q., Lin, F., & Wang, C. (2023). Oral feeding of nanoplastics affects brain function of mice by inducing macrophage IL-1 signal in the intestine. *Cell Reports*, 42(4). <https://doi.org/10.1016/j.celrep.2023.112346>

microplastics are more prevalent in the environment and can also contain harmful additives that are hazardous to human health, including PFAS, phthalates, and BPA,<sup>32, 33, 34, 35, 36, 37, 38</sup> that can easily leach into the environment or the human body as the plastic degrades.<sup>39</sup>

There are two critical respects in which DTSC should revise its current definition of microplastics. First, we recommend that DTSC expand its definition to include particles that contain at least *one* dimension that is less than 5,000 micrometers (µm). The proposed definition, which currently requires at least *three* dimensions less than 5,000 µm, is unduly narrow and does not adequately account for the full range of shapes of microplastics, which is critical given that microplastics' shape can influence their potential for toxicity.<sup>40</sup>

Additionally, we recommend that DTSC expand its definition of “polymeric material” to include all particles of any composition with *any* polymer content.<sup>41</sup> The proposed definition, which currently requires “polymer content greater than or equal to 1% by mass” excludes certain polymeric materials from consideration. For example, expanding this definition will allow for the inclusion of evidence on microplastics produced from surface coatings or tire wear.<sup>42</sup>

### **3. DTSC should consider additional scientific evidence demonstrating the health harms of microplastics to further support the Proposed Listing.**

DTSC is authorized to identify Candidate Chemicals if there is available “reliable information” demonstrating “one or more hazard traits and/or environmental or toxicological endpoints” or “potential exposures to the chemical.”<sup>43</sup> While DTSC included sufficient “reliable information”<sup>44</sup> to demonstrate potential for microplastics to exert adverse human health effects in its Proposed Listing, it did not consider the full array of scientific evidence demonstrating the human and environmental health harms of microplastics.

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<sup>32</sup> Agency for Toxic Substances and Disease Registry. (2021). Toxicological profile for perfluoroalkyls. <https://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf>

<sup>33</sup> U.S. Environmental Protection Agency Science Advisory Board (SAB). (2022). Review of EPA's analyses to support EPA's national primary drinking water rulemaking for PFAS FINAL REPORT. [https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18\\_ID:2601](https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601)

<sup>34</sup> Rogers, R. D., Reh, C. M., & Breysse, P. (2021). Advancing per- and polyfluoroalkyl substances (PFAS) research: an overview of ATSDR and NCEH activities and recommendations. *Journal of Exposure Science & Environmental Epidemiology*, 31(6), 961-971. <https://doi.org/10.1038/s41370-021-00316-6>

<sup>35</sup> National Academies of Sciences, Engineering, and Medicine. (2022). Guidance on PFAS exposure, testing, and clinical follow-up. <https://doi.org/10.17226/26156>

<sup>36</sup> Welch BM, Keil AP, Buckley JP, et al. Associations Between Prenatal Urinary Biomarkers of Phthalate Exposure and Preterm Birth: A Pooled Study of 16 US Cohorts. *JAMA Pediatr*. 2022;176(9):895–905. doi:10.1001/jamapediatrics.2022.2252

<sup>37</sup> Radke, E. G., Braun, J. M., Meeker, J. D., & Cooper, G. S. (2018). Phthalate exposure and male reproductive outcomes: A systematic review of the human epidemiological evidence. *Environment International*, 121, 764-793. <https://doi.org/https://doi.org/10.1016/j.envint.2018.07.029>

<sup>38</sup> Bisphenol A | EFSA n.d. Available: <https://www.efsa.europa.eu/en/topics/topic/bisphenol>

<sup>39</sup> Landrigan, P. J., Raps, H., Cropper, M., Bald, C., Brunner, M., Canonizado, E. M., ... Dunlop, S. (2023). The Minderoo-Monaco Commission on Plastics and Human Health. *Annals of Global Health*, 89(1), 23. DOI: <https://doi.org/10.5334/aogh.4056>

<sup>40</sup> Wieland, S., Balmes, A., Bender, J., Kitzinger, J., Meyer, F., Ramsperger, A. F. R. M., Roeder, F., Tengelmann, C., Wimmer, B. H., Laforsch, C., & Kress, H. (2022). From properties to toxicity: Comparing microplastics to other airborne microparticles. *Journal of Hazardous Materials*, 428, 128151. <https://doi.org/https://doi.org/10.1016/j.jhazmat.2021.128151>

<sup>41</sup> California State Policy Evidence Consortium (CalSPEC). Microplastics occurrence, health effects, and mitigation policies: An evidence review for the California state legislature. January 2023. Sacramento, CA. Available: <https://uccs.ucdavis.edu/calspec/2022-research-topic>

<sup>42</sup> Hartmann, N. B., Hüffer, T., Thompson, R. C., Hassellöv, M., Verschoor, A., Daugaard, A. E., Rist, S., Karlsson, T., Brennholt, N., Cole, M., Herrling, M. P., Hess, M. C., Ivleva, N. P., Lusher, A. L., & Wagner, M. (2019). Are We Speaking the Same Language? Recommendations for a Definition and Categorization Framework for Plastic Debris. *Environmental Science & Technology*, 53(3), 1039-1047. <https://doi.org/10.1021/acs.est.8b05297>

<sup>43</sup> 22 CCR § 69502.2(b), (b)(2)(A).

<sup>44</sup> 22 CCR § 69501.1(a)(57).

This body of evidence includes two recent scientific studies which found that microplastics have potential to increase the severity of infectious hematopoietic necrosis virus in fish and the susceptibility of seabirds to infections,<sup>45,46</sup> as well as studies demonstrating the bioaccumulation potential of microplastics in human tissues and the resulting biological changes, including oxidative stress and inflammation,<sup>47,48</sup> poor respiratory outcomes, metabolic disorders, gastrointestinal effects, and cancer.<sup>49,50,51,52,53</sup> This body of evidence also includes a recent report from an interdisciplinary international commission that summarizes animal and *in vitro* studies, outlining the gastrointestinal, pulmonary, dermal, placental, and systemic toxicity of microplastics as well as the mechanisms of microplastics toxicity.<sup>54</sup>

In addition, DTSC should consider a recent rapid systematic review of animal toxicology evidence, which relied on best practices in systematic review in environmental health<sup>55</sup> and identified associations between microplastics exposure and digestive and reproductive harms in humans, with a suspected link to colon cancer.<sup>56</sup> This conclusion stemmed from a rigorous evaluation of thirteen studies,

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<sup>45</sup> Seeley, M. E., Hale, R. C., Zwollo, P., Vogelbein, W., Verry, G., & Wargo, A. R. (2023). Microplastics exacerbate virus-mediated mortality in fish. *Science of the Total Environment*, 866, 161191. <https://doi.org/https://doi.org/10.1016/j.scitotenv.2022.161191>

<sup>46</sup> Charlton-Howard, H. S., Bond, A. L., Rivers-Auty, J., & Lavers, J. L. (2023). 'Plasticosis': Characterising macro- and microplastic-associated fibrosis in seabird tissues. *Journal of Hazardous Materials*, 450, 131090. <https://doi.org/10.1016/j.jhazmat.2023.131090>

<sup>47</sup> Ageel HK, Harrad S, Abdallah MA-E. Occurrence, human exposure, and risk of microplastics in the indoor environment. 10.1039/D1EM00301A. *Environ Sci Process Impacts*. 2022;24(1):17-31. doi:10.1039/D1EM00301A.

<sup>48</sup> Cho YM, Choi KH. The current status of studies of human exposure assessment of microplastics and their health effects: a rapid systematic review. *Environ Anal Health Toxicol*. 2021;36(1):e2021004-0. doi:10.5620/eaht.2021004. PMC8207003

<sup>49</sup> Campanale C, et al. A Detailed Review Study on Potential Effects of Microplastics and Additives of Concern on Human Health. *Int J Environ Res Public Health*. 2020;17(4):doi:10.3390/ijerph17041212. PMC7068600

<sup>50</sup> Ageel HK, et al. Occurrence, human exposure, and risk of microplastics in the indoor environment. 10.1039/D1EM00301A. *Environ Sci Process Impacts*. 2022;24(1):17-31. doi:10.1039/D1EM00301A.

<sup>51</sup> Cho YM, et al. The current status of studies of human exposure assessment of microplastics and their health effects: a rapid systematic review. *Environ Anal Health Toxicol*. 2021;36(1):e2021004-0. doi:10.5620/eaht.2021004. PMC8207003

<sup>52</sup> Rahman A, et al. Potential human health risks due to environmental exposure to nano- and microplastics and knowledge gaps: A scoping review. *Sci Total Environ*. 2021;757:143872. <https://doi.org/10.1016/j.scitotenv.2020.143872>

<sup>53</sup> Batool I, et al. Dynamics of airborne microplastics, appraisal and distributional behaviour in atmosphere; a review. *Sci Total Environ*. 2022;806:150745.

<sup>54</sup> Landrigan, P. J., Raps, H., Cropper, M., Bald, C., Brunner, M., Canonizado, E. M., ... Dunlop, S. (2023). The Minderoo-Monaco Commission on Plastics and Human Health. *Annals of Global Health*, 89(1), 23. DOI: <https://doi.org/10.5334/aogh.4056>

<sup>55</sup> We recommend that, when looking at systematic reviews, DTSC consider ones that use robust and scientifically-sound methods to gather "reliable information", such as the University of California, San Francisco's Navigation Guide (Woodruff, T. J., & Sutton, P. (2014). The Navigation Guide systematic review methodology: A rigorous and transparent method for translating environmental health science into better health outcomes. *Environmental Health Perspectives*, 122(10), 1007-1014. <https://doi.org/10.1289/ehp.1307175>) and/or the National Toxicology Program's Office of Health Assessment and Translation (NTP OHAT) methodology (National Toxicology Program (NTP). (2019). Handbook for conducting a literature-based health assessment using OHAT approach for systematic review and evidence integration. [https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019\\_508.pdf](https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019_508.pdf)). We also recommend that DTSC use the AMSTAR tool to assess the quality of identified systematic reviews (Shea, B. J., Reeves, B. C., Wells, G., Thuku, M., Hamel, C., Moran, J., Moher, D., Tugwell, P., Welch, V., Kristjansson, E., & Henry, D. A. (2017). AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*, 358, j4008. <https://doi.org/10.1136/bmj.j4008>).

<sup>56</sup> California State Policy Evidence Consortium (CalSPEC). Microplastics occurrence, health effects, and mitigation policies: An evidence review for the California state legislature. January 2023. Sacramento, CA. Available: <https://uccs.ucdavis.edu/calspec/2022-research-topic>

57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69 in which adverse health effects ranged from gross or microanatomic colonic and small intestinal effects, oxidative stress, chronic inflammation, immunosuppression, hormone level changes, cell proliferation, sperm/sperm related outcomes, and impacts on follicles/ovarian reserve capacity. Importantly, the dosages in most of the studies evaluated in this rapid systematic review fell within the expected range of human exposure, underscoring the detrimental impact of human exposure to microplastics.<sup>70, 71</sup>

Collectively, this additional evidence underscores and expands the list of serious health harms associated with microplastics exposure, including at exposure levels that are expected in the human population. DTSC should consider including these studies in the Proposed Listing to strengthen and expand the body of reliable information required to list microplastics as Candidate Chemicals.

#### **4. DTSC should account for industry sponsorship and author conflicts of interest when considering reliable information to support the Proposed Listing.**

When obtaining reliable information to support the Proposed Listing, DTSC should account for any industry sponsorship from the chemical or fossil fuels industries and author conflicts of interest to minimize potential bias in the underlying body of scientific evidence. The Proposed Listing currently cites one study with disclosed author financial conflicts of interest; two Coffin et al. 2022 authors

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<sup>58</sup> Lu, L., Wan, Z., Luo, T., Fu, Z., & Jin, Y. (2018). Polystyrene microplastics induce gut microbiota dysbiosis and hepatic lipid metabolism disorder in mice. *Science of the Total Environment*, 631-632, 449-458. <https://doi.org/https://doi.org/10.1016/j.scitotenv.2018.03.051>

<sup>59</sup> Li, B., Ding, Y., Cheng, X., Sheng, D., Xu, Z., Rong, Q., Wu, Y., Zhao, H., Ji, X., & Zhang, Y. (2020). Polyethylene microplastics affect the distribution of gut microbiota and inflammation development in mice. *Chemosphere*, 244, 125492. <https://doi.org/https://doi.org/10.1016/j.chemosphere.2019.125492>

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<sup>65</sup> Hou, B., Wang, F., Liu, T., & Wang, Z. (2021a). Reproductive toxicity of polystyrene microplastics: In vivo experimental study on testicular toxicity in mice. *Journal of Hazardous Materials*, 405, 124028. <https://doi.org/https://doi.org/10.1016/j.jhazmat.2020.124028>

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indicated financial affiliations with the American Chemistry Council and the European Chemical Industry Council—organizations with a vested interest in products that contain petrochemicals, including plastics.<sup>72</sup>

Industry sponsorship and author conflicts of interest can bias research through various mechanisms, including how they frame the research questions, design, and conduct a study, selectively report the results, code events, analyze the study data and spin conclusions.<sup>73, 74, 75, 76</sup> As highlighted by the National Academies of Sciences, Engineering, and Medicine (NASEM), author conflicts of interest (COI) and industry sponsorship can ultimately influence the findings of a study.<sup>77, 78</sup> Even when studies have the same methodological risk of bias (or internal validity), studies with industry sponsorship are associated with more favorable outcomes towards the study sponsor.<sup>79, 80</sup> For example, in studies examining harmful chemical exposures, industry sponsorship could be expected to bias the study findings towards the null (i.e., finding that the chemical does not have a toxic effect).

To account for this potential bias, DTSC should prioritize scientific evidence that does not have the presence of industry sponsorship and/or authors with a conflict of interest with the chemical or fossil fuels industries. At minimum, DTSC should acknowledge any known industry sponsorship or author conflicts of interest for evidence that is considered in the Proposed Listing.

## Conclusion

Microplastics are ubiquitous, persistent, highly mobile, and toxic environmental contaminants that present a major threat to planetary and human health. We strongly support DTSC’s Proposed Listing, which is a critical step for the State of California to continue reducing exposure to microplastics.<sup>81</sup> DTSC provided sufficient scientific evidence to demonstrate that microplastics have the potential to “contribute to or cause adverse impacts.”<sup>82</sup> Additional scientific evidence not included in the Proposed Listing further underscores the toxicity potential of microplastics and their widespread exposure in the human population. To strengthen the Proposed Listing, we urge DTSC to expand its definition of “microplastics” and “polymeric material” and ensure that any industry sponsorship and author financial conflicts of interest have been acknowledged.

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<sup>82</sup> 22 CCR § 69502.2(b)(1)(A).