**Breast Cancer Prevention Partners <> Defend Our Health <> Earthjustice**
**Environmental Working Group <> Natural Resources Defense Council**
**Safer Chemicals Healthy Families**

Jane Nishida
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC

Re: Request to Rescind January 19 Compliance Guide for PFAS SNUR under TSCA

Dear Ms. Nishida:

The undersigned groups are public health and environmental organizations that have long advocated strong action to address the serious risks to health and the environment of Per- and Polyfluoroalkyl Substances ("PFAS"), a class of chemicals that is uniquely persistent, bio-accumulative and toxic and is widely found in people and the environment.

On January 19, 2021, the outgoing Administration issued a Compliance Guide for EPA's Significant New Use Rule ("SNUR") for several PFAS under the Toxic Substances Control Act ("TSCA"). [1] We ask that the Guide be immediately revoked because of the highly flawed process by which it was issued and because it unlawfully narrows the scope of the SNUR and limits its critical protections against importation and use of articles containing harmful PFAS substances.

Rescinding the Compliance Guide would be an important first step in fulfilling the Biden-Harris Administration's commitment to strengthen protections against threats to human health and the environment from PFAS present in products and the environment.

The Compliance Guide was rushed to completion without any consideration of the serious concerns raised in public comments. The deadline for commenting on the draft Guide was January 15, 2021. The Guide was finalized the very next business day. Thus, the comments were either totally ignored or brushed off without meaningful consideration, making the public comment process a sham. This is itself a compelling reason to revoke the Guide.

In addition, the Guide misapplies and misinterprets the SNUR on which it was based and weakens the protections it provides. The SNUR was proposed in 2015 and finalized on July 27, 2020 at the direction of Congress. It applies to several long-chain perfluoroalkyl ("LCPFAC") chemical substances, including perfluorooctanoic acid ("PFOA"), that were phased out at EPA's request because of their serious risks to health and the environment. The SNUR preamble explained why restricting these substances was essential:

[1] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-imported-articles-covered-july-2020-pfas-rule.

> "LCPFAC and perfluoroalkyl sulfonate chemical substances have been found in the blood of the general human population, as well as in wildlife, indicating that exposure to these chemical substances is widespread (Refs. 5, 6, and 7). PFOA and its salts, which are considered LCPFAC chemical substances, have been a primary focus of studies related to the LCPFAC class of chemical substances. 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 (Refs. 5, 8, 9, 10, and 11). 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) (Ref. 12). PFOA precursors, chemicals which degrade or may degrade to PFOA, are also present worldwide in humans and the environment and, in some cases, might be more toxic and be present at higher concentrations than PFOA (Refs. 13, 14, 15, 16, and 17). Multiple pathways of exposure, including through drinking water, food, house dust, and releases from treated articles, are possible."

85 Fed. Reg. 45113 (July 27, 2020). The SNUR revokes the SNUR article exemption in §40 CFR § 721.45(f) for listed LCPFACs "when they are part of a surface coating of an article" and states that *any person* who imports such substances "as part of a surface coating on an article is not exempt from submitting a significant new use notice." 40 CFR § 721.10536(c)(1).

However, the Guide significantly limits the universe of surface coatings subject to the SNUR. On page 8, the Guide states that a surface coating containing an LCPFAC is only covered by the SNUR (1) if the article on which it is used is in "direct contact with humans or the environment during the article's normal use or reuse" or (2) where the surface coating is on an "internal component' of an article "facing the interior of the article . . .that component is in contact with humans or the environment during the article's normal use or reuse."

These limitations on the application of the SNUR were inserted by White House staff during the interagency review process managed by the Office of Management and Budget (OMB) and replaced broader language drafted by EPA.[2] The White House revisions significantly narrow EPA's initial draft of the Guide by adding a new requirement that is not part of the SNUR as promulgated. The SNUR applies to *all* articles with surface coatings containing an LCPFAC. However, the Guide rewrites the SNUR by requiring submission of a significant new use notice ("SNUN") *only* where the surface coating is "in direct contact with humans or the environment."

This limitation is not only contrary to the wording of the SNUR but violates its rationale. Given EPA's serious concerns about LCPFACs and other PFAS, the Agency concluded that the *possibility* that they may be released from surface coatings on articles and result in human exposure or environmental release warranted Agency review before "new" uses of these articles are introduced into commerce:

> "EPA has provided support that there is a reasonable potential for exposure through the citation of peer-reviewed literature, which documents that LCPFAC chemical substances either have the reasonable potential to migrate from articles or that LCPFAC chemical substances do migrate from articles. In order to require notification for the import or processing of an article under

[2] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2020-0621-0003.

> TSCA section 5, it is not necessary to definitively show or illustrate the mechanisms by which exposure to a chemical substance through an article may occur. Since the use designated as a significant new use does not currently exist, EPA defers a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review."

85 Fed. Reg. 45114. Thus, "EPA has reason to anticipate that importing articles that have certain LCPFAC chemical substances as part of a surface coating would create a reasonable potential for exposure to these LCPFAC chemical substances, and that EPA should have an opportunity to review the use before such use could occur."

In the preamble to the final rule, EPA explained that "[i]f there is evidence that a chemical substance is or may be released from an article such that there is a reasonable potential of exposure to the chemical substance, EPA thinks the Agency can reasonably find the statutory criterion to be met in most or all cases." 85 Fed Reg. 45120. Thus, the preamble explicitly states that the SNUR applies to "[a]rticles that have surface coatings that contain certain LCPFAC chemical substances that have been cured or undergone chemical reaction after being applied to an article." This is because "[e]ven when LCPFAC are bound within the matrix of the coating, they can still be released from the coating over time and present a reasonable potential for exposure." 85 Fed. Reg. 45114

By contrast, the Guide would enable importers to unilaterally bypass SNUR restrictions by determining that, in their judgment, an article or article component has no "direct contact with humans or the environment." If it received a SNUN for the article, EPA might reach a different conclusion – finding, for example, that release of the surface coating might occur under different use conditions or during disposal of the article. However, under the Guide, EPA have no opportunity make these judgments because a SNUN would never be filed.

Guidance interpreting an agency rule is invalid when "it conflict[s] with the text of the regulation the agency purported to interpret." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 104-05 (2015). Courts have "refused to give deference to an agency's interpretation of an unambiguous regulation, observing that to defer in such a case would allow the agency 'to create *de facto* a new regulation.' " *Id.* at 104 (quoting *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000)). Based on these principles, the Compliance Guide is unlawful because it is in conflict with the wording and intent of the SNUR.

We look forward to early action by the new Administration to withdraw the Compliance Guide. As a precaution, we are also submitting this request to the portal established by the Trump EPA for petitions to amend or revoke existing guidance.

Please contact Safer Chemicals Healthy Families counsel, Bob Sussman, with any questions about this letter at bobsussman1@comast.net.

Respectfully submitted,

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