UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments on Certain New Chemicals: Receipt and Status Information for July 2019

84 Fed. Reg. 46,723 (September 5, 2019)

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Safer Chemicals Healthy Families (SCHF), Toxic Free Future, Environmental Health Strategy Center and Natural Resources Defense Council submit these comments on EPA's September 5, 2019 Federal Register notice identifying new chemical submissions made during July of this year under section 5 of the Toxic Substances Control Act (TSCA).[1] Our organizations are national and grassroots groups committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day.

According to the September 5 notice, EPA received three premanufacture notices (PMNs) in July for Per- and Polyfluoroalkyl Substances (PFAS) chemicals:

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P–19–0138	7/25/2019	CBI	(G) Intermediate	(G) Perfluorodioxaalkanoyl fluoride.
P–19–0139	7/26/2019	CBI	(G) Intermediate	(G) Perfluoro-2-methyl-trioxaalkanoyl fluoride.
P–19–0140	7/29/2019	CBI	(G) Intermediate	(G) Perfluorodioxaalkyl vinyl ether.

A fourth PMN, P–17–0400A, was submitted on July 8 for a PFAS-based polymer, described as Terpolymer of Vinylidene fluoride, Tetrafluoroehylene,3-Tetrafluoropropene.

Extensive portions of the PMN's for the four PFAS chemicals have been claimed as Confidential Business Information (CBI). Thus, rather than providing specific comments on these PMNs, our goal in these comments is to provide a broad perspective on EPA's approach to PFAS in the new chemical program. As we show below, EPA is failing to take effective and necessary steps to protect the public from new PFAS. It should make significant improvements in how it reviews

[1] 84 Federal Register 46723 (July 1, 2019).

and acts on PFAS PMNs and engages with the public. Because PFAS as a class are uniquely dangerous to people and the environment, EPA should use its authority under TSCA section 5(f) to prohibit all new PFAS from entering commerce.

I. Unique and Far-reaching Impacts of PFAS on Human Health and the Environment

PFAS have a unique set of properties with an unusual ability to cause serious and widespread harm to public health and the environment. This large class of substances has been manufactured and used in a variety of industries in the US and around the globe. EPA estimates that over 4,000 PFAS may have been manufactured and used in a variety of industries worldwide since the 1940s and that over 1,000 PFAS are listed on the TSCA inventory (600 of which were reported for the Active Substance Inventory).

PFAS are known to be highly persistent and bio-accumulative and have been found in the blood of millions of people and in wildlife across the world. In the US, PFAS have caused widespread contamination of drinking water sources and industrial sites and pose a growing concern for impacted communities, drinking water suppliers and state and local regulators. PFAS have been linked to serious adverse health effects, including low infant birth weights, effects on the immune system, cancer and thyroid hormone disruption. They have been detected in food and are present in many household products to which millions of consumers are exposed.

II. Inadequacy of EPA's Approach to PFAS PMNs

In addition to its responsibility to address PFAS chemicals already in use, EPA plays a critical role in reviewing PFAS chemicals that are not listed on the TSCA Inventory but are proposed to be introduced into commerce. Before these "new chemical substances" can be imported or manufactured, a premanufacture notice (PMN) must be submitted to EPA under section 5 of TSCA. EPA has 90 days to review the PMN. Under section 5(a)(3)(C), EPA is required to restrict the new chemical unless it determines that it "is not likely to present an unreasonable risk of injury to health or the environment . . . under the conditions of use." Under sections 5(e) and 5(f), EPA can take a broad range of actions, including a prohibition on manufacture if necessary to assure that the new chemical does not present an unreasonable risk of injury.

Properly applied, the section 5 PMN review process provides critical safeguards against the introduction of new PFAS chemicals that will magnify the significant health and environmental impacts already caused by existing substances and lead to future contamination, increased human exposure and accumulation in people and biota, and additional adverse health effects. In light of the significant concerns about PFAS as a class, EPA has ample authority to prevent all new PFAS from entering commerce under section 5(f) given the adverse health and environmental effects of PFAS as a class and their known buildup in people and the environment. EPA's review process for new PFAS should be based on a core commitment to bar new PFAS from commercial production. Up to now, however, EPA's approach to PFAS in the new chemicals program has fallen far short of this goal and has wholly failed to protect health and the environment as TSCA requires.

EPA's February 2019 PFAS Action Plan reports that:

> More than 300 PMN or SNUN submissions for PFAS substances have been reviewed by the EPA since the beginning of the PFOA Stewardship Program, of which about 200 were regulated by the EPA, typically under a section 5(e) Order. Similarly, more than 300 Low Volume Exemption Applications have been reviewed by the EPA during this period, most of which were granted based on restrictions/controls in the original or amended submissions.

It is deeply troubling that EPA has given so many new PFAS a green light to enter commercial production when compelling evidence has emerged about the serious harm that existing PFAS as a class have caused to health and the environment. As EPA acknowledges, many of these new PFAS have not been restricted at all, and there is no assurance that controls imposed under section 5(e) orders have prevented worker and consumer exposure and release into the environment. Particularly disturbing is that EPA has allowed industry to make indiscriminate use of Low Volume Exemptions (LVEs) for PFAS. The LVE review process lacks the safeguards and elements of transparency that the law requires for other new chemicals and was intended to be used on a limited basis for chemicals of low toxicity and exposure. Approving large numbers of LVEs for substances of high concern like PFAS is inappropriate and irresponsible.

III. Principles for Effective Use of EPA's Section 5 Authorities

EPA must take several steps to strengthen how it uses its section 5 authorities to protect people and the environment from new PFAS:

Accountability for Past Decisions. To enable the public to understand the full impact of EPA's large-scale approval of PFAS PMNs, the Agency must provide considerably more information about its review decisions than it has made available to date. Critical unanswered questions include:

- What is the range of chemical structures within the universe of PFAS that have been reviewed under section 5?
- What are the uses and production volumes of these chemicals?
- What criteria has EPA used to determine whether specific PFAS may present an unreasonable risk of injury or lack sufficient information for a reasoned evaluation of health or environmental effects – the critical drivers for whether a new chemical should be regulated under section 5(e)?
- Has EPA treated PFAS as falling within its Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances? If so, how has EPA applied the requirements of its PBT policy for new chemicals?
- Has EPA considered the high mobility of PFAS as part of its criteria for evaluating the substances?

- What types of restrictions on exposure and release has EPA imposed under section 5(e)?
- What testing has EPA required under section 5(e) or otherwise on PFAS?
- What test data for new PFAS chemicals have been submitted to EPA and what do these data show?
- Has EPA determined that specific PFAS are "not likely to present an unreasonable risk of injury to health or the environment . . . under the conditions of use" and therefore do not require any regulation under section 5? If so, what is the basis for these determinations?
- Under 40 CFR § 723.50(d), EPA cannot approve a Low Volume Exemption (LVE) for a chemical that "may cause . . . serious acute (lethal or sublethal) effects or serious chronic (including carcinogenic and teratogenic) effects." For the large number of PFAS LVEs approved by EPA, on what basis did EPA conclude that the LVE substance could not cause these effects?
- What "restrictions/controls" were agreed to by submitters that enabled EPA to approve most of the PFAS LVEs it reviewed?
- Has EPA issued significant new use rules (SNURS) for any of the LVE substances?

We strongly recommend that EPA issue a detailed report addressing these questions so that the public is fully informed of its track record in reviewing PFAS PMNs.

Expanding the Availability of Information on Individual PFAS PMNs. The transparency of PMN reviews of PFAS is also impeded by the lack of information on individual PMNs and the evaluations EPA has conducted when reviewing them. Although EPA has begun to increase access to PMN information, the PMN program remains opaque to stakeholders who want to better understand the characteristics of new chemicals progressing through the review process and the basis for EPA determinations on these chemicals under TSCA section 5(a)(3). A major impediment is the broad scope and questionable justification for industry CBI claims. In the case of the four PFAS PMNs now under review, extensive information of critical importance has been withheld as CBI, limiting informed public comment. EPA must step up to its responsibility under section 14 of TSCA to expeditiously review the validity of CBI claims so that PMN information that does not merit protection is available on a timely basis to stakeholders who want to weigh in while the PMN is under review.

Another essential step is to increase access to section 5(e) orders for PFAS so the public can understand the restrictions imposed and their rationale. Although determined searchers can find these orders in EPA databases, the process is difficult and time-consuming. EPA should create a central point of access on its website for all PFAS section 5(e) orders that enables the public to compare the requirements for different PFAS and better understand the Agency's assessment of risk and exposure across the PFAS category.

Treating Short-chain PFAS as Raising the Same Level of Concern as Long-chain Compounds. Recent research and analysis demonstrate that short-chain PFAS have characteristics that raise

serious concern and should not be assumed to be less harmful than PFOS, PFOA and other long-chain PFAS. In its PFAS Action Plan, EPA recognized that, although the "toxicities of short-chain PFAS have generally been less thoroughly studied," they are "as persistent in the environment as their longer-chain analogues and are highly mobile in soil and water." Moreover, the EPA toxicity assessments for GenX chemicals and PFBS – two short-chain PFAS – identify several serious hazards based on available data. In its section 5(e) order for GenX, EPA based its "may present" finding on structural analogies to PFOS and PFOA; testing conducted by Chemours under the order then demonstrated many of the adverse health effects linked to these two long-chain compounds. We recommend that EPA presume that short-chain PFAS "may present an unreasonable risk of injury" under section 5(a)(3)(B) and should be banned based on the adverse health and environmental effects and potential for accumulation in people and the environment demonstrated by PFAS as a class.

Designating PFAS as a New Chemical Category. According to its Website, "EPA groups PMN chemicals with shared chemical and toxicological properties into categories in order to streamline the process for Agency review of new chemical substances." EPA has identified 56 new chemical categories, which are described in a detailed New Chemicals Program's Chemical Categories Document. For each listed category, the document identifies the category boundaries, describes hazard concerns and relevant studies, and sets out a "testing strategy" for PMN submitters. The analysis in the categories document then informs EPA's review of individual PMNs and shapes the restrictions on exposure and release, testing requirements and other provisions it includes in section 5(e) orders for category members.

Because PFAS have "shared chemical and toxicological properties," account for a large number of PMNs and LVEs and raise significant health and environmental concerns, they are ideal for inclusion in EPA's Chemical Categories Document. According to Linda Birnbaum, former senior EPA scientist and director of the National Institute for Environmental Health Science, "[a]pproaching PFAS as a class for assessing exposure and biological impact is the most prudent approach to protect public health."[2] It is surprising and disappointing that EPA has failed to take this obvious step before now in response to the urgent demand by stakeholders and Congress for EPA leadership on PFAS issues. Developing a new chemical category listing for PFAS would serve several critical functions: it would be a vehicle, for compiling available data and interpreting its significance, articulating the end-points and adverse effects of concern for the category, and providing a framework for decisions on individual new chemicals that assures consistency in requirements for the PFAS class.

Accelerating Use of SNURs. TSCA section 5(a)(2) authorizes EPA to issue SNURs which provide that significant new uses of a chemical cannot be introduced without submitting a notice (SNUN) at least 90 days before the new use is initiated. Under the law, the same criteria apply to SNUNs that EPA uses to review new chemicals. Upon reviewing a SNUN, EPA is required to

[2] Hearing on "Examining the Federal response to the risks associated with per- and polyfluoroalkylsubstances (PFAS)" Before the S. Comm. on Env't & Pub. Works, 13 (2019).

regulate the new use unless the Agency determines that the use "is not likely to present an unreasonable risk of injury to health or the environment . . . under the conditions of use."

SNURs should play a vital role in addressing PFAS under section 5 of TSCA. They can assure that EPA is notified in advance of any proposed reintroduction of PFAS that are no longer being manufactured and can then enable EPA to prohibit the new use using section 5 authorities. Given EPA's observation that half of the PFAS listed on the Inventory are not now being manufactured for commercial purposes, the real-world benefits of such a requirement would be substantial. Equally important, by promulgating SNURs for PFAS that have previously completed PMN review, EPA can assure that it is notified of proposed new uses or additional uses of these chemicals before they are initiated and is able to prohibit them as well.

The Agency must increase the pace and coverage of PFAS SNURs. EPA issued a set of SNURs following the phase-out of PFOS and related compounds in the late 1990s but they were narrow in scope, applying to long-chain perfluorinated sulfonates. In 2015, EPA proposed a SNUR that would require manufacturers and processors of long-chain PFOA and PFOA-related chemicals to submit SNUNs before starting or resuming new uses of these chemicals in any products. The Agency's PFAS Action Plan commits to re-propose and ultimately finalize this SNUR; EPA recently sent the re-proposal to OMB for review but the SNUR is months if not years from being issued in final form. Moreover, over the last few years, concerns have emerged about short-chain PFAS as they have replaced the longer-chain substances and been scrutinized more closely. A SNUR to prevent short-chain PFAS that are no longer in commerce from being reintroduced and to prohibit new uses of those short-chain PFAS that have been reviewed under section 5 should be a top priority for the PMN program but is not now on EPA's agenda.

Addressing PFAS That Are Not on The TSCA Inventory but Are Being Identified in the Environment. According to recent statements by New Hampshire officials,[3] between 40 and 50 percent of the PFAS found in the environment and at production facilities lack CAS numbers and are not listed on the TSCA Inventory. It appears that most if not all of these chemicals are being manufactured for commercial purposes and are subject to TSCA PMN requirements. Accordingly, the failure of companies to file PMNs would be a violation of TSCA that is preventing EPA from reviewing and restricting PFAS as required by section 5. EPA should immediately follow up to investigate why PMNs have not been filed and to make enforcement action against violators of PMN requirements for PFAS a top priority.

In sum, a "no regrets" approach under section 5 of TSCA is essential for all new PFAS because of their persistent, mobile, and accumulative properties: if commercialization is allowed, PFAS will build up in the environment, people and biota and this buildup will be difficult to reverse if restrictions are later imposed based on evidence of adverse effects to humans or ecological receptors.

[3] https://insideepa.com/daily-news/new-hampshire-warns-tsca-inventory-lacks-data-manufacturing-pfas

Given their multiple serious hazards, widespread exposure, PBT characteristics, high mobility in the environment and the difficulty of identifying and removing PFAS from environmental media, EPA should determine that all new PFAS present an unreasonable risk of injury and prohibit their manufacture and use. EPA should develop and seek comment on a "standardized" section 5(f) tailored to the special challenges of new PFAS chemicals, thus providing a roadmap to the prohibitions it will impose when addressing this chemical class under section 5.

We appreciate this opportunity to comment on PFAS new chemicals.

Please contact Liz Hitchcock (lizhitchcock@saferchemicals.org) with any follow-up questions.

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