

The Attorneys General of New York, Pennsylvania, California, Connecticut,
Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan,
Minnesota, New Jersey, Oregon, Rhode Island, Virginia, Washington, and
Wisconsin

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Via Regulations.gov

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: Comments on the Supplemental Notice of proposed rulemaking,
*Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate
Chemical Substances; Significant New Use Rule; Supplemental
Proposal*, 85 Fed. Reg. 12479 (March 3, 2020)

Docket ID No. EPA-HQ-OPPT-2013-0225

Dear Administrator Wheeler:

The attorneys general of New York, Pennsylvania, California, Connecticut, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, Oregon, Rhode Island, Virginia, Washington, and Wisconsin (the Attorneys General) appreciate the opportunity to offer comments on the *Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal*, 85 Fed. Reg. 12479 (March 3, 2020) (“Supplemental Proposal”).¹

The Attorneys General are significantly concerned about all perfluoroalkyl and polyfluoroalkyl substances (collectively “PFAS”). A limited number of “long-chain” PFAS are the subject of this rulemaking. PFAS are pernicious “forever chemicals” that pose serious adverse risks to human

¹ EPA (2020). 2020_03_03. Environmental Protection Agency. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal. <https://www.federalregister.gov/documents/2020/03/03/2020-03865/long-chain-perfluoroalkyl-carboxylate-and-perfluoroalkyl-sulfonate-chemical-substances-significant>

health and the environment at extremely low levels – e.g., parts per trillion in drinking water. Each of our states is working hard to address the public health challenge of PFAS-contaminated drinking water and widespread public exposure to PFAS at potentially harmful levels.² PFAS are a large class of thousands of unique chemical substances. The distribution and use of these chemicals are marked by a history of bringing new substances to market as existing substances in use become subject to regulation. It is now clear, based upon a robust body of science, that in order to protect human health and the environment, exposures to PFAS chemicals must be lowered to the greatest extent possible.

In its Supplemental Proposal, EPA proposes to require importers of articles³ that contain certain long-chain PFAS in their surface coating to notify EPA pre-importation, and receive EPA approval under the agency’s new use procedures before importing the article into the United States.⁴ This represented a significant change from the agency’s original proposal which would have applied those procedures to articles that contain certain long-chain PFAS anywhere within the article, not just in surface coatings.

The Attorneys General support EPA’s proposal to promulgate a final rule addressing long-chain PFAS in articles. However, the final rule should be broadened to more effectively serve the goals and mandates of the Toxic Substance Control Act (“TSCA”) to prevent exposures to harmful substances before they are introduced into the marketplace.

² CDC (2017). 2017_04_07. Centers For Disease Control and Protection. Per- and Polyfluorinated Substances (PFAS). Page last reviewed April 7, 2017. Factsheet. http://www.cdc.gov/biomonitoring/PFCs_FactSheet.html

³ An article is a manufactured item which, among other things is formed to a specific shape or design during manufacture, and whose end use functions are dependent in whole or in part upon its shape or design during end use. 40 CFR § 704.3. EPA acknowledges that for some articles, long-chain PFAS are “incorporated into the article and bound to the article matrix” as opposed to having been added or applied to the article as a surface coating. 85 Fed. Reg. at 12484.

⁴ While EPA does not define “surface coating,” the preamble says: “A coating is a material applied in a thin layer to a surface as a protective, decorative, or functional film. This term often refers to paints such as lacquers or enamels, but also refers to films applied to other materials including, but are not limited to, paints, varnishes, sealants, adhesives, inks, maskants, and temporary protective coatings. LCPFAC chemical substances have been used in surface coatings for numerous applications given their hydrophobic and lipophobic properties.” 85 Fed. Reg. at 12484.

We urge EPA to strengthen the supplemental proposal by: (1) including the entire chemical family of long-chain PFAS⁵ rather than the subset of these chemicals proposed in the Supplemental Proposal; (2) in accordance with its initial proposal, adopting a final rule that applies to articles containing long-chain PFAS anywhere in the article and not only to those articles in which PFAS are contained within the surface coatings; (3) applying the rule to the processing of articles and not just to the importing of them; and (4) disallowing any carve outs to the requirement to notify EPA for de minimis amounts of PFAS covered by the rule. Conducting broader review before permitting the introduction of new articles containing PFAS into the market would enable EPA to determine whether restricting or limiting such articles is appropriate to protect human health and the environment and would enable the public and state and local governments as front-line responders to participate in an informed dialogue concerning the introduction of these articles before their long-chain PFAS are released into the environment.

TSCA

TSCA was first enacted in 1976. In TSCA, Congress recognized “[t]he most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest.” S. Rep. No. 94-698, at 5.

TSCA provides EPA with authority to require reporting, record-keeping and testing, as well as rules to address unreasonable risks relating to chemical substances and/or mixtures. The goal of TSCA is to establish necessary and appropriate federal restrictions on the manufacture and use of chemicals that present an unreasonable risk of injury to human health or to the environment. TSCA is intended to be comprehensive and to assure protection of human health and the environment from unreasonable risks associated with new chemicals whether the chemicals are imported or produced or processed domestically.⁶

⁵ Polyfluoroalkyl substances are precursors which break down to perfluoroalkyl substances. Perfluoroalkyl substances include perfluoroalkyl carboxylic acids, perfluoroalkyl sulfonic acids, as well as other perfluoroalkyl substance families. Many PFAS come in numerous types of salts. We clarify the term “long-chain PFAS” to include all long-chain perfluoroalkyl substances, as well as all long-chain polyfluoroalkyl substances (precursors). This includes all substances previously or currently produced, or that may be produced in the future. A limited number of long-chain PFAS, including salts and precursors, were listed in the Supplemental Proposal.

⁶ 40 CFR § 707.20(b)(1); 15 U.S.C. § 2602(9).

TSCA Section 5 provides EPA with broad authority to require various entities to apply to it for approval of new chemical substances or uses. *See* 15 U.S.C. § 2604. While TSCA regulates new uses of chemical substances, it generally exempts importers and processors of articles from EPA review of new uses of *chemical substances in articles*. 40 C.F.R. § 721.45(f). That exemption can be made inapplicable by EPA regulation pursuant to Section 5 (a)(5). Under that provision, EPA may require by regulation an importer or processor to submit a Significant New Use Notification (“SNUN”) for the import or processing of a chemical substance *as part of an article* or category of articles if EPA finds that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification. *See* 15 U.S.C. § 2604(a)(5). EPA’s authority to require notification for the importation or processing of certain long-chain PFAS contained in articles rests on this provision of TSCA. The rule proposed here would require such notification.

If an article is subject to notification under this provision, an importer or processor submits a SNUN triggering a 90-day review period, during which time EPA reviews the notice and makes one of five possible determinations: 1) an article presents an unreasonable risk of injury to health or environment; 2) no determination can be made for lack of sufficient information; 3) in the absence of sufficient information about an article, the article may present an unreasonable risk of harm to human health or the environment; 4) there is a likelihood of substantial human exposure given the quantities at which the substance contained in an article is anticipated to escape into the environment; 5) an article is not likely to present an unreasonable risk of injury to health or the environment. *See* 15 U.S.C. §§ 2604(a)(3)(A), (B), (C).

Based on its determination, EPA can take a variety of actions to further regulate and control the article. EPA can issue an order to prohibit or limit the importation, processing, or distribution in commerce of the article. 15 U.S.C. § 2604(f)(3)(A). EPA can issue a rule controlling not only how and whether the article is permitted to be used in this country, but also controlling how the product is labeled or disposed. *Id.* § 2604(f)(2).

The Supplemental Proposal

In December 2019, in the National Defense Authorization Act,⁷ Congress directed EPA to take final action on its proposed 2015 PFAS

⁷ NDAA (2019). National Defense Authorization Act for Fiscal Year 2020. S. 1790. <https://www.congress.gov/116/bills/s1790/BILLS-116s1790enr.pdf>

Significant New Use Rule.⁸ In its 2015 proposal, EPA proposed, among other things, to require advance notification to EPA by importers of articles that contain a limited number of long-chain PFAS. 80 Fed. Reg. 2885. EPA took no action to finalize this rule. In December 2019, Congress directed EPA to take final action on its proposed 2015 PFAS Significant New Use Rule.⁹ The Supplemental Proposal which is the subject of these comments followed on March 3, 2020. EPA now proposes to narrow the scope of the 2015 proposal by limiting the notification, review and approval provisions to apply only to imported articles that contain these chemicals as part of the article's *surface coating*. EPA's proposed rule would amend 40 C.F.R. § 721.10536.

Risks to Human Health Posed by PFAS

PFAS, such as perfluorooctanoic acid ("PFOA"), are known as "forever chemicals" because they resist degradation and are highly persistent in the environment. These substances have been incorporated into countless consumer and industrial products since the 1940s and present a risk of harm to the environment and to human health. Many PFAS are linked to serious adverse health effects in humans and animals.

As explained in the Supplemental Proposal:

PFOA is persistent, widely present in humans and the environment, has a half-life in humans of 2.3-3.8 years, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity. . . . Human epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney). 85 Fed. Reg. at 12484.

Long-chain perfluoroalkyl substances, such as PFOA, are known to increase the risk of human health effects at extremely low concentrations in drinking water (*e.g.*, parts per trillion). These PFAS can show similar indicia

⁸ EPA (2015). 2015_01_21. United States Environmental Protection Agency. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. <https://www.federalregister.gov/documents/2015/01/21/2015-00636/long-chain-perfluoroalkyl-carboxylate-and-perfluoroalkyl-sulfonate-chemical-substances-significant>

⁹ NDAA 2019, *supra* fn 7.

of toxicity, persistence in the environment, and tendency to accumulate ubiquitously in the environment and in biota.¹⁰

The Agency for Toxic Substances and Disease Registry (“ATSDR”) has summarized relevant research for perfluoroalkyl substances, such as PFOA. Human exposure may occur from multiple contaminated media (air, water, soil, food, and house dust), and these chemicals do not break down in the environment, are persistent in soil and leach into groundwater, and have been detected in oceans and the Arctic, demonstrating the potential for long-range transport.¹¹ However, perfluoroalkyl substances are not the only category of PFAS that raises concerns. Perfluoroalkyl and polyfluoroalkyl substances can show similar indicia of toxicity, persistence in the environment, and tendency to accumulate ubiquitously in the environment and in biota.¹² Additionally, polyfluoroalkyl substances are precursors known to break down or transform to perfluoroalkyl substances in the environment and the human body through both non-biological and biological (metabolic) processes.¹³ Some perfluoroalkyl substances and precursors are covered by the proposed rule. Perfluoroalkyl carboxylates are the terminal degradation (biotic and abiotic) product for numerous families of polyfluoroalkyl substances.¹⁴ Polyfluoroalkyl substance precursors represent, at a minimum, the same toxicological threat as the endpoint perfluoroalkyl substances into which they may degrade or transform, and in some cases they are more toxic than the perfluoroalkyl substance into which they can

¹⁰ NYSOAG et al. (2020). 2020_02_03. The Attorneys General of the States of New York, California, Connecticut, Delaware, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, New Jersey, New Mexico, Oregon, Pennsylvania, Rhode Island, Virginia, Washington, and Wisconsin - Comments dated February 3, 2020 Re: Docket ID No. EPA-HQ-TRI-2019-0375 - Community Right-to-Know Toxic Chemical Release Reporting, 84 Fed. Reg. 66369 (Dec. 4, 2019).

¹¹ ATSDR 2018, Toxicological Profile for Perfluoroalkyls (Draft for Public Comment). U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. June 2018.

¹² NYSOAG et al. 2020, supra fn 10.

¹³ Buck et al. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. *Integrated Environmental Assessment and Management* 7 (4), 513–541. DOI: 10.1002/ieam.258; CONCAWE (2016). Environmental Fate and Effects of Poly- and Perfluoroalkyl Substances (PFAS). Report No. 8/16 - Environmental Science for the European Refining Industry.

¹⁴ Buck et al. 2011, supra fn 13.

transform.¹⁵ Nevertheless, the proposed rule applies only to a subset of long-chain PFAS in articles and does not cover the total family of long-chain PFAS in articles, including all polyfluoroalkyl precursors. Polyfluoroalkyl substances commonly transform to perfluoroalkyl carboxylates, but transformation to perfluoroalkyl sulfonates is also possible. Additional perfluoroalkyl substances exist. Regulations need to apply to all long-chain PFAS, including those which break down to perfluoroalkyl carboxylates, perfluoroalkyl sulfonates, or any other type of perfluoroalkyl substance.

Recommendation 1:

The PFAS covered by the rule should include all perfluoroalkyl substances as well as all known and possible future polyfluoroalkyl precursors which may transform to perfluoroalkyl substances.¹⁶

The definition of covered long-chain PFAS in the Supplemental Proposal includes only a subset of Long Chain perfluoroalkyl and polyfluoroalkyl substances. However, no scientific information or rationale has been provided to justify limiting the applicable substances.

Polyfluoroalkyl chemical substances are precursors that are known to break down or transform to perfluoroalkyl substances due to natural and/or anthropogenically induced industrial, environmental, or metabolic conditions regardless of the number of carbons. *See* fn 13, *supra*. Accordingly, all long-chain polyfluoroalkyl substances in articles should be covered by the rule.

The rule should cover articles containing the following: all known or possible future substances with perfluorinated carbon chain lengths equal to or greater than seven carbons, their salts, and all known or possible future substances which may break down or transform to perfluoroalkyl substances with perfluorinated carbon chain lengths equal to or greater than seven carbons (i.e., precursors).¹⁷ These chemicals are all related in that they can

¹⁵ Rice et al. (2020). 2020_02_19. Comparative analysis of the toxicological databases for 6:2 fluorotelomer alcohol (6:2 FTOH) and perfluorohexanoic acid (PFHxA). *Food Chem Toxicol.* 2020 Apr; 138:111210. doi: 10.1016/j.fct.2020.111210.

¹⁶ Perfluoroalkyl carboxylic acids can lose a proton to form their conjugate base, perfluoroalkyl carboxylates. Perfluoroalkyl sulfonic acids can lose a proton to form their conjugate base, perfluoroalkyl sulfonates. Other perfluoroalkyl substances can also deprotonate, allowing for the formation of a conjugate base.

¹⁷ EPA should consider PFAS with six, rather than seven, as the lower limit for perfluorinated carbon chain length. Perfluorohexane sulfonic acid (PFHxS) has six perfluorinated carbons and is considered a long-chain PFAS, *see* fn 13, *supra* (Buck et al 2011). Several states regulate perfluoroheptanoic acid (PFHpA) in drinking water, which has

break down or transform prior to reaching, or within, the human body (or other biota), and should be regulated as such. Ecosystems in our states are already at a sensitive tipping point; further pollution from these substances could cause additional significant adverse effects to natural resources, such as, contamination of drinking water resources, loss of economic resources (such as fisheries), and loss of species diversity.

In sum, the Supplemental Proposal vastly understates the number of chemicals in articles which should be covered by the rule. Including all of these chemicals is needed to best protect human health as well as prevent further ecosystem pollution and loss of resources. Failure to include all of the long-chain PFAS and precursors that threaten human health from this rulemaking is arbitrary and capricious.

Recommendation 2:

Require significant new use notifications for all articles containing PFAS covered by the rule.

In EPA's initial 2015 proposal, 80 Fed. Reg. 2885, the Agency sought to make inapplicable the exemption from notification for persons who import certain long-chain PFAS **as part of an article**. In the Supplemental Proposal, EPA now proposes to make the exemption only inapplicable for persons who import such chemicals **as part of a surface coating** on an article. The proposed amendment to EPA's 2015 proposal would undermine EPA's ability to review significant new uses of products containing those substances as it categorically excludes an entire group of products (articles containing these chemicals but not in surface coatings) from the SNUN requirement and subsequent EPA review. For the reasons set forth below, the Attorneys General strongly urge EPA to remove the limiting requirement that for EPA review to occur the chemical substances must be part of the surface coating of the article.

EPA fails to justify this significant change in the Supplemental Proposal. EPA claims it is issuing this Supplemental Proposal to be responsive to TSCA Section 5(a)(5), which provides that articles can be subject to notification requirements as a significant new use if the

six perfluorinated carbons attached to a seventh carbon that is not perfluorinated. EPA could also consider including all other PFAS as well. 6:2 FTOH, a polyfluoroalkyl precursor to short-chain perfluorohexanoic acid (PFHxA) (five perfluorinated carbons attached to a sixth carbon that is not perfluorinated), has been shown to be significantly more toxic than PFHxA, see fn 15, supra (Rice et al 2020). Many other short-chain PFAS are regulated globally and have been found ubiquitously in human and non-human biota as well as the environment (air, water and solids), see fn 10, supra (NYSOAG et al 2020).

Administrator makes an affirmative finding in a rulemaking that the reasonable potential for exposure to a chemical from an article or category of articles justifies notification. EPA further claims that this change in from the 2015 proposal is of limited impact because most long-chain PFAS are not “incorporated into the article and bound to the article matrix but are rather added or applied as a coating or as part of coating aid.” 85 Fed. Reg. at 12484. However, several statements made by EPA in the Supplemental Proposal show that its logic is flawed and its conclusion unsupported.

EPA states that it “is not making a finding on the reasonable potential for exposure from articles that do not contain [long-chain PFAS] as a surface coating.” 85 Fed. Reg. at 12484. If that is the case, EPA cannot categorically claim that there is no reasonable potential for exposure to chemical substances that are incorporated into an article rather than just used as a surface coating. Similarly, EPA claims that “[t]he article exemption at 40 CFR 721.45(f) is based on an assumption that people and the environment will generally not be exposed to chemical substances in articles.” *Id.* at 12485. Such reliance on nothing more than an assumption is unacceptable, lacking a reasoned basis in reality and science.

Articles containing long-chain PFAS will eventually need to be disposed of, regardless of how those chemicals are incorporated into an article. That disposal is likely to occur through either placement in a landfill or incineration. Under either scenario, there is more than just a reasonable potential for exposure to these chemical substances from disposal.

Disposal of articles containing PFAS in landfills, whether the PFAS are surface-coated onto or incorporated within the articles, is a common source of PFAS contamination throughout the country. Contamination often results from the discharge of leachate from these landfills into surface water or groundwater polluting the aquatic ecosystems of the states and impairing drinking water supplies. The New York State Department of Environmental Conservation has identified PFAS contamination emanating from landfills in New York. In addition to New York, the Vermont Department of Environmental Conservation (“VTDEC”) contracted with Weston & Sampson Engineers, Inc. to conduct sampling and analysis of landfill leachates; wastewater treatment facility (“WWTF”) influent, effluent, and sludge at several WWTF and surface water facilities for the presence of PFAS. In January 2018, VTDEC completed preliminary work to assess the presence and concentrations of PFAS within landfill leachate and at WWTFs that process that leachate. Analysis confirmed that PFAS were detected in all landfill leachate, WWTF influent, effluent, and sludges/biosolids sampled.

The PFAS detected included and exceeded the allowable limits for all five PFAS varieties then regulated by VTDEC, including PFOA and PFOS.¹⁸

Furthermore, the science is incomplete on protocols for destruction of PFAS using incineration, and it is not clear whether temperatures adequate to destroy other hazardous wastes are sufficient to destroy PFAS. No standard specifications for incineration (*e.g.*, temperature and burn duration) have been established by EPA. Accordingly, there remains a reasonable risk of atmospheric deposition of long-chain PFAS as a result of incomplete incineration. In addition, some PFAS are very stable in the atmosphere and have high global warming potential.¹⁹

The Attorneys General understand EPA's position that individuals using articles containing long-chain PFAS in surface coatings may be more likely to lead to exposure of that user. However, given the nature of these substances and the likelihood of exposure related to disposal, all applications of long-chain PFAS must be subject to SNUN requirements, as EPA's 2015 proposal required. As discussed above, long-chain PFAS are "forever chemicals" known to resist degradation in the environment. PFAS are also known to be toxic to, and to bioaccumulate in, humans and animals. These facts are not altered by whether the PFAS are applied to the surface or incorporated into an article.

EPA's failure to include all articles within the scope of the proposed rule is arbitrary and capricious.

Recommendation 3:

EPA should review both importing and processing of articles containing PFAS.

We urge EPA to finalize this rule by applying the full scope of TSCA's Section 5(a)(5) authority and include in the SNUR both importing and *processing* of long-chain PFAS contained in all articles.

EPA's proposal frustrates TSCA's intent to broadly regulate chemical substances. As described above, TSCA's broad scope includes regulation of manufacturing, processing, importing and disposal of chemical substances.

¹⁸ Weston & Sampson (2020). 2020_01_30. Weston & Sampson on behalf of Vermont Department of Environmental Conservation. Poly- and Perfluoroalkyl Substances at Wastewater Treatment Facilities and Landfill Leachate – 2019 Summary Report –Contract #38584.

¹⁹ 3M (1998). 1998_05_01. Environmentally Relevant Properties of 3M Fluorochemicals. 3MA10071137. <https://www.ag.state.mn.us/Office/Cases/3M/docs/PTX/PTX1502.pdf>

Generally, SNURs are necessary to ensure that EPA receives timely advance notice of any future activities related to a chemical substance for new uses that may produce changes in human and environmental exposures. In the instant SNUR, EPA proposes limiting EPA's oversight to the importing of articles. This does not address sources of exposure from *processing* of these chemicals in articles. Excluding processing as a source of exposure will frustrate TSCA's intent and will increase risks to human health and to our environment and natural resources from these significant uses.

EPA irrationally relies upon manufacturers/processors volunteering to not resume processing activities. EPA claims that there is no ongoing manufacturing or processing of long-chain PFAS chemical substances in the United State nor do they anticipate any such manufacturing or processing in the future. *See* 85 Fed. Reg. at 12480. Thus, EPA explicitly limited the scope of this Supplemental Proposal to apply only to importers, not processors. For a number of reasons this approach is unacceptable and both processors and importers should be included.

EPA's purported justification for applying the rule only to importing activities and not to processing activities appears to be the phase out commitments made by some domestic manufacturers/processors (eight companies) as a part of the 2010/2015 PFOA Stewardship Program.²⁰ In this agreement, eight global manufacturers of these toxic, persistent chemical substances agreed to voluntarily reduce, and commit to working toward elimination, of these chemicals from their products by 2015. These voluntary commitments are a positive development, though they are in no way binding, nor do they guarantee total elimination.²¹

However, it is unreasonable to rely upon a voluntary program to exclude these significant use avenues of exposure from this rule making. Any of these entities can resume processing. Moreover, other companies, not signatories to the voluntary agreement, may enter the market. Thus, EPA's confidence that there will be no future manufacturing or processing new uses of PFAS articles is unjustified.

²⁰ 85 Fed. Reg. 12480, 12485.

²¹ EPA (2018). 2018_08_09. Fact Sheet: 2010/2015 PFOA Stewardship Program. Last updated on August 9, 2018. <https://www.epa.gov/assessing-and-managing-chemicals-under-tsc/fact-sheet-20102015-pfoa-stewardship-program>

Despite the contradictory statements cited above, EPA recognized that processing could resume and that resumption would significantly increase the magnitude and duration of exposure to these chemicals, stating:

EPA is concerned that the manufacture or processing of these chemical substances for the SNUR could be reinitiated in the future. If reinitiated, EPA believes that such use would significantly increase the magnitude and duration of exposure to humans and the environment of these chemical substances.²²

To be protective, EPA must extend the SNUN requirement for articles to domestic processing to cover the signatories to the voluntary agreement if they resume these operations, and to cover any new processors. Since no total elimination commitment was ever made, all existing companies could be actively producing these chemicals, at currently unknown amounts. The perceived absence of any domestic ongoing manufacturing or processing of these substances is not a reasonable justification supporting removal of processors from this proposed rule, especially given EPA's own expressed concern over the impact that a resumption of domestic processing could have.

In addition, EPA recognizes that processing of long-chain PFAS chemicals is likely to resume where domestic processors have existing stocks of PFAS articles.²³ We urge EPA to apply the SNUR to processors of articles that begin any new uses of stockpiled articles.

In sum, EPA has not articulated a reasoned basis to exclude processing from the SNUR's scope. A final rule limited to importing would be arbitrary and capricious.

Recommendation 4:

De minimis exemptions should not be added to the Rule.

In the Supplemental Proposal, EPA asks whether it should create a de minimis exemption to the SNUR. Specifically, EPA asks "whether or not the Agency should affirmatively establish an explicit threshold at which, or explicit criteria for determining whether, a significant new use exhibits a reasonable potential for exposure that justifies notification." 85 Fed. Reg. at

²² See page 19/24 of 12/30/2009 Long-Chain Perfluorinated Chemical (PFCs) Action Plan, contained in 2019 Supplemental Proposal docket, EPA Docket No EPA-HQ-OPPT-2013-0225-0184. See also a similar statement at 85 Fed. Reg. 12484.

²³ See page 5/24 of 12/30/2009 Long-Chain Perfluorinated Chemical (PFCs) Action Plan, contained in 2019 Supplemental Proposal docket, EPA Docket ID No. EPA-HQ-OPPT-2013-0225-0184. See also, 85 Fed. Reg. 12484.

12481. Although caselaw does provide agencies with the discretion to create de minimis exceptions under some circumstances (*Alabama Power Co. v. Costle*, 636 F.2d 323, 360 (D.C. Cir. 1979)), there is nothing in the record to support such an exception given the substantial health and environmental risks of PFAS exposure at even extremely low levels.

In the Supplemental Proposal, EPA mentions two possibilities for a de minimis standard: a threshold below which “there is no ‘reasonable potential for exposure’” or a threshold below which exposure does not “‘justify notification’” despite the reasonable potential for exposure, due to the low level of long-chain PFAS in the product. 85 Fed. Reg. at 12482. EPA also suggests establishing criteria to determine “whether or not the ‘reasonable potential for exposure’ justifies notification,” or is insufficient to justify notification, due to the expected uses of the product, how the long-chain PFAS is incorporated into the surface coating of the product, or other criteria. *Id.* Both the 2015 proposal and the Supplemental Proposal seek to exclude articles from compliance with the SNUR if they contain sufficiently low levels of long-chain PFAS. However, and significantly, EPA does not affirmatively explain how those levels could be low enough to justify that exclusion.

EPA argues that de minimis exemptions are appropriate “when the burdens of regulation yield a gain of trivial or no value,” but the agency “bear[s] the burden of making the requisite showing” to justify the exemption. *Alabama Power Co. v. Costle*, 636 F.2d at 360-61. Given the toxicity of PFAS, the regulation of articles containing extremely low levels of PFAS in their surface coating or contained in the articles themselves is appropriate and would in fact yield substantive, nontrivial benefits. *Environmental Defense Fund, Inc. v. Environmental Protection Agency* provides a relevant example of the application of *Alabama Power* in the context of chemical regulation. 636 F.2d 1267 (D.C. Cir. 1980). In that case, the court evaluated an EPA regulation applicable to PCBs under TSCA, which excluded materials containing PCB concentrations of less than 50 parts per million from certain regulations. *Id.* at 1283. Because the record contained findings contrary to EPA’s proposed de minimis exemptions, including that any exposure to PCBs can cause adverse effects in humans and that the chemicals bioaccumulate, the court found that EPA could not “rationally conclude that the benefits of regulating [such] concentrations . . . are of no value.” *Id.* at 1284. The PFAS chemicals that should be regulated here are similarly harmful at any level of exposure and they or their breakdown products bioaccumulate. Thus, a de minimis exemption would not be appropriate for their regulation.

If EPA did seek to allow a de minimis exemption, it would bear the burden of reasonably determining that the exemption only foregoes benefits of “trivial or no value,” based on the administrative record. *Alabama Power*,

636 F.3d at 360. The current record does not support such a finding—i.e., that below a certain level long-chain PFAS public health risks do not justify regulation. *See Natural Resources Defense Council, Inc. v. U.S. E.P.A.*, 966 F.2d 1292, 1306 (9th Cir. 1992) (invalidating de minimis permitting exemption for small construction sites due in part to “lack of data”) Thus, if EPA did seek to promulgate a de minimis exemption, it would need to supplement the record with evidence that supports a determination that the imposition of significant new notification requirements for articles containing long-chain PFAS in their surface coatings below the designated threshold would yield at most “trivial value,” despite the chemicals’ known or anticipated dangers.

Due to the toxicity of long-chain PFAS even at extremely low levels of exposure, and the resulting lack of evidence in the rulemaking record to justify a de minimis exemption, EPA should refrain from including a de minimis exemption in its final SNUR. Including such an exemption in the final rule would be arbitrary and capricious.

Conclusion

The Attorneys General appreciate this opportunity to comment on the Supplemental Proposal. We strongly urge EPA to broaden and strengthen the proposed rule to maximize the agency’s review of new uses entailing the importing and processing of articles containing PFAS.

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