Case No.: 25-158
Consolidated with Nos. 25-572 and 25-573

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Alaska Community Action on Toxics, et al.,

Petitioners,

v.

United States Environmental Protection Agency and Lee Zeldin, in his official capacity as Administrator of the U.S. Environmental Protection Agency,

Respondents.

On Review Of Final Action Taken By United States Environmental Protection Agency and Administrator Michael S. Regan, published in the Federal Register at 89 Fed. Reg. 102,773 (Dec. 18, 2024), and titled "Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)"

BRIEF OF AMICUS CURIAE AMERICAN CHEMISTRY COUNCIL IN SUPPORT OF GOVERNMENT RESPONDENTS

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RULE 26.1 DISCLOSURE STATEMENT

Amicus Curiae, American Chemistry Council ("ACC"), does not have any parent corporation or any publicly held corporation that owns 10% or more of its stock. ACC has also filed a separate Form 34 Disclosure Statement.

/s Eric P. Gotting

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Amicus curiae American Chemistry Council ("ACC") submits this brief in support of the brief filed by Respondent United States Environmental Protection Agency ("EPA"), and in opposition to the brief filed by Petitioners Alaska Community Action on Toxics and the Environmental Defense Fund (collectively referred to herein as "Petitioners").[1]

STATEMENT OF AMICUS CURIAE

ACC represents the leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to provide innovative products, technologies and services that make people's lives better, healthier, and safer. ACC members are among the largest investors in research and development, and are advancing products, processes, and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.

ACC members actively participate in and continue to closely follow EPA rulemakings under the Toxic Substances Control Act ("TSCA") that directly impact both the low volume exemption ("LVE") and low release and exposure exemption ("LoREX"), which are the subject of the present litigation. ACC

[1] No party or party's counsel authored this brief in whole or in part, and no party, party's counsel, or any other person, other than amicus curiae or its counsel, contributed money to fund the preparation or filing of this brief. All parties consented to the filing of this amicus brief, with the exception of Petitioner Alaska Community Action On Toxics, which indicated it took no position.

members have relied on these exemptions for decades to bring critical new chemistries to market. Indeed, ACC was a driving force behind EPA's creation of the LVE exemption over 40 years ago.[2]

ACC, therefore, has a keen interest in the outcome of the present case because it could significantly impact how EPA reviews new chemicals submitted by ACC members under the LVE and LoREX exemptions. Given its long history with TSCA implementation, and in particular the LVE and LoREX exemptions, ACC is uniquely qualified to provide this Court with its perspectives on these exemptions and the critical roles they play. Most importantly, given that the briefs submitted by Petitioners and EPA are largely confined to these exemptions as they apply to certain types of chemicals, ACC submits this amicus brief to more broadly explain how EPA thoroughly reviews all LVE and LoREX notices to ensure that a given chemical will be used safely.

SUMMARY OF ARGUMENT

In enacting TSCA in 1976, the federal statute that regulates chemical substances, Congress provided EPA with the statutory means to tailor its review of new chemistries before they enter the marketplace to prevent unreasonable risk of

[2] In 1981, the Chemical Manufacturers Association (the predecessor trade association to ACC) submitted a petition for rulemaking under TSCA Section 5(h)(4) that ultimately led to EPA's promulgation of the LVE exemption. 50 Fed. Reg. 16477 (April 26, 1985).

injury to health or the environment, but without stifling technological innovation. The LVE and LoREX exemptions serve this dual purpose. And Congress left this key TSCA provision fundamentally unaltered when it amended TSCA in 2016.

In their opening brief, although Petitioners focus on persistent, bioaccumulative, and toxic ("PBT") chemicals and how those are regulated by EPA, Petitioners also mischaracterize the overall nature of the exemptions and ignore the many built-in safeguards EPA has developed over the years to ensure that *any* new chemical reviewed and approved under either exemption, whether a PBT or otherwise, will not present unreasonable risk.

To assist this Court in better understanding the contours of the LVE and LoREX exemptions, ACC makes the following points below:

(i) TSCA's exemption authority serves as a driver of chemical innovation because new chemicals can be safely commercialized, and introduced to the marketplace earlier and less expensively, under the LVE and LoREX exemptions in contrast to the lengthier review period for premanufacture notices ("PMNs").

(ii) Both exemptions incorporate risk mitigation measures to ensure that new chemicals submitted to EPA for approval do not pose unreasonable risk of injury to health or the environment.

(iii) EPA conducts a thorough risk assessment on each submitted chemical under both exemptions.

ARGUMENT

I. The LVE and LoREX Exemptions Promote the Development and Commercialization of Low Risk Chemistries

There is little doubt that "[c]hemistry is a foundational and central scientific discipline, and sustained investment in fundamental chemical research provides the chemical knowledge for technology development, generating unexpected discoveries that are the basis for innovation."[3] These innovations, in turn, "advance knowledge and discovery in many other scientific and technological disciplines, such as the life sciences, information technology, earth sciences, and engineering."[4]

Fifty years ago, Congress explicitly recognized the innovative power of chemistry when it enacted TSCA in 1976, the principal federal statute that regulates chemicals. Congress sought in that statute to ensure that the need to prevent "unreasonable risk" of injury to health or the environment from exposure

[3] National Academies of Sciences, Engineering, and Medicine, *The Importance of Chemical Research to the U.S. Economy*, The National Academies Press at 172, https://doi.org/10.17226/26568 (2022).

[4] *Id.* at 4.

to chemicals did not "impede unduly or create unnecessary economic barriers to technological innovation."[5] [6]

Of particular relevance to the present case, Congress empowered EPA to "exempt the manufacturer of any new chemical substance from all or part of the [PMN] requirements"[7] if the chemical once commercialized "will not present an unreasonable risk of injury to health or the environment […]."[8] [9] [10] TSCA exemption authority serves as a driver of chemical innovation because new

[5] It is important to note that "unreasonable risk" does not equate to zero risk. "Congress did not intend the section 5 review process to eliminate entirely all risk resulting from manufacture, processing, distribution in commerce, use, and disposal of new chemical substances, nor is it possible to do so." 50 Fed. Reg. at 16486 (internal citation omitted). "The risk associated with a given substance is a function of both the inherent toxicity (hazard) of the substance and the exposure of the relevant organism to the substance." 60 Fed. Reg. 16336, 16343 (Mar. 29, 1995). This is true whether the substance is a PBT or not. Because risk is necessarily a function of hazard and exposure, Petitioner's notion that a PBT may "inherently" pose "unreasonable risk" is simply wrong. *See* Pet'rs Br. at 37.

[6] 15 U.S.C. § 2601(b)(3).

[7] 15 U.S.C. § 2604(h)(4).

[8] EPA is required to compile and keep current an inventory of chemical substances in commerce. 15 U.S.C. § 2607(b). A new chemical substance is a substance that is not listed on the TSCA Inventory. Once approved by EPA and commercialized by the submitter, the chemical substance is then added to the Inventory.

[9] For many new chemicals, a PMN is required before they can be commercialized. Under the PMN process, a person who intends to manufacture or import a new chemical substance must submit a PMN to EPA at least 90 days prior to commencement of manufacture or importation. Once submitted, EPA conducts a risk assessment on the chemical to ensure that the chemical will not present unreasonable risk of injury to health or the environment.

[10] 15 U.S.C. § 2604(h)(1)(A).

chemicals manufactured or used under certain risk mitigating circumstances have the potential to be commercialized earlier under the LVE and LoREX exemptions than through the more lengthy review period for PMNs.[11] In addition, the LVE exemption allows companies to test if a product has market acceptance before investing in the more expensive and time-consuming PMN process. In short, LVE and LoREX exemptions "foster[] innovation while minimizing risks."[12]

To be clear, the LVE and LoREX exemptions are not blanket exemptions from risk review under TSCA Section 5. Rather, they are targeted programs aimed at facilitating more efficient commercialization for a subset of new chemicals with low volume or low exposure risk.

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[11] A protracted PMN review period, which often extends far beyond the statutory 90 days, may dash any prospects of new chemistries entering commerce and driving technological innovation in the United States. Congress significantly amended TSCA in 2016 to *inter alia* require EPA to render an affirmative determination on each PMN submission. 15 U.S.C. § 2604(a)(3).

[12] American Chemistry Council, Comment on Updates to New Chemical Regulations Under the Toxic Substances Control Act (TSCA): Proposed Rule, Docket No. EPA-HQ-OPPT-2022-0902, at 5 (August 8, 2023), https://www.regulations.gov/comment/ EPA-HQ-OPPT-2022-0902-0086. In promulgating the LVE requirements in 1985, EPA also recognized "one of the major benefits of this exemption is that it allows companies to respond more rapidly to market demand and to introduce new chemical substances more quickly into commerce." 50 Fed. Reg. at 16478. As a result, "[m]anufacturers, and the general public, will be able to take advantage of the benefits of individual new low volume substances […], including any increases in efficiency and decreases in cost." *Id*. at 16487.

In their opening brief, Petitioners completely ignore this fact and instead mischaracterize the 30-day review period for the LVE and LoREX exemptions as merely a "fast-track" to the marketplace without an adequate risk review period.[13] There is an important rationale, however, that explains the different review periods (90 days vs. 30 days) for chemicals submitted through a PMN rather than as LVE or LoREX exemptions, which Petitioners wholly fail to acknowledge. If the chemical ultimately passes the PMN review process and the chemical enters commerce, EPA then adds it to the TSCA Inventory,[14] which then allows other interested companies to also commercialize the same chemical. As such, EPA must factor into its PMN review of the new chemical not only the uses proposed by the applicant and which are set forth in the PMN itself, but other reasonably foreseeable uses[15] that other companies may wish to commercialize. But chemicals approved by EPA as LVE or LoREX exemptions are *not* added to the TSCA Inventory. Thus, EPA's review is less time-intensive because, in addition to

[13] "EPA's novel fast-track provision allows any new PBT chemical onto the market based on a cursory review; [….]" *See* Pet'rs Br. at 2. "The Agency then has just 30 days to review the application [….]" *See id.* at 20.

[14] Chemicals may be added to the Inventory only through TSCA Section 5(a) (the PMN process) and 40 C.F.R. Part 720 (establishing PMN requirements).

[15] In evaluating a chemical substance submitted through a PMN, EPA assesses the "conditions of use" for that chemical. TSCA defines "conditions of use" to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." 15 U.S.C. § 2602(4).

low volumes and low exposures driving expedited review, it is focused only on the uses identified in the exemption notice. Exemptions may be submitted for the same chemical by different manufacturers, but EPA, in reviewing those applications, will ensure that "aggregate production volume will not present an unreasonable risk of injury to human health or the environment."[16]

II. The LVE and LoREX Exemptions Have Built-In Risk Measures to Ensure a New Chemical Poses No Unreasonable Risk

EPA functions as a gatekeeper to ensure that new chemicals submitted as LVE or LoREX exemptions, including PBTs, do not pose unreasonable risk to health or the environment when they enter commerce. Stated differently, exemptions do not come at the expense of protecting against unreasonable risk; "and that means – *first and foremost—ensuring safety* […]."[17]

The LVE and LoREX exemption criteria are designed to limit risk to human health and the environment.[18] With respect to the LVE, "risks would generally be low because low production volume substances [capped at 10,000 kilograms (kg) per year] typically are not expected to result in high exposure to humans or the

[16] 40 C.F.R. § 723.50(f)(1).

[17] U.S. Environmental Protection Agency, Response to Comments on the Updates to New Chemical Regulations under the Toxic Substances Control Act (TSCA), at 81 (December 18, 2024) (emphasis added), https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0105.

[18] 40 C.F.R. § 723.50(c).

environment."[19] Although the LoREX exemption does not include a production volume limit, "the eligibility criteria […] directly limit permissible releases of and exposures to the exempted substances."[20] These regulatory limitations include, among others, no dermal exposure to consumers and the general population; severely limited releases of the chemical substance to ambient surface water and ambient air; and no dermal or inhalation exposures to workers.[21]

Notwithstanding these built-in risk mitigation features of both the LVE and LoREX exemptions, merely submitting an LVE or LoREX notice that meets the regulatory exemption criteria of 40 C.F.R. § 723.50(c) does not equate to automatic or "fast-track" approval by EPA. On the contrary, both the LVE and LoREX exemptions are subject to an array of additional regulatory safeguards refined over many decades so that EPA fully meets its statutory obligation to ensure that the chemical, once approved by EPA, "will not present an unreasonable risk of injury to human health or the environment." For example, EPA must consider whether a new chemical "may cause": (i) serious acute (lethal or sublethal) effects; (ii) serious chronic (including carcinogenic and teratogenic) effects; or (iii) significant environmental effects. Importantly, this analysis not

[19] 60 Fed. Reg. at 16345.

[20] *Id.*

[21] 40 C.F.R. § 723.50(c).

only includes the new chemical itself, but also any of the chemical's reasonably anticipated metabolites, environmental transformation products, byproducts, or impurities associated with its manufacture, processing, distribution, use, or disposal.[22] Indeed, EPA has recognized since the inception of the LVE exemption that impurities, for example, may pose risks that render the new chemical ineligible for the exemption.[23]

III. EPA Conducts a Thorough Risk Review Under the LVE and LoREX Exemptions

EPA conducts a thorough case-by-case risk assessment on each chemical substance under both exemptions to ensure that the chemical will not present unreasonable risk of injury to health or the environment.[24]

For instance, EPA evaluates extensive information and data submitted by the applicant in the notice, which may include *inter alia*: (i) worker exposure data (e.g., type of exposure (dermal and/or inhalation); protective equipment and engineering controls in place; number of workers exposed); (ii) environmental release information (e.g., type of release (transport, storage, disposal); quantity of the chemical released to the environment; releases of the chemical limited by

[22] 40 C.F.R. § 723.50(d)(1).

[23] 50 Fed. Reg. at 16479.

[24] 40 C.F.R. § 723.50(g). Indeed, for most if not all LVE and LoREX exemption submissions, EPA's reviews far exceed the 30-day review period.

control technology; identification, if any, of Clean Air Act emission and Clean Water Act discharge permits); (iii) chemical test data (e.g., health effects, ecological effects, environmental fate characteristics, human health and environmental monitoring data); and (iv) byproduct and impurities information.[25]

In conducting these risk assessments, EPA also generally applies very conservative assumptions with respect to production volume, chemical release estimates, and exposures, unless the submitter can provide data to replace those assumptions.[26] For example, unless the submitter agrees to be bound by a lower production volume in its LVE exemption submission, EPA will conduct its risk assessment on the new chemical assuming the annual production is 10,000 kg (the limit of the LVE exemption), even if the actual production volumes are intended to be far below this limit.[27]

Moreover, "when insufficient information is available," either because there is neither measured nor modelled data available, EPA will assume that the chemical is both persistent and bioaccumulative.[28] For chemicals eligible for LVE

[25] 40 C.F.R. § 723.50(e) (referencing 40 C.F.R. §§ 720.45(b), (d), (e), 720.50(a)).

[26] 60 Fed. Reg. at 16339.

[27] 40 C.F.R. § 723.50(e)(vi).

[28] U.S. Environmental Protection Agency, Response to Comments on the Updates to New Chemical Regulations under the Toxic Substances Control Act (TSCA), at 92 (December 18, 2024), https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0105.

or LoREX review, if EPA cannot resolve uncertainties critical to ensuring the chemical will not present unreasonable risk, then EPA will deny the exemption.[29] EPA may, for example, identify uncertainties pertaining to food-chain effects via accumulation of the new chemical substance in exposed organisms, or conclude that there is insufficient information to quantitatively assess hazards of the new chemical substance. Under either scenario EPA will predicate its denial of the exemption on its inability to determine that the manufacture, processing, distribution in commerce, use or disposal of the LVE substance will not present an unreasonable risk of injury to human health or the environment.[30]

Contrary to Petitioners' claims in their opening brief (*see* Pet'rs Br. at 20), as a practical matter EPA also has authority to eventually request additional information and data from the applicant if the contents of an exemption notice are insufficient to make an unreasonable risk determination. Specifically, where a notice is denied for lack of relevant information and data, the applicant may then file a PMN, at which time EPA may request additional material.[31]

In the preamble to EPA's most recent changes to the LVE and LoREX regulatory provisions, EPA once again reiterates its clear statutory mandate. In

[29] *Id*. at 80.

[30] 15 U.S.C. § 2604(h)(4).

[31] 15 U.S.C. § 2603(a)(2)(A)(i).

fact, EPA promulgated these regulatory revisions "to better ensure that chemical substances manufactured under LVEs and LoREXs will not present an unreasonable risk."[32] In particular, the regulations governing exemptions now make clear that EPA must approve an LVE or LoREX notice before the submitter may manufacture the new chemical substance.[33] Thus, Petitioners are mistaken in their assertion that EPA will deviate from this statutory standard in its review of PBT chemicals or other substances.

Indeed, Petitioners incorrectly assert that EPA will approve an exemption submission for a PBT if the PBT is not a "chemical substance with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms."[34] That is plainly wrong. "Only after EPA has reviewed the hazards and exposures to determine risk, will EPA make a decision to either grant or deny a PBT chemical substance submitted for an LVE or LoREX exemption."[35] The rule categorically excludes those PBTs with environmental releases and potentially unreasonable exposures from LVE and LoREX eligibility.

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[32] 89 Fed. Reg. 102774, 102783 (December 18, 2024).

[33] *Id.*

[34] 40 C.F.R. § 723.50(d)(2)(ii).

[35] U.S. Environmental Protection Agency, Response to Comments on the Updates to New Chemical Regulations under the Toxic Substances Control Act (TSCA), at 90 (December 18, 2024), https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0105.

IV. Additional Protections Under the LVE and LoREX Exemptions

For both the LVE and LoREX exemptions, "the uses of the new chemical substance are restricted to those approved in the exemption notice, and submitters must maintain any exposure or release controls throughout the period of the exemption."[36] These controls regularly include no release of the chemical substance to water or the use of certain personal protective equipment to minimize exposures to workers. And "[m]anufacturing sites identified in the exemption notice are binding unless specified conditions are satisfied."[37]

Moreover, manufacturers who have been granted an LVE or LoREX exemption "must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice […]."[38] And they must maintain records that *inter alia* "document[] compliance with the applicable requirements and restrictions of" certain provisions of 40 C.F.R. § 723.50. Failure to comply with these or any other provision of the LVE or LoREX exemption requirements may lead to severe civil and criminal penalties.[39]

Finally, even after EPA approves either an LVE or LoREX exemption, EPA has the authority and legal obligation to revoke the exemption if it "determines that

[36] 60 Fed. Reg. at 16337.

[37] *Id.*

[38] 40 C.F.R. § 723.50(k)(1).

[39] 40 C.F.R. §§ 723.50(n)(2)(ii); 723.50(o)(3).

manufacture of the new chemical substance does not meet the terms of [40 C.F.R. § 723.50] […].”[40]

In sum, the LVE and LoREX exemption criteria, coupled with an array of regulatory safeguards, ensure that chemistries reviewed and approved under these exemptions will not present unreasonable risk.

CONCLUSION

The LVE and LoREX exemptions serve important roles in advancing new chemistries that help drive technological innovation. EPA is well aware of this. But more importantly, EPA also recognizes its statutory obligation to ensure that these new chemistries, including those developed and commercialized by ACC members, will not present unreasonable risk. ACC, therefore, respectfully requests that this Court deny Petitioners’ petitions for review.

[40] 40 C.F.R. § 723.50(h)(2)(v).

Dated: March 9, 2026

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CERTIFICATE OF COMPLIANCE

I hereby certify the foregoing amicus brief contains 3302 words and therefore complies with the word limit of Fed. R. App. P. 29(a)(5). It complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and Cir. R. 32-1(d) because it is printed in 14-point Times New Roman font.

/s Eric P. Gotting

CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2026, a true and correct copy of the foregoing was filed via the Court's CM/ECF system and served via electronic filing upon all counsel of record in this case.

/s Eric P. Gotting