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Response to Comments

301 CMR 41.00
Toxic or Hazardous Substance List

Regulatory Authority:
M.G.L. Chapter 21I

November 2021

Toxic chemicals pose a range of risks to the environment and public health. The Toxics Use Reduction Act (TURA) is designed to supplement existing environmental and worker safety regulations. The aims of TURA are to help companies understand available options to reduce or eliminate toxic chemical use and to encourage them to implement the reduction options identified. These options are frequently cost-effective, and many create financial savings for companies. This law has been successful and, over the course of the program, the vast majority of companies have identified ways to cut toxics use and waste while saving money.

On August 19, 2021, The Toxics Use Reduction Act (TURA) Administrative Council voted to approve two proposed amendments to the TURA regulations. These proposed amendments were based on prior consideration by the TURA Science Advisory Board and TURA Advisory Committee. They included:

1. Defining the term 'substance' in 30 CMR 41.02: "Substance" is used in the definition in TURA of "Toxic or hazardous substance," but "substance" has not been further defined in TURA or associated regulations until now. Defining "substance" would clarify the term, which is used throughout the TURA regulations, including to refer to entries on the TURA list of Toxic or Hazardous Substances (TURA List).
2. Adding *Per- and Poly- Fluoroalkyl Substances Not Otherwise Listed (PFAS NOL)* to the TURA List: As described in the Policy Analysis, addition of PFAS NOL to the TURA List would help manufacturers understand how PFAS are being used, identify ways to reduce use of PFAS, and reduce company liability. Toxics Use Reduction makes it possible to proactively reduce PFAS contamination at its source and prevent harm before it occurs. Addition of PFAS to the TURA List would strengthen the Commonwealth's work to address PFAS comprehensively. As described below, the title and definition of this category has been modified to "Certain PFAS NOL" in the final regulations in response to comments.

EEA solicited public comments from September 24 to October 15, 2021 and held a public hearing on October 15, 2021 on these proposed revisions in accordance with M.G.L. Chapter 30A. A total of 100 written comments were received over the course of the public comment period. Of these comments, 87 were in favor of the proposed regulations and 13 were opposed. With regard to the 87 written comments in favor of the proposed amendments that did not propose substantive amendments, 43 of 87 (49%) were form letters submitted by unique individuals, an additional 30 comments (34%) were distinct letters from individuals. The remaining 14 (16%) written comments in favor of the regulation suggested revision or further action. The full text of all written comments received by EEA during the comment period can be found at https://www.mass.gov/doc/public-comments-on-amendments-to-301-cmr-41-september-october-2021/download.

A total of 40 public participants attended the public hearing, of whom 11 provided oral testimony (4 of the 11 spoke twice). The comments delivered during the oral testimony to the proposed amendments were provided by or on behalf of the same entities that submitted written comments and raised the same issues, and the below response to comments addresses the oral testimony. A transcript of the public hearing is available at https://www.mass.gov/doc/transcript-of-public-hearing-on-amendments-to-301-cmr-41-october-15-2021/download. The transcript is based on Zoom's automated closed captioning service. Software audio interpretation errors have been corrected wherever possible based on the contemporaneous notes of TURA Program staff.

RESPONSE TO COMMENTS

The table below summarizes comments that were received and contains the TURA Program's responses.

Comments In Favor of the Proposed Amendment		Response
Nina Aronoff	"I support the Administrative Council's decision to list PFAS on the state's Toxic and Hazardous Substances List."	Thank you for your comments. The TURA program acknowledges your support for the proposed regulations.
Todd Atkins		
Deborah Barolsky		
Bill Boehm		
Wolfgang Burger		
Nancy Burger		
Michelle Collar		
June Davenport		
Beverly Droz		
Sandra Gardiner		
Mary Gershanoff		
Carol Goslant		
Willis Gray		
James Hadcroft		
Kate Hermann-Wu		
Alisa Hermann-Wu		
Barry Ingber		
Mo Kafka		
Christine King		
Janet Kolodner		
Andee Krasner		
Teresia LaFleur		
Christine Lazar		
Janet Lyman		
Carole McAuliffe		
Maureen McCarthy		
Mike McCool		
Kathleen McHendry		
Brian McPherson		
David Miller		
Sherry Morgan		
Elizabeth Newton		
Lori Parkinson		

Isaiah Plovnick Jodi Rodar Emily Scott Barbara Spark Laurie Toner Peter Townsend David Tyler Donald Walker Alison Webster Rebecca Wish Esche		
Dawn Burau	"I am concerned about PFAS in drinking water and I support the Administrative Council's decision to list PFAS on the state's Toxic and Hazardous Substances List."	
Christopher Clark	"As a resident of a heavily contaminated community, a toxicologist, and a compassionate human being I am in full support of the proposed amendments regarding amendments for the definition of PFAS for the TURA Toxics or Hazardous Substance List."	
Meredith Fields	" I applaud the TURA Council voting to add PFAS NOS to the list of Toxics and Hazardous Substances."	
Constance Glore Dianne Plantamura	"I support the amendment and ask for your efforts to include PFAS NOL on the TURA list."	
Richard Keleher	"I think that PFAS should be added to the TURA list."	
Philip Marrone	"Per- and polyfluoroalkyl substances (PFAS) are persistent bioaccumulative and toxic chemicals. I am concerned about PFAS in drinking water and I support the Administrative Council's decision to list PFAS on the state's Toxic and Hazardous Substances List."	
Nancy Sarro	"I support the amendment and ask for your efforts to include PFAS NOL on the TURA list."	
Rebecca Stevenson	"Per- and polyfluoroalkyl substances (PFAS) are persistent bioaccumulative and toxic chemicals. I am concerned about PFAS in drinking water and I support the Administrative Council's decision to list PFAS on the state's Toxic and Hazardous Substances List."	
Charleen Strelke	"I support the Administrative Council's decision to list PFAS on the state's Toxic and Hazardous Substances List."	
Gary Martin	"I am writing today to voice my concerns about PFAS and to support amendment 301 CMR 41 that will add PFAS NOL to the TURA list."	
Jean Steinmetz	"I am concerned about PFAS in drinking water and I support the Administrative Council's decision to list PFAS on the state's Toxic and Hazardous Substances List."	
Karen Martin	"I am writing today to voice my concerns about PFAS and express my support for amendment 301 CMR 41 that will add PFAS NOL to the TURA list."	
Rich Bizzozero	"The definition of substance as proposed in 301 CMR 41.02: Definitions, is appropriately broad and inclusive. This definition is necessary in order to capture the wide variety of substances currently on the list of reportable substances 301 CMR 41.00: TOXIC OR HAZARDOUS SUBSTANCE LIST. A substance category for	**TURA Administrative Council Authority:** The Administrative Council is authorized to promulgate regulations to implement TURA. This authority extends to defining terms, including "substance."

	reporting purposes is reported as one combined total weight of all the substances meeting the definition of the category. Substance categories from the Emergency Planning and Community Right-to-Know Act (EPCRA), and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) are the foundation of reportable substances in the Toxics Use Reduction Act (TURA)."	**Listing PFAS as a Category / Class:** Listing of Certain PFAS NOL is consistent with Administrative Council authority and past practice. Many categories are already on the TURA List. Categories were specifically included on the original TURA List, and additional categories have been added to the List since that time, most recently in 2019.
Andrew Goldberg, Attorney General's Office	"The Toxics Use Reduction Act (TURA), G.L. c. 21I, §§ 1 et seq., expressly authorizes the Council to add toxic or hazardous substances to the List to trigger reporting and toxics use reduction planning by Massachusetts manufacturers and processors in order to satisfy the Legislature's purpose of protecting public health and the environment. Here, the Council appropriately used its statutory discretion in carrying out this legislative mandate by voting to add PFAS NOL to the List and to add a definition of "substance' to the regulations; both decisions carry out the Council's mandate of identifying those toxic or hazardous substances that warrant reporting and planning under TURA. The Proposed Amendments implement the Council's authorized actions." "The Council, chaired by the Secretary of the Executive Office of Energy and Environmental Affairs (EOEEA), is the governing body of the Commonwealth's TURA program and is authorized by statute to coordinate state enforcement of laws and regulations on chemical use and toxic waste generation and implement policies that promote worker health and safety, and safeguard public health. The Council is expressly authorized by TURA Section 9 to add substances to the List beyond those otherwise required to be on the List, e.g., chemicals identified on the Toxic Chemical List established pursuant to Section 313 of EPCRA."	
Wayne Chouinard, Wastewater Advisory Committee (WAC) to the Massachusetts Water Resources Authority (MWRA)	"WAC supports the definition of 'substances,' proposed in this regulation. It is important to treat PFAS has as an entire class, not individual chemicals. In the past, regulation of individual PFAS chemicals resulted in the proliferation of similar substances, thereby sidestepping control."	
Daryl Beardsley	"Please regulate PFAS as a class of chemicals."	**Listing PFAS as a category / class:** Listing of Certain PFAS NOL is consistent with Administrative Council authority and past practice. Many categories are already on the TURA List. Categories were specifically included on the original TURA List, and additional categories have been added to the List since that time, most recently in 2019. **Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance.
Rich Bizzozero	"Regulating these substances as a category rather than individually is appropriate and an important first step to preventing regrettable substitutions and protecting public health and the environment from the unanticipated and harmful properties of these 'forever' chemicals."	
Brown, et. al. Lilyana Ibañez Dr. Alissa Cordner, Associate Professor of	"We are strongly in support of listing PFAS as a class of chemicals rather than listing individual chemicals. Some manufacturers have phased out long-chain (containing seven or more fluorinated carbons) PFAS such as PFOA and PFOS that are linked with a variety of health problems and instead replaced them with similar short-chain PFAS that have been thought to be safer alternatives."	

Sociology, Whitman College Dr. Julia Varshavsky, Assistant Professor of Environmental Health, Northeastern University Dr. Phil Brown, University Distinguished Professor of Sociology and Health Sciences, Northeastern University For the PFAS Project Lab of the Social Science Environmental Health Research Institute		**Importance of listing as a category:** Listing Certain PFAS NOL as a category avoids the challenge of individually assessing, at minimum, hundreds of individual PFAS, which would take decades and would not achieve the TURA program's goal of proactive, preventive listing. In addition, the set of PFAS that are commercially available changes continually, and listing only PFAS that are currently in commerce risks encouraging adverse substitutions.
Wayne Chouinard, Wastewater Advisory Committee (WAC) to the Massachusetts Water Resources Authority (MWRA)	"WAC supports the definition of 'substances,' proposed in this regulation. It is important to treat PFAS has as an entire class, not individual chemicals. In the past, regulation of individual PFAS chemicals resulted in the proliferation of similar substances, thereby sidestepping control."	
Andrew Goldberg, Attorney General's Office	"And listing the category of PFAS NOL as set forth in the Proposed Amendments fully squares with TURA's annual ten-substance limit for adding substances to the List. The Council reasonably exercised its discretion to consider the PFAS NOL, which consists of closely related chemicals or compounds, as a single substance, and reinforced its position by clarifying its interpretation of the term 'substance' in the definition of the term in the Proposed Amendments."	
Wendy Heiger-Bernays, Thomas Webster, Jennifer Schlezinger, Rich Gurney, Greylin Nielsen, Emily	"Given the large number of PFAS and the tendency for new PFAS to replace older ones as the latter are phased out, regulation of individual compounds is not scientifically feasible. As a result, regulation of PFAS as a class is considered necessary by several groups of experts as well as various governments and agencies including the State of California and the USEPA."	

Hammel, Natalie Banacos - BUSPH	"Listing PFAS as a class of chemicals is a critical first step, but it does not reflect the hazard potential of these substances. After listing, PFAS should be listed as 'High Hazard Substances' in order for the Commonwealth to work with industries to identify and decrease and replace the use of these substances."	
Jennifer Liss Ohayon, PhD, Research Scientist, and Laurel Schaider, PhD, Senior Research Scientist, Silent Spring Institute	"We have several points regarding adding PFAS NOL to the TURA list, including the importance of a class-based approach, the necessity of reconsidering the reporting threshold given PFAS' persistence and toxicity at extremely low concentrations, the externalized social and health costs of PFAS for regulators and the public, and the extensive scientific deliberation that surrounded this amendment." "A strength of this listing is it applies a class-based approach to addressing PFAS. This class of chemicals is associated with a wide range of adverse health outcomes, including cancer, immunotoxicity, reproductive toxicity, developmental effects on the mammary gland, neurotoxicity, and thyroid, liver, and kidney…While industry has argued during oral testimony that fluoropolymers should be exempt from regulation, academic work indicates that fluoropolymers, particularly the degradants and incidental PFAS associated with their lifecycle, can pose serious toxicity concerns and TURA's Scientific Advisory Board debated at length about this subset of PFAS chemicals and decided they should be included due to similar rationale."	
Bisola Ojikutu, Boston Public Health Commission	Including PFAS as a category of substances allows TURA to address members of this chemical family for which full toxicity information is not yet available rather than responding one chemical at a time as full data is collected, often years after they have been in use in industry and released into the environment."	
Rick Reibstein	"The toxics list has always included mixtures and categories." "There are some chemicals that present the famous 'whack-a-mole' problem, (the amusement park game in which a 'mole' keeps popping up in different places). When one member of a chemical group is regulated, industry takes a very similar one, a sibling or cousin so to speak, off the shelf and substitutes that chemical, which presents similar threats."	
Mark Rossi, Clean Production Action	"Clean Production Action (CPA) supports…regulating PFAS as a class…	
Chris Allen, Water District Supply of Acton	"The District believes that source control (getting these compounds out of commerce and from getting into the environment) is critical to reduce future burden of having to remove PFAS in water at the source. While we recognize these regulations will not prohibit the use of PFAS, it will provide valuable information that might lead to source control measures."	**Identifying PFAS:** Listing PFAS under TURA would help manufacturers understand how PFAS are being used, identify ways to reduce their use, and reduce company liability. These activities will strengthen the Commonwealth's work to address PFAS comprehensively.
Dave Arndt	"PFAS are forever chemicals, however often overlooked is that since they are forever, we don't have the data on cumulative effects over the years and how they will continue being aggregated in humans and animals for years to come. Also, many of its uses are not tracked, so they can show up unexpectedly. Unlike batteries, disposal of products with PFAS are just seen as waste and not treated like hazardous waste."	

Daryl Beardsley	"In brief, my observations about this issue from industry's perspective include: · It is difficult to get clear information from suppliers about the presence of PFAS in the materials used by industrial facilities. This may be due to the loss of information from one step of the supply chain to another, proprietary formulation claims, lack of toxicity assessments such that the individual PFAS is not yet classified as hazardous, fear of liabilities resulting from disclosure of PFAS content, etc. · All of my clients prefer that no PFAS are present in their operations. Most do not have a specific need for the properties offered by PFAS. For those few that do, they are more than willing to accept alternatives, even if that means some changes in performance. Government support and customer tolerance of interim changes in product characteristics will be important if equally performing alternatives are not available immediately."	
Brown, et. al. Lilyana Ibañez Dr. Alissa Cordner, Associate Professor of Sociology, Whitman College Dr. Julia Varshavsky, Assistant Professor of Environmental Health, Northeastern University Dr. Phil Brown, University Distinguished Professor of Sociology and Health Sciences, Northeastern University For the PFAS Project Lab of the Social Science Environmental Health Research Institute	"In order to enhance the Commonwealth's continuous work to decrease PFAS use, PFAS must be listed under TURA. This action will help raise awareness among manufacturers about how PFAS are used and how to reduce existing use, and encourage them to reduce company involvement with PFAS and their liability of PFAS contamination. TURA has been a nationally prominent policy process, with TURI being the nation's model for toxics reduction. In tandem with Massachusetts' early provision of MCLs for 6 PFAS, this action can make the state even further a leader in the nationwide effort at PFAS Toxics reduction."	
Tom Cambareri	"Adding PFAS to the list will help identify responsible parties and assist in developing efficient strategies to cleanup and prevent additional releases."	
Wayne Chouinard, Wastewater	"The addition of PFAS-NOL to TURA would help publicly owned treatment works (POTWs) and industry determine where PFAS are used in industry and where	

Advisory Committee (WAC) to the Massachusetts Water Resources Authority (MWRA)	opportunities exist to reduce their use (and industry liability). The MWRA, like POTWs across the country, contains costs to ratepayers and enhances the environment by selling nutrient-rich biosolids as fertilizer. The solids from this process would otherwise have to be landfilled or incinerated. Recycling of biosolids is continually threatened because of contaminants of emerging concern, such as PFAS, in wastewater. With several New England states establishing guidance limiting PFAS to 20ppt or lower for drinking water and exploring limits on biosolids, it is increasingly important to reduce PFAS coming in to POTWs." "WAC supports the definition of 'substances,' proposed in this regulation. It is important to treat PFAS has as an entire class, not individual chemicals. In the past, regulation of individual PFAS chemicals resulted in the proliferation of similar substances, thereby sidestepping control."	
Mary Cordero, Community Action Works	"Placing PFAS on the TURA list is a necessary first step that will help state officials better understand how and where PFAS is being manufactured, used and released in Massachusetts."	
Cheryl Osimo, Massachusetts Breast Cancer Coalition	"The proposed group of PFAS should be added to the TURA list to ensure the protection of public health. Without increased knowledge of industry's use of PFAS, PFAS accumulation will only worsen and threaten our health and the health of our children and grandchildren. We strongly call for this listing to be finalized without delay – science and the experience of impacted communities demonstrates the urgency of this issue."	
Karl Palmer, Safer Consumer Products Program - California DTSC	"As the May 2021 Policy Analysis points out, the TURA program has the opportunity to enhance understanding of the uses of PFASs in manufacturing, which will greatly help prevention activities. This goal will be better achieved by expanding the definition of PFAS NOL to include ultra-short chains."	
Jennifer Pederson, Massachusetts Water Works Association	MWWA believes that source control (getting these compounds out of commerce and from getting into the environment) is critical to reduce future burden of having to remove PFAS in water at the source. While we recognize these regulations will not prohibit the use of PFAS, it will provide valuable information that might lead to source control measures."	
Monika Roy	"It is clear that PFAS as a class are an issue for environmental and human health, and that many individual PFAS chemicals are persistent, bioaccumulative, and toxic. Listing PFAS on the TUR list of Toxic or Hazardous Substances is a step in the right direction for companies to actively be aware of their PFAS usage and to make efforts to reduce it."	
David Slater	"Pfas users and manufacturers should be held financially liable for mitigation and cleanup. Further, we should have a target date for abolishing these chemicals in Massachusetts"	
Elodia Thomas	"I commend the work that the Tura Administrative Council is doing in expanding the substance category PFOS NOL to the TURA list of Toxic or Hazardous Substances. As I understand it, this work will summarize existing information about hazardous characteristics, examine how PFAS are used in manufacturing and in consumer	

	products, identify ways to regulate and reduce use, toxic use payment fees, and increase company control/prevention activities regarding potential contamination. These activities will strengthen the Commonwealth's work to reduce the use of PFAS."	
Rebekah Thomson	"Thank you for the opportunity to express my support for the proposed amendments. Communities deserve to know where PFAS are being used in Massachusetts. In the absence of a comprehensive list, communities have been forced to spend resources attempting to figure out where PFAS contamination is coming from."	
Diane Cotter	"This comment today is to give the TURA insight into the fire service complexities and to express our desire to support the actions to address, minimize, remove, PFAS chemicals from firefighter turnout gear, firehouse environments, and support the use of only independently proven fluorine free foams."	**Application to articles:** TURA requirements do not apply to articles, unless the facility processes the article. The TURA program follows the EPA TRI article exemption rules. **Firefighting Gear and Foam:** Since TURA covers only **manufacturers**, not first responders or local government agencies, this listing will not prevent first responders from using any sort of firefighting material or foam. However, this listing would require manufacturers to accurately report PFAS containing materials, which would help fire departments, first responders, local government agencies, and others make purchasing decisions based upon ingredient transparency.
Jaime Honkawa and Ayesha Khan, Nantucket PFAS Action Group	"We believe PFAS should be banned from turnout gear due to the toxicity, persistence, and the vast amounts of these compounds that are used and shed during each stage of the garment life cycle. We are hopeful that adding PFAS as a class to TURA's hazardous substance list would encourage textile companies to invest in innovation and look for safer alternatives that will remove toxic chemicals from the gear to not only be safe from fires but also the chemicals from their gear."	
Richard Clapp	"I recommend changing the proposed amendment of section 41.03. paragraph 14 to include "those PFAS that contain a perfluoroalkyl or polyfluoroalkyl moiety containing one or more fully fluorinated carbon that are not otherwise listed." "The current language distinguishing perfluoroalkyl from perfluoroalkylether moieties is confusing and needs to be simplified."	**Clarification of PFAS NOL Definition:** Based upon these and other comments, "PFAS NOL" will be revised to "Certain PFAS NOL" to clarify that only PFAS meeting the definition of "Certain PFAS NOL" are included in the listing. The definition of "Certain PFAS NOL" will be revised to clarify that it includes "those PFAS that contain a perfluoroalkyl moiety with three or more carbons (e.g., –CnF2n–, n ≥ 3; or CF3–CnF2n– , n≥2) or a perfluoroalkylether moiety with two or more carbons (e.g., –CnF2nOCmF2m− or –CnF2nOCmFm–, n and m ≥ 1), *wherein for the example structures shown, the dash (–) is not a bond to a hydrogen and may represent a straight or branched structure…*" The text in italics will clarify the structures covered by the definition of Certain PFAS NOL.
Wendy Heiger-Bernays, Thomas Webster, Jennifer Schlezinger, Rich Gurney, Greylin Nielsen, Emily Hammel, Natalie Banacos - BUSPH	"The listing's working title "PFAS not otherwise listed" is ambiguous and requires clarification. We suggest that the title be replaced with "selected" or "certain" PFAS not otherwise listed." "The SAB definition of the category of PFAS has ambiguity and it would be helpful to clarify the structural definition. For ease of use, a structural definition should be maintained, but specified, 'i.e.' instead of 'e.g.' Furthermore, said structural definition, as written, is ambiguous in that it does not provide great enough detail as to the identity of the groups on the left or the right side of each of the dashes. Once this listing is finalized, the health and safety of perfluorinated molecules with fewer than three perfluorinated carbons should be reviewed."	
Kyla Bennett, Public Employees for Environmental Responsibility	"Public Employees for Environmental Responsibility (PEER) and Massachusetts Sierra Club are writing to recommend that TURA adopt the U.S. Environmental Protection Agency (EPA) definition of per-and polyfluoroalkyl substances (PFAS)." "The EPA definition includes those PFAS with two contiguous carbons with fluorine, but only one needs to be fully fluorinated. In contrast, the proposed Massachusetts definition requires three contiguous carbons, all fully fluorinated, except for the two carbon Gen X molecules which are also included. The EPA	**Broadening the Definition of PFAS:** The definition of Certain PFAS NOL will not be revised as suggested. A broader definition of PFAS would include PFAS that were not reviewed by the Science Advisory Board (SAB). The definition of Certain PFAS NOL is based on the scope of the SAB's review to date. In the future, the SAB may examine and assess PFAS that are not captured within the definition of Certain PFAS NOL.

	definition is broader, includes more PFAS than the proposed Massachusetts definition, and therefore is more protective of public health and the environment."	
Richard Clapp	"I recommend changing the proposed amendment of section 41.03. paragraph 14 to include "those PFAS that contain a perfluoroalkyl or polyfluoroalkyl moiety containing one or more fully fluorinated carbon that are not otherwise listed." "The current language distinguishing perfluoroalkyl from perfluoroalkylether moieties is confusing and needs to be simplified."	
Clean Water Action, American Sustainable Business Council, Built Environment Plus, Clean Production Action, Community Action Works, Conservations Law Foundation, Environmental League of Massachusetts, Environment Massachusetts, GreenCape, Green Newton, Healthlink, Massachusetts Association for the Chemically Injured, Massachusetts Breast Cancer Coalition, Massachusetts Coalition for Occupational Safety and Health, MASSPIRG, Nantucket PFAS Action Group, Our Bodies, Ourselves, Public Employees for Environmental Responsibility,	"The Administrative Council should broaden the proposed definition of PFAS to align with language adopted by other states. PFAS should be defined as 'Perfluoroalkyl and polyfluoroalkyl substances are a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.' We recommend that Massachusetts expand the proposed definition of PFAS. In this current proposed amendment, PFAS is defined too narrowly (≥C3F6 more or less). A broader definition of PFAS that includes more types of PFAS will be more protective of public health and the environment." "For the sake of regulatory uniformity, we respectfully request that TURA use the same language adopted by other states and define PFAS as 'a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.'"	

Regeneration Massachusetts, Saugus Action Volunteers for the Environment, Seaside Sustainability, Sierra Club MA, Northeastern University Social Science Environmental Health Research Institute, Vineyard Conservation Society		
Mary Cordero, Community Action Works	"First, we recommend that Massachusetts expand the proposed definition of PFAS. In this current proposed amendment, PFAS is defined too narrowly (≥C3F6 more or less). A broader definition of PFAS that includes more types of PFAS will be more protective of public health and the environment. Neighboring states of Vermont, New Hampshire, Maine, and New York all define PFAS as 'a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.' Additionally, the proposed Massachusetts bills (S.1494 / H.2348) are also using this definition. TURA should also use this language for regulatory uniformity."	
Constance Glore, Climate Justice Group Dianne Plantamura, Climate Justice Group	"Adopts the PFAS definition, 'a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.'	
Wendy Heiger-Bernays, Thomas Webster, Jennifer Schlezinger, Rich Gurney, Greylin Nielsen, Emily Hammel, Natalie Banacos - BUSPH	"After completion of the current listing, it is imperative that TURI continue to examine PFAS that do not fall within the current listing's definition. Such chemistries include PFAS with fewer than three carbon atoms, among others."	
Jaime Honkawa and Ayesha Khan, Nantucket PFAS Action Group	"…we hope the Administrative Council will be open to reassessing the definition of PFAS to align with language adopted by other states. For the sake of regulatory uniformity, we respectfully request that TURA use the same language adopted by other states and define PFAS as 'a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.'"	

Kate McHugh	"Adopts the PFAS definition, 'a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.'"	
Kristin Mello, Westfield Residents Advocating For Themselves	"Of course, given the extraordinarily persistent, bioaccumulative, and toxic nature of these man-made substances obviously a broader definition to include any fluorinated monomers and fluoropolymers, and a much lower reporting threshold would be preferable. These adjustments would be much more protective against ongoing unnecessary PFAS exposure to our most vulnerable environmental justice populations."	
Jennifer Liss Ohayon, PhD, Research Scientist, and Laurel Schaider, PhD, Senior Research Scientist, Silent Spring Institute	"While this amendment would add PFAS NOL to the TURA list, it has defined PFAS as those that contain a perfluoroalkyl moiety with three or more carbons (e.g., –CnF2n–, n ≥ 3; or CF3–CnF2n– , n≥2) or a perfluoroalkylether moiety with two or more carbons (e.g., –CnF2nOCmF2m− or –CnF2nOCmFm–, n and m ≥ 1). This definition of PFAS is narrower than that which has been adopted by other states and institutions. For example, the Organization for Economic Cooperation and Development (OCED) defines PFAS as 'fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it).' While the best approach to defining PFAS is an evolving line of inquiry, TURA's definition will fail to encompass many high production volume PFAS of known concern by not including those PFAS with one fluorinated carbon atom. We hope that this can be considered in future amendments to the TURA list."	
Karl Palmer, Safer Consumer Products Program - California DTSC	"The California Department of Toxic Substances Control (DTSC) supports the proposal to add the category of per- and polyfluoroalkyl substances not otherwise listed (PFAS NOL) to the TURA list of Toxics or Hazardous Substances. Additionally, we recommend that TURA expand its definition of PFAS NOL to include ultra-short-chain compounds." "We encourage TURA to expand its definition of PFAS NOL to include ultra-short chains. While the shortest PFAS reviewed in the May 2021 Policy Analysis had three fluorinated carbons (i.e., PFBA), ultra-short-chain PFASs display some of the same hazards of concern, including very high persistence, mobility in the environment, and potential toxicity. For example, trifluoroacetic acid (TFA) is of growing concern due to its widespread detection, high persistence, and aquatic toxicity, yet it is not currently covered under the proposed PFAS NOL definition. To capture TFA and other ultra-short chain class members, DTSC recommends adopting the revised PFAS definition from the Organisation for Economic Cooperation and Development (OECD), which includes substances that contain at least one fully fluorinated methyl or methylene carbon atom. This is a straightforward definition, without arbitrary chain length requirements. "As the May 2021 Policy Analysis points out, the TURA program has the opportunity to enhance understanding of the uses of PFASs in manufacturing, which will greatly help prevention activities. This goal will be better achieved by expanding	

	the definition of PFAS NOL to include ultra-short chains."	
Clint Richmond, MA Sierra Club	"The Massachusetts Sierra Club has signed a letter recommending that TURA add "Per and Polyfluoroalkyl Substances Not Otherwise Listed (PFAS NOL)" to the TURA List. That letter urges a broad definition of per- and polyfluoroalkyl substances (PFAS), the one that has been adopted by the OECD and in laws in many other U.S. states. This definition is: a substance that contains at least one fully fluorinated carbon atom." "The Sierra Club would further suggest that the occupational and environmental risks stem from organofluorine chemistry itself." "We need to regulate and avoid any substance that could have carbon-fluorine degradants, which are generally extremely persistent…This includes fluoropolymers, which need to be included now on the TURA List." "…there are a number of extensions to the OECD definition that should be considered. 1) All polyfluorinated alkyl substances. This would implement the full literal meaning of PFAS. This would encompass, for example, all difluoromethyl moieties. Other extensions could include non-alkyl organic substances: 2) Polyfluorinated alkenes. This would include vinylidene fluoride, which is used as a monomer in fluoropolymers. 3) Any polyfluorinated organic group, i.e., with at least two C-F bonds. This would for example include difluorophenyl. Benzene is already on the TURA list, and this would capture several even more problematic fluorinated variants. This could be continued with various classes but the logical conclusion is to regulate all organofluorines." "The Sierra Club strongly urges adding PFAS and organofluorines to the TURA list."	
Mark Rossi, Clean Production Action	"…The Administrative Council should broaden the proposed definition of PFAS to align with language adopted by other states. PFAS should be defined as: 'Perfluoroalkyl and polyfluoroalkyl substances are a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.'" "… CPA recommends that Massachusetts expand the proposed definition of PFAS. In this current proposed amendment, PFAS is defined too narrowly (≥C3F6 more or less). A broader definition of PFAS that includes more types of PFAS will be more protective of public health and the environment." "The listing of PFAS, and using a broad definition will help raise awareness of companies towards PFAS and accelerate the search for alternatives. CPA and other organizations are searching for and finding preferred alternatives to PFAS in a number of applications, including firefighting foam, cleaners and degreasers used in manufacturing operations, furniture and fabrics, as well as food packaging. Given the	

	prevalence of alternatives on the market, Massachusetts can begin with the expanding the listing of PFAS to the TURA list of Toxic and Hazardous Substances, and added as a Higher Hazardous Substance."	
Rebekah Thomson	"I strongly encourage the State to move forward listing PFAS under TURA and to extend the list to cover the entire class of PFAS in subsequent legislation."	
Clean Water Action, American Sustainable Business Council, Built Environment Plus, Clean Production Action, Community Action Works, Conservations Law Foundation, Environmental League of Massachusetts, Environment Massachusetts, GreenCape, Green Newton, Healthlink, Massachusetts Association for the Chemically Injured, Massachusetts Breast Cancer Coalition, Massachusetts Coalition for Occupational Safety and Health, MASSPIRG, Nantucket PFAS Action Group, Our Bodies, Ourselves, Public Employees for Environmental Responsibility, Regeneration Massachusetts, Saugus Action	"PFAS should be listed as a Higher Hazardous Substance and reporting threshold lowered to 100 pounds per year."	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category.

Volunteers for the Environment, Seaside Sustainability, Sierra Club MA, Northeastern University Social Science Environmental Health Research Institute, Vineyard Conservation Society		
Mary Cordero, Community Action Works	"Second, we recommend lowering the reporting thresholds. PFAS chemicals are extremely toxic to human health and the environment, even in very small amounts. The TURA program requirements call for reporting if a facility manufactures or processes 25,000 lb/year, or otherwise uses 10,000 lb/year. A lowered reporting threshold will be more protective to public health and the environment."	
Constance Glore, Climate Justice Group Dianne Plantamura, Climate Justice Group	"Recognizes the bio-accumulative effects of PFAS and lists PFAS as a Higher Hazardous Substance. "	
Wendy Heiger-Bernays, Thomas Webster, Jennifer Schlezinger, Rich Gurney, Greylin Nielsen, Emily Hammel, Natalie Banacos - BUSPH	"Listing PFAS as a class of chemicals is a critical first step, but it does not reflect the hazard potential of these substances. After listing, PFAS should be listed as 'High Hazard Substances' in order for the Commonwealth to work with industries to identify and decrease and replace the use of these substances."	
Kate McHugh	"Recognizes the bio-accumulative effects of PFAS and lists PFAS as a Higher Hazardous Substance."	
Kristin Mello, Westfield Residents Advocating For Themselves	"Of course, given the extraordinarily persistent, bioaccumulative, and toxic nature of these man-made substances obviously a broader definition to include any fluorinated monomers and fluoropolymers, and a much lower reporting threshold would be preferable. These adjustments would be much more protective against ongoing unnecessary PFAS exposure to our most vulnerable environmental justice populations."	
Jennifer Liss Ohayon, PhD,	"We have several points regarding adding PFAS NOL to the TURA list, including the importance of a class-based approach, the necessity of reconsidering the reporting	

Research Scientist, and Laurel Schaider, PhD, Senior Research Scientist, Silent Spring Institute	threshold given PFAS' persistence and toxicity at extremely low concentrations, the externalized social and health costs of PFAS for regulators and the public, and the extensive scientific deliberation that surrounded this amendment."	
Mark Rossi, Clean Production Action	"Clean Production Action (CPA) supports…regulating PFAS as a class…CPA supports adding PFAS to TURA list as soon as possible…PFAS should be listed as a Higher Hazardous Substance and reporting threshold lowered to 100 pounds per year…"	
Clint Richmond, MA Sierra Club	"We need to regulate and avoid any substance that could have carbon-fluorine degradants, which are generally extremely persistent…This includes fluoropolymers, which need to be included now on the TURA List."	**Fluoropolymer Inclusion:** Fluoropolymers that meet the definition are included in this listing. The TURA program reviewed the chemicals included in the Certain PFAS NOL category and, using the OECD Comprehensive Global Database of PFASs as well as evidence found in the literature, determined that polymeric PFAS (including polymers meeting the OECD criteria for "polymers of low concern") have the potential to break down into perfluoroalkyl acids (PFAAs).
Jennifer Liss Ohayon, PhD, Research Scientist, and Laurel Schaider, PhD, Senior Research Scientist, Silent Spring Institute	"While industry has argued during oral testimony that fluoropolymers should be exempt from regulation, academic work indicates that fluoropolymers, particularly the degradants and incidental PFAS associated with their lifecycle, can pose serious toxicity concerns and TURA's Scientific Advisory Board debated at length about this subset of PFAS chemicals and decided they should be included due to similar rationale."	

Comments Opposed to the Proposed Amendment		Response
3M	"I. TURA DOES NOT ALLOW LISTING A GROUP OF HUNDREDS OF SUBSTANCES Massachusetts law does not permit the listing of hundreds of PFAS in one broad act by including them as a 'category.' Except for changes to the CERCLA hazardous substance list, TURA limits the Council's authority to add or delete substances to 'no more than 10 substances' for any one calendar year. There is no legal authority for the agency to list 'categories' of substances where the plain language of the statute limits the listing to no more than 10 'substances' annually. The proposed regulation allowing the listing of thousands of PFAS as a category would effectively render the statutory cap meaningless." "II. INCLUDING PFAS NOL AS A SINGLE CATEGORY IS NOT BASED ON SOUND SCIENCE Even if it were legally permissible under TURA, there is no scientific basis for the SAB's definition of PFAS as a category…. "A. Grouping PFAS as a category is scientifically flawed PFAS refers to a broad category of compounds that encompasses thousands of materials with distinct and widely varying properties, profiles, and uses…. Different	**Listing PFAS as a Category / Class:** Listing of Certain PFAS NOL is consistent with Administrative Council authority and past practice. Many categories are already on the TURA List. Categories were specifically included on the original TURA List, and additional categories have been added to the List since that time, most recently in 2019. **Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance. **Basis for SAB recommendation to list Certain PFAS NOL:** The SAB recommendation to list Certain PFAS NOL was based on discussions at 19 public meetings from 2016 to 2020. Summaries of these discussions, including detailed discussion of the scientific literature and examination of representative chemicals, are available in meeting minutes located on TURI's website. The SAB discussed the disparate results among studies and the

	PFAS have different toxicological properties, bioaccumulation potentials, toxicity levels and effects. Persistence alone is not a sufficient basis for regulating a chemical as toxic or hazardous…. Such assessments should consider potential exposure routes and identified hazards, not simply structural similarities… 3M requests that the Council identify what information it is using to classify hazardousness of the hundreds of PFAS that are subject to the Proposed Amendments based on its review of only twelve chemicals so that the public has an opportunity to participate meaningfully in the rulemaking process. "B. There is no support for listing PFAS as a group based on similar hazards…. "Rigorous, reliable scientific evidence indicates there is not a sound basis to treat thousands of PFAS as a group. 3M welcomes the opportunity to continue to engage with the Council in science-based dialogue to determine how these materials potentially could be grouped in a scientifically sound way. However, there is not currently any technical support in the Proposed Amendment or supporting documents that justify listing the defined group. "C. The Board's deficient analysis does not support the category listing "The Board does not adequately explain why this range of PFAAS is representative of the listing category. Further, the listing category appears so broad that virtually any PFAS chemical is included in some way. "Moreover, SAB's definition is over-inclusive because the range of substances encompassed by the definition includes substances with widely varying toxicity, fate and transport, and other characteristics…. "The Board cited repeatedly to the Organization for Economic Cooperation and Development (OECD) "database" but then ignored the groups and sub-groups created by the OECD and drafted a definition that would encompass all of them, (with the exception of specific substances within each group with less than three carbons). Going beyond its failure to explain how and why the individual PFAS it chose were representative of the entire category, SAB also did not explain why it was appropriate to list as hazardous an unknown number of chemicals for which the Board acknowledged there is no scientific data regarding health or environmental effects…. "Finally, the Board cited numerous studies and regulatory actions but failed to discuss any of the literature in detail or connect the studies or actions to its own conclusions." "D. Assuming Equal Properties Among Individual PFAS is Not Scientifically Supported "Available data demonstrate that there is a large spectrum of differences in the biological responses observed in laboratory animals under toxicological study conditions for most perfluoroalkyls evaluated…. The proposed definition of PFAS includes gaseous, liquid, and solid compounds with variation in properties such as volatility and water solubility. Therefore, it is scientifically inappropriate to assume they all have the same effects. "E. Generic Conclusions Provide Insufficient Support for the Hazard Listing The lengthy bibliography attached to the Policy Analysis cannot replace adequate analysis. SAB mentions its review of "the literature" and "primary research publications" but it fails to discuss the literature or research in a way that allows a reader to examine the basis for the Board's summary conclusions….	rationale for its recommendations at its meetings. Both the SAB and the Administrative Council determined to list Certain PFAS NOL based on their own independent consideration and determinations. The chemicals examined by the SAB are representative of the Certain PFAS NOL category. The SAB reviewed representative individual chemicals within each of the broad subcategories of the PFAAs: the carboxylic and sulfonic acids, which have been widely identified as contaminants in the environment; the phosphonic/phosphinic acids; and the ethers (GenX and ADONA). Similar toxicity issues were seen for all the chemicals that were reviewed. The SAB then built upon this work by reviewing the breakdown of PFAA precursors into PFAAs. Many of the chemicals in the Certain PFAS NOL category have the potential to break down into chemicals that were individually reviewed. The SAB reviewed at least one precursor for each of the OECD subcategories of PFAAs. The SAB also considered a number of breakdown pathways, including hydrolysis, photolysis, biodegradation and thermal degradation. The SAB examined the 2018 Comprehensive Global Database of PFASs group-by-group before deciding to recommend listing of Certain PFAS NOL. For each subgroup, the SAB determined that the subgroup consisted of either persistent end degradation products (e.g. PFAAs) or precursors. Persistence is a property that is found consistently across all the end degradation products. However, it was not the sole basis for the SAB's recommendation to list Certain PFAS NOL. Rather, it is one of several characteristics of concern taken into account. Information on SAB examinations was organized in an Excel file, available on TURI's website in the meeting materials for the June 16, 2020 SAB meeting. The Board did not review the C8 2020 meeting results (which pertain only to PFOA) as they were published after the Board's recommendation in June of 2020. These results may be considered by the SAB in the future. **Fluoropolymer Inclusion:** Fluoropolymers that meet the definition are included in this listing. The TURA program reviewed the chemicals included in the Certain PFAS NOL category and, using the OECD Comprehensive Global Database of PFASs as well as evidence found in the literature, determined that polymeric PFAS (including polymers meeting the OECD criteria for "polymers of low concern") have the potential to break down into perfluoroalkyl acids (PFAAs). **Toxicity of Certain PFAS NOL:** The Administrative Council makes listing decisions based on hazard. The vast body of scientific evidence, as reviewed by the SAB, shows serious concerns about chemicals in the Certain PFAS NOL category. The majority of studies reviewed showed adverse health effects in animals as well as biological mechanisms relevant to humans.

	"F. Other Agencies' Regulatory Activity is Not a Basis for the Proposed Listing…. The Policy Analysis treats other states' regulatory actions as evidence that it should list thousands of PFAS as hazardous, without identifying any relevant or similar action suggested by any one of the other measures. The Board should examine the regulatory action and the specific chemical at issue in a particular regulatory action it is citing, and explain why that action supports the Board's recommendation…. "III. THE BODY OF SCIENTIFIC EVIDENCE DOES NOT SHOW ADVERSE EFFECTS IN HUMANS FROM PFAS The vast body of scientific evidence does not show that the proposed listed category of PFAS cause adverse health effects in humans. While there remains some uncertainty in the science, the evidence available today does not support the conclusions regarding health effects drawn in the Policy Analysis…. "The TURA Policy Analysis repeatedly cites information from the "C8 Health Project." This information is misleading and outdated. In 2020, scientists and collaborators who had formed the "C8 Science Panel" reviewed the current literature with respect to each of the health conditions potentially linked to PFOA…. "3M requests that the Council reconsider its decision to list hundreds of PFAS in violation of TURA's requirements and without a sound basis in science."	
Margaret Gorman, ACC	"ACC strongly opposes adding the per-and-polyfluoroalkyl substances not otherwise listed (PFAS NOL) category as a high hazard category on the Toxic or Hazardous Substance List because: 1) the vote is contrary to the Massachusetts Toxics Use Reduction Act ("TURA"); 2) is the result of a flawed administrative process; and 3) is based on flawed scientific principles…. "However, while the proposed regulation would treat all PFAS compounds not otherwise listed as one 'substance', the regulated community, in order to comply with the regulation, would still have to gather information on each individual molecule that meets the definition. In other words, the Council might pretend that it has added only one new compound to the listed, but the effect on the regulated community would be no different than if the Council were to add each PFAS compound individually…. "2. The Administrative Process Leading to the PFAS Listing Was Flawed One of the primary purposes of the TURA statute is for the addition or deletion of chemicals on a list of hazardous substances. The process envisioned by the statute is a multi-stage decision-making method with a "robust and dynamic process for discussion, analysis and stakeholder input2." The Science Advisory Board ("SAB") recommendation and TUR Administrative Council's vote to list PFAS NOL, all conducted via virtual platform, lacked these important precepts. "ACC expressed concerns over deficiencies in process in a series of letters, phone calls and meetings with the Governor's Office in May and June 2020. More specifically, ACC raised concerns regarding procedural deficiencies in virtual meetings conducted by the SAB, Advisory Committee and Administrative Council. While Zoom technology, when effectively deployed, can be a useful method of facilitating public comment that is consistent with the spirit of the Governor's Executive Order of maximizing public participation, the SAB's meetings prohibited such meaningful participation. Those deficiencies included: (1) failure to provide periodic (at reasonably-timed intervals) opportunities for the	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category. **Listing PFAS as a Category / Class:** Listing of Certain PFAS NOL is consistent with Administrative Council authority and past practice. Many categories are already on the TURA List. Categories were specifically included on the original TURA List, and additional categories have been added to the List since that time, most recently in 2019. **Benefits to Regulated Entities of Listing as a Category:** Listing of Certain PFAS NOL as a category supports compliance and reduces costs to regulated entities. Individual chemical listings would require covered businesses to determine which specific PFAS are used at a facility, which is often difficult to obtain from suppliers, as noted in the Policy Analysis. In contrast, the category listing allows businesses to gather "yes/no" information from suppliers on the presence of any chemical meeting the definition. Listing of Certain PFAS NOL as a category also reduces costs to regulated entities. Facilities reporting on Certain PFAS NOL will pay just one per-substance fee for the use of all Certain PFAS NOL, whereas a separate fee would be required for each chemical listed individually. **Public participation:** The administrative process leading to this rulemaking allowed for ample public participation. The SAB reviewed PFAS in 19 meetings from November 2016 to June 2020. All meetings were posted and open to the public and provided public comment opportunities. The final three meetings were conducted through Zoom per the Governor's Executive Order of March 12, 2020, as amended. Public comment was allowed

	public to respond; (2) failure to ensure that public comments are allowed during the relevant portion of the debate and not at some point when they are no longer relevant to the discussion; (3) failure to permit enabling of cameras and microphones by participants; and (4) failure to consider public comment submitted electronically into the record and allowing the SAB members the opportunity to respond to public comment."	periodically during these meetings by audio and video. Additionally, participants could type comments into the "chat" at any time, and all such comments were maintained as part of the meeting minutes. Visitors were asked to turn off their video and mute when they were not speaking. After a recommendation was voted on by the SAB, the recommendation and policy analysis were presented at the Advisory Committee (10/30/20, and partial drafts at several meetings prior). These meetings were posted and open to the public, and public comment was allowed periodically during each meeting. Additionally, the Administrative Council meetings regarding this regulation (3/5/21 and 8/19/21) were posted and open to the public, and the Administrative Council received public comment during these meetings, including as detailed in this document.
Steve Korzeniowski, ACC	"ACC strongly opposes adding the per-and-polyfluoroalkyl substances not otherwise listed (PFAS NOL) category as a high hazard category on the Toxic or Hazardous Substance List because: the fundamental flawed principle behind this NOL Vote is that all PFAS compounds are treated as the same and they are all toxic and/or hazardous. We strongly oppose the concept and premise to 'Group as One and Regulate as a Class.'…. - Page 9 discusses fluoropolymers (FP's) and provides a number of factually incorrect statements and assumptions – not all FP's are made with PFAAs; in fact the majority of types are not made with PFAAs i.e PVDF. Given that most FP's meet the Polymer of Low Concern criteria, residuals and leachables are not expected to be an issue…. - Page 10 provides two Tables for your review – both of which provide a significantly unbalanced perspective leaving out many peer-reviewed papers and other articles that dispute some of these classifications, especially for PFHxA. Notably the studies left out were by the French agency ANSES and both the Luz et al and Anderson et al publications which provide RfD's or reference dose values clearly showing that PFHxA has a safety margin many orders of magnitude higher than PFOA, for example…. - Figure 3 on page 20 provides you with perspective from both a MA and NHANES PFAS human blood level analyses. It is noteworthy that this Figure does not list PFHxA, yet it has been classified as bioaccumulative by the SAB team (in the cited Tables) despite the complete lack of human population evidence in blood…. "The peer-reviewed paper ACC published in May in Integrated Environmental Assessment and Management (IEAM) indicated that the number of Commercially Relevant" compounds is more likely in the hundreds not in the 10,000's. This means we can assess these compounds by classic risk assessments rather than by a 'Group as One'/List as One approach singled out by this proposed vote…. "[T]hese compounds, whether they are Organic Compounds or Fluoro-organic Compounds, encompass a huge universe of very different, diverse substances with vastly different properties and functions. One simply cannot group them as One and together because significant fundamental property differences exist. "- Persistence alone is not an intrinsic hazard and does not in itself imply an adverse effect. "- Persistence of a substance does not eliminate the need for a risk assessment based on evidence of adverse effects and environmental releases.	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category. **Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance. **Importance of listing as a category:** Listing Certain PFAS NOL as a category avoids the challenge of individually assessing, at minimum, hundreds of individual PFAS, which would take decades and would not achieve the TURA program's goal of proactive, preventive listing. In addition, the set of PFAS that are commercially available changes continually, and listing only PFAS that are currently in commerce risks encouraging adverse substitutions. **Fluoropolymer Inclusion:** Fluoropolymers that meet the definition are included in this listing. The TURA program reviewed the chemicals included in the Certain PFAS NOL category and, using the OECD Comprehensive Global Database of PFASs as well as evidence found in the literature, determined that polymeric PFAS (including polymers meeting the OECD criteria for "polymers of low concern") have the potential to break down into perfluoroalkyl acids (PFAAs). **Consideration of C-F bond:** The SAB considered the presence of the C-F bond as a key consideration when developing its recommended definition of the Certain PFAS NOL category. The persistence of PFAS in the environment results from the strength of the C-F bond. The performance of this bond in its applications is not an argument against listing this category, as a listing is not a ban.

	"- The C-F bond strength responsible for the persistence property provides exceptional chemical stability enabling high performance and durability for key applications – that alternatives cannot provide…. "Many of today's Fluoropolymers meet a set of Polymer of Low Concern Criteria which indicate an extremely low concern for these fluorinated materials for the 'In-Life' use in products and systems…. "A recent publication calls out that the number of PFAS compounds in commerce or commercially relevant is actually in the hundreds – not thousands."	**Basis for SAB recommendation to list Certain PFAS NOL:** The SAB recommendation to list Certain PFAS NOL was based on discussions at 19 public meetings from 2016 to 2020. Summaries of these discussions, including detailed discussion of the scientific literature and examination of representative chemicals, are available in meeting minutes located on TURI's website. The SAB discussed the disparate results among studies and the rationale for its recommendations at its meetings. Both the SAB and the Administrative Council determined to list Certain PFAS NOL based on their own independent consideration and determinations. The chemicals examined by the SAB are representative of the Certain PFAS NOL category. The SAB reviewed representative individual chemicals within each of the broad subcategories of the PFAAs: the carboxylic and sulfonic acids, which have been widely identified as contaminants in the environment; the phosphonic/phosphinic acids; and the ethers (GenX and ADONA). Similar toxicity issues were seen for all the chemicals that were reviewed. The SAB then built upon this work by reviewing the breakdown of PFAA precursors into PFAAs. Many of the chemicals in the Certain PFAS NOL category have the potential to break down into chemicals that were individually reviewed. The SAB reviewed at least one precursor for each of the OECD subcategories of PFAAs. The SAB also considered a number of breakdown pathways, including hydrolysis, photolysis, biodegradation and thermal degradation. The SAB examined the 2018 Comprehensive Global Database of PFASs group-by-group before deciding to recommend listing of Certain PFAS NOL. For each subgroup, the SAB determined that the subgroup consisted of either persistent end degradation products (e.g. PFAAs) or precursors. Persistence is a property that is found consistently across all the end degradation products. However, it was not the sole basis for the SAB's recommendation to list Certain PFAS NOL. Rather, it is one of several characteristics of concern taken into account. Information on SAB examinations was organized in an Excel file, available on TURI's website in the meeting materials for the June 16, 2020 SAB meeting. The Board did not review the C8 2020 meeting results (which pertain only to PFOA) as they were published after the Board's recommendation in June of 2020. These results may be considered by the SAB in the future. **Inclusion of specific studies in the Policy Analysis:** The tables provided in the policy analysis are clearly labeled and present information that was used in support of listing. The tables were not designed to include all the scientific information that the SAB reviewed. The science the SAB reviewed was extensive and included many studies provided by the industry groups, including studies showing low or no effects. As stated in the policy analysis, studies supporting the SAB's recommendation are the ones that are cited. All the studies that the SAB reviewed can be found in SAB meeting minutes and related materials, including those cited by the commenter. The SAB reviewed the ANSES report for its April 2018 meeting, and the Luz and Anderson review papers for its January 2019 meeting, along with many other studies on PFHxA. The SAB recommended listing PFHxA and its salts on TURA list due to strong evidence on persistence, mobility, corrosivity, and mammalian toxicity: thyroid and liver,

		with concerns for kidney and developmental effects. The absence of PFHxA presence in blood in one study does not indicate that the chemical does not bioaccumulate. The SAB reviewed bioaccumulation information for PFHxA, as discussed summarized in the EH&S summary.
Greg Crist, AdvaMed	"AdvaMed opposes these actions because listing PFAS NOL as a class authorizes the listing of thousands of substances used by manufacturers and businesses in Massachusetts, increasing their costs and reducing their competitiveness…. "Medical devices made with fluoropolymers, a compound of PFAS, have been available to patients for over 50 years, with tens of millions of devices used without demonstrating adverse health effects like carcinogenicity and reproductive, developmental, or endocrine toxicity. The health risks of these medical devices are thoroughly assessed by the U.S. Food and Drug Administration ("FDA") before they make it on the market and must undergo multiple tests to prove biocompatibility in compliance with international biocompatibility standard, ISO 10993. Furthermore, manufacturers and the FDA, in compliance with the FDA Quality System Regulation, continue to monitor the safety of these products even after they are marketed. "The Food and Drug Administration doesn't just monitor and control the medical devices and drugs used in the U.S.—it also ensures the packaging used is safe and effective at keeping the contents clean and germ-free. The packaging used to seal and deliver medical devices is tested to ensure it will protect the sterility of instruments and implants. The resilient packaging must also meet rigorous labeling standards which let the FDA trace devices in use…. "Fluoropolymers are a subset of fluorinated polymers. Fluoropolymers used as components in polymer processing additives (PPAs) are high molecular weight polymers, have low levels of residual monomers or oligomers, exhibit very low water solubility, and are non-reactive and thermally stable. As an indication for the low risk, they generally meet simplified regulatory criteria – like OECD criteria of polymer of low concern – which indicate the overall low risk of environmental impacts of polymers used in packaging. They are present in certain plastic packaging components in only very small amounts. There are no commercially available alternatives to these fluoropolymers. "Should medical devices made with fluoropolymers be withdrawn from the market because of the adverse impact of state legislation, thousands of patients' lives will be at risk for lack of available treatment and life-saving options…. [T]his regulation unfairly penalizes this important Massachusetts industry even though these same devices have gone through the rigor of FDA approval and been cleared as safe for patients."	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category. **Consequences of Listing:** Listing under TURA does not prevent a facility from using the listed substance. In some cases, listing under TURA helps to promote research and development to facilitate future identification and adoption of safer alternatives. **Costs of Listing:** All potential TURA filers affected by this listing are estimated to be current TURA filers, so additional planning costs associated with listing Certain PFAS NOL are expected to be modest. All facilities currently reporting PFAS under Tier II are already filing under TURA for other chemicals, so these facilities would not incur a base fee due to this listing. If they are not already paying the maximum fee, they would begin to pay an additional per chemical fee of $1,100. **Benefits to Regulated Entities of Listing as a Category:** Listing of Certain PFAS NOL as a category supports compliance and reduces costs to regulated entities. Individual chemical listings would require covered businesses to determine which specific PFAS are used at a facility, which is often difficult to obtain from suppliers, as noted in the Policy Analysis. In contrast, the category listing allows businesses to gather "yes/no" information from suppliers on the presence of any chemical meeting the definition. Listing of Certain PFAS NOL as a category also reduces costs to regulated entities. Facilities reporting on Certain PFAS NOL will pay just one per-substance fee for the use of all Certain PFAS NOL, whereas a separate fee would be required for each chemical listed individually. **FDA Regulations:** The existence of FDA regulations to ensure the safety of medical devices is not relevant to whether the TURA Program should list this category. **Fluoropolymer Inclusion:** Fluoropolymers that meet the definition are included in this listing. The TURA program reviewed the chemicals included in the Certain PFAS NOL category and, using the OECD Comprehensive Global Database of PFASs as well as evidence found in the literature, determined that polymeric PFAS (including polymers meeting the OECD criteria for "polymers of low concern") have the potential to break down into perfluoroalkyl acids (PFAAs).

Robert Rio, AIM	"AIM opposes the addition of the definition of substance to the TURA regulations. The definition itself is arbitrary, overly broad, without regulatory precedent, and expands the scope of the TURA beyond its original intent without legislative authority. It is also unnecessary for the proper implementation of the TURA program…. This will result in thousands of chemicals swept into the toxics or hazardous list even though they are not toxic or hazardous."	**TURA Administrative Council Authority:** The Administrative Council is authorized to promulgate regulations to implement TURA. This authority extends to defining terms, including "substance."
John Keane, Association of Home Appliance Manufacturers	"The approach that Massachusetts is following, which is to treat thousands of PFAS chemicals as a single class is overly broad and may have unintended negative consequences. AHAM urges Massachusetts to narrow its approach to regulating PFAS substances…. "AHAM members indicated other portable and major kitchen appliances contain PFAS chemicals but in trace amounts…. "One unexpected example of how the overly broad definition of PFAS will have unintended consequences is the possible inclusion of hydrofluoroolefins (HFOs) within the PFAS definition….. It is critical that Massachusetts avoid inadvertently regulating other materials and substances that may be impacted by PFAS measures, when there is little to no consumer exposure…. Consumers will not come into contact with foam blowing agents during everyday use. In regards to exposure to employees during manufacturing and production, AHAM members indicated adherence to all federal and local worker safety regulations. This includes use of PPE and other hazardous protection equipment…. Massachusetts should narrow the definition of PFAS so that it does not include HFOs that contribute to slowing climate change. To do otherwise would contradict and undermine EPA's other actions. "The proposed PFAS expansion to include PFAS not otherwise listed are overly broad, burdensome on manufacturers, and difficult to manage for regulated entities including the EEA. By some definitions, the number of PFAS substances could include thousands of additional chemicals and EEA's choice of language makes a longer list possible. EEA should not treat this number of substances as a single class. AHAM understands that it is equally unrealistic to address each PFAS chemical individually in a reasonable amount of time. Therefore, AHAM recommends that Massachusetts divide its list of PFAS chemicals into subclasses that share physiochemical or toxicological properties. "EEA should exempt articles from regulations under TSCA unless it can demonstrate a clear need to remove the exemption. Withdrawing the exemption may be reasonable for specific uses that create exposure pathways, but there is no need eliminate the exemption for internal components where the risk of exposure to the public is minimal, or even non-existent…. Without a de minimis exemption, circular manufacturing pathways are unattainable."	**Application to articles:** TURA requirements do not apply to articles, unless the facility processes the article. The TURA program follows the EPA TRI article exemption rules. **Listing based on hazard:** The TURA Program lists substances based on hazard, not exposure. It is not only concerned with hazards to end users, but also with the hazards presented by toxics used during manufacturing. Compliance with other federal and local worker safety regulations and the use of PPE are not relevant to TURA's hazard-based approach. **Application of Certain PFAS NOL to hydrofluoroolefins:** Commercially available hydrofluoroolefins of which the TURA program is aware do not meet the Certain PFAS NOL definition, as the "olefin" portion of the chemical is not an alkyl chain. It is an unsaturated carbon chain with a double bond. **Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance. **Consequences of Listing:** Listing under TURA does not prevent a facility from using the listed substance. In some cases, listing under TURA helps to promote research and development to facilitate future identification and adoption of safer alternatives. **Costs of Listing:** All potential TURA filers affected by this listing are estimated to be current TURA filers, so additional planning costs associated with listing Certain PFAS NOL are expected to be modest. All facilities currently reporting PFAS under Tier II are already filing under TURA for other chemicals, so these facilities would not incur a base fee due to this listing. If they are not already paying the maximum fee, they would begin to pay an additional per chemical fee of $1,100. **Benefits to Regulated Entities of Listing as a Category:** Listing of Certain PFAS NOL as a category supports compliance and reduces costs to regulated entities. Individual chemical listings would require covered businesses to determine which specific PFAS are used at a facility, which is often difficult to obtain from suppliers, as noted in the Policy Analysis. In contrast, the category listing allows businesses to gather "yes/no" information from suppliers on the presence of any chemical meeting the definition. Listing of Certain PFAS NOL as a category also reduces costs to regulated entities. Facilities reporting on

		Certain PFAS NOL will pay just one per-substance fee for the use of all Certain PFAS NOL, whereas a separate fee would be required for each chemical listed individually. **Persistent, bioaccumulative and toxic substance:** Certain PFAS NOL is not currently defined as a PBT by EPA, so the existing de minimis exemption applies.
Ellen Mager, DuPont	"We strongly oppose adding the per-and-polyfluoroalkyl substances not otherwise listed (PFAS NOL) category as a high hazard category on the Toxic or Hazardous Substance List not only because the vote was based on flawed scientific principles but also due to deficiencies in process…. "As a member of the American Chemistry Council (ACC), we support the concerns that were expressed by the ACC over deficiencies in process outlined in a series of letters, phone calls and meetings with the Governor's Office in May and June 2020. More specifically, ACC raised concerns regarding procedural deficiencies in virtual meetings conducted by the SAB, Advisory Committee and Administrative Council. While Zoom technology, when effectively deployed, can be a useful method of facilitating public comment that is consistent with the spirit of the Governor's Executive Order of maximizing public participation, the SAB's meetings failed to allow for such meaningful participation. Those deficiencies included: (1) failure to provide periodic (at reasonably-timed intervals) opportunities for the public to respond; (2) failure to ensure that public comments are allowed during the relevant portion of the debate and not at some point when they are no longer relevant to the discussion; (3) failure to permit enabling of cameras and microphones by participants; and (4) failure to consider public comment submitted electronically into the record and allowing the Board members the opportunity to respond to public comment. "In order to allow for a measured and scientifically-sound assessment of substances, the law was designed to limit the annual review process. A 'categorical' review absent any unifying basis in the underlying toxicology and physiochemistry appears to be an 'end run' around the current law. "In addition to the procedural deficiencies and potential violations of existing Massachusetts law described above, the SAB's vote merits further discussion and input from the Advisory Committee to the Administrative Council, also established under TURA, to consider and provide input into the full impact that vote has on Massachusetts' businesses. Although the issue was on an October 2020 agenda of the Advisory Committee, along with other issues, an issue of this magnitude deserves the full attention of the Advisory Committee and Administrative Council."	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category. **Public participation:** The administrative process leading to this rulemaking allowed for ample public participation. The SAB reviewed PFAS in 19 meetings from November 2016 to June 2020. All meetings were posted and open to the public and provided public comment opportunities. The final three meetings were conducted through Zoom per the Governor's Executive Order of March 12, 2020, as amended. Public comment was allowed periodically during these meetings by audio and video. Additionally, participants could type comments into the "chat" at any time, and all such comments were maintained as part of the meeting minutes. Visitors were asked to turn off their video and mute when they were not speaking. After a recommendation was voted on by the SAB, the recommendation and policy analysis were presented at the Advisory Committee (10/30/20, and partial drafts at several meetings prior). These meetings were posted and open to the public, and public comment was allowed periodically during each meeting. Additionally, the Administrative Council meetings regarding this regulation (3/5/21 and 8/19/21) were posted and open to the public, and the Administrative Council received public comment during these meetings, including as detailed in this document. **Listing PFAS as a Category / Class:** Listing of Certain PFAS NOL is consistent with Administrative Council authority and past practice. Many categories are already on the TURA List. Categories were specifically included on the original TURA List, and additional categories have been added to the List since that time, most recently in 2019.
Glenn Battistelli	"I have never written a letter like this before, but as the owner of a construction business, I am concerned about new regulations being considered on flourotechnology. "PFAS" is used in many of the products we use in our daily operations, including infrastructure materials, insulation, solar panels and even pipes. "As I understand it, if these new and far-reaching regulations are adopted, users of thousands of PFAS in Massachusetts will need to pay a prohibitive user fee because	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category.

	they are listed as a high hazard substance. If this happens, my business as well as hundreds of small and medium-sized businesses and their vendors throughout the state will be affected. "I urge you and your office to recognize this and to not support these new regulations."	**Application to articles:** TURA requirements do not apply to articles, unless the facility processes the article. The TURA program follows the EPA TRI article exemption rules. **Costs of Listing:** All potential TURA filers affected by this listing are estimated to be current TURA filers, so additional planning costs associated with listing Certain PFAS NOL are expected to be modest. All facilities currently reporting PFAS under Tier II are already filing under TURA for other chemicals, so these facilities would not incur a base fee due to this listing. If they are not already paying the maximum fee, they would begin to pay an additional per chemical fee of $1,100.
Greg Rooke	"I take objection to the inclusion of all fluoropolymers in the PFAS Chemical purposed amendments with no exception for the molecular chain length. You are making unneeded regulations material that have a proven safety record and reduce risks in several industries around the world for chemical transfer hoses to fuel lines and brake line. "I find the proposal overreaching and detrimental to industry."	**Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance. **Fluoropolymer Inclusion:** Fluoropolymers that meet the definition are included in this listing. The TURA program reviewed the chemicals included in the Certain PFAS NOL category and, using the OECD Comprehensive Global Database of PFASs as well as evidence found in the literature, determined that polymeric PFAS (including polymers meeting the OECD criteria for "polymers of low concern") have the potential to break down into perfluoroalkyl acids (PFAAs). **Benefits to Regulated Entities of Listing as a Category:** Listing of Certain PFAS NOL as a category supports compliance and reduces costs to regulated entities. Individual chemical listings would require covered businesses to determine which specific PFAS are used at a facility, which is often difficult to obtain from suppliers, as noted in the Policy Analysis. In contrast, the category listing allows businesses to gather "yes/no" information from suppliers on the presence of any chemical meeting the definition. Listing of Certain PFAS NOL as a category also reduces costs to regulated entities. Facilities reporting on Certain PFAS NOL will pay just one per-substance fee for the use of all Certain PFAS NOL, whereas a separate fee would be required for each chemical listed individually.
Rajat Bhatnagar, India-US Business Partners	"[T]he Massachusetts Toxic Use Reduction Institute Advisory Council recently voted to list a full class of PFAS chemicals as high hazard substances. Grouping PFAS as a single class is scientifically flawed. Many PFAS have very different properties and often have essential functions and benefits. The concept that all PFAS are hazardous and/or toxic is simply not scientifically sound. Several reputable scientific bodies (ECOS, VT DEC, and National Academy of Sciences) have recently expressed concerns about grouping PFAS as a class. I direct you to: • ECOS1 - the Environmental Council of the States - which represents state and territorial environmental agency leaders, several of whom have implemented regulatory programs in their home states, has said: 'Many regulators and subject-	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category. **Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as

	matter experts advise against grouping PFAS as an entire class.' • The Vermont Department of Environmental Conservation, which was specifically charged by the legislature to develop a class regulation or to explain why such a regulation wasn't possible said, 'The Review Team spent over a year deliberating, researching, and discussing the potential to regulate PFAS as a Class. After reviewing the current peer-reviewed literature, as well as the available toxicology data for PFAS, the Review Team determined that at the current time it is not feasible to regulate PFAS as a Class.' • And federal scientists participating in a workshop convened last fall by the National Academies of Science, Engineering, and Medicine (NASEM) to review the federal PFAS research program acknowledged the broad diversity of properties with this group of substances, concluding that 'PFAS substances thus present unique challenges for grouping into classes for risk assessment.' "Please do everything without your power to stop these misguided PFAS regulations from placing more obstacles in the way of businesses in Massachusetts."	considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance. **Listing based on hazard:** The TURA Program lists substances based on hazard, not exposure. It is not only concerned with hazards to end users, but also with the hazards presented by toxics used during manufacturing. Compliance with other federal and local worker safety regulations and the use of PPE are not relevant to TURA's hazard-based approach. **Referenced Organizations:** All the referenced organizations and quotations are from discussions or decisions that involve quantitative risk assessment and the development of enforceable, risk-based quantitative standards, and are not relevant to TURA, which is a hazard-based planning, reporting and prevention program.
Brian Johnson, MassMEDIC	"MassMEDIC is concerned about 301 CMR 41.00: TOXIC OR HAZARDOUS SUBSTANCE LIST. If these rules are adopted, as approved by the Administrative Council, then Massachusetts users of the thousands of per-and-polyfluoroalkyl substances not otherwise listed (PFAS NOL) substances in that class will be subject to the rule and be required to pay user fees due to their listing as a high hazard substance. "Our concerns are that listing PFAS NOL as a class authorizes the listing of thousands of substances used by manufacturers and businesses in Massachusetts, increasing their costs and reducing their competitiveness. As our Commonwealth emerges from the COVID-19 pandemic, and many businesses are struggling, this decision to impose additional fees associated with the listing/use will uniquely disadvantage Massachusetts companies. "Medical devices made with fluoropolymers, a compound of PFAS, have been available to patients for over 50 years, with tens of millions of devices used without demonstrating adverse health effects like carcinogenicity and reproductive, developmental, or endocrine toxicity. The health risks of these medical devices are thoroughly assessed by the U.S. Food and Drug Administration ("FDA") before they make it on the market and must undergo multiple tests to prove biocompatibility in compliance with international biocompatibility standard, ISO 10993. Furthermore, manufacturers and the FDA, in compliance with the FDA Quality System Regulation, continue to monitor the safety of these products even after they are marketed. "The Food and Drug Administration doesn't just monitor and control the medical devices and drugs used in the U.S.—it also ensures the packaging used is safe and effective at keeping the contents clean and germ-free. The packaging used to seal and deliver medical devices is tested to ensure it will protect the sterility of instruments and implants. The resilient packaging must also meet rigorous labeling standards which let the FDA trace devices in use…. "Fluoropolymers are a subset of fluorinated polymers. Fluoropolymers used as components in polymer processing additives (PPAs) are high molecular weight polymers, have low levels of residual monomers or oligomers, exhibit very low water	**Higher Hazard Substance Designation:** PFAS will not be listed as a Higher Hazard Substance at this time. The TURA Science Advisory Board and Administrative Council have established processes for recommending and adopting Higher Hazard Substance designations, which have not been undertaken to date. In the future, the SAB may assess the suitability of recommending and adopting the Higher Hazard Substance designation for this category. **Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance. **Fluoropolymer Inclusion:** Fluoropolymers that meet the definition are included in this listing. The TURA program reviewed the chemicals included in the Certain PFAS NOL category and, using the OECD Comprehensive Global Database of PFASs as well as evidence found in the literature, determined that polymeric PFAS (including polymers meeting the OECD criteria for "polymers of low concern") have the potential to break down into perfluoroalkyl acids (PFAAs). **Consequences of Listing:** Listing under TURA does not prevent a facility from using the listed substance. In some cases, listing under TURA helps to promote research and development to facilitate future identification and adoption of safer alternatives. **Costs of Listing:** All potential TURA filers affected by this listing are estimated to be current TURA filers, so additional planning costs associated with listing Certain PFAS NOL are expected to be modest. All facilities currently reporting PFAS under Tier II are already filing under TURA for other chemicals, so these facilities would not incur a base fee due to this listing. If they are not already paying the maximum fee, they would begin to pay an additional per chemical fee of $1,100.

	solubility, and are non-reactive and thermally stable. As an indication for the low risk, they generally meet simplified regulatory criteria – like OECD criteria of polymer of low concern – which indicate the overall low risk of environmental impacts of polymers used in packaging. They are present in certain plastic packaging components in only very small amounts. There are no commercially available alternatives to these fluoropolymers. "Should medical devices made with fluoropolymers be withdrawn from the market because of the adverse impact of state legislation, thousands of patients' lives will be at risk for lack of available treatment and life-saving options…. [T]his regulation unfairly penalizes this important Massachusetts industry even though these same devices have gone through the rigor of FDA approval and been cleared as safe for patients."	**Benefits to Regulated Entities of Listing as a Category:** Listing of Certain PFAS NOL as a category supports compliance and reduces costs to regulated entities. Individual chemical listings would require covered businesses to determine which specific PFAS are used at a facility, which is often difficult to obtain from suppliers, as noted in the Policy Analysis. In contrast, the category listing allows businesses to gather "yes/no" information from suppliers on the presence of any chemical meeting the definition. Listing of Certain PFAS NOL as a category also reduces costs to regulated entities. Facilities reporting on Certain PFAS NOL will pay just one per-substance fee for the use of all Certain PFAS NOL, whereas a separate fee would be required for each chemical listed individually. **FDA Regulations:** The existence of FDA regulations to ensure the safety of medical devices is not relevant to whether the TURA Program should list this category.
Katherine Robertson, MCTA	"The proposed amendment is overly broad and lacks the clarity and specificity to provide any guidance to the regulated community. The language as written states that any 'agent or material' that share any 'similar, identifiable characteristics' will be considered a single substance. The repeated use of the term 'not limited to' strips the language of any meaning and of any use to the regulated community. In essence it says everything can be included in any grouping as a single substance that can be listed under TURA. "MCTA also is opposed to the inclusion of 'any agent or material' that share 'physical characteristics,' i.e. size, shape, weight, etc., regardless of chemical formula or identity in the definition. Conceivably, thousands of different chemicals or materials could be swept on to the TURA list as a single 'substance' due to solely to their shared physical characteristics. "MCTA would also like clarification of what is meant by 'chemical manufacture' and why it provides justification for a listing a substance. Is 'chemical manufacture' the point of origin? The process used? The company manufacturing the material or agent? This is unclear…. "In short, MCTA contends that the proposed definition is overly broad and lack specificity and clarity. It is punitive and poses an undue hardship on a small universe of statutorily defined facilities in the Commonwealth. "Please note that MassDEP is proposing that the listing of the PFAS NOL category be effective for the calendar year reporting period 2021 and thereafter (301 CMR 41.03(14)). However, 301 CMR 41.04(1) requires that "any addition or deletion of a substance shall take effect the calendar year immediately following the year in which the addition or deletion is codified in 301 CMR 41.00." Since the PFAS category was not listed as a toxic and hazardous substance, companies subject to TURA were not tracking it."	**TURA Administrative Council Authority:** The Administrative Council is authorized to promulgate regulations to implement TURA. This authority extends to defining terms, including "substance." **Effect of definition of substance:** The proposed definition of "substance" clarifies the meaning of this term only and does not indicate that all substances are eligible for addition to the TURA List. To be added to the TURA List, a substance must be a "Toxic or Hazardous Substance" as defined in 301 CMR 41.02. **Effective date:** We agree with the commenter regarding the year when the Certain PFAS NOL listing should take effect. The effective year of the listing has been corrected to calendar year reporting period 2022. Companies will track use throughout 2022 and reports will be due on July 1, 2023.
Peggy Horst, W.L.Gore and Associates	"The Massachusetts Toxics Use Reduction Act (TURA's) proposed definition of "PFAS NOL" includes "perfluoroalkyl moiety with three or more carbons (e.g., –CnF2n–, n ≥ 3; or CF3–CnF2n–, n≥2)," and describes the broad PFAS group that includes thousands of substances with different properties: polymers and non-	**Certain PFAS NOL Characteristics of Concern:** The Certain PFAS NOL category includes chemicals with a variety of properties. However, these chemicals share characteristics of concern or are precursors to chemicals with characteristics of concern, as

	polymers; solids, liquids, and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and nontoxic chemicals." "High molecular weight fluoropolymers like PTFE, FEP, PFA and ETFE are highly stable, too large to be bioavailable, non-toxic, and are not mobile in the environment.1 According to the OECD criteria for Polymers of Low Concern2, many fluoropolymers like PTFE, when evaluated, meet all the OECD criteria and show that their properties present low health and environmental hazards." "We respectfully suggest narrowing the definition of PFAS to focus on a sub-class of PFAS by using terminology such as 'PFAA', 'non-polymeric PFAS', or even 'PFAS that do not meet the OECD criteria for a polymer of low concern.'	considered by the SAB and summarized in the Policy Analysis. These characteristics support listing of Certain PFAS NOL as a single substance. **Fluoropolymer Inclusion:** Fluoropolymers that meet the definition are included in this listing. The TURA program reviewed the chemicals included in the Certain PFAS NOL category and, using the OECD Comprehensive Global Database of PFASs as well as evidence found in the literature, determined that polymeric PFAS (including polymers meeting the OECD criteria for "polymers of low concern") have the potential to break down into perfluoroalkyl acids (PFAAs).