April 7, 2021

Dr. Michal Freedhoff
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460

Re: New Direction for TSCA PMN Program

Dear Acting Assistant Administrator Freedhoff:

On March 29, you announced that the Environmental Protection Agency (EPA) was reversing two policies of the last Administration that compromised the effectiveness of the premanufacture notice (PMN) program under the Toxic Substances Control Act (TSCA). We strongly support this change in direction, which realigns the PMN program with the letter and intent of TSCA after unlawful rollbacks by the Trump EPA.

Because of your announcement, EPA will no longer rely on Significant New Use Rules (SNURs) to justify avoiding section 5(e) orders required by TSCA and will require protection of workers exposed to chemical risks rather than unjustifiably assuming that voluntary use of Personal Protective Equipment (PPE) will prevent harm. As our groups have repeatedly argued, both policies greatly weakened TSCA's public health protections and violated the law. Their elimination is a necessary first step in rebuilding the PMN program so it achieves the Congressional goal of preventing unsafe new chemicals from entering commerce. EPA should continue to identify and reverse problematic Trump EPA policies that undermine the PMN process.

The chemical industry has responded to your March 29 announcement with indignation, threats of litigation and overwrought claims of imminent damage to innovation and competitiveness. This reaction is disappointing but not surprising. Industry refused to accept the improvements in new chemical review that Congress required in 2016 and worked to block their implementation after EPA staff had conscientiously begun to comply with the new law. Ultimately industry succeeded in pressuring EPA to reverse course and it not only resurrected the weak PMN program that predated the 2016 law but went further by abandoning health protective approaches to new chemical review that had been in place for decades.

Industry's apparent objection to the elimination of these approaches is that most new chemicals will no longer get a free pass from EPA and skate through the PMN process without limits on exposure or requirements for testing. But a "free pass" for new chemicals was exactly what Congress did not want when it created the PMN program in 1976 and is even more indefensible now with the increased protections against new chemicals of concern that Congress mandated in 2016.

Below, we examine the core requirements of section 5 as amended and reiterate why the two Trump policies you rescinded violated TSCA and put public health at risk. We then identify key priorities for further reversals of unsupportable Trump PMN policies and strengthening of the new chemicals program.

EPA's Obligation to Make an Affirmative Determination of Safety for All New Chemicals

To assure that all new chemicals are adequately reviewed, the 2016 amendments require EPA to make an *affirmative determination of safety* before any new chemical is cleared to enter production. New substances can no longer be commercialized automatically after 90 days if EPA fails to act. Instead, EPA must specifically determine that the new chemical is *not likely to present an unreasonable risk of injury to health or the environment.* If EPA cannot make this finding, it must determine that the new chemical presents or may present an unreasonable risk of injury, has the potential for substantial human exposure or environmental release and/or lacks sufficient information to permit a reasoned evaluation of its health and environmental effects. These determinations in turn require the Agency to place restrictions on the substance using its order authority under section 5(e).

Because most PMN submitters failed to demonstrate that their new chemicals were "not likely" to present an unreasonable risk, EPA was obligated to address these chemicals under section 5(e) orders. For the first 18 months following enactment of the new law, EPA carried out this obligation and issued orders for a majority of PMNs. Although industry has implied that these orders imposed crippling restrictions, few barred production of new chemicals or prevented their commercialization for the uses intended by the PMN submitter. Instead, the orders mainly placed limits on environmental discharges, prevented unsafe exposure by workers and consumers, required clear labeling and warnings and directed the submitter to conduct testing so that potential risks could be more fully evaluated. The use of orders to accomplish these objectives assured that they were legally enforceable and achieved tangible improvements in health and environmental protection. Despite industry's current claims, there is no evidence that the orders inhibited useful innovation or development of environmentally beneficial chemistry.

Circumventing Issuance of Section 5(e) Orders

Bending to industry demands, however, the Agency's political leaders set out to dramatically scale back enforceable orders under section 5(e) and the number of orders dropped sharply starting in 2018. The two policies you recently reversed were designed to bypass section 5(e) by creating a pretext to find that most new chemicals were "not likely to present an unreasonable risk" – even where the evidence in the PMN failed to support this finding – and thus could begin production without any limitation by EPA. As described below, these policies did not comply with the law and eliminating them will restore the integrity of the PMN program.

Non-5(e) SNURs. As TSCA expressly requires, EPA initially issued section 5(e) orders when it identified "reasonably foreseen" conditions of use of the PMN chemical, beyond the "intended" use conditions in the PMN, with the potential to present unreasonable risks. However, the Trump EPA discontinued issuing such orders on the ground that the risks of "reasonably foreseen" future uses could be addressed under SNURs and therefore the PMN substance was "not likely to present an unreasonable risk." This approach violated TSCA because Congress required EPA to consider *all* conditions of use when reviewing PMNs and the law is explicit that when EPA determines that a "reasonably foreseen" future use may present an unreasonable risk, "the Administrator *shall issue* an order" regulating the use under section 5(e) (emphasis added). Thus, SNURs were never intended to replace section 5(e) orders in addressing new chemicals of concern, and they are inherently less protective against health and environmental risks.

Your March 29 announcement recognizes that the proper role of SNURs for new chemicals is to build on section 5(e) orders by extending their requirements to other manufacturers and processors – not to circumvent issuing these orders in the first instance. We are pleased that you have ended this indefensible practice.

Eroding Worker Protection. EPA also bypassed the use of section 5(e) orders by dramatically reducing their role in protecting workers exposed to serious health risks from new chemicals. Ending a decades-long effort to safeguard workers under section 5, EPA's political leaders embraced industry's extreme theory that new chemicals were "not likely" to present unreasonable occupational risks because employers would provide, and workers would use, PPE sufficient to prevent unsafe exposure. Our review found that from October 2018 to January 31, 2020, EPA issued 160 "not likely" determinations for new chemicals that its scientists found may cause serious health effects to workers, including developmental and reproductive harm, cancer, lung overload and neurotoxicity. In many of these cases, EPA's analysis even concluded that anticipated exposure levels under the submitter's conditions of use would not provide an adequate margin of protection. With no supporting evidence, however, EPA asserted that workers "are expected" to voluntarily use respirators and/or gloves that would eliminate the potential for harm.

This "expectation" is simply without basis in light of the lack of any enforceable obligation to use PPE for new chemicals and the abundant evidence cited by EPA itself that PPE are often not used effectively (or at all) to prevent exposure. It is also fundamentally inconsistent with the well-established occupational "hierarchy of controls," which prioritizes chemical elimination, substitution, engineering controls and administrative controls over the use of PPE and permits the use of PPE only after all preferred controls have been exhausted.

EPA's draft risk evaluation for 1,4-dioxane recognizes that "[t]he use of a respirator would not necessarily resolve inhalation exposures since it cannot be assumed that employers have or will implement comprehensive respiratory protection programs for their employees." It adds that gloves provide effective protection only "if proven impervious to the hazardous chemical, and if worn on clean hands and replaced when contaminated or compromised." As cited in EPA's draft risk evaluation for carbon tetrachloride, a NIOSH survey found that establishments subject to respirator requirements had the following program deficiencies:

- 59% provided training to workers on respirator use;
- 34% had a written respiratory protection program;
- 47% performed an assessment of the employees' medical fitness to wear respirators;
- 24% included air sampling to determine respirator selection.

If proper respirator use is sporadic and limited where legally required, it is necessarily even less effective where (as for new chemicals) it is not required.

In reviewing the 1,4-dioxane evaluation, the EPA Science Advisory Committee on Chemicals (SACC) concluded that the "consensus of the Committee believes that PPE may not be consistently and properly worn" and that "[g]love use should not always be assumed to be protective." Recognizing that PPE are the control measure of last resort and less effective than engineering controls, the SACC emphasized that, "[b]ecause respirators are inherently uncomfortable and potentially unreliable for long-term use, the use of respirators for more than relatively short terms is not considered appropriate in typical

industrial hygiene practice." As it concluded, "[r]isk estimates should be presented without the use of PPE as reasonable worst case."

With no justification to conclude that exposed workers will be adequately protected by PPE, a determination that these workers are "not likely" to be at risk of harmful health effects is unsupportable. Where EPA finds that a new chemical may present an unreasonable risk to workers without the use of PPE, TSCA obligates EPA to issue a section 5(e) order requiring the PMN submitter to protect against that risk. We welcome your actions to restore section 5(e) to its rightful role in protecting workers.

Need for Further Strengthening of the PMN Program

Despite these strong initial steps, EPA must continue to identify and correct flawed new chemical policies put in place by the Trump Administration. We strongly encourage you to continue reexamining and improving the TSCA PMN program and recommend that this review address the following concerns:

1. In addition to eliminating section 5(e) orders for "reasonably foreseen" uses of the PMN chemical, the Trump EPA defined these uses narrowly to exclude future use scenarios that are plausible and reasonably anticipated based on professional judgment and expert knowledge. EPA must revise and broaden its interpretation to assure that future changes in use that could increase exposure and risk are effectively addressed under section 5(e) orders and, subsequently, SNURs.

2. Although PMNs typically contain little or no test data, the Trump EPA has severely curtailed the use of section 5(e) to require testing. As a result, the amount of health and environmental effects data developed under section 5 has drastically declined. The 2016 amendments envision more testing of new chemicals, not less: section 5(a)(3)(B)(i) directs EPA to use its section 5(e) authority whenever available information is insufficient to determine a new chemical's health and environmental effects. Although the PMN program uses modeling and other predictive tools to evaluate new chemicals in the absence of data, these tools are often less sensitive and precise than actual testing and either miss concerns for certain endpoints or understate the level of potential risk. EPA must revitalize and expand testing requirements for new substances using its section 5 authorities.

3. Working closely with industry "partners" but excluding other stakeholders, the Trump EPA revamped and greatly weakened the standard "boilerplate" section 5(e) order that had long formed the basis for negotiations with PMN submitters. Industry's extensive involvement in this effort was never disclosed and the modified order was finalized without any opportunity for public comment. Because of this tainted process, the new order should be immediately withdrawn and the previous order reinstated.

4. Timely information about the PMN program is still largely unavailable. It is difficult to track PMN submissions in the EPA review process. In addition, opportunities for public scrutiny of the basis for EPA's risk determinations are limited and thus informed oversight of the Agency's decisions on specific new chemicals is difficult if not impossible. Further reducing information availability are extensive redactions of Confidential Business Information (CBI). Improving the transparency of the PMN program, and facilitating public engagement beyond the chemical industry, must be a high priority for OCSPP leadership.

5. EPA must update and strengthen the "TSCA New Chemicals Program Chemical Categories"" list that informs its risk determinations for PMNs. EPA's descriptions of these categories often do not reflect

current science and recommended testing strategies may no longer be adequate for sound determinations of risk. In addition, new categories of concern need to be added to the list, reflecting current knowledge of the toxicity and other characteristics of chemical classes. One candidate for inclusion is PFAS substances, for which a class approach to PMNs and exemption applications is urgently needed in light of the harmful properties of these chemicals and EPA's track record of inadequate scrutiny and regulation of new PFAS. EPA should also include PFAS and other categories of concern on the "unreasonable risk list" authorized in section 5(b)(4)(A). This would trigger section 5(b)(2), underscoring the importance of conducting studies that demonstrate whether a new chemical or new use presents an unreasonable risk before PMNs are submitted.

6. EPA's enforcement capacity was decimated during the Trump Administration. As a result, EPA's ability to assure compliance with TSCA has seriously eroded even as the 2016 amendments have significantly increased the obligations imposed on industry. The broad scope of section 5 and the many rules and orders EPA issues for new chemicals place a premium on vigorous compliance monitoring and enforcement. These rules and orders require important protections of health and the environment and violations of their provisions may cause significant harm. Both the Office of Chemical Safety and Pollution Prevention (OCSPP) and the Office of Enforcement and Compliance Assurance (OECA) must redouble their commitment to maximizing section 5 compliance and taking strong action against violators, and must ensure that all limits contained in section 5 orders are incorporated into relevant permits and timely shared with state and federal environmental enforcement officials.

In conclusion, we applaud your leadership in restoring the public health goals of the TSCA PMN program in compliance with the law and urge you to continue to reverse unlawful Trump new chemical policies that endanger public health and the environment.

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

Respectfully submitted,

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