CALIFORNIA
Water Boards

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Peer Review Comments and Responses for the Proposed Definition of 'Microplastics in Drinking Water' (Version February 1, 2020)

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Introduction

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' (ECHA 2019).

During the initial drafting and internal review of the proposed definition of 'microplastics in drinking water', several key defining aspects were deliberated without clear resolve. In some instances, this was due to the absence of a defined, standardized methodology to measure microplastics in drinking water as well as a full understanding of the human health effects of microplastics (in drinking water or otherwise), while in other cases there was simply a lack of occurrence or physical data to justify proposed thresholds for certain criteria. Until a more thorough understanding of the human health effects is available, it is the intention of the State Water Board to define microplastics in drinking water broadly to ensure that ensuing policies and further standardized methodologies capture a wide diversity of plastic particles.

Accordingly, the State Water Board requested that experts in the field review the proposed definition of 'microplastics in drinking water'. The peer review process was facilitated by a third-party institution, The Southern California Coastal Water Research Project. Five experts from four countries were provided with the February 1, 2020 version of "The Proposed Definition of Microplastics in Drinking Water" and were asked to specifically consider six questions and provide science-based recommendations.

Following is the February 1, 2020 version of "The Proposed Definition of Microplastics in Drinking Water" followed by a summary of responses received from the experts, specific responses to questions, and responses from the State Water Board. Based on the recommendations from this group of experts, certain revisions were made to the proposed definition of "Microplastics in drinking water". Experts provided comments on specific items on the February 1 version , thus line numbers are included in this document to assist the reader in interpreting the expert's comments.

Proposed Definition of Microplastics in Drinking Water (Version 2-1-2020)*

'Microplastics in drinking water' is defined as a material consisting of one or more solid[1] *polymer-containing particles*[2]*, to which additives or other substances may have been added, and where at least 1% of particles (by mass) have any one dimension greater than 1 and less than 5,000 micrometers (µm). Polymers that occur 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 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.
[2] '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 synthetic 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.

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' (ECHA 2019).

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.

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 occur 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. The proposed definition of 'polymer-containing particle'[3] includes synthetic polymer composites, co-polymers, modified natural polymers (i.e. synthetic polymer-encapsulated natural polymers or natural polymers with greater than or equal to 1% by mass). Additionally, particles comprised of <99% additives are included[4].

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[3] '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 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…".

The *state* criterion considers the practicality of measuring particles[5] 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[6] or gas[7] 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 exception that ECHA includes an additional size criteria for “fibres”**Error! Bookmark not defined.**. A distinct *dimensions* criterion for “fibres” is not included based on current information regarding methodology, human health toxicological information, and occurrence data.

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 (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).Background

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[5]Particle 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 any one dimension greater than 1 and less than 5,000 micrometers (µm*)…”*

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, 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.

By January 31, 2020, the State Water Board will submit the proposed definition of microplastics in drinking water to the Southern California Coastal Water Research Project (SCCWRP), who will facilitate a peer review of the scientific basis of the definition through an external panel of experts by March 1, 2020. 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.

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*.

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 (OPC and NOAA 2018). The OPC is mandated by Public Resources Code 35635 to develop and implement a Statewide Microplastics Strategy (California Code of Regulations 2018); 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 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 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 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 Dimensions or Fiber Dimension* 2011)

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

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 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[9], 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 (ECHA 2019). 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* (ECHA 2019). 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

[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 (ECHA 2019).

> been chemically modified (other than by hydrolysis) are excluded, as are polymers that are (bio)degradable. (ECHA 2019)

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. (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.” (ECHA 2019)

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. (ECHA 2019, 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"[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) (ECHA 2019).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' (ECHA 2019). In the ECHA definition of 'microplastics', criteria for the demonstration of biodegradation of microplastics are included, in which several standardized test methods are recommended (ECHA 2019). ECHA acknowledges that commonly used plastics do not degrade rapidly or primarily through biological mechanisms, rather under photooxidation

[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.

or hydrolysis, resulting in extremely long resistance time in the environment (decades to hundreds of years) (ECHA 2019, 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 (ECHA 2019).

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, ECHA 2019). 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. (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). 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. man-made rubbers) would be excluded (Hartmann et al. 2019).

'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, man-made 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 any 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. man-made) 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[11], thermoplastics[12], chemically- or mechanically- modified elastomers[13]) and/or to certain polymer characteristics (e.g. those that retain their shape during use) (ECHA 2019, 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 polymer origin such that only man-made polymers are included.

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”, under the rationale that *persistence* is a principle defining characteristic of problems associated ‘microplastics’ (ECHA 2019). 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 (Green et al. 2017; 2016). 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’[14] in which ‘polymer’ (as it appears in the ISO definition) would include the IUPAC definition[15], but additionally includes man-made

[11]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 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.
[12]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.
[13] Elastomer is defined as a polymer that exhibits elastic properties (IUPAC 2008).
[14] (ISO 2013).
[15] (IUPAC 2008).

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 man-made elastomers, man-made 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 (Hartmann et al. 2019).

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
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*

[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.

substances may have been added". Additive content (e.g. plasticizers, colorants, reinforcements, fillers, flame retardants, stabilizers) varies widely in man-made polymers and may change once in the environment (Hartmann et al. 2019; Rochman et al. 2019). Additionally, many additives are known to be toxic (i.e. BPA, DEHP) (Manikkam et al. 2013) and may contribute to the toxicity of exposure to man-made 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 do not occur 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.

<u>Exclusions</u>

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 occur in nature that have not been chemically modified (other than by hydrolysis) are excluded". Slightly modified natural polymers (<1% synthetic polymers by mass) (e.g., dyed wool) are also excluded, as their essential ingredient is a natural polymer.

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[17] (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) (ECHA 2019).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.

[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.

Defining Criteria: Dimensions

The proposed lower size limit for "any one dimension being" at least 1 µm is based on the fundamental physical differences of plastic particles smaller than 1 µm. Specifically, particles between 1-1,000 nm exhibit strong colloidal behavior (Gigault et al. 2018), and cannot be identified using light-based microscopy, thus requiring fundamentally different techniques and instrumentation for characterization (Frias et al. 2018).

The proposed upper size limit for "any one dimension" 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'[18] (ECHA 2019). 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 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 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.

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, sand filtration (70% removal); coagulation/flocculation, sedimentation, sand filtration and granular activated carbon filtration (81% removal);

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[18] 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" (ECHA 2019).

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 (Wright and Kelly 2017; Wu et al. 2019). 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).

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 (Hartmann et. al 2019):

- sphere - every surface point has the same distance from the center;
- spheroid- imperfect but approximate sphere;
- fiber- length to diameter ratio of >3;
- cylindrical pellet- rod-shaped, cylindrical particle with length to diameter ratio <3;
- fragment- particle with irregular shape;
- film- planar, considerably smaller in one than in the other dimensions;

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 (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 agglomeration with other particles, cross-linking, coating of flocculated composites, and other mechanisms (Berndt et al. 1991; Rivas, Urbano, and Sánchez 2018). 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). 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 (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 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 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 (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 PVV (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;
- 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, Lee, 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).

Peer Reviewer Comments and State Water Board Responses

General Comments from Peer Reviewers

General Comments from Dr. Rae McNeish [comment 01-00]

[No general comments were provided.]

General Comments from Dr. Rae McNeish: State Water Board Response [comment 01-00]

The State Water Board thanks Dr. Rae McNeish for reviewing this document and providing to specific questions.

General Comments from Dr. Sebastian Primpke [comment 02-00]

"The document provides a very detailed and well presented reasoning for the defined criteria and definitions. From a polymer science point of view it is also well designed and reads to include all potential existing and future plastic materials."

General Comments from Dr. Sebastian Primpke: State Water Board Response [comment 02-00]

The State Water Board thanks Dr. Sebastian Primpke for reviewing this document and providing feedback.

General Comments from Dr. Martin Wagner [comment 03-00]:

"Thank you for giving me the opportunity to provide feedback on the proposed definition of microplastics (version Feb. 1st, 2020). Overall, the definition is scientifically sound and represents a pragmatic compromise between the diverse definitions published previously. The rationales provided for each of the components of the definition are convincing and in line with the state of the science. In particular, the inclusion of important defining criteria beyond size (i.e., substance and state) is important and welcome.

While accepting the proposed definition is pertinent from a scientific perspective, obviously, the main tension arises from the need to implement it in practice on a scale sufficiently large to monitor microplastics in drinking water. Here, the proposed definition may be incompatible due to current limitations in analytical methodology and resources. As an example, analyzing microplastics in the size range between 1 and 10 µm is technically impossible in a monitoring scale and analyzing 10 to 50 µm microplastics will require an enormous amount of resources. The latter is also true for determining the polymer and additive content (% mass) of individual particles, the identity of modified natural polymers (e.g., cellulose vs. cellophane) and dissolved polymers.
One pragmatic way forward would be to operationalize the proposed definition for the developing the "standard methodology" according to Senate Bill 1422. For instance, a working definition would include a positive and negative list of synthetic polymers to analyze and refine the size range to something that is achievable (e.g., 50-5,000 µm). It could then propose different techniques to apply to certain subgroups, including µFTIR or Raman spectroscopy for microplastics < 500 µm, thermoanalytical techniques to derive mass fractions, FTIR for microplastics > 500 µm.

Here are some general observations not covered by your specific questions addressed below:

- "at least 1 % of particles (by mass) have…" (page 2) For me, in practice that means that you need to analyze a population of particles and you would call them "microplastics" if 1 % of those conform to the proposed size class. I am not sure whether this is intended or needed because that would mean that you would need to characterize the 99 % of particles that are larger or smaller. An additional caveat is the "mass %" because the mass cannot be derived using spectroscopic techniques (needed to determine particle size) and additional thermoanalytical methods would need to be used to determine mass fractions. A more pragmatic approach would be to use "each particle has a maximum dimension of".
- "a particle of any composition with a synthetic polymer content of greater or equal to 1% by mass" (footnote 2 on page 2) and "particles comprised of < 99% additives are included" (page 3). Similar feasibility problem like above: This would require a thermoanalysis of each individual particle which is not feasible.
- Suggest replacing "man-made" by "human-made" or "synthetic" throughout the text.

- "BPA" (page 14) is not an additive but a monomer"

In conclusion, the proposed definition is well thought through from a scientific perspective but the SWRCB needs to consider the proportionality of the analytical methods to be developed for a 4-y monitoring of drinking water. Adopting the proposed definition for monitoring purposes would require enormous resources in terms of R&D as well as instrumentation. Accordingly, I believe that using the proposed definition as a point of departure to develop an additional, pragmatic working definition for a monitoring is one way forward.

I am happy to discuss these aspects with you further and suggest you get in contact to the Norwegian Water Research Institute (NIVA) and the Danish Technical University, who both have performed extensive analyses of microplastics in drinking water. They might have important feedback regarding feasibility considerations."

General Comments from Dr. Martin Wagner: State Water Board Response [comment 03-00]

The State Water Board thanks Dr. Martin Wagner for reviewing this document and providing feedback.

In response to the comment regarding the need for a more pragmatic definition, the State Water Board acknowledges the technical challenges of characterizing particles below 10 µm, but understands the increased toxicity known to occur with such sizes of particles. As such, the proposed definition is not intended to fully reflect technical or economic capabilities (current or prospective), but rather describes theoretically the contaminant class with 1 µm included as a lower size limit goal. For monitoring purposes, a lower size limit of detection (LSLOD) threshold may be set in accordance with monitoring objectives, technical capabilities, and economic feasibilities.

In response to the comment regarding "at least 1 % of particles (by mass) have…" (page 2), the proposed definition has been revised to describe a single particle, as opposed to plural particles (see responses to comments 04-01 and 05-00] for additional rationale and discussion).

In response to the comment regarding "a particle of any composition with a synthetic polymer content of greater or equal to 1% by mass" (footnote 2 on page 2) and "particles comprised of < 99% additives are included" (page 3), the State Water Board acknowledges the technical challenges associated with measuring such parameters. In the absence of any standardized methods for the characterization of microplastics, the definition cannot be reliably based on technical feasibilities. The mass-based component of the *substance* criteria should be interpreted as a theoretical limit, with operational limits defined within specific methods.

The State Water Board thanks Dr. Wagner for suggesting the replacement of the gendered term "man-made" with a genderless term such as "human-made" or "synthetic" throughout the text. The text has been revised with the term, "anthropogenic" in place of any instance of the term "man-made."

The sentence referencing "BPA" has been updated to improve it's accuracy, "Additionally, many additives and monomers are known to be toxic (i.e. BPA, DEHP)…".

General Comments from Dr. Chelsea Rochman [04-00]

[Dr. Rochman chose to make comments on specific items within the document and did not respond to specific questions, nor prepare summary comments. The following is a list of comments in association with specified line numbers within the February 1,2020 version of the 'Microplastics in Drinking Water' definition. Following each line-number comment is the State Water Board response.]

Dr. Chelsea Rochman [comment 04-01]

Line Number 1: "what does "one or more solid polymer-containing particles" mean? I think this is because the definition is "microplastics" versus "microplastic". I'm not sure I agree the definition should be plural. I think it is useful to define what makes a microplastic particle.

If that, I'd change that part of the definition to state, "A microplastic in drinking water is defined as a solid polymeric material, to which chemical additives or other substances may have been added, which is a particle which has at least one dimension that is greater than 1um and less than 5000um. Polymeric materials that are DERIVED in nature and have not been chemically modified (other than by hydrolysis) are excluded."

I'd add DERIVED in nature versus occur in nature, because microplastics ultimately occur in nature once emitted there.

Is the 1% of particles part related to a mixture of microplastics or one particle. I took this out above because I assumed relevant to a mixture of particles. I find this confusing as written.

I think it is smart to include the second paragraph to be flexible to an updated definition as the science evolves.

Otherwise, I think this looks good and I comment in more detail below."

State Water Board Response [comment 04-01]

State Water Board staff thank Dr. Rochman for these comments and agree that it is useful to define a microplastic particle. As such, the definition and document have been revised throughout. State Water Board staff further acknowledge that specific wording and aspects of the February 1, 2020 definition was based on the 2019 ECHA definition of 'microplastics' in the context of intentional use and may not be applicable to 'microplastic' in the context of environmental monitoring. As such, certain suggestions to the definition proposed by Dr. Rochman are interpreted to pertain to artifacts related to the aforementioned contextual distinctions in agency definitions.

State Water Board staff concur with Dr. Rochman's suggested edit to the definition, and agree to implement this edit. The previous wording in the definition regarding "1% of particles" was used to describe the plural, "microplastics in drinking water," and has been revised per Dr. Rochman's suggestion. Changing of the word "occur" to "derive" in context to polymer's origin and respect to nature is acknowledged to be a more accurate description of the common understanding of plastic.

Dr. Chelsea Rochman [comment 04-02]

Line Number 26: "I think this is really important and I'm glad this is included so that it can be adapted for our method and in relation to what we learn about health.

State Water Board Response [comment 04-02]

State Water Board staff appreciate this comment and again thank Dr. Rochman for the review.

Dr. Chelsea Rochman [comment 04-03]

Line Number 37: "Great decision about biodegradability. This was a sticking point with microbeads and the decision you've made is the same as the current microbead legislation - which I agree with."

State Water Board Response [comment 04-03]

State Water Board staff appreciate this comment and again thank Dr. Rochman for the review.

Dr. Chelsea Rochman [comment 04-04]

Line Number 40: "I'd change this to "that are derived in nature" so there is no confusion about synthetic microplastics being in nature - which they are. I worry it could create some loophole, maybe.

One thing to note - does this definition include dyed cotton textiles? It may, and maybe that's okay, but I wanted to flag it. It's not a "microplastic" per se."

State Water Board Response [comment 04-04]

State Water Board staff appreciate this comment and agree that wording regarding exclusions should use the word, "derived" to reduce the possibility of a loophole. This revision has been integrated throughout the document. Additionally, the following explanation has been included under the section, "Rationale for Defining Criteria: Defining Criteria: Substance",

> 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 terminology is intentional, and is aimed to reduce possible loopholes in interpretation of this exception, as chemically-modified anthropogenic polymers are clearly observed ("occur") in nature due to environmental contamination.

Dr. Chelsea Rochman [comment 04-05]

Line Number 44: [*highlighted: …natural polymers with greater than or equal to 1% by mass]. "*what does this highlighted bit mean?"

State Water Board Response [comment 04-05]

State Water Board staff thank Dr. Rochman for highlighting this typographical error. This has been changed to the intended text, "…natural polymers with synthetic polymer content greater than or equal to 1% by mass."

Dr. Chelsea Rochman [comment 04-6]

Line Number 55: "I'm happy with this, but am noting that this means it includes the wax polyethylene beads that I think escaped the microbead leg and are still used in personal care products (PCPs). I also know that microcrystaline cellulose is often used in PCPs and won't melt at this temp - but I'm not sure it counts as a synthetic polymer. I'd think about this one just in case this is an issue. There may be pushback from industry if you don't have a clear answer for how those beads would fit or not fit under this definition.

But I like this inclusion of 'solid-ness'"

State Water Board Response [comment 04-06]

State Water Board staff appreciate this comment and insight. To the knowledge of State Water Board staff, granted microcrystalline cellulose does not contain added synthetic polymers or chemical modifications, it would be considered a naturally-derived mechanically-modified polymer, and thus would not be considered 'microplastic in drinking water' under the proposed definition.

Dr. Chelsea Rochman [comment 04-07]

Line Number 60: "I think it's smart not to dip into nano. I like the limit being 1um. Which makes me wonder about a limit of 1000um. BUT, I think i'd stick to the NOAA 5000um for policy sake and to allow for inclusion of longer fibers.

State Water Board Response [comment 04-07]

State Water Board staff appreciate this comment and again thank Dr. Rochman for the review. No revisions were identified to be necessary in response to this comment.

Dr. Chelsea Rochman [comment 04-08]

Line Number 69: "Do you want to use the British spelling?"

State Water Board Response [comment 04-08]

APA Style Guide recommends that quotations preserve exact spelling of source material. No revisions have been made to address the comment.

Dr. Chelsea Rochman [comment 04-09]

Line Number 73: "I agree with this decision. My comment above is just food for thought regarding how to respond to this decision by people who disagree."

State Water Board Response [comment 04-09]

State Water Board staff appreciate this comment and again thank Dr. Rochman for the review. No revisions were identified to be necessary in response to this comment.

Dr. Chelsea Rochman [comment 04-10]

Line Number 121: "This is a nice statement."

State Water Board Response [comment 04-10]

State Water Board staff appreciate this comment and again thank Dr. Rochman for the review. No revisions were identified to be necessary in response to this comment.

Dr. Chelsea Rochman [comment 04-11]

Line Number 423 (Table 1): "Add dyed cotton?

How do other anthropogenic microparticles fit into this definition?"

State Water Board Response [comment 04-11]

State Water Board staff appreciate this comment and have added "dyed cotton" to the example list of chemically-modified natural polymers. Additional information regarding the comment on "other anthropogenic microparticles" would be required in order to adequately respond or make revisions. State Water Board staff understand that an exhaustive list of particle types to be included/excluded in this definition is currently not feasible, but acknowledge the usefulness and need for such a list.

Dr. Chelsea Rochman [comment 04-12]

Line Number 459: "Okay, so here is the situation for dyed cotton I assume?

Although Table 1 suggests it's included. This is inconsistent.

State Water Board Response [comment 04-12]

The following revision was made in the section *Rationale for Defining Criteria: Defining Criteria: Substance: Exclusions* in order to reduce confusion and eliminate inconsistencies: "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."

Dr. Chelsea Rochman [comment 04-13]

Line Number 602: "Do you want to include fiber bundles?"

State Water Board Response [comment 04-13]

The following morphology classification has been added to the section *Rationale for Defining Criteria :Non-defining criteria: Morphology and Color:* "fiber bundle – typically inseparable group of >2 fibers;"

Dr. Chelsea Rochman [comment 04-14]

Line Number 606: "I have never seen this. I'd drop it. I feel like pellet covers this."

State Water Board Response [comment 04-14]

The term in question ("spheroid") has been deleted in response to this comment. Additionally, "sphere" has been replaced with the more common term, "pellet", as implied by this comment and the following comment.

Dr. Chelsea Rochman *[comment 04-15]*

Line Number 608: "I'd just say pellet."

State Water Board Response [comment 04-15]

The term in question ("cylindrical pellet") has been deleted in response to this comment.

Dr. Chelsea Rochman [comment 04-16]

Line Number 610: "rubber is hard to characterize via spectroscopy, you might consider black rubbery fragment or particles as a category to be able to account for them if there are many."

State Water Board Response [comment 04-16]

State Water Board staff appreciate this insightful comment and have included the following revision to account for this unique morphological class: "black rubbery fragment- typically anthropogenic crumb rubber derived from tires which is technically challenging to identify using common spectroscopic techniques."

General Comments from Dr. Andrew Gray [comment 05-00]

"The State Water Resources Control Board (SWB) Proposed Definition of Microplastics in Drinking Water presents a microplastic definition based on the most recent (2019) European Chemicals Agency (ECHA) definition. The proposed SWB definition differs from the ECHA definition in some dimensional and substance details. The SWB definition requires only that any one dimension of a particle is between 1 µm and 5 mm, while the ECHA definition requires that all dimensions are between 1 nm and 5 mm. The ECHA definition also includes dimensional standards for microfibers, while the SWB definition does not. In terms of substance (i.e. composition) the ECHA definition excludes biodegradable polymers, while the SWB definition does not.

Overall the reviewed document is very well written and organized. Each component of the microplastic definition is linked to explicitly stated goals, and supported by clearly reasoned arguments that are very thoroughly vetted through careful consideration of the relevant literature. I agree with many of the choices made in the structuring and level of specificity of the proposed microplastic definition relative to the SWB goals that it must serve, but suggest that the definition is modified to the following (with reasoning supplied as a lettered list below):

[Suggested revisions to the definition are denoted with strikethroughs and underlines corresponding to deletions and additions, respectively.]

Microplastic in drinking water' is defined as a ~~material consisting of one or more~~ solid polymer-containing particle, to which additives or other substances may have been added, ~~and where at least 1% of particles (by mass) have~~ <u>with</u> any ~~one~~ <u>two</u> dimension greater than 1 and less than 5,000 micrometers (µm). Particles composed of polymers that occur in nature that have not been chemically modified (other than by hydrolysis) are excluded.

A. Use of the plural '*microplastics*.' I understand that microplastics are a class of contaminants, which may have influenced the choice of a plural term. But, the SWB is really concerned with the classification of any given particle as a microplastic (or not). I suggest changing the title and definition to '*microplastic in drinking water*.' If not, at least modify the definition for grammar: e.g. '*Microplastics in drinking water' <u>are</u> defined…*

B. Defining microplastics '*as a material*.' Use of the term '*a material*' implies composition/substance, could be further interpreted as a uniformed substance, which subverts the fact that we are dealing with a complex suit of particulate contaminants. I suggest defining microplastic as a particle, and recommend modifying this part of the definition to: '*Microplastic in drinking water' is defined as a solid polymer-containing particle…*

C. The use of a mass based particle size distribution threshold *'where at least 1% of particles (by mass) have any one dimension greater than 1 and less than 5,000 micrometers*,' is not well aligned with the needs of the SWB. The current wording suggests that an entire population of plastic particles could be classified as microplastics as long as 1% of the particles had one dimension less than 5 mm. In sedimentology, this would be analogous to classifying a coarse gravel as clay if only 1% of clay was present. The ECHA definition from which this criteria was obtained is more restrictive in terms of dimensions (all dimensions must be at or below the 5 mm maximum threshold) and was primarily developed as guidance for consumer product additives. In the context of introducing microplastics to the waste stream, using a plural, population-based definition with such a low %mass particle size distribution threshold is consistent with a conservative approach. However, the SWB is concerned with identifying individual particles in drinking water and should structure its definition on an individual particle basis."

General Comments from Dr. Andrew Gray: State Water Board Response [comment 05-00]

State Water Board staff thank Dr. Gray for the thoughtful review and insightful comments. Reponses to suggested revisions to the definition correspond with the lettered list provided by Dr. Gray.

A. State Water Board staff agree with this rationale and have revised the definition accordingly. See response to comment 04-01 for additional discussion.
B. The suggested revision is nearly identical to the suggestion provided by Dr. Chelsea Rochman [comment 04-01]. The definition has been revised in accordance with these recommendations. See response to comment 04-01 for additional details.
C. State Water Board staff appreciate this valuable insight and concur with Dr. Gray's suggested revision. The definition has been revised in accordance with this comment, which addresses the same component that Dr. Rochman addresses in comment [04-01]. See response to comment 04-01 for additional details.

Reviewer Responses to Specific Questions from the State Water Board and State Water Board Responses to Comments

Question 1: Should a solubility threshold be defined (i.e. dissolved concentration in water at a given temperature)?

If so, what are the relevant technical and health-related criteria on which a solubility threshold would depend? If a solubility threshold is defined, (e.g., <1 mg L^{-1} at 20 ˚C), would temperature need to be recorded or controlled during sampling? Given the finding that water-insoluble polymers may be found in particle form through agglomeration with other particles, cross-linking, coating of flocculated composites, and other mechanisms, solubility criteria may not strictly define the types of plastic particles found within in a sample (Berndt et al. 1991; Rivas, Urbano, and Sánchez 2018). It follows that setting a threshold criterion for solubility of a specific polymer to be defined as 'microplastics' may result in the lack of reporting of certain detected particles.

Dr. Rae McNeish [comment 01-01]

"My microplastic expertise is lacking in studying the solubility of polymers; as such, I will not provide review comments on this question."

State Water Board Response [comment 01-01]

No revisions were identified to be necessary in response to this comment.

Dr. Sebastian Primpke [comment 02-01]

"As water is the target "solvent" most of the studies particles present in water are insoluble already by definition. From a material science perspective a threshold may be suitable for a pure polymer these would not be valid for cross-linked or polymer networks which are of the same material but insoluble in water. I would suggest not to define a solubility threshold but still sampling temperature should be monitored."

State Water Board Response [comment 02-01]

No revisions were identified to be necessary in response to this comment. The State Water Board acknowledges the importance of monitoring temperature during sampling.

Dr. Martin Wagner [comment 03-01]

"Yes, microplastics should be "insoluble" simply because dissolved polymers will not be "particles" according to the proposed definition. Instead of determining solubility of individual microplastics found in drinking water (not feasible, if they are particulates they would not be dissolved by definition), I would use the solubility criterium to define a list of polymers to be included in the analysis. I would exclude soluble or "liquid" polymers for pragmatic reasons because you would need to apply a completely different analytical technique (e.g., LC-MS/MS) to analyze those."

State Water Board Response [comment 03-01]

While the State Water Board acknowledges the low likelihood of soluble polymers occurring in a drinking water sample, soluble polymers (e.g. PAM) have been identified as particles in environmental samples using typical microplastics extraction and characterization methods (Duncan et al. 2019; de Jesus Piñon-Colin et al. 2018). Exclusion of polymers based on theoretical solubility limits may reduce monitoring information relevant to public health. No revisions have been made.

Dr. Chelsea Rochman [comment 04-01]

[Dr. Rochman provided comments within the document and did not respond to specific questions from the State Water Board].

State Water Board Response [comment 04-01]

No comments were provided for this specific question, so a response was not formulated.

Dr. Andrew Gray [comment 05-01]

"I do not find that a solubility threshold is required in the microplastic definition at this time. A solubility threshold was explicitly omitted from the proposed microplastic definition criteria to avoid potential exclusion of water-soluble polymers because of their persistence, potential and known toxicity and of such polymers, their potential presence in particulate form both alone and in association with other particles, and the existence of analytical techniques for detection. I agree with this argument for an inclusive, conservative approach. While comprehensive characterization of more soluble polymers in drinking water may require additional analyses of the concentration of the dissolve phase, this should not exclude their characterization as or in association with particulates."

State Water Board Response [comment 05-01]

No revisions were identified to be necessary in response to this comment.

Question 2: Is the proposed definition for 'solid' (i.e. 'does not meet the definitions of liquid[19] or gas[20]') practical and appropriate? Is this definition overly inclusive or exclusive?

Understanding that melting temperature (T_M) cannot be measured for amorphous polymers, glass-transition temperature (T_G) could be included as an alternative threshold value. A principal issue concerning the use of T_G as a defining threshold for solidity is that 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 and would behave in many regards as a "solid".

The measurement of T_M and T_G for small particles within a sample is virtually impossible, so if T_G is adopted as a defining trait, the criteria could be satisfied by comparing characterizing polymers with a reference library of melting temperature and glass-transition temperatures, then exclude from counting particles which have reference values below the proposed threshold during the sampling and analysis of microplastics in drinking water. However, T_M and T_G have relatively large value ranges for a given polymer due to variations with copolymer content and particle size.

This criterion may also be satisfied by ensuring that extraction, analysis (and possible sampling) are performed at or above 20 ˚C, thus theoretically excluding substances that are not 'solid' at this temperature. Implementation of one, or either of these methods may result in enhanced comparability between sample data. Alternatively, if the current definition for solidity is adopted, it is expected that a greater diversity of polymer and particle types may be characterized from samples, however data may be less comparable.

Dr. Rae McNeish [comment 01-02]

"I agree with the proposed definition for state criterion that a particle is to be classified as microplastic if it is not a liquid or a solid as defined by ECHA (2019). I am obligated to point out that I have little experience in the polymer chemistry associated with 'solid' state as it refers to the semi-solid. I would like to share that occasionally we have come

[19] '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.

[20] '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.

across wax-like particles in our samples and have taken note of these particles but did not include them in our microplastic estimates. This was because we were unsure of how to proceed with such unique particles due to lack of information in the scientific literature. I would appreciate clear definition on the state criterion for more unique and amorphous particles would be appreciated."

State Water Board Response [comment 01-02]

No revisions were identified to be necessary in response to this comment. The State Water Board acknowledges the importance of reporting such wax-like or 'semi-solid' polymeric particles in environmental media.

Dr. Sebastian Primpke [comment 02-02]

"I agree with the definition of solid as it includes most of the polymers and is the best solution to include all potential microplastics as these parameters are not measureable at low particle sizes. Still, in the current state it may exclude particles as part of a suspension mixture which are currently used as liquid replacement for solid materials e.g. in cosmetic.

By this definition it may also include other materials like paraffin which behave in seawater similar to polyethylene but have a melting point slightly above 20°C. These may melt or reshape during extraction protocols but can be found on analytical filters still."

State Water Board Response [comment 02-02]

No revisions were identified to be necessary in response to this comment. The State Water Board acknowledges the relevance of maintaining a consistent temperature during extraction procedures, if possible. Inclusion of a sampling and analysis temperature threshold may be further considered when adopting a standardized method.

Dr. Martin Wagner [comment 03-02]

"Again, I do not suggest determining T_M or T_G for individual particles found in drinking water. This is neither feasible nor desirable. Instead, a pragmatic way forward would be to use T_M or T_G to define which synthetic polymers are covered by the analysis. So, I am in favor of a more exclusive approach to start with, simply because I believe feasibility matters a lot. I agree that sampling will drive what is detected: Everything that is a particle on your filter will be "solid" not matter the individual T_M or T_G."

State Water Board Response [comment 03-02]

No revisions were identified to be necessary in response to this comment. The State Water Board acknowledges the relevance of maintaining a consistent temperature during sampling and analysis to achieve greater consistency. However, T_M and T_G are typically theoretical values determined for pure polymers that have not undergone environmental transformations, and it is likely that such values may change in the environment (especially for multi-polymer particles or agglomerates). Thus, exclusion of particles based on theoretical thresholds may be inappropriate and overly exclusive.

Dr. Chelsea Rochman [comment 04-02]

[Dr. Rochman provided comments within the document and did not respond to specific questions from the State Water Board].

State Water Board Response [comment 04-02]

No comments were provided for this specific question, so a response was not formulated.

Dr. Andrew Gray [comment 05-02]

"The proposed definition is appropriately inclusive."

State Water Board Response [comment 05-02]

No revisions were identified to be necessary in response to this comment.

Question 3: Is the proposed lower size limit of 1 µm sufficiently inclusive of anticipated technological advances of spectral-based methodologies for characterization (i.e. µ-FTIR/Raman, excluding nano-FTIR/Raman)?

It should be noted that the State Water Board considers plastic particles <1 *µm* to be contaminants of emerging concern, however due to the current economic barriers of detecting and characterizing such particles- which requires the use of either fundamentally distinct instrumentation compared with the analysis of larger particles (e.g. pyr-GC/MS vs. *µ*-FTIR/Raman) and/or cost-prohibitive instrumentation (i.e. nano-FTIR/Raman)- would like to distinguish such particles at the current time (prospectively to be defined as "nanoplastics").

Dr. Rae McNeish [comment 01-03]

"The proposed lower size limit of 1 µm is acceptable and is sufficiently inclusive of anticipated technological advances as I understand them for spectral-based methodologies. In my experience, the smaller the particles are the more challenging they are to identify and characterize. I do not expect these challenges to change.

- Given the increased challenges in handling and identification challenges associated with particles less than 1 µm, I recommend separate standardized methods for processing and identifying these particles compare to plastic particles that are larger than 1 µm. Classifying plastic particles that are less than 1 µm in size as "nanoplastics" would be more informative in classification as this suggests these particles are on a smaller scale in terms of size and may exhibit some of the unique properties that are typically associated with nanoparticles; however, nanoparticles are typically classified as particles ranging from 1 – 100 nm (Horiba), whereas a definition of less than 1 µm would be unique to microplastics specifically as I understand it.
- I concur with the State Water Board that plastic particles less than 1 µm is an emerging contaminant of concern.

Nanoparticle Reference: https://www.horiba.com/scientific/products/particle-characterization/applications/what-is-a-nanoparticle/"

State Water Board Response [comment 01-03]

No revisions were identified to be necessary in response to this comment. The State Water Board appreciates feedback regarding a prospective definition of "nanoplastics", and how such a definition would contrast with the consensus definition of "nanoparticles."

Dr. Sebastian Primpke [comment 02-03]

"This is completely fine and will fulfill the needs demanded for microplastics as nanoplastics are currently hard to investigate with no clear method available to fulfill all necessary analytical needs."

State Water Board Response [comment 02-03]

No revisions were identified to be necessary in response to this comment.

Dr. Martin Wagner [comment 03-03]

"I think a lower size cut-off of 1 µm is inclusive enough and may be even too inclusive given that the spatial resolution of µFTIR/Raman spectroscopy is limited to about 10 and 2 µm based on physics (diffraction limit). Accordingly, it is worth to consider increasing the lower size limit in a working definition. The inclusion of nanoplastics (1-1,000 nm) is not feasible at the moment but R&D on methodologies should be promoted."

Dr. Chelsea Rochman [comment 04-03]

[Dr. Rochman provided comments within the document and did not respond to specific questions from the State Water Board].

State Water Board Response [comment 04-03]

No comments were provided for this specific question, so a response was not formulated.

Dr. Andrew Gray [comment 05-03]

"Yes, based on current and near-future advances plastic particle monitoring and laboratory characterization techniques I believe that a lower particle size bound of 1 µm is appropriate. Currently lower limits of detection are more like 20-100 µm for most techniques. Furthermore, the characteristics of particulate transport are expected to be quite different in the nano- size range, as noted in the document. Nanoplastics may indeed be of concern, and should be addressed in the future in their own right."

State Water Board Response [comment 05-03]

No revisions were identified to be necessary in response to this comment.

Question 4: Is the proposed upper size limit of 5,000 µm anticipated to be feasible in the standardized methodology? Additionally, should an upper limit of 15,000 µm be adopted for fibers to mirror the ECHA (2019) definition (i.e. "(i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3")?

Considerations should include relevant human health toxicological information and/or methodological feasibilities and/or occurrence data.

Dr. Rae McNeish [comment 01-04]

"I have experience processing water, sediment, fish, and invertebrate samples for microplastics for my research. Based on my expertise, I believe the proposed upper size limit of 5,000 µm is feasible in the standardized methodology. Part of my lab's standard operating procedure is to fractionate samples with the top sieve 4.75 mm (closest sieve size to 5 mm based on standardized size classes) and to retain and process separately material that is caught on the 4.75 mm sieve. Rarely have we found plastics retained on the upper sieve, and those that we do are typically a cm or larger in size and are not fibers.

- One aspect of fibers that is challenging is how long is too long for a fiber and how short is too short to no longer be considered a fiber anymore. In my lab we only count a particle as a fiber if it is greater than 3 times the length relative to the width. We have found this practice helps with the efficiency of counting and classifying particles as fibers; therefore, I would recommend that the state adopt the length to diameter ratio of greater than 3.
- I recommend that an upper limit of 15,000 µm be adopted. This is because under the "length to diameter ratio of greater than three" recommendation for a fiber, a fiber that is 15,000 µm long with a 5,000 µm width would be feasible in size for easy consumption for humans via drinking water and feasible for current common microplastic methodologies for extraction from samples and identification."

State Water Board Response [comment 01-04]

The State Water Board thanks Dr. Mcneish for the comment regarding the adoption of a length to diameter ratio of 3 or greater for fibers. This classification is reflected in the proposed definition. Particles greater than 15 mm are not expected to be found at significant quantities in drinking water, nor are health effects associated with such particles expected to be significant to humans (World Health Organization 2019; Eerkes-Medrano, Leslie, and Quinn 2019).

Dr. Sebastian Primpke [comment 02-04]

"Yes, it is feasible to use 5000 µm and in agreement with most monitoring guidelines for environmental compartments. The proposed fiber length reads not really suitable as it found exclude very long but fine fibers which may be a risk or a contamination (e.g. hairs). As the health issues of these fibers are currently not fully resolved I would not give an upper limit here (see response to question 5)."

State Water Board Response [comment 02-04]

See response to comment 01-04 and comment 03-04 for justification.

Dr. Martin Wagner [comment 03-04]

"Keeping in mind that the probability of detecting microplastics > 500 µm in drinking water is very low, I believe an upper size limit of 5,000 µm is sufficient. The ECHA definition is meant to target intentionally used microplastics and, thus, larger microplastics are more relevant for their definition. I do, however, not see the benefit of extending that size limit for fibers other than conforming to the 1:3 ratio idea. From a human health perspective, there is no indication that we should be more concerned about those large microplastics."

State Water Board Response [comment 03-04]

This comment is in line with recent findings (World Health Organization 2019; Eerkes-Medrano, Leslie, and Quinn 2019).

Dr. Chelsea Rochman [comment 04-04]

[Dr. Rochman provided comments within the document and did not respond to specific questions from the State Water Board].

State Water Board Response [comment 04-04]

No comments were provided for this specific question, so a response was not formulated.

Dr. Andrew Gray [comment 05-04]

"The ECHA included the further definition of microfibers because their size criteria for microplastic was based on all particle dimensions. Because the proposed SWB definition employs an upper size limit for 'any one dimension' of the particle, there would be no need for expansion of the upper size threshold for microfibers. Further definition of microfibers is also not needed if the proposed SWB definition is modified on the basis of my recommendations to require that 2 particle dimensions meet the size criterial, because the two short dimensions of microfibers will already satisfy the aforementioned rule. If the SWB would like to further define given microplastic morphologies, then they should do this in a thorough fashion, taking on the definition or films, fragments, etc. However, I do not think this is necessary in a fundamental definition of microplastics."

State Water Board Response [comment 05-04]

The proposal to require that two particle dimensions meet the size criteria is scientifically sound and pragmatic. The proposed definition will be revised to include this criteria.

Question 5: Is it sufficient to define a particle as microplastic if 'any one dimension' is within the defined size range (in accordance with the US EPA definition, "plastic particles <5 mm in size in any one dimension"), or should 'all dimensions' be within the defined size range (as is the case for the ECHA 2019 definition, " all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3)? Further, Is the current proposed definition the most health protective?

Considerations should include technical (i.e. methodological) feasibilities (i.e. should measuring of all dimensions for each particle be required or would sieve sizes suffice as implied thresholds?) and associated impacts to method costs (analysis time, technologies) if methodological recommendations are proposed.

Dr. Rae McNeish [comment 01-05]

"I recommend that it is sufficient to define a particle as microplastic if 'any one dimension' is within the defined size range that will be decided by the state. For my research we define microplastic as a particle less than 5mm along at least one axis. This practice for my lab has allowed for effective methodologies and feasibility of obtaining data within a reasonable timeframe. We measure microplastic with an ocular micrometer or using a computer software program and have had challenges measuring all dimensions when it comes to fibers. Fibers are often tangled, coiled, or tightly bound in a bundle, which is challenging to measure and increases the processing time if one attempts to detangle fibers.

- Sieve sizes is another strategy used in my lab for fractioning particles. This strategy decreases the amount of time invested in sample processing and allows for a rapid assessment of the frequency of particles in sieve size classes. Sieve sizes works well for particle morphologies except for fibers. Fibers do not fractionate well due to having a longer dimension than their width. This results in fibers of different lengths captured in different sieve sizes even if they have the same width. Due to the challenges of fractioning fibers, our methodology includes taking actual measurements of a sub-sample of all fibers because fibers using a micrometer or computer software because sieve sizes are not indicative of fiber dimensions."

State Water Board Response [comment 01-05]

This comment is useful and provides further justification for the requirement of two dimensions meeting size threshold criteria (see comments 05-04, 05-05, and responses to comments for additional discussion).

Dr. Sebastian Primpke [comment 02-05]

"The US EPA definition fits better the propose as it would automatically include long fibers independent from their length, which might be even more inclusive. Secondly, these parameters should be measured and determined by image analysis or manual measurement if applicable. Sieve sizes may be working but would not allow the determination of shape which is important for monitoring and potential source tracking. Still, these definition should be part of a standard operational protocol but not for the definition of a particle."

State Water Board Response [comment 02-05]

While different standardized methods may require different methodology for determining or inferring (via fractionation) size, a definition should fully describe a substance- regardless of certain feasibilities of measuring such substance. By requiring two dimensions meet size threshold criteria, infinitely long particles would be exclude. Such theoretically infinite particles would undoubtedly be considered to not be microplastics by most scientists. Additionally, measuring all dimensions (or three dimensions) would be technically challenging and unnecessary to define a particle within rational boundaries. Further discussion regarding this point may be found in comment 05-04.

Dr. Martin Wagner [comment 03-05]

"To be honest, I understand "any one" and "all dimensions" to refer to the same, namely, that the maximum dimension falls within the defined size range. This is pragmatic in the sense that determining the size in three dimensions is technically challenging as spectroscopic imaging will only provide two-dimensional size information which likely covers the largest dimension of a particle. Additional problems will arise during implementation because filtering drinking water with a 5,000 μm mesh will not retain longer fibers. Thus, fibers with a diameter of > 1 μm and any length will be retained.

Regarding you last question, it is impossible to evaluate how protective any microplastics definition will be given that we cannot assess the health risks so far. Personally, I agree with WHO that drinking water is not the most relevant source of exposure to microplastics. Accordingly, measures should be proportionate."

State Water Board Response [comment 03-05]

The State Water Board thanks Dr. Wagner for this comment and finds no need for revisions.

Dr. Chelsea Rochman [comment 04-05]

[Dr. Rochman provided comments within the document and did not respond to specific questions from the State Water Board].

State Water Board Response [comment 04-05]

No comments were provided for this specific question, so no response was formulated.

Dr. Andrew Gray [comment 05-05]

"As stated in my summary above using a size threshold applied to any one dimension of a particle presents epistemological and operational challenges. By this definition large swaths of film and thin plastic sheets/fragments/plates would be defined as microplastic. Perhaps this is not of concern in the context of drinking water where such larger materials may not be found, but this environmental scientist/sedimentologist finds it to be inconsistent with the broader field of microplastic pollution."

State Water Board Response [comment 05-05]

See response to comment 05-04.

Question 6: Evaluate the proposed chemical composition criteria (i.e. 'polymer-containing particle', including definitions for 'polymer' 'monomer unit' and 'monomer', and exceptions for polymers that occur in nature that have not been chemically modified [other than by hydrolysis]) and determine if: the definition encompasses all synthetic plastic polymers produced; additional exceptions should be included based on either human health toxicological rationale or prospective technical infeasibilities of successful characterization (e.g.- "biodegradability", as is proposed by ECHA (European Chemicals Agency 2019)).

Dr. Rae McNeish [comment 01-06]

"I concur with the proposed chemical composition criteria of 'polymer-containing particle' and consider the definition to be broad enough to capture particles that are or will be considered of concern to human health that are synthetic. I also concur that additional exceptions that go beyond the ECHA definition to include biodegradable particles should be included in the proposed chemical composition criteria. As indicated in the document, biodegradable plastics have variable rates of breakdown and retention time and may need certain conditions for biological breakdown to occur. In addition, biodegradable synthetic plastic polymers are synthetic are still plastic until they fully breakdown and should be treated the same as non-biodegradable plastic polymers of concern. I also agree that additional exceptions should also be based on rationale."

State Water Board Response [comment 01-06]

The State Water Board thanks Dr. McNeish for this comment and finds no need for revisions.

Dr. Sebastian Primpke [comment 02-06]

"The definition includes all potential synthetic plastic particles including varnish binders and it should include biodegradable polymers as this term is defined by parameters, which often do not normal environmental conditions."

State Water Board Response [comment 02-06]

Varnish binders would be included in the proposed definition so long they contain >1% synthetic polymer by mass.

Dr. Martin Wagner [comment 03-06]

"The definition of "polymer", "monomer" and "monomer units" are sound, as is the exclusion of biodegradability as criterion (biodegradable plastics will form nano- and microplastics). However, complying with the "polymer containing" criterion will be challenging in practice because that would require a thermoanalytical determination of the components of each particle which is not feasible (e.g., each soot particle with 99 % carbon black and 1 % plastic would need to be identifiable). Again, a way forward might be to produce an inclusion list of polymers using the 1 % criterion."

State Water Board Response [comment 03-06]

This comment is in line with comment 04-01 and 04-06 and further supports the revision of the proposed definition to specifically define a single particle within drinking water.

Dr. Chelsea Rochman [comment 04-06]

[Dr. Rochman provided comments within the document and did not respond to specific questions from the State Water Board].

State Water Board Response [comment 04-06]

No comments were provided for this specific question, so a response was not formulated.

Dr. Andrew Gray [comment 05-06]

"I am not an analytical chemist by training, and will defer to such specialists reviewing this definition. However, in my view as a user of analytical tools to characterize the chemical composition of plastic particles, the proposed chemical composition criteria strikes the right balance between inclusion of human produced and modified polymers and exclusion of natural polymers. I think the decision to not address biodegradability in the proposed SWB definition is well supported by the state of knowledge on biodegradable polymer toxicity."

State Water Board Response [comment 05-06]

No revisions were identified to be necessary in response to this comment.

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