



State Water Resources Control Board

Proposed Definition of Microplastics in Drinking Water

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Proposed Definition of 'Microplastics in Drinking Water'*

'Microplastics in Drinking Water' are defined as solid¹ polymeric materials² to which chemical additives or other substances may have been added, which are particles² which have at least two dimensions that are greater than 1 and less than 5,000 micrometers (µm). 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&#}x27;Solid' means a substance or mixture which does not meet the definitions of liquid or gas.

^{&#}x27;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 greater than 20 °C at a standard pressure of 101.3 kPa.

^{&#}x27;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 synthetic polymer content of greater than or equal to 1% by mass.

^{&#}x27;Particle' means a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface.

^{&#}x27;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.

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' [1].

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 [2]. Three primary routes of exposure of humans to microplastics are known – air, food and water [3]. However, the relative magnitude of exposure from these and other sources are not fully understood and may vary significantly between individuals and groups [3]. Few studies have measured microplastics in drinking water, and available information indicates groundwater wells are likely to contain very low (if any) levels of microplastics [4], however surface water sources are known to contain microplastics at high detection frequencies, and at a range of levels [5]. Additionally, test methods are in early stages of development.

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 (i) the lack of adopted standards within the State Water Board to determine biodegradability and (ii) uncertainties regarding the human health effects of biodegradable polymers. 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

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microplastic particle is defined principally as being 'polymeric material'³, 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 included⁴.

The *state* criterion considers the practicality of measuring particles⁵ 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 liquid⁶ or gas⁷ 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*⁸ criterion in the proposed 'definition of microplastics in drinking water' is based on considerations of health hazards, other existing regulations, and current and anticipated analytical technical feasibilities. Current toxicological knowledge suggests that smaller particles are more hazardous. However, below the lower size limit of 1 µm, particles may not be characterized directly using light-based microscopy, thus requiring fundamentally different techniques and instrumentation. 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

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³'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 synthetic polymer content of greater than or equal to 1% by mass.

⁴ According to the definition, "...to which additives or other substances may have been added...".

⁵Particle is defined as a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface (ECHA 2019).

⁶'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 greater than 20 °C at a standard pressure of 101.3 kPa.

⁷ '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.

⁸"...have at least two dimensions greater than 1 and less than 5,000 micrometers (µm)..."

exception that ECHA includes an additional size criteria for "fibres". The requirement that two dimensions meet threshold criteria would exclude fibers and films that may have dimensions longer than 5 mm.

A criterion for solubility is not included. This omission is congruous with the ECHA definition of 'microplastics' (2019), despite the inclusion in previous definitions and other recommendations [6], [7]. 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 [8].

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Background

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:

- (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.

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. 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" [10]. Few studies are available regarding human exposure and health hazards of plastic particles, and significant data gaps remain [2]. 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 [11]. 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'

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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.

Current Definitions of Microplastics and Related Items 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

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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 [12]. The OPC is mandated by Public Resources Code 35635 to develop and implement a Statewide Microplastics Strategy [13]; 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" [14]. The State Water Board-adopted 2019 Review of the Ocean Plan does not include "microplastics" as a priority issue [15].

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. [16]

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 [16]. 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" [17], 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.

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(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.[18, p. 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" [19].

National Oceanic and Atmospheric Administration

The National Oceanic and Atmospheric Administration (NOAA) defines microplastics as "plastic particles smaller than 5mm" [20]. This maximum size was chosen based on possible ecological effects other than physical blockage of gastrointestinal tracts [20].

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 μ m to 1 mm) [21]. 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 μ m and 1 mm [21].

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)" [10]. 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

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consumer products⁹, which ECHA then defined as "synthetic water-insoluble polymers of 5mm or less in any dimension" [7]. 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" [22]. In all versions of ECHA's definitions of 'microplastics', 'polymer' is defined according to the REACH definition for polymers [23].

After requesting and reviewing stakeholder input on the March 2018 working definition of 'microplastics,' ECHA proposed a revised definition for 'microplastics' in August 2019 [1]. 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* [1]. 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 $\geq 1\%$ w/w of particles have (i) all dimensions $1 \text{nm} \leq x \leq 5 \text{mm}$, or (ii), for fibres, a length of $3 \text{nm} \leq x \leq 15 \text{mm}$ 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. [1]

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 sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. [23]

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⁹ 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 [1].

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." [1]

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. [1], [22]

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

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definitions of liquid or gas"¹⁰ 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) [1]. 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' [1]. In the ECHA definition of 'microplastics', criteria for the demonstration of biodegradation of microplastics are included, in which several standardized test methods are recommended [1]. 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) [1], [24], [25]. 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) [26], there is a high variability in the biodegradation potential of different types of plastic in the environment [1].

ECHA included solubility criteria in a previous working definition of 'microplastics', such that only "water-insoluble" were included [7]. 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 [1], [22]. ECHA's rationale for the removal of solubility criteria is explained in a response to these critiques:

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. [22]

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¹⁰ 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 greater than 20 °C 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.

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 [27].

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). (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..." [29]. ECHA (2019) critiques the ISO definition of '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 [6]. The ASTM definition is more narrow than the ISO definition due to their explicit exclusion of rubber, textiles, adhesives, and paint [29].

'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" [30]. Typically, anthropogenic polymers are created with a molecular mass >10,000 g mol⁻¹ [31] 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" [30]. 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

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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. [23]

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 [32]-[34]. Still, few toxicological studies have compared synthetic polymers with natural polymers, resulting in strong uncertainties [35]. Despite these marked uncertainties, most definitions of 'microplastics' refer to either 'synthetic polymers' and/or to specific polymer classes (e.g. thermosets¹¹, thermoplastics¹², chemically- or mechanically- modified elastomers¹³) and/or to certain polymer characteristics (e.g. those that retain their shape during use) [1], [6]. 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

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¹¹Thermoset 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 [36]. Examples of thermoset polymers includes vulcanized rubber, polyester resins, epoxy resins, silicon resins. Some polymers, such as polyurethane, can be either thermoplastic or thermoset.

¹²Thermoplastic 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 biobase. Examples include polylactic acid, nylon, polyethylene, polypropylene, polyethylene terephthalate, polystyrene, and polyvinyl chloride.

¹³ Elastomer is defined as a polymer that exhibits elastic properties [30].

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" [7]. "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", under the rationale that *persistence* is a principle defining characteristic of problems associated 'microplastics' [1]. It is worth noting that "biodegradable" polymers (e.g. poly-lactic acid [PLA]) have demonstrated *in vivo* toxic effects similar or equivalent to their conventional, non-biodegradable counterparts [37], [38]. Due to a lack of refined and widely accepted standards to determine biodegradability as well as 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' in which 'polymer' (as it appears in the ISO definition) would include the IUPAC definition¹⁵, 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*¹⁶.

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 [6].

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¹⁴ (ISO 2013).

¹⁵ [30].

¹⁶ 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.

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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 polymers	Dyed wool, dyed cotton
Chemically modified natural rubber	Tire wear particles
Chemically modified cellulose	rayon, cellophane
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) 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 [6], [11]. Additionally, many additives and monomers are known to be toxic (i.e. BPA, DEHP) [39] and may contribute to the toxicity of exposure to anthropogenic polymeric particles [40].

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 [6]. 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

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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) may be excluded so long as they satisfy the criteria of being composed of <1% synthetic polymer by mass.

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 [41]. 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 [6]. 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 [6]. 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 [6]. In the field of polymer science, polymer gels are considered solids within an additional medium (i.e., liquid) [42]. 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 [43]. Further, the U.S. EPA regulates polymer applications so that dissolved acrylamide concentrations do not exceed 500 ng/L [44]. Despite the documented and undocumented toxicity of polymer gels, inclusion of such constituents in the definition of

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'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 methods¹⁷ [6].

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) [1]. 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 proposed lower size limit for "at least two dimensions being" at least 1 μ m is based on the fundamental physical differences of plastic particles smaller than 1 μ m. Specifically, particles between 1-1,000 nm exhibit strong colloidal behavior [45], [46], and cannot be identified using light-based microscopy, thus requiring fundamentally different techniques and instrumentation for characterization [47]. The rationale for at least two dimensions 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 dimensions longer than 5,000 μ m are not typically considered to be microplastics and are expected to behave fundamentally differently than smaller microplastic particles. Furthermore, defining microplastic particles as having at least two dimensions between defined size thresholds would require the measurement or reliable interpolation of at least two dimensions, thus improving size-specific data for samples.

The proposed upper size limit for of 5,000 µm is the most widely used in the scientific literature, dating back to 2003 [6], [48]. NOAA adopted this upper size limit based on the likelihood of particles smaller than these dimensions being ingested relative to larger items [49]. Further, this upper size limit is congruous with ECHA's definition of 'microplastics'¹⁸ [1]. 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.

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¹⁷ 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.

¹⁸ Except in the case of "fibres", which ECHA further defines as having, "a length of 3nm $\leq x \leq 15$ mm and length to diameter ratio of >3" [1].

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 [17]. 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

 $(5,000~\mu m)$ was ultimately chosen based on reliability and performance sensitivity under varying loads [16]. 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 $5,000~\mu m$ 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.

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 [50]. 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) [51]. 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%) [51]. 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 [51]. One study found that ultrafiltration using polyvinylidene fluoride membranes (30 nm average pore diameter) effectively rejected all polyethylene microplastics (<500 µm) [52]. 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 [4]. Self-contamination during sampling and analysis of microplastics is widely reported [53], and, despite extensive efforts documented by Mintenig et al. (2019), there is skepticism regarding the validity of the findings of microplastics in groundwater [54].

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 [2].

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Mammalian studies demonstrate that smaller particles have an increased efficiency to translocate across the gut and be further distributed into target organs [55]–[57]. 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 [55], [56]. Paracellular persorption of microplastic particles has been documented in mammalian models, including polyvinyl chloride (PVC) microplastic particles in dogs [56], [58]. Following the ingestion of 5-110 μm PVC microplastics by dogs, PVC particles were found in bile, urine, cerebrospinal fluid, tissue and organs [56]. 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 [57], [59]. 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 [56].

In addition to the enhanced uptake and distribution of smaller microplastics, hazards increase with smaller dimensions due to the interaction with target systems [55], [60]. The desorption rate of sorbed chemicals is inversely correlated with size due to increased surface area [61], [62]. 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 [63], [64]. Due to the biopersistence of microplastics, interactions with cells and tissues may lead to biological responses including inflammation, genotoxicity, oxidative stress, apoptosis, and necrosis [55], [56]. If sustained, these conditions may cause adverse health outcomes such as tissue damage, fibrosis, and carcinogenesis [55].

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 taxonomy for the morphology of microplastics, and thus tentatively recommends the following guidelines based on previous recommendations [6]:

- pellet every surface point has the same distance from the center;
- fiber- length to diameter ratio of >3:
- fiber bundle typically inseparable group of >2 fibers;

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- fragment- particle with irregular shape;
- film- planar, considerably smaller in one than in the other dimensions;
- black rubbery fragment- typically anthropogenic crumb rubber derived from tires which is technically challenging to identify using common spectroscopic techniques.

A standardized color palette should be employed to characterize color.

Non-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 [65], [66]. 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 [66]. 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 [8].

Water-soluble polymers may appear as microscopic particles due to agglomeration with other particles, cross-linking, coating of flocculated composites, and other mechanisms [67], [68]. 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 [8]. 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).

Plastic-associated chemicals regulated in drinking water in California

It is understood that plastic can transfer chemicals to biota once ingested [69]. In aquatic biota, plastic may or may not be a relevant transfer mechanism for such chemicals relative to other environmental exposure media [70], [71]. 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 [2]. 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.

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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 [72]. 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 [73], [74]. 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 [75];
- Di(2-ethylhexyl)adipate a reagent used to make plastic [76];
- antimony (Sb)- used in the form of antimony trioxide (Sb₂O₃) as an important catalyst in the manufacture of polyethylene terephthalate (PET) plastic and known to leach from PET water bottles [77];
- methyl-tert-butyl ether (MTBE) a reagent used to make plastic [78] that has been found to leach from plastic including cross-bonded polyethylene (PEX) [79];
- styrene- a monomer used to make polystyrene plastic [80];
- vinyl chloride- a monomer used to make PVC [81];
- benzene, ethylbenzene byproducts of the thermo-oxidation degradation pathway of plastic [82];
- arsenic a degradation product of arsenic-based biocides used in plastics such as soft PVC and foamed polyurethanes [83];
- cadmium and lead- degradation products of cadmium- and lead-based compounds used as heat stabilizers and slip agents [84];
- 2,3,7,8-TCDD (dioxin), and cyanide released from chlorine-containing plastics (e.g., PVC) during thermal degradation [85];
- fluoride released from fluorine-containing polymers (e.g. polytetrafluoroethylene [PTFE]) and polyvinylidene fluoride) by a chain-stripping mechanism and other degradation pathways [85];
- chromium- used as pigment [86];
- polychlorinated biphenyls (PCBs) including congeners 77, 110,114, and 206, which, although generally banned for use in the United States under the Toxic

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Substances Control Act of 1979, are still found in plastics produced in the United States and China likely as impurities in dyes and pigments [87]–[89].

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. [85], [87], [90]. Extremely limited evidence regarding the transfer of such chemicals to humans from microplastics is currently available [2], [3].

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