January 30, 2026

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

Office of Legislation and Regulatory Review
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806

Re: Comments of an Industry Coalition on the Background Document on DTSC's Microplastics in Consumer Products Research

Dear Sir or Madam:

The organizations below welcome the opportunity to present comments on the Department of Toxic Substances Control (DTSC) Background Document on DTSC's Microplastics in Consumer Products Research. We believe it is premature for DTSC to identify and call for additional information on products prior to a final action to list microplastics on the Candidate Chemical List.

Sincerely,

Alliance for Chemical Distribution
American Chemistry Council
American Institute for Packaging and the Environment (AMERIPEN)
Foodservice Packaging Institute
National Association of Printing Ink Manufacturers
Plastics Industry Association
Plastic Pipe and Fittings Association
Plastics Pipe Institute
PRINTING United Alliance
Silicones Environmental, Health, and Safety Center
The Vinyl Institute

Industry Coalition Comments on the Background Document on DTSC's Microplastics in Consumer Products Research

January 30, 2026

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EXECUTIVE SUMMARY

The Background Document[1] puts the cart before the horse. It seeks external engagement on preliminary research by the Department of Toxic Substances Control (DTSC) on microplastics in or from selected products or categories of products. The external engagement is expected to help DTSC decide whether to conduct additional research or potentially list one or more products that contain or have the potential to generate microplastics as Priority Products. This effort is premature and unnecessary, because microplastics should not be listed on the Candidate Chemical List or confirmed as a Chemical of Concern, a necessary predicate for identifying Priority Products.

As indicated in previous coalition comments, microplastics are not a single substance, and they do not meet the DTSC definition of a chemical. Secondary microplastics, as well as some primary microplastics such as nurdles, are not even in consumer products. Listing microplastics as a Candidate Chemical would therefore be inconsistent with the Safer Consumer Products Program.

Before proceeding with further consideration of microplastics, consider whether a credible alternatives analysis is possible, given the state of the science on microplastics. It should also prepare a clearer definition of "plastic" that considers their key properties, such as solubility and biodegradability. It should also consider whether a credible alternatives analysis is possible, given the state of the science on microplastics. There is considerable room for doubt.

The information presented in the Background Document on release of microplastics from food contact materials does not acknowledge the problems with the methods used to detect microplastics, or that several authorities have found that the trace amounts of microplastics in food do not present any risk to health or the environment.

DISCUSSION

1. Microplastics Do Not Qualify as Candidate Chemicals

The Background Document is premised on DTSC's ability to treat microplastics as Candidate Chemicals that can be added to the Candidate Chemical List. A coalition of industry trade associations submitted comments on the 2023 DTSC proposal to add microplastics to the

[1] DTSC, Background Document on DTSC's Microplastics in Consumer Products Research (Nov. 2025) (Background Document), https://dtsc.ca.gov/wp-content/uploads/sites/31/2025/11/Background-Document-on-DTSCs-Microplastics-in-Consumer-Products-Research.pdf.

Candidate Chemicals List[2] and on the 2025 proposal to do the same.[3] Both sets of comments are incorporated herein by reference. Along with other comments from industry, those comments amply demonstrated that DTSC cannot add microplastics to the Candidate Chemical List.

a. Microplastics Are Not a Chemical

DTSC's proposal to list microplastics as a single candidate chemical exceeds its authority under the Health and Safety Code and is inconsistent with DTSC's own regulations. The statute authorizes DTSC to identify and prioritize chemicals or chemical ingredients in consumer products.[4] DTSC regulations define a "chemical" and "chemical ingredient" as a substance with a particular molecular identity.[5] By contrast, DTSC defines microplastics as plastic particles below a specified size, whether intentionally manufactured or formed through fragmentation.[6] Microplastics are therefore not substances themselves, but rather they are size-based descriptions of materials made from plastics. Because microplastics are not a substance and do not constitute a single chemical, they cannot be added to the Candidate Chemical List. The statutory context and legislative history of AB 1879 further confirm that the Legislature intended DTSC to regulate hazardous chemicals contained in products, not fragments or degraded forms of finished products.[7]

Individual microplastic particles typically consist of one or more polymers (each manufactured from one or more monomers and other reactants) combined with additives such as colorants or stabilizers. Such particles are mixtures rather than single chemical substances. Microplastics are a category that represents mixtures of mixtures, encompassing numerous polymers, additive packages, and physical forms. Consistent with this understanding, the U.S. Environmental Protection Agency (EPA) regulates microplastics under TSCA as mixtures, with the individual polymers and additives in microplastics having to be each listed on the TSCA Inventory or subject to an exemption. EPA has never treated microplastics as a distinct chemical substance, as DTSC proposes to do. EPA instead describes microplastics as particles composed of one or more chemical substances, not as a single chemical entity. Microplastics are far from having a single, particular molecular identity.

In its 2023 proposal, DTSC asserted that microplastics have a single "molecular identity" due to their "polymeric structure" and "size distribution."[8] Polymeric structure, however, is not one of

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[2] Industry coalition comments (July 27, 2023), https://calsafer.dtsc.ca.gov/documentitem/index/?guid=081f1c26-064b-40b0-b211-d9e08e388109.
[3] Industry coalition comments (Aug. 4, 2025), https://calsafer.dtsc.ca.gov/documentitem/index/?guid=7f9eb9fc-a004-4b84-947c-d8882c1a99ee.
[4] Health & Safety Code § 25252(a).
[5] 22 CCR § 69501.1(a)(2)(A).
[6] DTSC Proposed Microplastics Regulation, https://dtsc.ca.gov/wp-content/uploads/sites/31/2025/06/R-2023-05R-2.-Proposed-Regulatory-Text.pdf (defining microplastics as "plastics that are less than 5 millimeters in their longest dimension, inclusive of those intentionally manufactured at those dimensions or generated by fragmentation of larger plastics.").
[7] Bill Analysis, AB 1879 available at http://leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_cfa_20080830_154547_asm_floor.html.
[8] DTSC, Proposal to Add Microplastics to the Candidate Chemicals List (2023), https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/04/Background-Document-Proposal-to-Add-Microplastics-to-the-Candidate-

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 the chemical elements making up a compound by way of chemical and atomic bonds.[9]

Chemical composition, which is often described using molecular formulas (e.g., H_2O), is unique to particular compounds; it is inapplicable to broad categories such as plastics of a particular particle size range. "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.[10] Like chemical composition, molecular structure is specific to individual substances; it does not apply to broad descriptions such as "polymeric."

In order to label microplastics as a "chemical," DTSC relies on generalized hazard considerations, which are relevant only after a substance has been properly identified as a chemical and cannot substitute for the required showing of a particular molecular identity.[11]

DTSC's own scientific advisors and international health authorities have recognized this fundamental problem. The Green Ribbon Science Panel has acknowledged that microplastics encompass a wide range of materials and that treating them as a single chemical would require highly constrained definitions tied to polymer type, particle characteristics, and shared hazards, and even then would present significant challenges.[12] Similarly, the World Health Organization (WHO) has described microplastics as a heterogeneous mixture of particles with diverse compositions and properties that change over time in the environment.[13] DTSC's historical practice further underscores this point, as the Candidate Chemical List has consistently been limited to individual chemicals or narrowly defined groups sharing common chemical structures, typically identified by CAS numbers. Microplastics lack such a shared chemical identity. For these reasons, microplastics do not qualify as a single chemical and cannot be listed as a candidate chemical under DTSC's statutory and regulatory framework.

Chemical-List_May272023.pdf ("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.").

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

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

[11] 22 CCR § 69502.2(b) (identifying hazard traits as a separate consideration from chemical identity).

[12] Green Ribbon Science Panel Background Document: Microplastics (2021), https://dtsc.ca.gov/wp-content/uploads/sites/31/2021/10/Fall-2021_GRSP-Background-Document_accessible.pdf.

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

Furthermore, to the extent that DTSC justifies its classification of microplastics as a single chemical on the assumption that microplastics have common physicochemical properties, the scientific evidence does not support that assumption. As noted in the 2022 WHO report on microplastics, "The properties and composition of [microplastics] change during their lifecycle in the environment." WHO described microplastics has having "various shapes, sizes, polymer composition, surface chemistry…"

Nevertheless, the 2025 Technical Document asserts that microplastics should be added to the Candidate Chemical List as a single chemical they do have a particular molecular identity:

> 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."[14]

b. Some Microplastics Are Not Contained in Consumer Products

Besides the fundamental requirement that a Candidate Chemical be a "chemical," another essential requirement for any chemical added to the Candidate Chemical List is that it be in a consumer product. The statute directs DTSC to establish the Safer Consumer Products Program regulations to address "chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern."[15]

Many microplastics are not present in "consumer products" as that term is defined in the statute[16] and the regulations.[17] Certainly, secondary microplastics are not "used, brought, or leased for use" by a consumer, nor are they part or component of an assembled consumer product, as the Green Ribbon Science Panel has noted.[18] Accordingly, they also fall outside the scope of Health & Safety Code § 25253(a)(1), which requires DTSC to establish a process for evaluating chemicals of concern in consumer products, and 22 CCR § 69501(b)(1), which provides that the Safer Consumer Products regulations apply to consumer products placed into the stream of commerce in California.

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[14] DTSC, Technical Document for the Proposal to Add Microplastics to the Candidate Chemicals List (June 20, 2025), https://dtsc.ca.gov/wp-content/uploads/sites/31/2025/06/Technical-Document-for-the-Proposal-to-Add-Microplastics-to-the-Candidate-Chemicals-List.pdf.

[15] Health & Safety Code § 25252(a).

[16] Health & Safety Code § 25251(b) ("'Consumer product' means a product or part of the product that is used, brought, or leased for use by a person for any purposes.").

[17] 22 CCR § 69501.1(a)(24)(A) ("'Consumer product" or "Product" means any of the following: 1. A "consumer product" as defined in Health & Safety Code § 25251; or 2. When applicable, a component of an assembled 'consumer product.'").

[18] Green Ribbon Science Panel Background Document: Microplastics (2021), https://dtsc.ca.gov/wp-content/uploads/sites/31/2021/10/Fall-2021_GRSP-Background-Document_accessible.pdf ("By definition, secondary microplastics are not present in consumer products when they are sold or distributed in California.").

Many of the products evaluated during DTSC's preliminary screening research that are claimed to "contain microplastics" (Background Document p. 4) are listed in part or solely because after disposal they may form secondary microplastics. The Background document defines "secondary microplastics" as those "that arise from the degradation of plastic products, such as plastic bags or water bottles." In other words, the listed consumer products do not "contain" secondary microplastics at all. Secondary microplastics are formed, if at all, only after a product is discarded and loses its status as a consumer product.

As another example, one of the products evaluated by DTSC was "pre-production pellets" (i.e., "nurdles") used in the downstream production of various plastic products" (Background Document p. 24). Pre-production pellets are industrial products, not consumer products. During the product production process industrial companies form them into consumer products, by which time their separate existence is undetectable. Pre-production pellets are destined for further industrial processing and are not considered consumer products. If DTSC intends to address every aspect of plastic production before the plastic ever becomes part of a consumer product, there are few limits to the scope of its inquiry.

This is not an academic concern – it goes to the rest of the Safer Consumer Products Program. For example, after identification of a Candidate Chemical, the next step in the regulations is identification and prioritization of "products containing Candidate Chemicals."[19] The prioritization process applies to "all products that contain one or more Candidate Chemicals and that are placed into the stream of commerce in California."[20] A key prioritization principle is that there is potential exposure to "the Candidate Chemical(s) in the product."[21] DTSC is charged to give special consideration to the potential for "the Candidate Chemical(s) in the product" to contribute to or cause adverse impacts.[22] Accordingly, no Priority Products can be identified for either secondary microplastics or some primary microplastics because they are not contained in any consumer products.

2. Before Proceeding Further, DTSC Should Consider Whether Microplastics Can Be Addressed Credibly in Alternatives Analyses

Another Safer Consumer Products Program requirement cautions against adding microplastics to the Candidate Chemicals list. If DTSC were to add microplastics to the Candidate Chemicals list and identify Priority Products, the next step in the process laid out in the regulations would be for manufacturers of the products identified in the final product-chemical combinations to conduct

[19] 22 CCR § 69503.
[20] 22 CCR § 69503.1.
[21] 22 CCR § 69503.2(a)(1).
[22] 22 CCR § 69503.3(a)(2).

alternatives analyses or alternatives thereto for their Priority Products. The regulations require alternatives analyses to consider and evaluate a long list of factors relevant for consideration of alternatives.[23] While that might make sense for individual Candidate Chemicals, it poses substantial challenges for something as varied as microplastics.

The current state of microplastics science is insufficient to support alternatives analyses. Currently, there is a lack of objective, fit-for-purpose criteria for evaluating studies, limitations to analytical and exposure characterization, and the absence of a consistent, comparable hazard profile across microplastic types. These limitations prevent meaningful comparison between materials. Together, these gaps make it scientifically impossible at present to conduct a defensible alternatives assessment for microplastics.

a. There is a Need for Objective, Fit-for-Purpose Criteria for Evaluating Microplastics Research in Regulatory Decision-Making

Regulatory decisions concerning microplastics should be grounded in objective, transparent, and fit-for-purpose criteria for evaluating scientific literature. The body of microplastic research has expanded rapidly, but studies vary widely in their relevance, reliability, and applicability to risk assessment. Without clearly defined evaluation criteria, there is a risk that regulatory conclusions may be driven by selective citation, inconsistent weighting of evidence, or over-interpretation of studies that were not designed to inform regulatory decision-making. Objective criteria provide a necessary framework to distinguish exploratory or mechanistic research from studies that can credibly support hazard identification, dose–response evaluation, and risk characterization.

A central challenge in the microplastics literature is the frequent absence of standardized quality assurance and quality control practices, particularly with respect to particle characterization, exposure verification, and study design. Many studies rely on test materials that are poorly characterized or not representative of environmentally relevant exposures. Often they lack sufficient reporting to allow independent evaluation of reliability. As demonstrated in systematic assessments of microplastic and nanoplastic toxicity studies, very few published studies meet minimum criteria across particle characterization, experimental design, and applicability for risk

[23] 22 CCR § 69505.5(c)(2) ("The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors listed below and the associated exposure pathways and life cycle segments, if applicable, that are relevant for the comparison of the Priority Product and the alternatives under consideration: (A) Adverse environmental impacts; (B) Adverse public health impacts; (C) Adverse waste and end-of-life effects; (D) Environmental fate; (E) Materials and resource consumption impacts; (F) Physical chemical hazards; and (G) Physicochemical properties.").

assessment, even when using a tiered and flexible screening approach.[24,25] Additionally, most toxicity studies of microplastics lack consistency within the microplastics being tested, as it is extremely difficult to generate reproducibly-sized microplastic particles that are uniform in size and/or lack cross-contamination from grinding down plastic materials. This variability underscores the importance of applying consistent criteria to identify which studies are fit for regulatory use.

Objective evaluation frameworks also help ensure that regulatory decisions are aligned with established risk assessment principles and best practices. Criteria such as clear dose metrics, appropriate controls, sufficient exposure ranges, and the ability to derive effect thresholds are fundamental to regulatory science, regardless of whether the stressor is a chemical substance or a particulate material. Applying these criteria does not diminish the scientific value of exploratory or hypothesis-generating studies; rather, it clarifies their role within the broader weight-of-evidence and prevents their misuse in regulatory contexts for which they were not intended.

Finally, the use of transparent, pre-defined evaluation criteria supports regulatory credibility and stakeholder confidence. A structured approach to screening and prioritizing microplastic studies enables regulators to clearly articulate why certain studies were relied upon and others were not, and how uncertainties were identified and managed. This transparency is particularly important in emerging areas of science, such as microplastics, where public interest is high and the evidence base is still evolving. Objective criteria therefore serve not only as a scientific safeguard, but also as a foundation for defensible, science-based regulatory decision-making.

b. Current Technologies Are Not Adequate to Characterize Microplastic Exposure, Release, or Hazard

In evaluating potential Priority Products (for which the Background Document is an initial step), the Safer Consumer Products regulations mandate that DTSC consider the availability and quality of the available information.[26] Even at this early stage in the process, DTSC should take a cautious approach due to demonstrated deficiencies in the available information.

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[24] de Ruijter, V., et al., Quality Criteria for Microplastic Effect Studies in the Context of Risk Assessment: A Critical Review, Environmental Science & Technology (2020), 54(19):11692-11705, https://pubs.acs.org/doi/pdf/10.1021/acs.est.0c03057?ref=article_openPDF.

[25] Gouin, T., et al., Screening and prioritization of nano- and microplastic particle toxicity studies for evaluating human health risks – development and application of a toxicity study assessment tool, Microplastics and Nanoplastics, 2(1):2 (2022), https://link.springer.com/content/pdf/10.1186/s43591-021-00023-x.pdf.

[26] 22 CCR § 69503.2(b)(1)(C) ("The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. In evaluating the quality of the available information, the Department shall consider, as applicable: 1. The level of rigor attendant to the generation of the information, including, when relevant, the use of quality controls; 2. The degree to which the information has been independently reviewed by qualified disinterested parties; 3. The degree to which the information has been independently confirmed, corroborated, or replicated; 4. The credentials and education and experience qualifications of the person(s) who prepared and/or

DTSC's proposal to list both primary and secondary microplastics on the Candidate Chemical List presents a unique challenge. While a primary microplastic may be manufactured for a specific reason and have a known range of characteristics, secondary microplastics do not. As a second microplastic degrades or biodegrades in the environment, its chemical composition changes, including any plastic additives that may have been used. It would be difficult to nearly impossible to evaluate a secondary microplastic with variable compositions over time, let alone conduct an alternatives assessment.

In recent months, a growing number of peer-reviewed commentaries and formal scientific responses have raised substantive questions about the reliability of several highly publicized microplastics studies, highlighting the need for objective study criteria. These critiques do not dispute that exposure to microplastics occurs. They do, however, emphasize that some prominent findings may be driven by methodological artifacts rather than true biological presence. Common concerns include inadequate contamination control, inappropriate analytical techniques, and insufficient validation that detected signals represent plastic polymers rather than endogenous biological materials or laboratory background.[27,28] Together, these critiques reinforce the need for careful scrutiny from the scientific community and technical experts before such studies are relied upon to inform regulatory or public health decisions.

Beyond the widely discussed "microplastics in the human brain" claims, additional high-profile studies have been called into question for similar shortcomings. A notable example is the study reporting microplastics in carotid artery plaques, published in the New England Journal of Medicine.[29] Subsequent correspondence to the journal raised concerns regarding potential contamination and the absence of key procedural controls, noting that the analytical approach may not have adequately distinguished between true *in situ* particles and background contamination introduced during sample handling or processing.[30] These critiques underscore that extraordinary claims about particle presence in sensitive human tissues require particularly rigorous contamination prevention and verification.

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reviewed the information; and 5. The degree to which the information is relevant for the purpose for which it is being considered by the Department.").

[27] Monikh, F., et al., Challenges in studying microplastics in human brain, Nature Medicine, 31, 4034–4035 (2025), https://www.nature.com/articles/s41591-025-04045-3.
[28] Rauert, C, et al., Assessing the Efficacy of Pyrolysis-Gas Chromatography-Mass Spectrometry for Nanoplastic and Microplastic Analysis in Human Blood, Environmental Science & Technology), 59(4):1984-1994 (2025), https://pubs.acs.org/doi/pdf/10.1021/acs.est.4c12599?ref=article_openPDF.
[29] Marfella, C., et al., Microplastics and Nanoplastics in Atheromas and Cardiovascular Events, New England Journal of Medicine, 390:900-910 (2024), https://www.nejm.org/doi/full/10.1056/NEJMoa2309822.
[30] Id.

Similar issues have been raised with respect to studies reporting microplastics in human and canine testes.[31,32] Follow-up analyses published in Toxicological Sciences questioned the suitability of the analytical methods used and highlighted the potential for misidentification of biological materials as plastic particles. Commentators further noted that contamination controls were either insufficiently described or absent, limiting confidence in the reported findings. These exchanges illustrate the analytical challenges inherent in microplastics research, particularly when studying complex biological matrices where false positives are difficult to rule out without robust validation.

Methodological concerns have also extended to environmental exposure studies with major public visibility, including the report estimating approximately 240,000 microplastic and nanoplastic particles per liter of bottled water.[33] Subsequent critiques published in the Proceedings of the National Academy of Sciences identified weaknesses in the use and interpretation of blank control samples, suggesting that background contamination may have materially influenced the reported particle counts.[34] As with the human tissue studies, these critiques do not negate the presence of microplastics in bottled water, but they call into question the quantitative magnitude of the reported findings and the relevance to real-world exposures and risk.

Taken together, these examples highlight a recurring pattern in which novel or striking microplastics findings are later tempered by closer examination of study design and analytical rigor. The evolving scientific literature reinforces the importance of applying objective, fit-for-purpose criteria when evaluating individual studies and weighing the overall evidence base.

Microplastics are heterogenous mixtures. There is very little scientific evidence that demonstrates one microplastic particle (size, shape, polymer type, other characteristics) can be compared to another. Rather, research demonstrates that even the "same type" of microplastic can have drastically different toxicities (i.e., hazards).[35] Therefore, responsible parties cannot

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[31] Chelan, H., et al., Microplastic presence in dog and human testis and its potential association with sperm count and weights of testis and epididymis, Toxicological Sciences, 200:2, 235–240 (2024), https://academic.oup.com/toxsci/article-pdf/200/2/235/58666270/kfae060.pdf.

[32] Uppu, R., et al., Comment on: "Microplastic presence in dog and human testis and its potential association with sperm count and weights of testis and epididymis," Toxicological Sciences, 106:2, 456–457 (2024), https://academic.oup.com/toxsci/article-pdf/206/2/456/60578740/kfae136.pdf.

[33] Qian, N., et al, Rapid single-particle chemical imaging of nanoplastics by SRS microscopy, Proceedings of the National Academy of Sciences, 121:3 (2024), https://www.pnas.org/doi/epdf/10.1073/pnas.2300582121.

[34] Materić, D. et al, Nanoplastics measurements must have appropriate blanks, Proceedings of the National Academy of Sciences, 121:48 (2024), https://www.pnas.org/doi/epdf/10.1073/pnas.2411099121.

[35] Ramsperger, F., et al., Supposedly identical microplastic particles substantially differ in their material properties influencing particle-cell interactions and cellular responses, Journal of Hazardous Materials, 425:127961 (2021), https://doi.org/10.1016/j.jhazmat.2021.127961; Wieland, S., et al., Nominally identical microplastic models differ greatly in their particle-cell interactions, Nature Communications, 15:922 (2024), https://www.nature.com/articles/s41467-024-45281-4.pdf.

necessarily conduct an alternatives assessment using the experimental data from a different type of microplastic when assessing for hazards and potential risks.

c. Regulatory Agencies Acknowledge Limitations of Current Science and Dispute Findings of Risk from Microplastics

To a significant degree, regulatory agencies have evaluated the scientific evidence and have found that the literature is of poor quality, likely overestimates the amount of microplastics released, and does not indicate a hazard or risk for human health. A good example is plastic tea bags, one of the potential product-chemical combinations identified in the Background Document.

The German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung (BfR)) recently evaluated a widely cited study reporting the release of microplastic and nanoplastic particles from plastic tea bags during brewing. In its 2025 assessment,[36] BfR concluded that, based on current scientific knowledge, no adverse health effects are expected for consumers. BfR emphasized that the study demonstrated that particle release occurred under specific laboratory conditions but did not provide evidence of toxicological relevance (i.e., hazard) or health impairment at realistic exposure levels. The BfR assessment emphasized that detection of particles alone does not establish risk, and that conclusions regarding consumer safety require hazard identification, dose–response information, and an understanding of biologically relevant exposure.

The BfR evaluation further highlighted significant scientific uncertainties related to exposure characterization and biological relevance. These include limitations and variability in analytical methods, challenges in distinguishing test-related particles from background contamination, and the absence of validated data demonstrating uptake, accumulation, or adverse effects in humans at reported exposure levels. On this basis, BfR determined that the available evidence does not support consumer health warnings or regulatory action specific to plastic tea bags.

These conclusions are aligned with the 2024 assessment by the U.S. Food and Drug Administration (FDA) of microplastics and nanoplastics in foods.[37] Key findings by FDA include:

> Current scientific evidence does not demonstrate that levels of microplastics or nanoplastics detected in foods pose a risk to human health.

[36] BfR, BfR assesses study on tea bags and microplastic particles: No health impairments expected based on current knowledge (2025), https://www.bfr.bund.de/assets/01_Ver%C3%B6ffentlichungen/Mitteilungen_englisch/bfr-assesses-study-on-tea-bags-and-microplastic-particles.pdf.
[37] FDA, Microplastics and Nanoplastics in Foods (2024), https://www.fda.gov/food/environmental-contaminants-food/microplastics-and-nanoplastics-foods.

> There is not sufficient scientific evidence to show that microplastics and nanoplastics from plastic food packaging migrate into foods and beverages.
>
> The presence of environmentally derived microplastics and nanoplastics in food alone does not indicate a risk and does not violate FDA regulations unless it creates a health concern. While many studies have reported the presence of microplastics in several foods, including salt, seafood, sugar, beer, bottled water, honey, milk, and tea, current scientific evidence does not demonstrate that the levels of microplastics or nanoplastics detected in foods pose a risk to human health. Additionally, because there are no standardized methods for how to detect, quantify, or characterize microplastics and nanoplastics, many of the scientific studies have used methods of variable, questionable, and/or limited accuracy and specificity.

Similarly, the European Food Safety Authority (EFSA) has expressed reservations about risk findings regarding microplastics in food. In its 2025 literature review on the release of micro- and nanoplastics from food contact materials during use,[38] EFSA found that reported release levels vary widely depending on material type, testing conditions, and analytical approach, and that many studies rely on non-standardized methods that limit comparability and regulatory interpretation. EFSA concluded that the current evidence base does not allow for reliable exposure assessment or risk characterization for consumers. It identified the need for harmonized methodologies, improved quality control, and better linkage between particle measurements and toxicological relevance.

Taken together, the assessments by BfR, FDA, and EFSA present a coherent regulatory science position. While microplastic and nanoplastic particles may be detected from certain food contact materials under specific conditions, current evidence does not demonstrate that such findings translate into adverse health effects for consumers. All three authorities emphasize that further method development, robust exposure assessment, and targeted toxicological research are needed before health hazards and potential risks can be evaluated with confidence or risk management measures considered.

Further, perception-based information is not sufficient to drive regulation. Last year, BfR reported that there is a significant gap between what the public perceives as high levels of concern about health effects and what the current data supports, while calling for higher-quality data:

[38] EFSA, Literature review on micro- and nanoplastic release from food contact materials during their use (2025), https://eumeps.eu/images/_spe/Publications-spe/2025-EFSA_Technical_Report_on_microplastics.pdf.

> The current state of knowledge suggests that the risk to consumers from microplastics is relatively low, given that the majority of particles do not become bioavailable, and the overall quantities taken up are likely insufficient to trigger health effects. Research is required in particular into mechanisms of action in order to establish a causal link between particle exposure and possible effects. There is also a need for robust, validated analytical methods capable of reliably quantifying microplastics in biological matrices. At the same time, the public perception of microplastics is characterized by an increasing awareness of the topic, comparatively limited knowledge, and high concern regarding the health effects. This prevailing discrepancy between the state of knowledge and public perception should be taken into account when communicating on this topic.[39]

This coalition supports the development of high-quality data that can inform risk assessment while that additional research is conducted. DTSC should recall that chemical exposures from food contact materials are subject to comprehensive regulatory oversight designed to ensure a high level of consumer protection. In both the United States and the European Union, substances used in food contact materials are evaluated prior to authorization, with a focus on limiting migration into food to levels that are not expected to pose a risk to human health. In the United States, FDA regulates food contact substances under a premarket authorization framework that requires a demonstration of safety, commonly expressed as a reasonable certainty of no harm under the intended conditions of use.[40] This framework includes conservative exposure assumptions, migration testing, and, where appropriate, toxicological data to ensure that dietary exposures remain well below levels of concern.

A similarly rigorous approach applies in the European Union, where food contact materials are regulated under a harmonized system that establishes positive lists of authorized substances and specific migration limits. To ensure a high level of food safety, all food contact materials must comply with Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food when placed on the European market. In addition to this Regulation, all food contact materials must be manufactured in accordance with Good Manufacturing Practices (GMP, Commission Regulation (EC) No 2023/2006), and specific EU legislation on certain materials, including on plastic and ceramics, as well as with national legislation on other materials. More than 300 substances are authorised for use as food additives in the EU. EFSA has evaluated the safety of the majority of these, while the remainder were assessed by the European Commission's Scientific Committee on Food before EFSA was established.[41]

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[39] BfR,, Microplastics: State of the Evidence on Health Effects and Public Perception, Deutsches Ärzteblatt International, 122: 546–51 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12620896/pdf/Dtsch_Arztebl_Int-122_546.pdf. .

[40] 21 C.F.R. Parts 170-186.

[41] EFSA, Food additives (2026), https://www.efsa.europa.eu/en/topics/topic/food-additives.

These regulatory systems are designed to address chemical substances that may migrate into food, including low-level and chronic exposures, and they incorporate substantial safety margins. As a result, chemical exposures from compliant food contact materials are already tightly controlled, and any additional considerations related to particulate materials must be evaluated within the context of these existing, protective regulatory frameworks.

d. Misalignment Between Additives in Microplastics and the Product-Based Structure of the Safer Consumer Products Program

Even if DTSC had authority to treat microplastics as a chemical and thought now was an appropriate time to evaluate microplastics in products, its proposal to evaluate chemical additives in microplastics[42] and products that have the potential to release microplastics[43] falls outside the scope of the Safer Consumer Products Program. As DTSC recognizes, after a chemical is listed on the Candidate Chemical List, DTSC identifies priority products "which are specific product-chemical combinations that can expose people or the environment to . . . [the] Candidate Chemical[]." Thereafter, "manufacturers of Priority Products" must "conduct a comprehensive Alternatives Analysis[.]"[44] The treatment of additives associated with microplastic particles, especially secondary microplastics, departs from the Program's focus on defined chemical–product combinations and product-specific alternatives analysis.[45]

DTSC would be hard pressed to require a comprehensive product-specific alternatives analysis for Priority Products involving secondary microplastics. While a primary microplastic may be manufactured for a specific reason and have a known range of characteristics, secondary microplastics do not. As a secondary microplastic degrades or biodegrades in the environment, its chemical composition changes, including the breakdown of any additives that may have been used, which have their own degradation profile to consider. It would be difficult or nearly impossible to evaluate an additive in a secondary microplastic with variable concentrations, let alone conduct an alternatives assessment.

The Legislature intentionally structured the Safer Consumer Products Program to regulate chemicals in the context of their use in identifiable consumer products, recognizing that hazard, exposure, and feasible alternatives are inseparable from product function, use patterns, and lifecycle.[46,47] DTSC's regulations reinforce this product-specific framework by requiring that

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[42] See Background Document at 2 (stating that "[m]icroplastics can have additional hazards depending on . . . additives they contain"); 11 (seeking "[a]vailable studies assessing the potential for migration of chemical additives from snack and candy wrappers into food"), 12 (seeking "[a]vailable studies that assess the potential for migration of chemical additives from plant-based foodware into food"),
[43] See Background Document at 5-8.
[44] SCP Program Overview, https://dtsc.ca.gov/scp/safer-consumer-products-program-overview/.
[45] Health & Safety Code §§ 25251-25257.
[46] 22 CCR § 25253(a).
[47] 22 CCR § 69503.2.

Priority Products be defined as particular product categories containing a Candidate Chemical and that alternatives analyses evaluate substitutes for the Priority Product (e.g., nail products containing methyl methacrylate (MMA) at concentrations greater than 1,000 parts per million).[48, 49] Evaluating an additive in secondary microplastics, rather than as part of a defined chemical–product pair, bypasses the core analytical safeguards embedded in the statute, including product-specific exposure assessment, market relevance, and the identification of feasible alternatives. In doing so, DTSC risks exceeding its authority by regulating chemicals outside the product-based framework required by law.

3. Definitions and Criteria Needed for a Scientifically Defensible Approach

If, notwithstanding the foregoing, DTSC decides to pursue listing microplastics as a Candidate Chemical, it should provide a definition for "plastics" to provide clarity to stakeholders and consistency in its decisions. The use of internationally recognized standards (e.g., ASTM, ISO) provides a common language and best practices to ensure all stakeholders have clarity on what products are in or out of scope.

a. DTSC Should Define "Plastic"

DTSC's proposed definition of "microplastics" starts with the idea that all are plastics in origin, but DTSC nowhere defines "plastics" or "plastic." The Background Document alternately describes polymers and their properties as the object of regulatory concern and as potential alternatives, such as biodegradable polymers and silicones. This internal inconsistency undermines scientific clarity and regulatory credibility, particularly when the same material characteristics are used both to justify regulation and to exempt materials from it. A durable regulatory framework requires a stable and technically defensible definition that does not shift based on context or desired outcome.

Anchoring the definition of "plastic" in an internationally recognized standard would provide this certainty. ASTM D883-25 offers a well-established and widely accepted definition that is fit for regulatory purposes:

> "Plastic" means a material that contains, as an essential ingredient, one or more organic polymeric substances of high molecular weight, is solid in its finished state, and, at some stage in its manufacture or processing into a finished article, can be shaped by flow.

[48] 22 CCR § 69505.1(a)
[49] Product-Chemical Profile for Nail Products Containing Methyl Methacrylate (MMA). 2024. https://dtsc.ca.gov/wp-content/uploads/sites/31/2024/10/Profile_Methyl-Methacrylate-in-Nail-Products_FINAL.pdf.

To remain consistent, such a definition should explicitly exclude biodegradable plastics, water-soluble polymers, and natural polymers, with natural polymers defined as polymers resulting from polymerization processes occurring in nature that are not chemically modified.

Exclusions for water-soluble polymers and biodegradable polymers would need to rely on definitions of solubility and biodegradability. Fortunately, these are established characteristics that can be used to distinguish different categories of polymers from each other. Both properties are discussed below.

b. The Definition Should Address Solubility

Over several decades, internationally standardized approaches for characterizing the water solubility of chemical substances, including polymers, have developed into a globally harmonized testing framework. A central element of this framework is the work of the Organisation for Economic Co-operation and Development (OECD), which coordinates international efforts to align chemical safety testing across regulatory systems. Through its Chemicals and Biotechnology Programme, the OECD has established a portfolio of Test Guidelines that define how key physicochemical properties, toxicological endpoints, and environmental fate parameters are measured. These guidelines are developed through collaborative processes involving regulatory authorities, scientific experts, and industry stakeholders and are widely relied upon by governments as the technical foundation for chemical evaluations, including assessments of polymeric substances.

Water solubility is a core physicochemical parameter that directly influences exposure pathways, environmental transport, and persistence. For polymeric materials used in formulated products, solubility is often a favorable attribute because materials that dissolve or are readily dispersed in water are less likely to re persistent and more available for subsequent microbial transformation. As a result, solubility information is routinely used in regulatory screening to inform classification, environmental fate modeling, and prioritization for further testing.
The OECD has established dedicated test methods to characterize solubility behavior in water, most notably Test Guideline 105, which determines the equilibrium solubility of a substance under defined laboratory conditions. This guideline is based on equilibrating the test material with water at a controlled temperature, separating undissolved material, and analytically measuring the dissolved fraction. While originally developed for low-molecular-weight substances, OECD TG 105[50] is still used as a screening tool for polymers where applicable, providing bounding information on whether any fraction of the material is present in true solution.

[50] OECD (1995), *Test No. 105: Water Solubility*, OECD Guidelines for the Testing of Chemicals, Section 1, OECD Publishing, Paris, https://doi.org/10.1787/9789264069589-en.

Recognizing that conventional solubility concepts do not always adequately describe the behavior of polymers, particularly those with high molecular weight or complex structures, the OECD developed Test Guideline 120[51] to address polymer-specific considerations. OECD TG 120 is designed to evaluate the solution and extraction behavior of polymers in water rather than assigning a single solubility value. The method employs modified experimental conditions, including higher test material loadings, extended contact times, and enhanced separation procedures, to distinguish between dissolved, colloidal, extractable, and undissolved fractions. By focusing on the extent to which polymer material can enter the aqueous phase under environmentally relevant conditions, TG 120 provides information that is directly relevant to understanding polymer transport, dilution, and potential bioavailability in aquatic systems and wastewater treatment processes.

Together, OECD TG 105 and TG 120 provide a scientifically coherent and complementary framework for assessing water interaction of polymers and other substances. TG 105 offers a standardized point of reference for solubility screening, while TG 120 enables a more nuanced characterization of polymer behavior that is aligned with regulatory needs for environmental fate and exposure assessment.

c. The Definition Should Address Biodegradability

Biodegradation testing is a central component of environmental fate assessment because it provides information on the persistence of polymeric substances, including water-soluble polymers, non-soluble polymers, and plastics. Standardized biodegradation tests therefore play a key role in determining how rapidly polymers and plastics undergo microbial transformation under environmentally relevant conditions.

The OECD has established a tiered suite of internationally harmonized Test Guidelines that are used to evaluate biodegradability across a wide range of substances, including polymers with varying degrees of solubility. The OECD 301[52] series comprises stringent screening tests for ready biodegradability that assess mineralization or oxygen consumption under conservative conditions using a non-acclimated microbial inoculum and a limited test duration, typically 28 days. For non-soluble polymers and plastics, these tests are generally applicable only where measurable dissolved or bioavailable fractions are present, and negative results are therefore interpreted as indicating a lack of rapid biodegradation under unfavorable screening conditions rather than definitive environmental persistence. Where ready biodegradability criteria are not

[51] OECD (2000), Test No. 120: Solution/Extraction Behaviour of Polymers in Water, OECD Guidelines for the Testing of Chemicals, Section 1, https://doi.org/10.1787/9789264069886-en.
[52] OECD (1992), Test No. 301: Ready Biodegradability, OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264070349-en.

met, OECD 302 (A-C)[53,54,55] guidelines are used to assess inherent biodegradability under less stringent and more environmentally realistic conditions, and OECD 303[56] simulation tests evaluate long-term removal mechanisms in continuous wastewater treatment systems.

In parallel with OECD chemical fate methods, standardized test methods have also been developed specifically to measure biodegradation of plastic materials as finished articles under defined environmental scenarios. These material-focused standards are primarily maintained by the International Organization for Standardization (ISO) and ASTM International and are widely used to evaluate biodegradation under composting, soil, freshwater, and marine conditions.[57,58,59,60,61,62,63,64,65,66,67] While these ASTM and ISO standards are scientifically robust for evaluating biodegradation of plastic materials under specific environmental conditions, they are not designed to assess environmental persistence of polymeric substances across compartments and are therefore complementary to, rather than substitutes for, OECD Test Guidelines in chemical regulatory frameworks. Together, these approaches provide a scientifically coherent and internationally recognized basis for evaluating biodegradation across both polymer substances and plastic materials.

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[53] OECD (1981), Test No. 302A: Inherent Biodegradability: Modified SCAS Test, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, https://doi.org/10.1787/9789264070363-en.
[54] OECD (1992), Test No. 302B: Inherent Biodegradability: Zahn-Wellens/ EVPA Test, OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264070387-en.
[55] OECD (2009), Test No. 302C: Inherent Biodegradability: Modified MITI Test (II), OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264070400-en.
[56] OECD (2001), Test No. 303: Simulation Test - Aerobic Sewage Treatment -- A: Activated Sludge Units; B: Biofilms, OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264070424-en.
[57] ISO 14855-1:2012 Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions — Method by analysis of evolved carbon dioxide. Part 1: General method
[58] ISO 14855-2:2018. Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions — Method by analysis of evolved carbon dioxide.
[59] ASTM D5338-15(2021). Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials Under Controlled Composting Conditions, Incorporating Thermophilic Temperatures
[60] ISO 17556:2019. Plastics — Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved
[61] ASTM D5988-18. Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil
[62] ASTM D6400-21. Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities.
[63] ASTM D6868-21. Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities.
[64] ASTM D8410-21. Standard Specification for Evaluation of Cellulosic-Fiber-Based Packaging Materials and Products for Composability in Municipal or Industrial Aerobic Composting Facilities
[65] EN 17033:20. Plastics - Biodegradable mulch films for use in agriculture and horticulture - Requirements and test methods.
[66] ISO 23517:2021. Plastics — Soil biodegradable materials for mulch films for use in agriculture and horticulture — Requirements and test methods regarding biodegradation, ecotoxicity and control of constituents
[67] ISO 22403:2020. Plastics — Assessment of the intrinsic biodegradability of materials exposed to marine inocula under mesophilic aerobic laboratory conditions — Test methods and requirements

d. DTSC Should Add a Lower Size Limit for Microplastics

DTSC's proposed definition of "microplastics" has an upper size limit, 5 mm. Equally important, the definition should include a lower size limit that reflects what is technologically feasible to measure and regulate.

Exposure and concentration assessments are inherently constrained by the capabilities of available analytical methods. Accurately detecting and quantifying particles below ~1 μm remains a significant technical challenge, even in a research setting, and is not achievable in a high throughput regulatory context.

Absent a realistic size threshold, regulatory programs risk being enforced on measurements that are not reproducible, not comparable across laboratories, and not suitable for compliance determinations or alternatives assessments. Current validated methods are generally unable to reliably quantify microplastics below approximately 5 to 10 μm, a constraint widely recognized in the scientific literature. DTSC should therefore establish a technically feasible lower size limit grounded in existing high-throughput capabilities, rather than theoretical detectability under specialized conditions.

DTSC could further strengthen this approach by articulating performance criteria for acceptable analytical methods, analogous to the concept of Best Available Technology. This would ensure that regulations are aligned with what can actually be measured in a reliable and reproducible manner and enhance both scientific rigor and regulatory legitimacy.

CONCLUSION

The Background Document appears to signal that DTSC is plunging ahead with its drive to add microplastics to the Candidate Chemical List and proceed further, all the way to alternatives analyses and potential regulation of microplastics. This is inappropriate and unnecessary. Microplastics do not belong on the Candidate Chemical List in the first place, for the reasons explained above and in prior industry coalition comments.

The Background Document fails to appreciate the challenges that adding microplastics to the Candidate Chemical List would precipitate. Some of these problems arise because microplastics are not a single substance with a particular molecular identity, notwithstanding DTSC's efforts to force-fit microplastics into its own regulatory definitions. Other problems arise because the science is not sufficiently mature to be able to make reliable judgments about exposure to microplastics and whether exposure to them causes adverse effects.

DTSC should recognize that it may not be possible to prepare credible alternatives analyses of Priority Products that include microplastics. If that is the case, DTSC should not proceed beyond gathering information about microplastics. It should not add microplastics to the Candidate Chemical List or consider potential Priority Products.