California Water Boards

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**State Water Resources Control Board**

# Proposed Definition of 'Microplastics in Drinking Water' (June 3, 2020)

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## Proposed Definition of 'Microplastics in Drinking Water'*

*'Microplastics in Drinking Water' are defined as solid*[1] *polymeric materials*[2] *to which chemical additives or other substances may have been added, which are particles*[2] *which have at least three dimensions that are greater than 1nm and less than 5,000 micrometers (µm)*[3]*. Polymers that are derived in nature that have not been chemically modified (other than by hydrolysis) are excluded.*

*Evidence concerning the toxicity and exposure of humans to microplastics is nascent and rapidly evolving, and the proposed definition of 'Microplastics in Drinking Water' is subject to change in response to new information. The definition may also change in response to advances in analytical techniques and/or the standardization of analytical methods.

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[1]'Solid' means a substance or mixture which does not meet the definitions of liquid or gas.
'Liquid' means a substance or mixture which (i) at 50 degrees Celsius (˚C) has a vapor pressure less than or equal to 300 kPa; (ii) is not completely gaseous at 20 ˚C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 ˚C or less at a standard pressure of 101.3 kPa.
'Gas' means a substance which (i) at 50 ˚C has a vapor pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 ˚C at a standard pressure of 101.3 kPa.
[2]'Polymeric material' means either (i) a particle of any composition with a continuous polymer surface coating of any thickness, or (ii) a particle of any composition with a polymer content of greater than or equal to 1% by mass.
'Particle' means a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface.
'Polymer' means a substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight.
'Monomer unit' means the reacted form of a monomer substance in a polymer.
'Monomer' means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.
[3]Size-based nomenclature for plastic particles with dimensions within the criteria for 'microplastics in drinking' as well as larger particles outside the threshold dimensions are as follows: "nanoplastics" (1 nm to <100 nm); "sub-micron plastics" (100 nm - <1 µm); "small microplastics" (1 µm to < 100 µm); "large microplastics" (100 µm to <1 mm); "mesoplastics" (1 mm to <2.5 cm); "macroplastics" (>2.5 cm).

## Executive Summary

Health and Safety Code (HSC) section 116376 requires the State Water Resources Control Board (State Water Board) to adopt a definition of microplastics in drinking water on or before July 1, 2020. The adopted definition will be used in successive regulatory efforts concerning microplastics in drinking water as required by HSC 116376. Although the State Water Board will be the first regulatory agency in the world to specifically define 'Microplastics in Drinking Water', other governmental agencies have defined 'microplastics' in other contexts, including the European Chemicals Agency (ECHA), which has recently proposed a definition related to intentional uses of 'microplastics' (European Chemicals Agency 2019a).

Evidence concerning the hazards and exposure of humans to 'microplastics' is nascent and rapidly evolving, and currently no standardized methods for the detection of 'microplastics' exist. Accordingly, the proposed definition of 'Microplastics in Drinking Water' is subject to change in response to new information. With respect to public health, hazards of microplastics in humans is poorly understood (World Health Organization 2019). Three primary routes of exposure of humans to microplastics are known – air, food and water (Q. Zhang et al. 2020). However, the relative magnitude of exposure from these and other sources are not fully understood and may vary significantly between individuals and groups (Q. Zhang et al. 2020). In regards to contamination of microplastics in drinking water, available information indicates groundwater wells are likely to contain very low (if any) levels of microplastics (Mintenig et al. 2019), however surface water sources are known to contain microplastics at high detection frequencies, and at a range of levels (Eerkes-Medrano, Leslie, and Quinn 2019). Additionally, test methods of different size plastic particles are in varying stages of development (Primpke et al. 2020).

The following criteria must all be satisfied to define a particle as 'Microplastics in Drinking Water': *substance, state, and dimensions*. Additional characteristics should be recorded in the characterization of 'Microplastics in Drinking Water', including morphology and color, but are not critical to the definition. The proposed definition of 'Microplastics in Drinking Water' is based on the definition of 'microplastics' proposed by ECHA (2019), however with a few notable differences in *dimensions*, and *substance*.

The *substance* criterion is based on the substance criterion in the proposed definition of 'microplastics' by ECHA (2019) with one exception: 'biodegradable polymers' are specifically excluded by ECHA, whereas no such exclusion is included here. The proposed definition of 'Microplastics in Drinking Water' does not exclude biodegradable polymers due to significant uncertainties regarding the human health effects of biodegradable polymers (Zuo et al. 2019; Liao and Yang 2020). Currently, the proposed definition of 'Microplastics in Drinking Water' excludes "polymers that are derived in nature that have not been chemically modified (other than by hydrolysis)." Examples of such natural polymers include cellulose, natural rubber, DNA, proteins, wool, and silk. *Substance* criteria for a microplastic particle is defined principally as being 'polymeric material'[4], and includes synthetic polymer composites, co-polymers, modified natural polymers (i.e. synthetic polymer-encapsulated natural polymers or natural polymers with synthetic polymer content greater than or equal to 1% by mass). Additionally, particles comprised of <99% additives are included[5].

The *state* criterion considers the practicality of measuring particles[6] that are 'solid' at room temperature (20 ˚C) and standard pressure (101.3 kPa). The Globally Harmonized System for Classification and Labelling of Chemicals (GHS) considers melting temperature ($T_m$) a defining criterion for solids and liquids. Some polymers (e.g. amorphous polymers) lack a specific $T_m$ or may have a $T_m$ above 20 ˚C but have a glass transition temperature ($T_G$) below 20 ˚C and would therefore behave in many regards as a "solid" but may be classified as "semi-solid". For these reasons, 'solid' is defined as a substance or mixture which does not meet the definitions of liquid[7] or gas[8] and would therefore include such 'semi-solid' polymers. This criterion is identical to the *state* criterion in the definition of 'microplastics' proposed by ECHA (2019).

The *dimensions*[9] criterion in the proposed 'definition of microplastics in drinking water' is based on considerations of health hazards, and harmonization with definitions from the vast majority of regulatory and scientific agencies. Current toxicological knowledge suggests that smaller particles are more hazardous to humans, with extreme uncertainties regarding plastic particles in the nanoscale range (World Health Organization 2019). The upper size limit of 5 mm corresponds with the lower size limit for the requirement of particle filtration by "full capture systems" in storm drains as required by the Water Quality Control Plan for Ocean Waters of California, and thus representing a *de facto* upper dimensions limited regulatory definition for "trash" by the State Water Board. Further, the upper size limit matches the upper size limit in the 'microplastic' definition proposed by ECHA, with the exception that ECHA includes an additional size criteria for "fibres". The requirement that three dimensions meet threshold criteria would exclude fibers and films that may have dimensions longer than

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[4] 'Polymeric material' means either (i) a particle of any composition with a continuous polymer surface coating of any thickness, or (ii) a particle of any composition with a polymer content of greater than or equal to 1% by mass.

[5] According to the definition, "…to which additives or other substances may have been added…".

[6] Particle is defined as a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface (ECHA 2019).

[7] 'Liquid' means a substance or mixture which (i) at 50 degrees Celsius (˚C) has a vapor pressure less than or equal to 300 kPa; (ii) is not completely gaseous at 20 ˚C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 ˚C or less at a standard pressure of 101.3 kPa.

[8] 'Gas' means a substance which (i) at 50 ˚C has a vapor pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 ˚C at a standard pressure of 101.3 kPa.

[9] "…have at least three dimensions less than 5,000 micrometers (μm*)…"*

5 mm. Based on the expected toxicity (and extreme uncertainties of hazards and exposure) of sub-micron plastic particles (World Health Organization 2019), the proposed definition has a lower size limit of 1nm, which is synonymous with the ECHA (2019) definition, and effectively synonymous with the majority of regulatory and scientific definitions of microplastics[10]. Analytical techniques to separate and detect sub-micron plastic particles are relatively less developed than for larger plastic particles (Primpke et al. 2020), and the State Water Board does not expect that methods will be readily available for all particle types within the definition of 'microplastics in drinking water'. For many drinking water contaminants, available analytical methodologies are are unable to detect concentrations of contaminants at levels which are known or expected to be toxic (public health goals), and both detection limits for the purposes of reporting and maximum contaminant levels are established at concentrations above toxic levels[11]. Likewise, measurements of 'microplastics in drinking water' likely may never fully reflect the theoretical definition.

A criterion for solubility is not included. This omission is congruous with the ECHA definition of 'microplastics' (2019) and the vast majority of other regulatory and scientific definitions of 'microplastics'[10], despite the inclusion of such criteria in previous ECHA definitions and other recommendations (Hartmann et al. 2019; COM 2017). The omission of solubility criteria in the proposed definition of 'Microplastics in Drinking Water' is intentional and acknowledges that limited toxicological information is available for soluble polymers, and that such polymers may be found in 'solid' form in water through agglomeration with other particles and other mechanisms (Arp and Knutsen 2019).

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[10] No lower size limit is included in the definitions adopted by the Ocean Protection Council and National Oceanic (Ocean Protection Council and National Ocean and Atmospheric Administration Marine Debris Program 2018), US EPA (Murphy 2017), National Oceanic and Atmospheric Administration (Courtney Arthur, Baker, and Bamford 2008), International Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP 2019).

[11] https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/MCLsandPHGs.html

## Background and Process

The State Water Board is responsible for the administration of provisions related to drinking water to protect public health. The California Safe Drinking Water Act (SDWA) authorizes the State Water Board to conduct research, studies, and demonstration programs to ensure provision of a dependable, safe supply of drinking water, which may include improving methods to identify and measure the existence of contaminants in drinking water and the source of the contaminants (California Code of Regulations [CCR] 1996). The SDWA also grants the State Water Board the authority to implement regulations that may include monitoring of contaminants and requirements for notifying the public of the quality of the water delivered to customers (CCR 1996).

On September 28, 2018, Senate Bill No. 1422 was filed with the Secretary of State, adding section 116376 to California's Health and Safety Code (HSC), and requiring the State Water Board to adopt a definition of 'Microplastics in Drinking Water' on or before July 1, 2020. HSC section 116376 also requires the State Water Board on or before July 1, 2021, to accomplish the following (figure 1):

(1) adopt a standard methodology to be used in the testing of drinking water for microplastics;
(2) adopt requirements for four (4) years of testing and reporting of microplastics in drinking water, including public disclosure of those results;
(3) consider issuing a notification level or other guidance to aid consumer interpretation of results; and
(4) accredit qualified California laboratories to analyze microplastics.

HSC section 116376 allows the State Water Board to implement these requirements through adoption of a Policy Handbook.

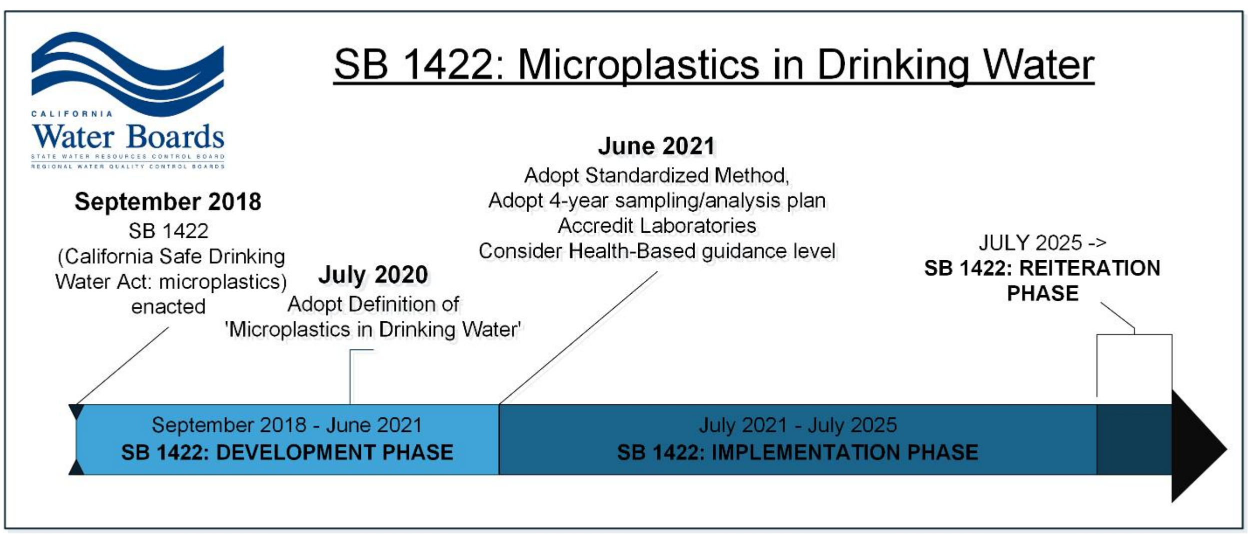


Figure 1. Timeline of requirements of Senate Bill (SB) 1422 (Health and Safety Code section 116376): microplastics in drinking water.

On January 31, 2020, the State Water Board submitted the proposed definition of microplastics in drinking water to the Southern California Coastal Water Research Project (SCCWRP), who then facilitated a peer review of the scientific basis of the definition through an external panel of experts[12]. Following the formal adoption of the definition by the State Water Board on or before July 1, 2020, the proposed definition may be re-evaluated in response to new information and may be further reviewed by additional expert panels. To date, there is no universally agreed-upon definition for “microplastics” (GESAMP 2019). Few studies are available regarding human exposure and health hazards of plastic particles, and significant data gaps remain (World Health Organization 2019). Plastic particles are a diverse contaminant suite and may be differentiated by a variety of criteria such as substance, state at a given temperature and pressure (e.g., solid at room temperature and standard pressure), dimensions, shape and structure (morphology), and color (Rochman et al. 2019). The influence of these parameters in the environmental fate, transport, and human health impacts of microplastics are not fully understood. To prioritize the protection of public health in light of the significant scientific uncertainties, the ’Microplastics in Drinking Water’ should be defined broadly, and with as few exclusions as possible, to ensure that policies, regulations, and standardized methodologies based on the definition capture a wide diversity of plastic particle types. Furthermore, while technological limitations in the measurement of plastic particles may be informative to a regulatory definition, it should be observed that such limitations are likely transient and serve only as a rough guide for prospective technical and economic feasibility of sampling and monitoring.

A Board Workshop was held on April 7th (Coffin 2020b) to discuss the March 9 version of the proposed definition (Coffin 2020a). A 30-day public comment period was held from March 24- April 24. Responses to comments are available on the State Water Board program webpage[13]. In response to stakeholder comments, the proposed definition and staff report were revised (current version). Definition revisions include a change in the lower size limit from 1 micron to 1 nanometer, the requirement that three dimensions satisfy the state criteria instead of two, and the adoption of a nomenclature framework (page 23). The staff report was updated to include rationale describing the adopted size-based nomenclature framework (page 23), refined morphology classification (page 25), and additional justification for the following: lack of solubility threshold criteria (pages 25-26); lack of density threshold criteria (page 26); lack of biodegradability threshold criteria (pages 15-16); and inclusion of natural polymers with >1% non-natural polymer content (by mass) (pages 18-19).

[12] https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/docs/pr_rvw_mcrplstcs.pdf

[13] https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/microplastics.html

The proposed definition contains an asterisk[14] which provides justification for revisions based on updated information. At the time of writing (May 11, 2020), there are no standardized methods for the detection of microplastics in drinking water or any other media. Furthermore, less than 10 studies have been published detailing the occurrence of microplastics in drinking water (Q. Zhang et al. 2020), and human health effects of exposure to microplastics are extremely uncertain (World Health Organization 2019). The State Water Board intends to revisit the definition of 'microplastics in drinking water' prior to the adoption of additional HSC section 116376 requirements (June 2021), and will provide opportunity for public comment prior to the adoption of a revised definition. Further information regarding public comments, revisions to the definition, and additional HSC section 116376 requirements will be made available on the State Water Board microplastics webpage[15].

## Current Definitions of Microplastics in Regulatory Agencies

The term "microplastics" has been defined by several national and international regulatory agencies and scientific bodies in varying contexts. Some agencies use the term "microplastics" in reports, yet do not include a definition. Additionally, some agencies define related items, such as trash, marine debris, microfibers, etc. Most agencies' definitions of "microplastics" include criteria for *dimensions*, however few include criteria for *substance* or *state*.

Staff have reviewed the work in this regard of other state and federal agencies as well as other organizations and agencies. Highlight of the work of the following organizations is provided below:

1. California Natural Resources Agency: Ocean Protection Council
2. California Environmental Protection Agency: State Water Resources; Control Board Division of Water Quality
3. California Environmental Protection Agency: Department of Toxic Substances Control
4. United States Environmental Protection Agency
5. National Oceanic and Atmospheric Administration
6. European Marine Strategy Framework Directive
7. International Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection
8. European Chemicals Agency

[14] *Evidence concerning the toxicity and exposure of humans to microplastics is nascent and rapidly evolving, and the proposed definition of 'Microplastics in Drinking Water' is subject to change in response to new information. The definition may also change in response to advances in analytical techniques and/or the standardization of analytical methods

[15] https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/microplastics.html

### *California Natural Resources Agency: Ocean Protection Council*

The Ocean Protection Council (OPC), in collaboration with the National Oceanic and Atmospheric Administration (NOAA) and Sea Grant California, define microplastics as "materials smaller than 5 mm" in a 2018 report on the California Ocean Litter Prevention Strategy (Ocean Protection Council and National Ocean and Atmospheric Administration Marine Debris Program 2018). The OPC is mandated by Public Resources Code 35635 to develop and implement a Statewide Microplastics Strategy (California Code of Regulations 2018b); however, no further criteria (e.g. substance, state, solubility, lower dimensions limit, etc.) for the definition of microplastics are provided in the statute or in additional OPC reports (*Holly Wyer, personal communication, October 31, 2019)*.

### *California Environmental Protection Agency: State Water Resources; Control Board Division of Water Quality*

"Microplastics and microfibers" are identified as an issue that may be addressed in coming years in the Final Staff Report of the State Water Board's 2019 Review of the Water Quality Control Plan for Ocean Waters of California (Ocean Plan), which includes a non-regulatory description of microplastics as, "…a variety of both types and forms of plastic" (Dolan et al. 2019). The State Water Board-adopted 2019 Review of the Ocean Plan does not include "microplastics" as a priority issue (State Water Board 2019).

In 2015, the State Water Resources Control Board adopted an Amendment to the Water Quality Control Plan for Ocean Waters of California to Control Trash ("The Trash Provisions"), and defines water quality objectives for trash, which is defined as

> all improperly discarded solid material from any production, manufacturing, or processing operation, including, but not limited to, products, product packaging, or containers constructed of plastic, steel, aluminum, glass, paper, or other synthetic or natural materials. (State Water Resources Control Board 2016b)

Based on the understanding that small particles are difficult to remove from the environment, the State Water Board's definition of trash specifically does not include criteria for dimensions (State Water Resources Control Board 2016b). However, included in the Trash Provisions is the requirement to implement a "full capture system" that, "…traps all particles that are 5 mm or greater" (State Water Resources Control Board 2016a), thus effectively leaving a regulatory gap for trash that falls below this size limit.

### *California Environmental Protection Agency: Department of Toxic Substances Control*

The Department of Toxic Substances Control (DTSC) does not specifically describe "microplastics" or a related term; however, DTSC observes particle sizes and fiber sizes as hazard traits:

(a) The particle dimensions or fiber dimension hazard trait is defined as the 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.

(b) Evidence for the particle dimensions or fiber dimension hazard trait includes, but is not limited to: measures of particle dimensions 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.(*22 CCR § 69405.7. Particle Size or Fiber Dimension* 2011, 7)

### *United States Environmental Protection Agency*

The United States Environmental Protection Agency (U.S. EPA) defines microplastics broadly as “plastic particles <5 mm in dimensions in any one dimension” (Murphy 2017).

### *National Oceanic and Atmospheric Administration*

The National Oceanic and Atmospheric Administration (NOAA) defines microplastics as “plastic particles smaller than 5mm” (Courtney Arthur, Baker, and Bamford 2008). This maximum size was chosen based on possible ecological effects other than physical blockage of gastrointestinal tracts (Courtney Arthur, Baker, and Bamford 2008).

### *European Marine Strategy Framework Directive*

A report published in 2013 by the European Marine Strategy Framework Directive (MFSD) Working Group on Good Environmental Status defines plastic litter into four dimensions classes based on biological relevance and analytical limitations: macroplastics (>25 mm), mesoplastics (5 to 25 mm), large microplastics (1 to 5 mm), and small microplastics (20 μm to 1 mm) (Institute for Environment and Sustainability (Joint Research Centre) , MSFD Technical Subgroup on Marine Litter 2013). The MFSD rationalizes separating microplastics into two subfractions (small and large) due to the relative ease of separating and quantifying visually recognizable 1-5 mm particles compared to the more technically challenging aspects of particles between 20 μm and 1 mm (Institute for Environment and Sustainability (Joint Research Centre) , MSFD Technical Subgroup on Marine Litter 2013).

### *International Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection*

Microplastics are defined by the International Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP) as “plastic particles < 5 mm in diameter, which include particles in the nano-dimensions range (1 nm)” (GESAMP 2019). No apparent *state* or *substance* criteria are included.

### *European Chemicals Agency*

In 2017, the European Commission requested the European Chemicals Agency (ECHA), an agency which manages the technical and administrative aspects of the implementation of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), to develop a restriction proposal for the intentional uses of microplastics in consumer products[16], which ECHA then defined as "*synthetic water-insoluble polymers of 5mm or less in any dimension"* (COM 2017). In March 2018 ECHA adopted an updated working definition for 'microplastics': "*any polymer or polymer-containing, solid or semi-solid particle having a size of 5mm or less in at least one external dimension"* (ECHA 2018). In all versions of ECHA's definitions of 'microplastics', 'polymer' is defined according to the REACH definition for polymers (REACH 2006).

After requesting and reviewing stakeholder input on the March 2018 working definition of 'microplastics,' ECHA proposed a revised definition for 'microplastics' in August 2019 (European Chemicals Agency 2019a). The proposed definition follows a similar approach to the definition presented by Hartmann et al. (2019), and includes four criteria which must all be met, including *substance, state, morphology*, and *dimensions* (European Chemicals Agency 2019a). In the proposed definition, ECHA defines 'microplastics' as:

> A material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis) are excluded, as are polymers that are (bio)degradable. (European Chemicals Agency 2019a)

Where 'polymer' is defined in Article 3(5) of Regulation (EC) No 1907/2006 (REACH) as:

> A substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
> (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
> (b) less than a simple weight majority of molecules of the same molecular weight.
> In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;
> monomer: means a substance which is capable of forming covalent bonds with a

[16] To the knowledge of the State Water Board, REACH has not adopted a definition for 'microplastics' specifically in the context of drinking water or other environmental matrices, and that the proposed definition of 'microplastics' by ECHA mentioned within this report is meant to apply to the intentional uses of microplastics in consumer products (European Chemicals Agency 2019a).

> sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. (REACH 2006)

and

> 'Particle' is defined as, "a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface";
> 'Polymer-containing particle' means "either
> (i) a particle of any composition with a continuous polymer surface coating of any thickness; or
> (ii) a particle of any composition with a polymer content of ≥ 1% w/w";
>
> 'Solid' means, "a substance or a mixture which does not meet the definitions of liquid or gas";
> 'Gas' means, "a substance which
> (i) at 50 ˚C has a vapour pressure greater than 300 kPa (absolute); or
> (ii) is completely gaseous at 20 ˚C at a standard pressure of 101.3 kPa;
>
> 'Liquid' means, "a substance or mixture which
> (i) at 50 ˚C has a vapour pressure of not more than 300 kPa (3 bar);
> (ii) is not completely gaseous at 20 ˚C and at a standard pressure of 101.3 kPa; and
> (iii) which has a melting point or initial melting point of 20 ˚C or less at a standard pressure of 101.3 kPa." (European Chemicals Agency 2019a)

Note that the August 2019 proposed definition of 'microplastics' by ECHA does not include any explicit *state*-defining criteria for polymers that lack melting points (i.e. amorphous polymers) other than that such polymers would fall under the definition of 'solid' based on their inability to fit the definition of either 'liquid' or 'gas.' In contrast, the earlier, March 2018 working definition of 'microplastics' *state* criteria include specific criteria for particles that are either "solid or semi-solid", whereby:

> The 'solid' form of a polymer in the environment (at ambient temperature and pressure of 101.3 kPa) may, for example, be defined via a melting point above 20 °C (includes waxes). Thermosetting plastics, however, will decompose rather than melt above 20 °C.
> 'Semi-solid' refers to a material which is in a physical state between a solid and a liquid. A polymer can, for example, be defined to be a semi-solid when its melting point (at ambient temperature and pressure of 101.3 kPa) is above 20 °C and its glass transition temperature is below 20 °C. (European Chemicals Agency 2019a; ECHA 2018)

These definitions for 'solid' and 'semi-solid' were based upon the GHS definitions for solids and liquids, which utilize $T_m$ as a defining threshold. Since some polymers (e.g. amorphous polymers) lack a specific $T_m$ or may have a $T_m$ above 20 ˚C but have a $T_G$ below 20 ˚C, they would behave in many regards like a "solid" but could be classified as a "semi-solid". In the August 2019 proposed definition, ECHA revised the *state* criteria such that 'solid' is defined as "a substance or mixture which does not meet the definitions of liquid or gas"[17] and would therefore include such "semi-solid" polymers. Although the August 2019 ECHA definition of "solid" does not depend on more explicit defining properties suggested by Hartmann et al. to classify *state*, such as "$T_G$, viscosity, modulus of elasticity, or tension at constant elongation" (2019), the *state* criteria is likely to be highly inclusive of particle diversities while remaining technically feasible.

ECHA acknowledges that conventional threshold-based risk assessments cannot be reliably conducted for microplastics due to an insufficient amount of information; therefore, it has defined microplastics based on dimensions and persistence, which are classified as persistent, bioaccumulating and toxic (PBT) and/or very persistent and very bioaccumulating (vPvB) (European Chemicals Agency 2019a).Therefore, naturally occurring polymers that have not been chemically modified (other than by hydrolysis), and "biodegradable" polymers are excluded from their proposed definition of 'microplastics' (European Chemicals Agency 2019a). In the ECHA definition of 'microplastics', criteria for the demonstration of biodegradation of microplastics are included, in which several standardized test methods are recommended (European Chemicals Agency 2019a). ECHA acknowledges that commonly used plastics do not degrade rapidly or primarily through biological mechanisms, rather under photooxidation or hydrolysis, resulting in extremely long resistance time in the environment (decades to hundreds of years) (European Chemicals Agency 2019a; Duis and Coors 2016; Klein et al. 2018). ECHA further cites that although some plastics are available which rapidly biodegrade, such as PHBV (66-88% mineralization after 28 days using a modified standardized method) (McDonough et al. 2017), there is a high variability in the biodegradation potential of different types of plastic in the environment (European Chemicals Agency 2019a).

ECHA included solubility criteria in a previous working definition of 'microplastics', such that only "water-insoluble" were included (COM 2017). ECHA has since removed solubility criteria from subsequent working and proposed definitions, despite critiques that solubility parameters are important for risk assessment, that soluble polymers "do not contribute to the microplastics concern", and analytical techniques may not detect certain soluble polymers (ECHA 2018; European Chemicals Agency 2019a). ECHA's rationale for the removal of solubility criteria is explained in a response to these critiques:

[17] Where liquid' means a substance or mixture which (i) at 50 degrees Celsius (˚C) has a vapor pressure less than or equal to 300 kPa; (ii) is not completely gaseous at 20 ˚C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 ˚C or less at a standard pressure of 101.3 kPa.
'Gas' means a substance which (i) at 50 ˚C has a vapor pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 ˚C at a standard pressure of 101.3 kPa.

> Whilst soluble polymers may be considered as not contributing to the ‘microplastic’ concern, this is not equivalent to a conclusion that they do not pose any risk to the environment….However, we need to explore if appropriate standard methods are available and whether there should be threshold (cut-off) values for demonstrating solubility. (ECHA 2018)

The restriction proposal dossier for the intentional uses of microplastics in consumer products was open to public consultation from March to September 2019. The dossier is expected to be submitted to the European Commission in spring 2020, who will then decide whether to amend REACH’s regulations with the proposed restrictions and formally adopt the proposed definition of ‘microplastics’ in the context of intentionally added microplastics in products (European Commission 2019).

## Rationale for Defining Criteria

### *Defining Criteria: Substance*

The *substance* of plastic is a fundamental defining characteristic for a definition of ‘microplastics’; however varying threshold criteria exist within research and regulatory agencies. For instance, according to the ISO, plastic is a “material which contains as an essential ingredient a high molecular weight polymer and which, at some stage in its processing into finished products, can be shaped by flow” (ISO 2013). Similar to the ISO definition, ASTM International defines ‘plastic(s)’ as, “a material that contains as an essential ingredient one or more organic polymeric substances of large molecular weight, is solid in its finished state, and at some stage in its manufacture or processing into finished articles, can be shaped be flow…rubber, textiles, adhesives, and paint, which may in some cases meet this definition, are not considered plastics…” (ASTM 2020). ECHA (2019) critiques this ISO definition for ‘plastic’ for its dependence on terms which are not defined by ISO nor are universally accepted or standardized (i.e., ‘material’, ‘high molecular weight polymer’, and “shaped by flow”). Further, the ISO definition of ‘plastic’ has been criticized for being too narrow, as while it would include common, high-production classes of polymers such as thermoplastics and thermosets, some elastomers (e.g. anthropogenic rubbers) would be excluded (Hartmann et al. 2019). The ASTM definition is more narrow than the ISO definition due to their explicit exclusion of rubber, textiles, adhesives, and paint (ASTM 2020)[18].

[18] Exclusion of textile- and rubber-derived microparticles from a definition of ‘microplastics in drinking water’ may exclude a significant portion of particles from analysis. Textile-derived fibers that would meet the ISO definition of ‘plastic’ may constitute 50-99% of ‘microplastics’ found in drinking water (Pivokonsky et al. 2018), and rubber-derived particles that would meet the ISO definition of ‘plastic’ have been found at high concentrations in aqueous samples (48% of 11 trillion microparticles entering the San Francisco Bay) (Sutton et al. 2016). Furthermore, the *substance* criteria in the proposed definition is virtually synonymous (with the exception of biodegradability criteria) with the proposed definition of ‘microplastics’ by the European Chemicals Agency (European Chemicals Agency 2019a), and is supported unanimously by a panel of five leading experts commissioned for external peer review (California State Water Resources Control Board 2020).

'Polymer' is a fundamental term in the ISO definition of 'plastic,' although it lacks a discrete, robust definition by ISO. Alternatively, a widely accepted definition for 'polymer' is defined by IUPAC as; "molecule of high relative molecular mass, the structure of which essentially comprises the multiple repetition of units derived, actually or conceptually, from molecules of low relative molecular mass" (IUPAC 2008). Typically, anthropogenic polymers are created with a molecular mass >10,000 g $mol^{-1}$ (Lechner et al. 2003) resulting in a high likelihood for most polymers to be least 1 µm in one *dimension*. The IUPAC definition of 'polymer' is relatively widely inclusive, and would include copolymers, which are produced from "more than one species of monomer" (IUPAC 2008). Yet, an even more inclusive definition of 'polymer' is defined by REACH and used in the definition of 'microplastics' proposed by ECHA (2019):

> 'Polymer' means a substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
> (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
> (b) less than a simple weight majority of molecules of the same molecular weight.
> 'Monomer unit' means the reacted form of a monomer substance in a polymer.
> 'Monomer' means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. (REACH 2006)

Since the REACH definition of 'polymer' is more inclusive than the IUPAC definition, the REACH definition should be considered to be more health-protective based on its ability to characterize a wider breadth of constituents, and is therefore considered for adoption into the proposed definition of 'Microplastics in Drinking Water'.

It is worth noting that the REACH definition of 'polymer' includes both naturally occurring and synthetic (i.e. anthropogenic) polymers. ECHA observes that, "the microplastic concern is, in general, associated with synthetic polymers" (2019). As such, the ECHA definition specifically excludes, "Polymers that occur in nature that have not been chemically modified (other than by hydrolysis)" (2019). While there is no clear scientific consensus regarding the importance of a polymer's origin/persistence in determining its toxicity and behavior in the environment, recent evidence suggests that synthetic polymers are more toxic to various biota (Scherer et al. 2020; Le Guen et al. 2020; Schür et al. 2019). Still, few toxicological studies have compared synthetic polymers with natural polymers, resulting in strong uncertainties (Backhaus and Wagner 2019). Despite these marked uncertainties, most definitions of 'microplastics' refer to either 'synthetic polymers' and/or to specific polymer classes (e.g. thermosets[19], thermoplastics[20], chemically- or mechanically- modified elastomers[21]) and/or to certain polymer characteristics (e.g. those that retain their shape during use) (European Chemicals Agency 2019a; Hartmann et al. 2019). In maintaining consistency with nearly all academic and regulatory definitions of 'microplastics,' the proposed State Water Board definition of 'Microplastics in Drinking Water' includes a criterion for chemical origin such that only polymeric materials that are derived in nature and have not been chemically modified (other than by hydrolysis) are excluded. Note that the State Water Board definition uses the term, "derived in nature" as opposed to the ECHA (2019) term, "occur in nature". This difference in wording is intentional and is aimed to reduce potential loopholes in the interpretation of this exception, as chemically modified anthropogenic polymers are clearly occur in nature as a result of environmental contamination.

ECHA's 2017 working definition of 'microplastics' in the context of intentionally added microplastics to products includes criterion for polymer origin under the term, "synthetic" (COM 2017). "Synthetic" is later removed from ECHA's proposed definition for 'microplastics', and is replaced with a statement to exclude "polymers that occur in nature that have not been chemically modified (other than by hydrolysis)… [and] are polymers that are (bio)degradable"[22], under the rationale that *persistence* is a principle defining characteristic of problems associated 'microplastics' (European Chemicals Agency 2019a). It is worth noting that "biodegradable" polymers (e.g. poly-lactic acid [PLA]) have demonstrated both *in vitro* and *in vivo* toxic effects similar to or even greater than their conventional, non-biodegradable counterparts in non-human models (Green et al. 2017; 2016; Zimmermann et al. 2019). Despite limited evidence of toxicological effects of biodegradable polymers in ecologically-relevant biota, exceptionally few studies have been conducted in models relevant to humans (Shruti and Kutralam-Muniasamy 2019). One recent study assessing the ability of microplastic

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[19]Thermoset polymers are polymers that are irreversibly hardened by curing, which results in cross-linked polymer chains. When exposed to high temperatures, thermoset polymers do not melt, but will decompose. Thermoset polymers cannot be reshaped, thus preventing most forms of recycling (The Open University (UK) 2000). Examples of thermoset polymers includes vulcanized rubber, polyester resins, epoxy resins, silicon resins. Some polymers, such as polyurethane, can be either thermoplastic or thermoset.
[20]Thermoplastic polymers are associated by intermolecular forces, meaning that they are chemically reversible and will soften when heated and become fluid with additional heat. Thermoplastics are produced at relatively high volumes and as such are found at high quantities in the environment. Thermoplastics may be recycled through re-melting and forming via injection molding. Thermoplastic polymers can be petroleum- or bio-base. Examples include polylactic acid, nylon, polyethylene, polypropylene, polyethylene terephthalate, polystyrene, and polyvinyl chloride.
[21] Elastomer is defined as a polymer that exhibits elastic properties (IUPAC 2008).
[22] Polymer biodegradability may determined using standardized methods in various environmental conditions (e.g. seawater and marine sediment) are available (International Standards Organisation Under Development; 2019)

particles to transfer sorbed hexavalent chromium into a simulated human gut found that a common biodegradable polymer (polylactic acid) demonstrated higher oral bioaccessibility of hexavalent chromium than four non-biodegradable polymers (polyethylene, polypropylene, polyvinyl chloride, polystyrene) (Liao and Yang 2020). In addition to evidence demonstrating enhanced transfer of sorbed contaminants (e.g. hexavalent chromium, phenanthrene) (Liao and Yang 2020; Zuo et al. 2019), biodegradable polymers have demonstrated enhanced *in vivo* toxicity relative to non-biodegradable polymers due to a more rapid formation of nanoplastics particles (Shen et al. 2020; González-Pleiter et al. 2019). While ECHA’s proposed definition of ‘microplastics’ excludes biodegradable polymers (2019), the general scientific consensus is that synthetic biodegradable polymers are considered to be ‘microplastics’ (Shruti and Kutralam-Muniasamy 2019; Markowicz and Szymańska-Pulikowska 2019). Due to significant uncertainties regarding the human toxicological effects of biodegradable polymers, the proposed State Water Board definition of ’Microplastics in Drinking Water’ does not exclude “biodegradable” polymers.

To further clarify the types of polymers included in the proposed definition of ’Microplastics in Drinking Water’, a discrete, non-exhaustive list of polymer types and monomer units are listed, along with examples, in *Table 1*. The *substance* criteria in the proposed definition of ’Microplastics in Drinking Water’ could be summarized as being an expansion of the ISO definition of ‘plastic’[23] in which ‘polymer’ (as it appears in the ISO definition) would include the IUPAC definition[24], but additionally includes anthropogenic polymers that are not shaped by flow (e.g. elastomers). The proposed *substance* criteria include all forms of thermoplastic and thermoset polymers, in addition to anthropogenic elastomers, anthropogenic inorganic/hybrid polymers, and elastomers and inorganic/hybrid polymers that have been chemically modified. The proposed *substance* criteria includes polymers in which least one base monomer unit is derived from petroleum or non-petroleum biologically-derived chemicals (except for natural polymers that have not been chemically modified other than by hydrolysis), and would also include chemically-modified inorganic chemicals, inorganic-organic hybrid chemicals/polymers, chemically-modified natural rubber, and chemically-modified cellulose. Several examples of polymer categories are in *Table 1*[25].

Rationale for the inclusion of chemically-modified natural polymers, chemically-modified natural rubber, and cellulose that have been further processed to produce a final polymer (i.e. chemically-modified) is that these particles have been heavily modified such that their toxicological properties and environmental fate and transport are likely altered (Hartmann et al. 2019).

[23] (ISO 2013).
[24] (IUPAC 2008).
[25] It is important to note that the listed polymer categories in this section and *Table 1* are not exhaustive and are only provided for additional guidance in the interpretation of this proposed definition.

*Table 1. Examples of Substances Included in the Proposed Definition*

| **Derived monomer or physical constituent** | **Examples** |
|---|---|
| Petroleum | polyethylene, polypropylene, polyurethane, polyethylene terephthalate, polystyrene, polyvinyl chloride (PVC) |
| non-petroleum biologically derived chemicals | bio-polyethylene terephthalate, bio-polyethylene, polylactic acid, polyhydroxyalkanoates |
| Inorganic or inorganic-organic hybrid polymers | elastomers such as silicone |
| Chemically modified natural rubber | Tire wear particles |
| Chemically modified cellulose | rayon, cellophane, cellulose acetate |
| Copolymers | acrylonitrile-butadiene-styrene [ABS], ethylene-vinyl acetate [EVA], styrene-butadiene rubber [SBR] |
| Polymer composites | nylon, glass fiber-reinforced polyester, graphite reinforced epoxy, cotton-polyester or wool-polyester textile blends |

Polymers containing high quantities of non-polymeric additives (e.g., PVC), as well as polymers without additives or additional substances that otherwise meet the state criterion are also be included in the proposed definition per the clause, “*to which additives or other substances may have been added*”. Additive content (e.g. plasticizers, colorants, reinforcements, fillers, flame retardants, stabilizers) varies widely in anthropogenic polymers and may change once in the environment (Hartmann et al. 2019; Rochman et al. 2019). Additionally, many additives and monomers are known to be toxic (i.e. BPA, DEHP) (Manikkam et al. 2013) and may contribute to the toxicity of exposure to anthropogenic polymeric particles (Lithner, Larsson, and Dave 2011).

Copolymers, or synthetic polymers produced from more than one species of monomer (e.g., acrylonitrile-butadiene-styrene [ABS], ethylene-vinyl acetate [EVA], styrene-butadiene rubber [SBR]) are also included as these polymers are not derived in nature (Hartmann et al. 2019). Notably, ABS and EVA would be considered ‘plastic’ according to ISO (2013) as they are thermoplastics, however SBR would not be considered ‘plastic’ by the ISO definition since it is an elastomer. Accordingly, these, and other copolymers (e.g. synthetic rubber copolymers) are included in the *substance* criteria for the definition of ’Microplastics in Drinking Water’.

In addition to copolymers and high-additive content polymers, polymer composite materials such as nylon, glass fiber-reinforced polyester, graphite reinforced epoxy, cotton-polyester or wool-polyester textile blends are included in the *substance* criteria for the definition of ’Microplastics in Drinking Water’ granted they satisfy the following criteria:

(i) a particle of any composition with a continuous polymer surface coating of any thickness, or;
(ii) a particle of any composition with a synthetic polymer content of greater than or equal to 1% by mass.

*Exclusions*

The definition of microplastics in drinking water excludes polymers derived exclusively from natural origins and materials (e.g., DNA, proteins, wool, silk, cellulose) according to the clause, "polymers that are derived in nature that have not been chemically modified (other than by hydrolysis) are excluded". Slightly modified natural polymers (e.g., dyed wool, dyed cotton) are unlikely to be considered 'microplastics in drinking water' based on the proposed definition, as their principle ingredient is a natural polymer and would be expected to contain less than 1% synthetic polymer (by mass). Justification for the inclusion of slightly modified natural polymers (>1% mass synthetic polymers, or continuous synthetic polymer coating) is detailed below.

*Justification for the inclusion of slightly modified natural polymers*

Natural and biodegradable fibers differ from most synthetic fibers in their predicted degradation rate in the environment, thus reducing the likelihood that natural fibers would interact with biota (or be ingested by humans) over time (Barrows, Cathey, and Petersen 2018). Despite this predicted higher degradation rate, natural fibers are found in many environmental compartments, including rivers (Hoellein et al. 2015; Mccormick 2015), guts of birds, fish and macrofauna (A. L. Lusher, McHugh, and Thompson 2013; A. Lusher 2015; Remy et al. 2015; Rochman et al. 2015; Wilcox, Van Sebille, and Hardesty 2015), and air (Dris et al. 2017; 2016). Many dyes and chemicals used in natural textiles are carcinogenic to animals (Lithner et al. 2009; Remy et al. 2015), which may be transferred into biota upon ingestion (Zhao, Zhu, and Li 2016). Based on this limited, but suggestive evidence that dyed natural fibers may be present in the environment (and therefore potentially in freshwater used as a drinking water source) and exhibit toxicological effects similar to synthetic fibers, the proposed definition of 'microplastics in drinking water' includes the following *composition* criterion defining "polymeric material" as "either (i) a particle of any composition with a continuous polymer surface coating of any thickness, or (ii) a particle of any composition with a synthetic polymer content of greater than or equal to 1% by mass". This inclusion is identical to the proposed definition of 'microplastics' considered by the European Union (European Chemicals Agency 2019a).

Depending on the standardized methodology adopted by the State Water Board, dyed natural fibers with less than 1% synthetic polymer by mass may or may not be able to be differentiated from dyed natural fibers with greater than 1% synthetic polymer using the adopted standardized methodology (identification of natural fibers using spectroscopic techniques such as FTIR may be challenging (Cai et al. 2019), especially when dyes are present (Halstead et al. 2018)), and the proposed definition may require updating to specifically exclude dyed natural fibers with guidance for their classification through complimentary use of additional spectroscopic techniques (i.e. Raman), interpolation from a single reliable factor (e.g. rotation of incident polarized light), or a combination of factors (e.g. size, crimp, color, luster) (Goodpaster and Liszewski 2009).

### *Defining Criteria: State*

While it may be commonly thought that all plastic polymers are 'solid' materials at room temperature and standard pressure, some polymers can be wax-like, semisolid, or liquid. Most polymers have a vapor pressure <300 kPa (at 50 ˚C) and an initial melting point >20 ˚C ($T_m$ at 101.3 kPa), which would therefore be considered solids under the GHS (United Nations 2013). While melting temperature ($T_m$) determines the difference between solid and liquid state for most materials, amorphous and semicrystalline plastics will behave differently when heated (Hartmann et al. 2019). Amorphous polymers (e.g., polystyrene, ABS) are hard, brittle materials at temperatures below their glass transition temperature ($T_G$) but become viscous and free flowing above their $T_G$ (Hartmann et al. 2019). Semicrystalline polymers (e.g., polyamide, polyethylene terephthalate, polypropylene, PVC, polyethylene, polycarbonate) have both a $T_G$ and a $T_M$, in which they are hard and brittle below their $T_G$; ductile, soft, and form-stable below their $T_M$ and liquid above their $T_M$. (Hartmann et al. 2019). While $T_M$ may adequately predict the state of semicrystalline polymers, amorphous polymers lack a specific $T_M$. (Hartmann et al. 2019). Based on the lack of $T_M$ for some polymers, Hartmann et al. propose that $T_G$ should be used to define *state*, with a proposed threshold of $T_G$ > 20 °C (i.e. ambient room temperature), based on practical purposes of conducting measurements of plastic under standard laboratory conditions (2019).

A *state* threshold of $T_G$ > 20 °C would exclude some wax-like polymers as well as soft polymer gels. Polymer gels may be derived from natural (e.g., gelatin, agarose) or synthetic feedstock (e.g., polyacrylamide, polyvinyl alcohol, polyethylene glycol) and are used in various applications, such as polyacrylamide copolymers which are used as flocculation agents during wastewater treatment (Hartmann et al. 2019). In the field of polymer science, polymer gels are considered solids within an additional medium (i.e., liquid) (Rogovina, Vasil'ev, and Braudo 2008). Some polymer gels or their monomeric units are known to be toxic to humans. For example, the monomeric constituent of polyacrylamide- acrylamide- is a potent human neurotoxicant and suspected carcinogen, and is regulated in drinking water by the U.S. EPA (Rudén 2004). Further, the U.S. EPA regulates polymer applications so that dissolved acrylamide concentrations do not exceed 500 ng/L (U.S. EPA 2003). Despite the documented and undocumented toxicity of polymer gels, inclusion of such constituents in the definition of 'Microplastics in Drinking Water' is not technically feasible due to the fact that in aqueous solutions, polymer gels become soft and viscous and may be difficult to separate using traditional microplastics extraction methods[26] (Hartmann et al. 2019).

ECHA included $T_G$ and $T_m$ thresholds within the *state* criteria of a previous working definition of ‘microplastics’ to define ‘solid’ and ‘semi-solid’ polymers, but later removed $T_G$ as a defining feature in the *state* criteria, defining ‘solid’ as “a substance or mixture which does not meet the definitions of liquid or gas” and would therefore include such ‘semi-solid’ polymers (e.g. amorphous polymers) (European Chemicals Agency 2019a).The *state* criteria included in the proposed definition of ’Microplastics in Drinking Water’, which is synonymous with the *state* criteria included in the proposed definition by ECHA in August 2019, is likely to be highly inclusive of particle diversities while remaining technically feasible using typical methods and instruments used to characterize microplastics.

### *Defining Criteria: Dimensions*

The lower size limit of 1nm in the proposed definition is nearly synonymous with the definitions of ‘microplastics’ by the Ocean Protection Council (Ocean Protection Council and National Ocean and Atmospheric Administration Marine Debris Program 2018), US EPA (Murphy 2017), National Oceanic and Atmospheric Administration (Courtney Arthur, Baker, and Bamford 2008), International Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP 2019), which do not have lower size limits, and synonymous with the proposed definition of ‘microplastics’ by the European Chemicals Agency (2019a), which currently has a lower size limit of 1nm. Based on extreme uncertainties regarding the exposure and human health impacts of plastic particles below 1 micron (World Health Organization 2019; Lehner et al. 2019; X. Chang et al. 2020; Q. Wang et al. 2020), the inclusion of particles in this size range in the definition of ‘microplastics in drinking water’ is warranted to collect information regarding their occurrence in drinking water in order to better estimate total exposure routes to humans, and to encourage research into additional exposure routes and hazards. Analytical techniques to separate and detect sub-micron plastic particles are relatively less developed than for larger plastic particles (Primpke et al. 2020), and the State Water Board does not expect that all particles within the defined range of ‘microplastics in drinking water’ will be able to measured in all samples at all times. For many drinking water contaminants, detection limits for the purposes of reporting are unable to detect concentrations of contaminants at levels which are known or expected to be toxic (public health goals), as is the case for many contaminants with maximum

[26] Polymer gels, such as polyacrylamide, may appear as ‘solids’ in water due to agglomeration and other mechanisms. A further discussion regarding water-soluble polymers is included on page 20.

contaminant levels[27]. Likewise, measurements of 'microplastics in drinking water' likely may never fully reflect the theoretical definition.

The proposed upper size limit for of 5,000 µm is the most widely used in the scientific literature, dating back to 2003 (Hartmann et al. 2019; A. L. Andrady 2003). NOAA adopted this upper size limit based on the likelihood of particles smaller than these dimensions being ingested relative to larger items (C. Arthur, Baker, and Bamford 2009). Further, this upper size limit is congruous with ECHA's definition of 'microplastics'[28] (European Chemicals Agency 2019a). A distinctive dimensions criterion for fibers may be included in a future definition of 'Microplastics in Drinking Water' if available standardized methodology, human health toxicological information, and occurrence data suggest that such a distinction is necessary.

In 2016, California amended the Ocean Plan to include provisions for the control of trash, including a requirement to install "full capture systems" in storm drains to restrict trash particles larger than 5 mm (State Water Resources Control Board 2016a). While it was understood that the smaller particles that would pass through these devices would negatively impact water quality due to their dimensions-dependent biological hazard, 5mm (5,000 µm) was ultimately chosen based on reliability and performance sensitivity under varying loads (State Water Resources Control Board 2016b). While the State Water Board definition of 'Microplastics in Drinking Water' is not a *de facto* regulatory definition of microplastics in other media, the adoption of 5,000 µm as an upper limit would eliminate contrasting definitions of 'microplastics' within the State Water Board or the need for development of another dimensions-based plastic classification.

The rationale for at least three dimensions (i.e. width, height, length) meeting threshold criteria is to exclude large fibers and films that would be considered microplastics under the US EPA definition of "any one dimension." Such fibers and films with any one dimension longer than 5,000 µm are not typically considered to be 'microplastics' and are expected to behave fundamentally differently than smaller 'microplastic' particles. A previous proposed definition of 'microplastics in drinking water' required that "*at least two dimensions*" met the stated size thresholds (Coffin 2020a). A fault in this criterion was described in a public comment letter[29] using the case of a theoretical fiber which would meet the stated size threshold criteria for two dimensions (i.e. height and width, which are equivalent in a straight cylinder), but exceed the upper size limit for a third

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27 https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/MCLsandPHGs.html

28 Except in the case of "fibres", which ECHA further defines as having, "a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3" (European Chemicals Agency 2019a).

29 Comment 1.09. Comment letters and response to comments are available at the State Water Board program webpage. https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/microplastics.html

dimension (i.e. length). Furthermore, defining microplastic particles as having at least three dimensions fall below the upper size thresholds would require the measurement or reliable interpolation of at least three dimensions, thus improving size-specific data for samples.

While the occurrence of microplastics in drinking water is not considered a primary factor in the formulation of the *dimensions* criterion in the proposed ’Microplastics in Drinking Water’, it is worthwhile to consider such occurrences. Currently there are no treatment technologies directly targeted at the removal of microplastics from drinking water. Nevertheless, several drinking water treatment technologies have anecdotally been found to remove microplastics, with dimensions being a significant factor (Novotna et al. 2019). In a study that measured microplastic content (> 1 µm) at the inlet (raw surface water) and subsequently at the outlet (treated water) of three drinking water treatment plants, removal rates for treatment technologies were as follows: coagulation/flocculation and sand filtration (70% removal); coagulation/flocculation, sedimentation, sand filtration and granular activated carbon filtration (81% removal); coagulation/flocculation, flotation, sand filtration and granular activated carbon filtration (83% removal) (Pivokonsky et al. 2018). For all three drinking water treatment plants, microplastics in the 1-5 µm range were most abundant (25-60%), followed by microplastics between 5-10 µm (30-50%) (Pivokonsky et al. 2018). Microplastics >50 µm in dimensions were virtually not detected in treated water, and no microplastics >100 µm were detected in treated water, despite their observed occurrence in raw water (Pivokonsky et al. 2018). One study found that ultrafiltration using polyvinylidene fluoride membranes (30 nm average pore diameter) effectively rejected all polyethylene microplastics (<500 µm) (Ma et al. 2019). Very few studies have measured microplastics in groundwater, with the highest abundance being 0.007 microplastics/liter (>20 um), although very small microplastics were not measured (Mintenig et al. 2019). Self-contamination during sampling and analysis of microplastics is widely reported (Scopetani et al. 2020), and, despite extensive efforts documented by Mintenig et al. (2019), there is skepticism regarding the validity of the findings of microplastics in groundwater (Kniggendorf, Wetzel, and Roth 2019).

While there is currently insufficient evidence to determine the risk to humans from the ingestion of microplastics in drinking water due to incomplete hazard identification and exposure, sufficient evidence exists to suggest that smaller microplastic particles are likely more toxic to humans than larger particles and should therefore be prioritized for monitoring in drinking water (World Health Organization 2019).

Mammalian studies demonstrate that smaller particles have an increased efficiency to translocate across the gut and be further distributed into target organs (Wright and Kelly 2017; Volkheimer 1975; Jani et al. 1989). Once ingested, nondegradable particles (i.e., microplastics) may be distributed into the gastrointestinal tract via multiple processes, including paracellular persorption and endocytosis- which depend largely on the dimensions and shape of the particle (Wright and Kelly 2017; Volkheimer 1975).

Paracellular persorption of microplastic particles has been documented in mammalian models, including polyvinyl chloride (PVC) microplastic particles in dogs (Steffens 1995; Volkheimer 1975). Following the ingestion of 5-110 µm PVC microplastics by dogs, PVC particles were found in bile, urine, cerebrospinal fluid, tissue and organs (Volkheimer 1975). The uptake of microplastic particles (1-2.2 µm) into the gastrointestinal tract via endocytosis by Peyer’s patches has been documented in mammalian models, including rats and mice (Jani et al. 1989; LeFevre, Boccio, and Joel 1989). Once taken up into the gastrointestinal tract, microplastic particles may be further transported into sensitive organs via the chyle (lumen) of underlying lymph vessels, as demonstrated for PVC particles (5-110 µm) in rats, guinea pigs, rabbits, chickens, dogs and pigs; or by portal circulation, as demonstrated in dogs (Volkheimer 1975).

In addition to the enhanced uptake and distribution of smaller microplastics, hazards increase with smaller dimensions due to the interaction with target systems (Wu et al. 2019; Wright and Kelly 2017). The desorption rate of sorbed chemicals is inversely correlated with size due to increased surface area (Coffin, Lee, et al. 2019; Koelmans et al. 2013). However, some externally mixed additives such as decaBDE and inorganic pigments may mechanically separate from particles at different rates, thus larger particles with orders of magnitude more chemical mass may also release chemicals at relevant rates if ingested (Reche et al. 2019; De la Torre et al. 2018). Due to the biopersistence of microplastics, interactions with cells and tissues may lead to biological responses including inflammation, genotoxicity, oxidative stress, apoptosis, and necrosis (Wright and Kelly 2017; Volkheimer 1975). If sustained, these conditions may cause adverse health outcomes such as tissue damage, fibrosis, and carcinogenesis (Wright and Kelly 2017).

*Nomenclature*

The defining size range of ‘microplastics in drinking water’ covers over six orders of magnitude (nanoscale to millimeter scale). Particle abundance and transport behavior in the environment (Lebreton et al. 2018), sources of pollution, sampling and characterization methods (Primpke et al. 2020), and toxicological effects (Besseling et al. 2019) may vary significantly within the defined size range. Additionally, drinking water treatment techniques will differ in efficacy within the defined size range (Y. Zhang et al. 2020).

To reduce complexities and clarify communications dealing with plastic in the environment, various size-based classification schemes are often used (Hartmann et al. 2019). Despite an overall lack of consensus on size classifications, one particular schema has been promulgated frequently in recent peer-reviewed publications (Van Cauwenberghe et al. 2015; Gigault et al. 2018), and was agreed upon at a recent microplastics monitoring workshop (Bessa et al. 2019; Frias et al. 2018). Due to significant distinctions in both analytical techniques (Primpke et al. 2020) and toxicological behavior of particles below 100 µm in size (e.g. potential translocation of particles into tissues in humans) (Wright and Kelly 2017), and particles greater than 1 mm, as well as harmonizing with SI units (such that the "micro" prefix refers specifically to particles within the micrometer range) and the widely accepted definition of "nanomaterials" (European Chemicals Agency 2019b) this classification framework is revised slightly[30] as follows:

i. "Nanoplastics" (1 nm to <100 nm);
ii. "sub-micron plastics" (100 nm - <1 μm)
iii. "small microplastics" (1 μm to < 100 μm);
iv. "large microplastics" (100 μm to <1 mm)
v. "mesoplastics" (1 mm to <2.5 cm);
vi. "macroplastics" (>2.5 cm)

Within the definition of 'microplastics in drinking water', the "macroplastics" classification (and part of the "mesoplastics" classification) would not be included due to their minimum size ranges not overlapping with the upper size range of 'microplastics in drinking water'. Within the defined size range for 'microplastics in drinking water', "nanoplastics", "sub-micron plastics", "small microplastics", and "large microplastics" should be used for reporting purposes. Such distinctions are important to distinguish between "large microplastics" (which can be seen with the naked eye and chemically characterized with relatively inexpensive spectroscopic instruments), "small microplastics" (which are challenging or impossible to identify with the naked eye, and typically require the use of a microscope and more expensive instrumentation to characterize chemically), and "sub-micron plastics", and "nanoplastics" (which cannot be visualized using light-based microscopy, and typically require more expensive instrumentation to characterize chemically) (Primpke et al. 2020). Agencies that adopt the State Water Board's definition of 'microplastics in drinking water' (or use as a departure) should consider adopting the above classification framework to harmonize reporting.

### *Non-defining Criteria: Morphology and Color*

Morphology and color are useful descriptors for microplastics that may be relevant to toxicological risk assessments, fate and transport models, and origin, however, are not considered to be defining criteria for the proposed definition of 'Microplastics in Drinking Water'. Regardless, such non-defining criteria should be recorded, to the extent possible, in standard methods for microplastics in drinking water. Once available, the use of standardized terminology to describe the morphology and color of identified microplastics in drinking water should be employed.

Common classifications for the morphology of microplastics include spheres, pellets, fragments, films, and fibers. The State Water Board is not yet aware of a standardized

[30] The original framework cited (Bessa et al. 2019; Frias et al. 2018)) distinguishes "small microplastics" from "large microplastics" at 1,000 μm, and distinguishes between "large microplastics" and "mesoplastics" at 5mm.

taxonomy for the morphology of microplastics, and thus tentatively recommends the following guidelines based on previous recommendations (Hartmann et al. 2019):

- sphere/pellet/bead - every surface point has the same distance from the center;
- spheroid - imperfect, but approximate sphere
- cylinder – rod-shaped, cylindrical object
- fiber- length to diameter ratio of >3;
- fiber bundle – typically inseparable group of >2 fibers;
- fragment- particle with irregular shape;
- film- planar, considerably smaller in one than in the other dimensions;
- tire-road wear particle: black in color, elongated/cylindrical in shape, rough surface texture/encrustations, rubbery consistency that maintains its shape when manipulated with forceps (Leads and Weinstein 2019).

A standardized color palette may be employed to characterize color. The use of a systematic, semi-automated method to analyze colors using reference palettes such as the method developed by (Marti et al. 2020) would likely improve and standardeized data reporting and enhance comparability.

### *Non-defining criteria: Solubility*

While many conventional polymers are poorly soluble in water, some synthetic polymers readily dissolve in water (e.g., low molecular polyethylene glycol, polyvinyl alcohol). As mentioned earlier, one such water-soluble polymer, polyacrylamide, persists in the environment and degrades into the potent neurotoxicant monomer- acrylamide- under anaerobic conditions (Hennecke et al. 2018; Xiong et al. 2018). Polyacrylamide is widely used as a flocculant in water treatment, soil conditioner in agriculture, and viscosity enhancer in oil and gas drilling and fracking, with high concentrations (10-1,000 mg/L) reported in wastewater effluent concentrations (Xiong et al. 2018). Due to the persistence, toxicity, and widespread use of polyacrylamide and other water-soluble polymers, there is concern that the exclusion of water-soluble polymers from a regulatory definition of ‘microplastics’ may cause them to be ignored (Arp and Knutsen 2019).

Water-soluble polymers may appear as microscopic particles due to a number of poorly understood factors, including low pH synthesis (Berndt et al. 1991), cross-linking (Rivas, Urbano, and Sánchez 2018), or other processes (Arp and Knutsen 2019). Moreover, water-soluble polymers may be measured using analytical techniques that are used to measure water-insoluble polymers, such as dimensions exclusion chromatography, infrared spectroscopy, and mass spectrometry (Arp and Knutsen 2019). This heterogeneity and uncertainty in the solubility of so-called, “soluble polymers” is demonstrated in the findings of such polymers as solid particles in environmental monitoring studies. For instance, polyvinyl alcohol has been found as solid particle in the guts of deep-sea amphipods (Jamieson et al. 2019), benthic crustaceans (Cau et al. 2020), wastewater treatment plant influent and effluent (Kang et al. 2018; Mintenig et al. 2017), and stormwater (Liu et al. 2019). In a 2018 review of environmental microplastic monitoring studies, polyvinyl alcohol (in solid particulate form) represented approximately 1% of the total relative polymer composition in water, and approximately 11% of the total relative polymer composition in sediment (Burns and Boxall 2018). Polyethylene glycol, which is a type of synthetic "polymer gel" industrially produced in large quantities, has been detected in solid particulate form in various environmental compartments (e.g. stormwater (Liu et al. 2019), fish guts (Collard et al. 2017)) using typical microplastic sampling protocols and detection techniques (i.e. Raman or FTIR spectroscopy).

The concept of a solubility threshold becomes particularly challenging when considering nanoscale sized polymeric particles. For instance, degraded polyacrylamide (a "soluble" polymer) appears as a solid particle ranging from 18 to 350 nm in size (Jop et al. 1997), which can agglomerate to make larger polymeric nanocomposites and micro-scale particles (Rivas, Urbano, and Sánchez 2018). Furthermore, test methods to determine solubility can be confounded for particle dispersion, which is highlighted in a recent regulatory registration guidance document for nanoparticles (European Chemicals Agency 2019b). In consideration of challenges over the determination of solubility of particles (particularly in the nano-sized range), the European Chemicals Agency considers polymer solubility to, "not be a useful term to define 'microplastics'", concluding that additional defining terms such as "solid" and "particle" sufficiently captures, "that a polymer has kept its shape in the medium into which it is placed and can move as a unit" (European Chemicals Agency 2019a).Based on the persistence, toxicity, and potential for detection of water-soluble polymers using a variety of analytical techniques that are also used to detect water-insoluble polymers, there are no solubility threshold criteria in the proposed definition of 'microplastics in drinking water.' The exclusion of a solubility threshold is consistent with ECHA's proposed definition of 'microplastics' (2019).

### *Non-defining criteria: Density*

Physical properties of particles can be useful predictors of their behavior in the environment. In addition to *composition, state, dimensions,* and morphology, the density of microplastics is a key property that influences the ability for particles to sink or float in water (Rochman et al. 2019). The density of plastics and their buoyancy in water can also be influenced by the coating of plastics with microorganisms, algae, or plants (i.e., biofilms) (Woodall et al. 2014). In general, particles with densities greater than 1 g/cm$^3$ sink in freshwater, and as a result, would be expected to have a low likelihood of being found in drinking water. Accordingly, density may serve as useful defining criterion for the inclusion of particle types within the definition of 'microplastics in drinking water'.

Despite the expectation that particles with densities greater than 1 g/cm$^3$ would not be found in raw water or treated drinking water, such particles have been found in a number of studies. For instance, one study found that polyacrylamide particles (density

= 1.30 g/cm$^3$)[31] comprised approximately 7-25% of total polymeric particles characterized (338-628 particles/liter) in treated drinking water across three different treatment plants (Pivokonsky et al. 2018). Another study found that polyacrylamide particle abundance significantly increased approximately three times following sedimentation, with a raw water abundance of (37 ± 33 particles/liter) and advanced-treated[32] drinking water abundance of 112 ± 15 particles/liter), however particle concentrations of all other polymer types characterized were significantly reduced following sedimentation (Z. Wang, Lin, and Chen 2020). The study's conclusion that sedimentation significantly contributed to the quantity of polyacrylamide particles is supported by the fact that polyacrylamide is commonly used as a coagulant in drinking water treatment plants. While the use of polyacrylamide in water treatment processes result in the occurrence of such particles in treated drinking water, it's use is known to effectively remove other polymeric particles such as polyethylene (Ma et al. 2019).

In addition to polyacrylamide, other polymers with densities greater than 1 g/cm$^3$ have been characterized in raw and treated drinking water. For instance, polyethylene terephthalate (density = 1.34 g/cm$^3$) accounted for 55.4-63.1% of polymeric particles (3,843 ± 598 particles/L) in influent (raw surface water), and made up 47.2-58.8% of polymeric particles in effluent (advanced treated drinking water)[32] (485 ± 53 particles/L) (Z. Wang, Lin, and Chen 2020). In an additional study characterizing microplastics in 38 tap water samples taken from different cities in China, polyethylene terephthalate represented 3.3% of total polymeric particles (Tong et al. 2020)

In bottled water, polyamide ("nylon") (density=1.14 g/cm$^3$) and polystyrene (density= 1.05 g/cm$^3$) were reported as being 16% and 11% of total polymeric particles, respectively, in 11 brands of bottled water (Mason, Welch, and Neratko 2018). However, the source of such particles in bottled water samples could not be determined as the abundance of particles in raw water was not characterized (Mason, Welch, and Neratko 2018). Additionally, contamination of certain polymeric particles in bottled water has been attributed to the degradation of plastic bottle caps and bottles (Winkler et al. 2019), and in the case of fibers, contamination is highly likely to occur due to shedding from clothing of anyone involved in the process (e.g. operators in bottling plants, treatment plants, or during the sampling process) (Scopetani et al. 2020).

Based on the limited available evidence regarding microplastics in treated drinking water and their source waters, polymers cannot be reliably excluded from the definition of 'microplastics in drinking water' based on density thresholds.

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[31] https://polymerdatabase.com/polymers/polyacrylamide.html

[32] Treatment processes included sedimentation, followed by sand filtration, followed by ozonation, then granular activated carbon filtration (Z. Wang, Lin, and Chen 2020). Polyacrylamide accounted for 10.1-14.7% of the total polymeric particle content characterized in the final effluent (Z. Wang, Lin, and Chen 2020).

## Plastic-associated chemicals regulated in drinking water in California

It is understood that plastic can transfer chemicals to biota once ingested (Koelmans et al. 2016). In aquatic biota, plastic may or may not be a relevant transfer mechanism for such chemicals relative to other environmental exposure media (Bakir et al. 2016; Burns and Boxall 2018). It remains uncertain if the transfer of chemicals from a particle via ingestion through drinking water is a relevant factor in the hazards of microplastics to humans, despite a preliminary risk assessment based on highly conservative assumptions (World Health Organization 2019). While not a defining feature (critical or otherwise) to the proposed definition of 'Microplastics in Drinking Water', included here is a discussion of chemicals associated with plastic that are currently regulated in drinking water in California (per Title 22 and 17 of the California Code of Regulations) to provide a basis for examining potential, poorly documented hazards associated with such chemicals and microplastic particles in regards to human health.

Some chemicals may be intentionally added to plastic during manufacturing to be used as a functional additive (i.e., plasticizer, flame retardant, stabilizer, antioxidant, slip agent, lubricant, anti-static, curing agent, blowing agent, biocide), colorant (i.e. inorganic pigment, organic pigment, soluble colorant), filler, reinforcement, or monomer (Hahladakis et al. 2018). Additionally, some compounds may be unintentionally added to plastic through the manufacturing process or may be generated as a result of the breakdown of plastic in the environment (Gewert, Plassmann, and MacLeod 2015; Van et al. 2012). For the purposes of this discussion, the aforementioned attributes are requisite criteria for a chemical to be classified as a "plastic-associated chemical." Chemicals that sorb to plastic in the environment after the manufacturing process are excluded from the classification of "plastic-associated chemicals" in recognition that plastic is not the source of such chemicals, but rather a transport mechanism.

Many known plastic-associated chemicals are currently regulated in drinking water in California (i.e., have a Maximum Contaminant Level or MCL per Title 22 and 17 of the California Code of Regulations) and are known to leach from plastic in the environment. These include, but are not limited to:

- Di(2-ethylhexyl)phthalate (DEHP)- a commonly-used plastic additive in a wide range of products including food packages, cosmetics, medical devices, and PVC (Hauser and Calafat 2005);
- Di(2-ethylhexyl)adipate – a reagent used to make plastic (Fasano et al. 2012);
- antimony (Sb)- used in the form of antimony trioxide ($Sb_2O_3$) as an important catalyst in the manufacture of polyethylene terephthalate (PET) plastic and known to leach from PET water bottles (Shotyk and Krachler 2007);
- methyl-tert-butyl ether (MTBE) – a reagent used to make plastic (C.-C. Chang et al. 2003) that has been found to leach from plastic including cross-bonded polyethylene (PEX) (Skjevrak et al. 2003);
- styrene- a monomer used to make polystyrene plastic (Garrigós et al. 2004);
- vinyl chloride- a monomer used to make PVC (Fayad et al. 1997);

- benzene, ethylbenzene – byproducts of the thermo-oxidation degradation pathway of plastic (Hoff et al. 1982);
- arsenic – a degradation product of arsenic-based biocides used in plastics such as soft PVC and foamed polyurethanes (Nichols 2005);
- cadmium and lead- degradation products of cadmium- and lead-based compounds used as heat stabilizers and slip agents (Al-Malack 2001);
- 2,3,7,8-TCDD (dioxin), and cyanide – released from chlorine-containing plastics (e.g., PVC) during thermal degradation (Lokensgard 2016);
- fluoride – released from fluorine-containing polymers (e.g. polytetrafluoroethylene [PTFE]) and polyvinylidene fluoride) by a chain-stripping mechanism and other degradation pathways (Lokensgard 2016);
- chromium- used as pigment (Anthony L. Andrady and Rajapakse 2016);
- polychlorinated biphenyls (PCBs) including congeners 77, 110,114, and 206, which, although generally banned for use in the United States under the Toxic Substances Control Act of 1979, are still found in plastics produced in the United States and China likely as impurities in dyes and pigments (Coffin et al. 2018; Hu and Hornbuckle 2010; Rodenburg et al. 2010).

It should be noted that plastic-associated chemicals range drastically in terms of use and their ability to leach from plastics in the environment, and depend on a wide range of factors such as polymer type, intended use, production facility, production processes, and environmental parameters such as ultraviolet light exposure, salinity, heat, chemical interactions, enzymes, dissolved organic carbon, dimensions, etc. (Coffin, Huang, et al. 2019; Coffin et al. 2018; Lokensgard 2016). Extremely limited evidence regarding the transfer of such chemicals to humans from microplastics is currently available (World Health Organization 2019; Q. Zhang et al. 2020).

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