

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, *et al.*,

Respondents,

On Petition for Review of
Final Action of the U.S. Environmental Protection Agency

RESPONDENTS' ANSWERING BRIEF

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GLOSSARY

2024 Rule	<i>Updates to New Chemical Regulations under the Toxic Substances Control Act (TSCA)</i> , 89 Fed. Reg. 102773 (Dec. 18, 2024)
EPA	Respondent U.S. Environmental Protection Agency
PBT Chemicals	Persistent, Bioaccumulative, and Toxic Chemicals
TSCA	Toxic Substances Control Act, 15 U.S.C. § 2601, <i>et seq.</i>
Environmental Petitioners	Petitioners in Case Nos. 25-158 and 25-573, Alaska Community Action on Toxics and Environmental Defense Fund
Labor Petitioner	Petitioner in Case No. 25-572, United Automobile, Aerospace & Agricultural Implement Workers of America, American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)
Low-Volume/Low-Exposure Exemptions	Low-Volume Exemptions and Low-Exposure-and-Release Exemptions to the Standard Premanufacturing Review Process under 40 C.F.R. § 723.50

INTRODUCTION

EPA has long recognized and addressed the risks to human health and the environment posed by chemicals that are persistent in the environment, bioaccumulative in organisms, and toxic (referred to as PBT chemicals). Since 1999 and continuing through the present, EPA has largely denied requests by manufacturers to exempt new PBT chemicals from EPA's standard premanufacturing review process for new chemicals (*i.e.*, chemicals that have not previously been manufactured in the United States) under the Toxic Substances Control Act, 15 U.S.C. § 2601, *et seq.* In the 2024 Rule at issue, EPA codified this longstanding practice when updating its new chemical regulations. Specifically, in *addition* to all other bases for denying a request for an exemption from the standard new chemicals premanufacturing review process, EPA codified a category of ineligibility for PBT chemicals for which there are anticipated environmental releases of the chemical and potentially unreasonable exposures to humans or environmental organisms. In other words, PBT chemicals can still be found ineligible for an exemption on any previously existing regulatory basis of ineligibility and can also be found ineligible under the new provision specific to PBT chemicals.

Environmental Petitioners challenge the new PBT ineligibility regulation, asserting that EPA has somehow *relaxed* the exemption criteria for PBT chemicals,

and arguing EPA is required to categorically preclude these chemicals from the exemptions. Both assertions are incorrect. EPA did not remove a single criterion for seeking an exemption for a PBT chemical; to the contrary, it codified an *additional* basis on which to deny the exemption request. And EPA reasonably and lawfully declined to categorically exclude all potential new PBT chemicals from the exemptions. EPA recognized that these requests relate to a diverse set of *new* chemicals. EPA thus could not anticipate every possible new PBT chemical and every possible way in which that chemical may be manufactured, processed, distributed in commerce, used, or disposed to determine *ex ante* that no possible scenario could exist in which an exemption could be granted. EPA thus reasonably decided to continue to review requests for exemptions for these chemicals on a case-by-case basis rather than categorically preclude them.

Taking a different tack, Labor Petitioner does not challenge *any* aspect of the 2024 Rule. Instead, Labor Petitioner asserts that EPA should have drafted new regulations on an entirely different subject—disclosure of new chemicals information by companies to their potentially affected employees. But when Labor Petitioner raised this suggestion in its comments on the challenged rule, EPA properly determined the suggestion was outside the scope of the rulemaking. EPA thus reasonably declined to respond to the merits of or adopt Labor Petitioner’s

suggestions—which were unrelated to *any* aspect of the proposed rule—in the final rule.

Because Petitioners have not demonstrated that any aspect of EPA’s rulemaking is arbitrary, capricious, or otherwise not in accordance with law, the Court should deny the petitions for review.

STATEMENT OF JURISDICTION

This Court has jurisdiction under 15 U.S.C. § 2618(a)(1)(A) to review the challenged rule, *Updates to New Chemical Regulations under the Toxic Substances Control Act (TSCA)*, 89 Fed. Reg. 102773 (Dec. 18, 2024) (“2024 Rule”). The petitions for review were timely filed because the 2024 Rule was published on December 18, 2024, and promulgated for purposes of judicial review on January 2, 2025. *Id.*; *see also* 40 C.F.R. §§ 23.5, 23.11 (setting date of promulgation first business day that is two weeks after Federal Register publication date); Dkt. No. 1, Case No. 25-158 (Jan. 9, 2025); Dkt. No. 1, Case No. 25-572 (Jan. 29, 2025); Dkt. No. 1, Case No. 25-573 (Jan. 29, 2025).

ISSUES PRESENTED FOR REVIEW

1. Whether EPA’s decision to preclude *most*—but not necessarily all—PBT chemicals from qualifying for low-volume exemptions and low-release-and-

exposure exemptions¹ from the TSCA's standard new chemicals premanufacturing review process was arbitrary, capricious, or otherwise not in accordance with law.

2. Whether EPA erred by not responding to the merits of Labor Petitioner's comments or adopting Labor Petitioner's suggested regulatory revisions, which were outside the scope of the rulemaking.

PERTINENT STATUTES AND REGULATIONS

Pertinent regulations not included in Petitioners' addenda are included in the addendum filed concurrently with this brief.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

Congress enacted TSCA in 1976 "to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1 (1976), as reprinted in 1976 U.S.C.C.A.N. 4491. Congress amended TSCA in 2016 through the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Pub. L. No. 114-182, 130 Stat. 448 (2016). These amendments generally required EPA to

¹ For ease of reference, these exemptions will be referred to collectively as "low-volume/low-exposure exemptions" throughout the brief.

review and manage potential unreasonable risks from chemicals not previously manufactured in the United States before manufacturing of that chemical begins.

TSCA provides separate procedures for the review and management of unreasonable risks from chemicals that have previously been manufactured in the United States (“existing chemicals”) and those that have not (“new chemicals”). 15 U.S.C. §§ 2604, 2605. TSCA required EPA to compile a list of all chemical substances manufactured or processed in the United States when TSCA was enacted, referred to as the inventory. 15 U.S.C. § 2607(b). Any entity can manufacture and process these chemicals in the United States, subject to applicable regulations. *See* 15 U.S.C. §§ 2602(11), 2604(a)(1)(A).

The primary procedure by which EPA reviews and manages unreasonable risk of a new chemical is through the Agency’s standard premanufacturing review process. 15 U.S.C. § 2604(a). Under this process, the manufacturer submits a notice to EPA containing information it knows or can reasonably ascertain about the chemical substance, including information regarding the environmental and health effects of the substance, the number of people likely exposed in their places of employment, and information about how the substance will be disposed. *Id.* §§ 2604(d), 2607(a)(2). EPA reviews the notice and considers the information submitted, as well as information otherwise available to EPA. *Id.* §§ 2604(a)(1)(B)(ii), (a)(3), (e)-(g), 2625(k). The Agency then must make one of

five possible determinations pertaining to the likelihood of unreasonable risk of injury to health or the environment and take appropriate action to manage unreasonable risks. *Id.* §§ 2604(a)(1)(B)(ii), (a)(3), (e)-(g), 2625(k). EPA generally has 90 days to complete this review, which can be extended an additional 90 days. *Id.* § 2604(a), (c), (i)(3). When a person begins manufacturing a new chemical substance following this standard premanufacturing review process, EPA adds the chemical to the inventory of existing chemicals, which (as noted above) allows any person to manufacture the chemical, subject to any applicable regulations. *Id.* §§ 2602(11), 2604(a)(1)(A), 2607(b)(1).

TSCA authorizes EPA to exempt the manufacturer of any new chemical substance from the standard premanufacturing review process “upon application and by rule” if EPA determines that “the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance . . . will not present an unreasonable risk of injury to health or the environment” 15 U.S.C.

§ 2604(h)(4). As relevant here, EPA has promulgated regulations for two such exemptions: the low-volume/low-exposure exemptions. EPA promulgated a rule in 1985 granting a limited exemption under § 2604(h)(4) for persons who manufacture certain new chemical substances below a certain volume threshold. 50 Fed. Reg. 16477 (Apr. 26, 1985). EPA then amended that rule in 1995 to increase the volume limit and to add a second exemption category for certain chemical

substances with low environmental releases and human exposures. 60 Fed. Reg. 16336 (Mar. 29, 1995).

Accordingly, since 1995, manufacturers of new chemical substances have been able to apply for exemptions from the standard premanufacturing review process for new chemical substances for which either the volume of manufacturing will be low or the environmental releases of and human exposures to the chemical substance will be low. *Id.*; 40 C.F.R. § 723.50 (1995); 40 C.F.R. § 723.50 (2025). But the manufacturer may only apply for such a low-volume/low-exposure exemption if it will manufacture 10,000 kilograms or less of the substance per year or if the substance meets five exacting types of exposure criteria. 40 C.F.R. § 723.50(c). As in the standard premanufacturing review process, the manufacturer requesting the exemption must provide EPA with available information about the chemical, including the volume of intended production, descriptions of intended uses of the chemical, test data, and information regarding employee exposure and environmental releases. *Id.* § 723.50(e). And, to ensure that low-volume/low-exposure exempted chemical substances will not present an unreasonable risk, the exemption process includes a 30-day period (which may be suspended) for EPA to review the exemption request, and other conditions in the exemption. 40 C.F.R. § 723.50(g) (1995); 40 C.F.R. § 723.50(g)(1) (2025); 60 Fed. Reg. at 16336; *see also* 50 Fed. Reg. at 16477.

Since 1995, even if the manufacturing of the chemical substance meets the volume limit or the release and exposure criteria, substances still are ineligible for the low-volume/low-exposure exemptions if EPA determines that the substance “under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance” may cause serious acute or chronic health effects or significant environmental effects.² 40 C.F.R. § 723.50(d) (1995); 40 C.F.R. § 723.50(d)(1) (2025). Additionally, EPA denies exemption applications when “there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30-day review period.” 40 C.F.R. § 723.50(h)(1) (1995); 40 C.F.R. § 723.50(h)(1) (2025).

If EPA approves a low-volume/low-exposure exemption, the manufacturer who requested the exemption may manufacture the chemical, but its manufacturing and uses are restricted to those approved in the exemption notice, including limitations on volume manufactured. 60 Fed. Reg. at 16337; 40 C.F.R. § 723.50(j). Manufacturers must continue to maintain exposure and release controls to ensure they meet the approved exposure limitations throughout the period of time that

² In addition to the substance itself, EPA also considers the manufacturing, processing, distribution, use, and disposal of “any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance.” 40 C.F.R. § 723.50(d) (1995); 40 C.F.R. § 723.50(d)(1) (2025).

they manufacture the chemical under the exemption. 60 Fed. Reg. 16337; 40 C.F.R. § 723.50(j). Moreover, chemicals approved under these exemptions are not added to the inventory of existing chemicals (unless the chemical undergoes premanufacturing review by EPA under the standard process), and thus the chemical cannot be manufactured by anyone other than the manufacturer who received the exemption and only under the specific conditions for which the exemption was sought. *See* 50 Fed. Reg. at 16483-84; *compare* 40 C.F.R. § 723.50 with § 720.120(a); *see generally* 15 U.S.C. § 2607(b).

II. FACTUAL BACKGROUND

On May 26, 2023, EPA published a proposed rule to update the new chemicals regulations to align with the 2016 TSCA amendments, improve the efficiency of EPA's review processes, and make other limited updates to the regulations based on existing Agency policies and experience implementing the new chemicals program. ACAT-ER-234 to ACAT-ER-259 (88 Fed. Reg. 34100 (May 26, 2023)). After a notice and comment period, EPA issued the final 2024 Rule updating the new chemicals regulations. ACAT-ER-004 to ACAT-ER-031 (89 Fed. Reg. 102773 (Dec. 18, 2024)).

At issue in this litigation, EPA clarified and formally codified its longstanding practice of finding certain chemicals ineligible for the low-volume/low-exposure exemptions. In 1999, EPA began classifying certain

chemicals as “PBT” chemicals based on their “characteristics of persistence (P) in the environment, accumulation in biological organisms (bioaccumulation (B)), and toxicity (T) that make them priority pollutants and potential risks to humans and ecosystems.” ACAT-ER-262 (64 Fed. Reg. 60194, 60196 (Nov. 4, 1999)). EPA’s 1999 PBT policy formally acknowledged PBT chemical substances as a category of chemical substances and established criteria for identifying new chemicals that fall within this category. *Id.*; ACAT-ER-248; ACAT-ER-017. Since 1999, EPA has assessed both applications to manufacture PBT chemicals through the standard premanufacturing review process and applications for low-volume/low-exposure exemptions from that process on a case-by-case basis. ACAT-ER-264 (“New chemicals identified as potential PBT chemicals are assessed on a case-by-case basis.”); ACAT-ER-249. When EPA has identified PBT chemicals in the low-volume/low-exposure exemption process that have “the potential for unreasonable exposures,” EPA has denied the exemption application. ACAT-ER-249.

In the rule challenged here, EPA proposed and finalized several amendments to the regulations for low-volume/low-exposure exemptions to the standard premanufacturing review process. ACAT-ER-234, ACAT-ER-236. One of these amendments codified EPA’s process for classifying chemicals as PBT chemicals set forth in the 1999 PBT policy. ACAT-ER-249. Another amendment codified EPA’s longstanding practice of deeming PBT chemicals “with anticipated

environmental releases and potentially unreasonable exposures to humans or environmental organisms” to be “ineligible” for the exemptions. *Id.* EPA thus proposed continuing the status quo of allowing these applications for the exemptions with a new regulatory provision providing regulated parties with notice of how EPA assesses those applications. *Id.*

EPA explained the scientific and technical process that it undertakes for all requests for low-volume/low-exposure exemptions to assess whether the chemical substance is a PBT chemical. *Id.* EPA further explained that it expected the regulatory provision may reduce the number of applications it received for PBT chemicals. *Id.* Although EPA noted that a manufacturer “may not be able to determine in advance of submitting an exemption notice if EPA would find the substance to be PBT [chemical],” EPA anticipated that those manufacturers “who possess data indicating that their new chemical substances could be PBT and could be handled in such a way as to result in anticipated or unreasonable exposures may be less likely to expend the time and resources” to submit an exemption application. *Id.*

Notably, EPA did *not* alter or remove any existing limitations on eligibility for the low-volume/low-exposure exemptions. *Compare* 40 C.F.R. § 723.50(c), (d), (h)(1) (2023) *with* 40 C.F.R. § 723.50(c), (d)(1), (h)(1) (2025). It only codified an *additional* basis to find a PBT chemical ineligible for the exemptions. 40 C.F.R.

§ 723.50(d)(2) (2025). Additionally, new in the 2024 Rule, EPA clarified that a manufacturer cannot begin manufacturing under the exemption until EPA actually approves the exemption (rather than simply waiting for EPA’s 30-day time period for review to expire). *Compare id.* § 723.50(g)(2) with 40 C.F.R. § 723.50(g) (2023). EPA explained that the combination of these regulatory changes “better ensure[s] that chemical substances manufactured under [the exemptions] will not present an unreasonable risk.” ACAT-ER-014.

EPA also proposed and finalized other limited updates to the new chemicals regulations, including a regulation describing EPA’s publication of Federal Register notices pursuant to § 2604(d)(2). *See* ACAT-ER-239, ACAT-ER-244; ACAT-ER-008, ACAT-ER-013 (codified at 40 C.F.R. § 720.70); *see generally* 15 U.S.C. § 2604(d)(2) (requiring EPA to publish a notice in the Federal Register containing specified information, subject to confidentiality protections). Specifically, EPA clarified its practice of publishing a notice of receipt of a premanufacture notice in the Federal Register only once the notice is *complete*. ACAT-ER-244; ACAT-ER-013; ACAT-ER-055. *Compare* 40 C.F.R. § 720.70(a) (2025) with 40 C.F.R. § 720.70(a) (2023). Additionally, EPA removed a non-statutory requirement to publish a list of certain data submitted with the premanufacture notice in the Federal Register. ACAT-ER-239; ACAT-ER-008; ACAT-ER-053 to ACAT-ER-054; *compare* 40 C.F.R. § 720.70(b)(3) (2025) with

40 C.F.R. § 720.70(b)(3) (2023). In removing this requirement, EPA explained that the Agency makes the same information available on ChemView, EPA’s online database containing information EPA receives and develops about chemicals under TSCA. ACAT-ER-008; ACAT-ER-239.

EPA received 51 comments on all aspects of the proposed rule, including certain comments on the newly codified criteria for consideration of applications for low-volume/low-exposure exemptions involving new PBT chemicals. ACAT-ER-006. Some comments requested that EPA categorically preclude all PBT chemicals from the exemptions, while others commented that EPA could not categorically preclude them. EPA considered both sets of comments before finalizing the 2024 Rule as proposed, which codified its existing practice of considering low-volume/low-exposure exemption applications for new PBT chemicals on a case-by-case basis rather than categorically precluding the exemptions for all new PBT chemicals. ACAT-ER-017; ACAT-ER-120 to ACAT-ER-122.

EPA also received certain comments outside the scope of the rulemaking submitted by the American Federation of Labor and Congress of Industrial Organizations, the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America and the United Steelworkers (collectively, “Labor Unions”). The Labor Unions filed a collective comment letter

focusing on information disclosure provisions for the new chemicals regulations. Labor ER-31. They asserted that EPA's use of the Federal Register and ChemView to inform the public about premanufacture notices does not provide sufficient notice to workers and their representatives to meet TSCA's purported worker safety-related transparency goals.

The Labor Unions suggested that EPA should craft a new regulatory disclosure process that would require employers submitting premanufacture notices to (1) certify that they met various requirements recommended by the Labor Unions to disclose information to affected workers and their authorized representatives before EPA would approve the manufacture of a new chemical or a significant new use of a chemical, and (2) post any § 2604(e) order or significant new use rule in any workplace where there are affected employees. They further asserted that there is no reason to keep the details of a § 2604(e) order confidential, where the disclosure of such information could protect workers from the risks a new chemical may pose. EPA acknowledged these comments and explained that they were outside the scope of the rulemaking, because the proposed rule did not address access to information other than the limited updates regarding publication of Federal Register notices pursuant to § 2604(d)(2). 40 C.F.R. § 720.70. Accordingly, EPA declined to respond to the merits of or adopt the suggestions. ACAT-ER-135, ACAT-ER-137.

SUMMARY OF ARGUMENT

1. EPA strengthened its approach to regulating PBT chemicals in the 2024 Rule by codifying and providing notice of the bases on which it considers applications to exempt PBT chemicals from the standard premanufacturing review process through low-volume/low-exposure exemptions. Critically, EPA did not remove or alter *any* existing criteria required for the exemptions. Instead, it codified an additional category of ineligibility specific to PBT chemicals whereby a PBT chemical is also ineligible for the exemptions if it has “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.” 40 C.F.R. § 723.50(d)(2)(ii). Recognizing that this is an approval process for *new* chemicals and that EPA cannot foretell every possible manner in which the chemical may be manufactured, processed, distributed in commerce, used, or disposed of, EPA lawfully and reasonably retained its authority to consider applications for the exemptions on a case-by-case basis rather than categorically precluding all potential new PBT chemicals from receiving exemptions.

2. EPA properly determined that Labor Petitioner’s comments during the notice-and-comment process were outside the scope of the rulemaking and appropriately declined to respond to the merits of or adopt those suggestions. Labor Petitioner asked EPA to require manufacturers submitting a premanufacture

notice to inform their employees of the notice, provide the information contained in the notice to employees (including information the company asserts is confidential), ensure employees have the opportunity to provide comment before any § 2604(e) order mitigating potential risk from a new chemical or significant new use is finalized, and post any § 2604(e) order or significant new use rule in any workplace where there are affected employees. But these comments were outside the scope of the rulemaking and not logically related to any of the revisions proposed or finalized by EPA. EPA thus did not err when it acknowledged the comments, but did not respond to their merits and did not adopt Labor Petitioner's suggestions in this rulemaking. Moreover, Labor Petitioner points to no statutory requirement that the 2024 Rule failed to meet.

STANDARD OF REVIEW

With limited exceptions not applicable here, EPA rules promulgated under TSCA are reviewed in accordance with the standard set forth in the Administrative Procedure Act, 5 U.S.C. § 706. 15 U.S.C. § 2618(c)(1)(B). “Under the APA, [this Court] set[s] aside an agency’s decision if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” *Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1047 (9th Cir. 2008) (citation omitted). The familiar arbitrary-or-capricious standard is highly deferential, presuming the validity of agency actions and upholding them if they satisfy minimum standards

of rationality. *Kern Cnty. Farm Bureau v. Allen*, 450 F.3d 1072, 1075-76 (9th Cir. 2006). “The scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency.” *Motor Vehicles Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The pertinent question is “whether the [agency’s] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Id.* at 42-43 (internal quotation marks and citation omitted).

The Court reviews questions of statutory interpretation *de novo*. *Lopez v. Garland*, 116 F.4th 1032, 1036 (9th Cir. 2024). In deciding questions of statutory interpretation, “[c]ourts must exercise their independent judgment,” but “[c]areful attention to the judgment of the Executive Branch may help inform that inquiry.” *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412-13 (2024). To resolve the meaning of disputed statutory language, a court shall adopt the interpretation that it, “after applying all relevant interpretive tools, concludes is best.” *Id.* at 400. “[W]hen a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it.” *Id.* at 413.

ARGUMENT

I. EPA Reasonably and Lawfully Retained Its Authority to Consider Applications for Low-Volume/Low-Exposure Exemptions on a Case-by-Case Basis.

The 2024 Rule retained all existing criteria and limitations for applications for low-volume/low-exposure exemptions from the standard premanufacturing review process, and codified an additional category of *ineligibility* for these exemptions: PBT chemicals with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.

ACAT-ER-017. Critically, this addition did not *lower* the standard for granting these exemptions for new PBT chemicals but instead simply provided notice of the basis on which EPA, through its longstanding practice, denies these applications.

Prior to the 2024 Rule, new PBT chemicals could be eligible for the low-volume/low-exposure exemption if (1) the chemical would be produced below the regulatory volume limit or with environmental releases and human exposures below the regulatory thresholds; and (2) the chemical would not cause serious acute or chronic health effects or significant environmental effects. 40 C.F.R. § 723.50(c), (d) (2023). These same criteria *still* exist for new PBT chemicals in the challenged rule. *See* 40 C.F.R. § 723.50(c), (d)(1) (2025). In addition to these criteria, however, EPA also made clear that it would deny any applications for PBT chemicals if there were *any* “anticipated environmental releases and potentially

unreasonable exposures to humans or environmental organisms.” 40 C.F.R. § 723.50(d)(2)(ii) (2025); ACAT-ER-017.

Although Environmental Petitioners assert that EPA’s new regulation should have gone further and categorically precluded any PBT chemical from the low-volume/low-exposure exemptions, EPA’s decision to leave open the possibility that a request to manufacture a new PBT chemical could satisfy the exemption’s standard is both consistent with the statute and supported by the record.

A. EPA Has Statutory Authority to Consider Applications for Low-Volume/Low-Exposure Exemptions for PBT Chemicals on a Case-by-Case Basis.

EPA lawfully maintained its authority to consider new PBT chemical applications for low-volume/low-exposure exemptions from the standard premanufacturing review process on a case-by-case basis. Although Environmental Petitioners assert that EPA was statutorily mandated to categorically preclude PBT chemicals from the exemptions, nothing in the statute requires any such categorical preclusion.

When interpreting a statute, this Court’s role is to determine the “best reading” of the statute, applying “all relevant interpretive tools.” *Loper Bright*, 603 U.S. at 400. This analysis “begin[s] with the plain language of the statute.” *Moran v. Screening Pros, LLC*, 943 F.3d 1175, 1183 (9th Cir. 2019). “The plainness or ambiguity of statutory language is determined by reference to the language itself,

the specific context in which that language is used, and the broader context of the statute as a whole.” *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). Here, the plain language of § 2604(h)(4) expressly authorizes EPA to consider applications to exempt new chemicals, including new PBT chemicals, from the standard premanufacturing review process on a case-by-case basis. And, neither § 2604(h)(4) nor § 2625(c) requires EPA to categorically preclude any PBT chemical from an exemption.

Section 2604(h)(4) provides:

The Administrator *may, upon application* and by rule, exempt the manufacturer of *any* new chemical substance from all or part of the requirements of this section [15 U.S.C. § 2604 setting forth procedures for review of new chemicals] if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

15 U.S.C. § 2604(h)(4) (emphasis added).

Section 2604(h)(4) thus explicitly authorizes EPA to consider exemptions by “application” on a case-by-case basis. *Id.* Here, EPA’s rule sets forth additional criteria on how each individual “application” for an exemption for a new PBT chemical will be evaluated and clarifies that *most* PBT chemicals will be ineligible for the exemption. 40 C.F.R. § 723.50(d)(2); ACAT-ER-017; ACAT-ER-121 to ACAT-ER-122.

Specifically, the 2024 Rule provides that applications to exempt new PBT chemicals will be denied if they do not meet the requirements of 40 C.F.R. § 723.50(c), (d)(1), and now (d)(2). Applicants thus still must seek to manufacture a new PBT chemical either below the volume threshold of § 723.50(c)(1) or pursuant to the release and exposure requirements of § 723.50(c)(2). Applicants still must seek to manufacture the chemical under conditions that meet the health and environmental effects eligibility criteria under § 723.50(d)(1). And EPA has now codified that an application for a PBT chemical will also be denied if EPA identifies any “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms” under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the PBT chemical. *Id.* § 723.50(d)(2)(ii). Moreover, the 2024 Rule retained EPA’s longstanding authority to deny *any* application where “there are issues concerning toxicity or exposure that require further review,” even if EPA has not made any of the findings described in § 723.50(d). *Id.* § 723.50(h)(1); *see* 50 Fed. Reg. at 16481 (describing EPA’s ability to deny an exemption because of unresolved issues rather than affirmative evidence as “an essential element of the rule and the no unreasonable risk finding”).

EPA’s regulation thus plainly complies with the statutory mandate that EPA not exempt any chemical substance from the standard premanufacturing review

process unless the EPA determines that “the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment” 15 U.S.C. § 2604(h)(4); *see* 60 Fed. Reg. at 16337 (“Any exemption application will be denied if the Agency is unable to affirmatively find that manufacture, processing, distribution in commerce, use, and disposal of the exempted substance pursuant to the exemption will not present an unreasonable risk of injury to human health or the environment.”). And, consistent with the plain text of the statute, the regulation retains EPA’s authority to consider each exemption request “upon application.” 15 U.S.C. § 2604(h)(4).

Environmental Petitioners’ assertion that § 2604(h)(4) mandates that EPA categorically preclude exempting PBT chemicals from the standard premanufacturing review process is not supported by the statutory language. *Contra* Env. Br. at 33-36. Indeed, the plain language of the statute expressly authorizes EPA to consider an exemption of “*any* new chemical substance” “upon application.” 15 U.S.C. § 2604(h)(4) (emphasis added).

Nor are Environmental Petitioners correct that the statute requires EPA to make a “category [of chemicals] ineligible” for an exemption if EPA “cannot be certain *in advance*” of receiving any applications “that the terms of an exemption ensure a category meets” the statutory requirements. *Contra* Env. Br. at 35

(emphasis added). Notably, Environmental Petitioners do not even attempt to ground that argument in the statutory text of § 2604(h)(4). *See id.* Nor could they; inherent in EPA’s statutory authority to consider exemption requests “upon application” is EPA’s authority to consider data and information on a case-by-case basis as it is presented in the application. 15 U.S.C. § 2604(h)(4). And although Environmental Petitioners note that EPA precluded PFAS chemicals (a particular subgroup of chemicals defined according to their molecular structure) from obtaining these exemptions, *see* Env. Br. at 26-27; 40 C.F.R. § 723.50(d)(2)(i), this is irrelevant. Section 2604(h)(4) plainly authorizes EPA to continue considering “any new chemical substance” on a case-by-case basis “upon application.”

Similarly, the mere fact that TSCA authorizes EPA to take certain actions with respect to a category of chemical substances does not mandate that EPA preclude the entire category of substances from eligibility for an exemption. 15 U.S.C. § 2625(c); *contra* Env. Br. at 18, 34-35. Section 2625(c) simply provides that “[a]ny action authorized or required to be taken by the Administrator under any provision [of TSCA] with respect to a chemical substance or mixture *may* be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures.” 15 U.S.C. § 2625(c)(1) (emphasis added). Here again, the Court must start with the plain language of the statute. *Moran*, 943 F.3d at 1183. And, as the Supreme Court has made clear, the statute’s

use of “‘may’ does not just suggest discretion, it *clearly* connotes it.” *Biden v. Texas*, 597 U.S. 785, 802 (2022) (emphasis in original; internal quotations omitted). Thus, nothing in § 2625(c) mandates that EPA categorically preclude PBT chemicals from the low-volume/low-exposure exemptions simply because EPA has defined that category. And § 2604(h)(4) expressly authorizes EPA to continue considering exemptions sought for any new chemical, including PBT chemicals, “upon application.” 15 U.S.C. §§ 2604(h)(4), 2625(c).

B. EPA’s Decision to Consider Exemptions for PBT Chemicals on a Case-by-Case Basis Is Reasonable and Supported by the Record.

Under the 2024 Rule, EPA requires manufacturers seeking low-volume/low-exposure exemptions for new PBT chemicals to satisfy all existing criteria for the exemptions and clarifies that such chemicals are also ineligible if EPA determines there would be anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms. 40 C.F.R. § 723.50(c), (d)(1), (d)(2)(ii), (h)(1). EPA reached this decision after full consideration of input from various stakeholder groups. Because this decision is well supported by the record and is not arbitrary or capricious, it should be upheld.

This Court’s consideration of the reasonableness of an agency’s decision is “narrow and a court is not to substitute its judgment for that of the agency . . .” *Cascadia Wildlands v. U.S. Bureau of Land Mgmt.*, 153 F.4th 869, 892 (9th Cir.

2025). The Court considers whether EPA “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action.” *Id.* Here, EPA considered all relevant information and articulated a reasonable decision in light of that information.

1. The PBT Ineligibility Regulation Is Well Reasoned and Well Supported by the Record.

To implement § 2604(h)(4), EPA has, since at least 1995, conducted a case-by-case review of each proposed manufacture of a new chemical substance for which an exemption to the standard premanufacturing review process is sought to determine if the specific instance of manufacturing of that chemical could present a serious risk to health or significant risk to the environment. 40 C.F.R. § 723.50(d) (1995); 40 C.F.R. § 723.50(d)(1) (2025) (precluding exemption if EPA determines the substance “[m]ay cause (i) [s]erious acute (lethal or sublethal) effects; (ii) [s]erious chronic (including carcinogenic and teratogenic) effects; or (iii) [s]ignificant environmental effects”). In the 2024 Rule, EPA codified its longstanding practice of denying exemption applications whenever the available evidence indicates that the substances are PBT chemicals with “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.” 40 C.F.R. § 723.50(d)(2)(ii).

Since 1999, EPA has more carefully scrutinized applications for low-volume/low-exposure exemptions for new PBT chemicals. ACAT-ER-249. When

EPA identified PBT chemicals in the exemption process that had “the potential for unreasonable exposures,” EPA denied the exemption application. *Id.* To provide notice to regulated parties on the Agency’s review process for PBT chemicals, EPA proposed a regulation codifying both its 1999 PBT policy detailing how EPA identifies PBT chemicals and its longstanding practice of denying applications for low-volume/low-exposure exemptions for PBT chemicals where there are anticipated environmental releases and potentially unreasonable exposures to the chemical. *Id.* EPA explained that it anticipated that codifying and providing notice of its longstanding practice of denying applications on this basis may reduce the number of exemption applications for PBT chemicals. *Id.*

EPA received comments on the proposed regulation from both stakeholders requesting that EPA categorically preclude all PBT chemicals from eligibility for the low-volume/low-exposure exemptions and stakeholders that asserted EPA could not categorically preclude these substances because it lacked “data to support that each of the substances no longer meets the unreasonable safety standard.” ACAT-ER-121. EPA considered both sets of comments before deciding to simply codify its existing practice of considering exemption applications for PBT chemicals on a case-by-case basis rather than categorically precluding exemptions for PBT chemicals. ACAT-ER-017; ACAT-ER-120 to ACAT-ER-122. Because EPA’s determination that a chemical is a PBT chemical is not information the

manufacturer necessarily would have prior to the application process, EPA first must review the application “to determine if the substance is a PBT [chemical] and then review the environmental releases and exposures to humans or environmental organism[s] to determine if releases and exposures are expected.” ACAT-ER-122. EPA explained that, only after reviewing the hazards and exposures of the chemical substance would it decide whether to grant or deny the exemption. *Id.*

EPA further explained that it expected that “most exemptions for PBT chemical substances will not be granted.” *Id.* But EPA agreed with commenters that “there are instances where PBT[chemicals] can be managed under an exemption.” *Id.* Specifically, EPA could not preclude the possibility that it may receive an application for a new PBT chemical that “will not result in worker, general population, or consumer exposure and that is not expected to result in releases to the environment, such as chemical substances used in a closed system to make semiconductors or other electronic components.” *Id.* EPA explained that “[i]n such a negligible exposure and environmental release scenario where worker exposure is fully mitigated and general population exposures are not expected, if EPA has sufficient information on the substance and the conditions of use to ensure that such PBT chemical substances can be disposed of properly and no consumer exposure is expected, EPA generally expects to grant the exemption.” *Id.*

Based on the information available to EPA, it thus reasonably determined to continue its case-by-case analysis of applications for low-volume/low-exposure exemptions for PBT chemicals and codified its long-standing practice of denying exemptions for PBT chemicals that have *any* “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.” ACAT-ER-017; 40 C.F.R. § 723.50(d)(2)(ii).

2. Environmental Petitioners’ Arguments Misstate the Regulation and Regulatory Structure.

Environmental Petitioners assert a number of challenges to EPA’s regulation, all of which demonstrate a fundamental misunderstanding of the regulation itself.

1. At the outset, Environmental Petitioners assert three arguments that run directly counter to how the *additional* ineligibility criteria for PBT chemicals function within the overall regulatory scheme of the low-volume/low-exposure exemptions. First, Environmental Petitioners incorrectly assert that “EPA found that the terms of [the exemptions] do not protect against the inherent risks of new PBT [chemicals]” because they assert the exemptions are based exclusively on limits on production volume and the amount of release and exposure. Env. Br. at 36-40; *see also* Env. Br. at 42. Second, Environmental Petitioners are flatly wrong that “each and every new PBT [chemical]” is now “eligible for expedited review under the Exemptions unless EPA affirmatively determines that a specific PBT [chemical] is unsafe.” Env. Br. at 40; *see also* Env. Br. at 42 (arguing the PBT

ineligibility regulation somehow relaxes the exemption evaluation criteria by *only* authorizing a denial of an exemption if “EPA affirmatively determines the chemical ‘likely’ presents an unreasonable risk of injury”). And third, Environmental Petitioners’ assertion that EPA’s preclusion of the exemptions for PBT chemicals with “potentially unreasonable exposures to humans or environmental organisms” has somehow supplanted an analysis of the risks the chemicals present is erroneous. Env. Br. at 43-44. All three arguments ignore the clear text of the regulation and the fact that it functions *within* and not *in lieu of* the general regulatory scheme of the exemptions.

No chemical substance—including PBT chemicals—may receive the exemptions if the substance “under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal . . . [m]ay cause (i) [s]erious acute (lethal or sublethal) effects; (ii) [s]erious chronic (including carcinogenic and teratogenic) effects; or (iii) [s]ignificant environmental effects.” 40 C.F.R. § 723.50(d)(1) (emphasis added). The 2024 Rule repeatedly makes clear these criteria remain in effect. *See, e.g.*, ACAT-ER-005; ACAT-ER-014; ACAT-ER-017; ACAT-ER-111; ACAT-ER-122 to ACAT-ER-125. The 2024 Rule simply established an additional basis of ineligibility precluding exemption of a new PBT chemical that has “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.” 40 C.F.R. § 723.50(d)(2)(ii). To

the extent any manufacture of a new PBT chemical could exist that meets the criteria under (d)(2) but fails the criteria under (d)(1) (or vice versa), the chemical would still be ineligible for the exemption because it must satisfy *all* criteria.

The structure of the regulation plainly makes these requirements independent bases to deny an exemption application for a new PBT chemical. The text provides that “[a] new chemical substance *cannot* be manufactured under this [exemption] *if* EPA determines” the chemical “[m]ay cause” the health or environmental effects in (d)(1) “[o]r is . . . [a] PBT chemical substance with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms” under (d)(2)(ii). *Id.* § 723.50(d) (emphasis added). EPA’s use of “or” to separate the criteria of (d)(1) from (d)(2) is disjunctive, meaning that *either* of the provisions will preclude the chemical’s exemption. *Loughrin v. United States*, 573 U.S. 351, 357 (2014) (The “ordinary use” of the term “or” “is almost always disjunctive, that is, the words it connects are to be given separate meanings.”).

2. Moreover, Environmental Petitioners’ assertion that “if EPA lacks exposure or release information that would allow it to [determine there are no anticipated releases or potentially unreasonable exposures of the PBT chemical] . . . a new PBT [chemical] would be eligible” for the exemption is similarly incorrect. Env. Br. at 41. A separate provision of the regulation expressly provides

that “[i]f the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section *or that there are issues concerning toxicity or exposure that require further review* . . . EPA will notify the manufacturer . . . that the substance is not eligible” and the “manufacturer may not begin manufacture of the new chemical substance without complying with” the standard premanufacturing review process. 40 C.F.R. § 723.50(h)(1) (emphasis added); *see* 50 Fed. Reg. at 16481 (explaining that EPA’s ability to deny an exemption because of unresolved issues “rather than because of affirmative evidence that a substance may be a problem” is “an essential element of the rule and the no unreasonable risk finding”).

The 2024 Rule thus explicitly does *not* “treat[] an absence of evidence on releases and exposures as a reason to approve an exemption for a new PBT chemical”; this same basis for denial remains for PBT chemicals as has always existed for all new chemicals for which an exemption is sought. *Contra* Env. Br. at 41. And furthermore, EPA explicitly amended the regulations in the 2024 Rule to require an express approval of an exemption before manufacturing can begin; simply seeking the exemption without obtaining affirmative approval does not authorize manufacturing. 40 C.F.R. § 723.50(g)(2).

3. Environmental Petitioners’ assertion that the PBT ineligibility regulation contravenes EPA’s past practice is similarly erroneous. Environmental

Petitioners first erroneously conflate the low-volume/low-exposure regulation with an entirely different exemption that exempts certain polymers from the standard premanufacturing review process. *See* Env. Br. at 45-46. But the polymer exemption is neither the same nor even analogous to the low-volume/low-exposure exemptions here. Unlike the low-volume/low-exposure exemption, the polymer exemption exempts certain polymers from the standard premanufacturing review process with *no* application process and *no* opportunity for EPA review. *Compare* 40 C.F.R. § 723.250 *with id.* § 723.50. Thus, in 2010, EPA made a category of “polymers containing PFAS or PFAC” ineligible for that exemption, while explicitly noting that manufacturers of affected polymers could submit requests for a *different* § 2604(h)(4) exemption such as the low-volume/low-exposure exemptions at issue here. 75 Fed. Reg. 4295, 4296, 4300 (Jan. 27, 2010); 40 C.F.R. § 723.250(d)(6). The complete lack of any review procedure for the polymer exemption is thus critically different from the regulation at issue here which *sets the criteria* by which EPA will conduct its review of applications for low-volume/low-exposure exemptions for PBT chemicals. *Compare* 40 C.F.R. § 723.250 *with id.* § 723.50.

And, although Environmental Petitioners argue that the PBT ineligibility regulation departs from EPA’s 1999 PBT policy, this too is incorrect. *Contra* Env. Br. 50-52. At the outset, the 1999 PBT policy did not address how EPA considers

applications for low-volume/low-exposure exemptions and certainly did not preclude PBT chemicals from those exemptions. *See* ACAT-ER-260 to ACAT-ER-270. Instead, the policy details how EPA determines whether a chemical is a PBT chemical, a process that is now codified at 40 C.F.R. § 723.50(b)(12). In addition to codifying that categorization process, EPA also codified its longstanding practice to deny exemption applications for PBT chemicals with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms to provide additional clarity and transparency. ACAT-ER-249.

Moreover, the mere fact that Petitioners cannot identify a PBT chemical that has been approved for an exemption “for a period of several years” prior to the 2024 Rule does not demonstrate that the current regulation is a departure from the 1999 PBT policy. *Contra* Env. Br. at 51.³ EPA expressly stated that based on its experience considering low-volume/low-exposure exemption applications for PBT chemicals, “EPA expects that most exemptions for PBT chemical substances will

³ Although Environmental Petitioners assert that their comments stated EPA “categorically rejected all [low-volume/low-exposure exemptions] applications for *all* new PBTs for a period of several years,” Env. Br. at 51 (emphasis in original), in fact their comment stated no such thing. Instead, the comment stated that EPA denied “*essentially* all” applications for exemptions of PBT chemicals during a four-year period. ACAT-ER-226 (emphasis added). Although Environmental Petitioners included no support for this statement in their public comment, it is in line with EPA’s stated expectation that “most” exemption applications for PBT chemicals will continue to be denied and that the regulation may reduce the number of applications. ACAT-ER-122; ACAT-ER-017; ACAT-ER-249.

not be granted.” ACAT-ER-122; ACAT-ER-017. The mere fact that EPA rarely (if ever) granted these exemptions for PBT chemicals prior to this regulation and expects to rarely (if ever) grant these exemptions for PBT chemicals under this regulation evidences consistency in EPA’s practice rather than a departure.

4. Finally, Environmental Petitioners assert that EPA provided “no evidence” and “failed to identify a single real-world example” that any manufacturing of PBT chemicals could exist that would meet the requirement that the chemical has no “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.” Env. Br. 46-49; 40 C.F.R. § 723.50(d)(2)(ii). But by definition, this is a regulatory scheme for manufacturing of chemicals that *have not yet* been manufactured. 15 U.S.C. § 2602(11). The fact that EPA is not willing to categorically preclude the mere *possibility* that any such scenario may exist is not arbitrary; it is simply realistic.

Moreover, EPA *did* posit a scenario that it thought could potentially meet the criteria. *See* ACAT-ER-122; ACAT-ER-017. EPA explained that in a scenario in which the PBT chemical is “used in a closed system to make semiconductors or other electronic components” where “worker exposure is fully mitigated and general population exposures are not expected,” and “EPA has sufficient information on the substance and the conditions of use to ensure that such PBT chemical substances can be disposed of properly and no consumer exposure is

expected,” EPA could grant the exemption. ACAT-ER-017. EPA fully recognized that such a scenario where approval could actually happen would be rare. *Id.* But the mere fact that the scenario is unlikely to occur does not render EPA’s accounting for its possibility arbitrary.

C. Environmental Petitioners’ Proposed Remedy Is Invalid.

Environmental Petitioners implicitly recognize the new PBT ineligibility regulation is at least as limiting of exemptions of PBT chemicals as the prior regulatory regime when they expressly ask this Court *not* to vacate the PBT ineligibility regulation but instead to substantively rewrite it to substitute their preferred policy judgment for EPA’s. Env. Br. at 52-54. Although they frame their request as “partial vacatur,” they ask this Court to strike only specific words in the new regulation to create a fundamentally different regulation than *either* the current regulation or prior regulatory landscape. *Id.* Striking out only the limiting language of the PBT ineligibility regulation rather than either maintaining or vacating the full regulatory text would fundamentally alter and supplant EPA’s careful weighing of policy objectives and improperly thrust this Court into a policy-setting role. Compare 40 C.F.R. § 723.50(d)(2)(ii) (2025) with 40 C.F.R. § 723.50(d) (2023). Because this request is improper, and because Environmental Petitioners have not sought vacatur of the regulation as a remedy, if the Court finds

EPA erred in promulgating the PBT ineligibility regulation, it should instead remand that provision of the 2024 Rule to EPA for reconsideration.

At the outset, this Court has no policy-making authority and cannot rewrite EPA's new PBT ineligibility regulation by striking out only the limiting language. It is bedrock principle of administrative law that this Court "may not substitute its own policy judgment for that of the agency." *Waterkeeper All. v. EPA*, 140 F. 4th 1193, 1214 (9th Cir. 2025) (internal quotations omitted); *see also Juliana v. EPA*, 947 F.3d 1159, 1171-72 (9th Cir. 2020) (holding courts lack authority to grant relief directing "complex policy decisions entrusted, for better or worse, to the wisdom and discretion of the executive and legislative branches"). And here, EPA carefully detailed its policy judgment, explaining that it could not *ex ante* determine that *no* situation could exist in which a PBT chemical could qualify for a low-volume/low-exposure exemption. ACAT-ER-017; ACAT-ER-120 to ACAT-ER-122. If EPA insufficiently explained its rationale, the proper remedy is remand and reconsideration. If the Court believes EPA's error is so grievous as to warrant vacatur, it must vacate the *full* PBT ineligibility regulation (i.e., 40 C.F.R. § 723.50(d)(2)(ii)). But this Court *cannot* strike out only certain words and *rewrite* the regulation.

As this Court has explained, "[w]hether agency action should be vacated depends on how serious the agency's errors are and the disruptive consequences of

an interim change that may itself be changed.” *Mont. Wildlife Fed’n v. Haaland*, 127 F. 4th 1, 50-51 (9th Cir. 2025) (internal citations omitted). For the first factor, “the seriousness of the error,” the court considers “whether on remand, a different result may be reached” including “whether the agency would likely be able to offer better reasoning or whether by complying with procedural rules it could adopt the same rule or decision on remand.” *Id.* (cleaned up).

Here, EPA has not erred in any regard; the PBT ineligibility regulation is lawful and EPA has explained its reasoning. But if *any* error exists it is merely an error in explanation that EPA may resolve on remand. Moreover, although vacating the *full* regulatory text of the PBT ineligibility regulatory provision would not have any disruptive consequences, as it would allow EPA to continue considering low-volume/low-exposure exemptions for PBT chemicals on a case-by-case basis just as it has always done, the same cannot be said of Environmental Petitioners’ request that the Court rewrite the regulation to preclude *all* PBT chemicals from the exemptions. This would fundamentally alter EPA’s decades-long process for reviewing exemption applications.

And although Petitioners attempt to hang their unlawful remedy proposal on EPA’s statement in the 2024 Rule that different regulatory components are severable, this too fails to support their position. Env. Br. at 54-55. Nothing in

EPA’s severability analysis suggests this Court could excise words to fundamentally change the nature of a new regulation. ACAT-ER-018.

In short, there is no legal basis for the Court to undertake the fundamentally policy-making function of rewriting the regulation. If the Court disagrees with the reasonableness or lawfulness of EPA’s regulation, the 2024 Rule should simply be remanded to the agency for further consideration.

II. EPA Properly Declined to Respond to the Merits or Adopt Labor Petitioner’s Suggested Information Disclosure Requirements, Which Were Outside the Scope of the Rulemaking.

A. EPA Properly Determined Labor Petitioner’s Suggested Requirements Were Beyond the Scope of the Rulemaking.

EPA properly declined to respond to the merits or adopt Labor Petitioner’s suggested disclosure requirements purportedly aimed at making the new chemicals review process more transparent for workers impacted by new chemicals, because its comments were not logically related to any part of the proposed rule and thus were outside the scope of the rulemaking. EPA did not err by responding to Labor Petitioner’s comments solely to note they were not responsive to the proposed rule.

EPA is not required to adopt *any* suggestions raised for the first time in comments and need only respond to those comments that are “‘significant’ comments, i.e., those which raise relevant points and which, if adopted, would require a change in the agency’s proposed rule,” submitted during the comment period. *Am. Min. Cong. v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992); 5 U.S.C.

§ 553(c); 15 U.S.C. § 2618(c)(1)(B)(ii) (acknowledging rules promulgated under TSCA must comply with 5 U.S.C. § 553(c) requirements); *cf. Lab. Council for Latin Am. Advancement v. EPA*, 12 F.4th 234, 249–50 (2d Cir. 2021) (“15 U.S.C. § 2618(c)(1)(B), does not impose an obligation to reconcile the rule with every comment submitted, much less to accept the validity of every such comment”). Indeed, adopting a provision suggested in comments that is outside the scope of the proposal might well violate notice-and-comment requirements. *Transp. Div. of the Int’l Ass’n of Sheet Metal, Air, Rail, & Transp. Workers v. Fed. R.R. Admin.*, 988 F.3d 1170, 1180 (9th Cir. 2021) (“a final rule which departs from a proposed rule must be a logical outgrowth of the proposed rule”) (quoting *Nat. Res. Def. Council v. U.S. E.P.A. (NRDC II)*, 279 F.3d 1180, 1186 (9th Cir. 2002)).

Moreover, an agency’s failure to respond to comments in the course of a rulemaking is significant only insofar as it demonstrates that an agency’s decision was not based on the consideration of *relevant* factors. *See id.*; *Sierra Club v. EPA*, 353 F.3d 976, 986 (D.C. Cir. 2004). And an agency is not required to respond to the merits of a comment where the comment made is beyond the scope of the rulemaking. *See Am. Fuel & Petrochemical Mfrs. v. EPA*, 937 F.3d 559, 585 (D.C. Cir. 2019) (EPA correctly dismissed comments as outside the scope of the rule where EPA specifically delineated the issues for which it was soliciting comment); *Nat’l Min. Ass’n v. Mine Safety & Health Admin.*, 116 F.3d 520, 549 (D.C. Cir.

1997) (agency was not required to respond to the merits of comments where the comment was beyond the scope of the rulemaking); *see also Cmty. Voice v. EPA*, 997 F.3d 983, 1010 (9th Cir. 2021) (dissent) (“EPA is not required to address comments outside the scope of the rulemaking”).⁴

Here, EPA proposed and finalized updates to the new chemicals regulations unrelated to any of Labor Petitioner’s suggested disclosure requirements. EPA specifically delineated the topics on which it was and was not soliciting comment. *See, e.g.*, ACAT-ER-242 to ACAT-ER-243; ACAT-ER-245, ACAT-ER-247, ACAT-ER-249 (generally noting that EPA was soliciting comment on information required to be submitted to EPA in a premanufacture notice, how EPA will process premanufacture notices, and exemptions from the standard premanufacturing review process). Notably, Labor Petitioner does not challenge *any* aspect of the 2024 Rule that EPA actually proposed, solicited comment on, or finalized—including the Rule’s discrete change describing EPA’s publication of Federal Register notices pursuant to § 2604(d)(2). *See* ACAT-ER-239, ACAT-ER-244, ACAT-ER-008, ACAT-ER-013.

⁴ Unlike in *A Community Voice* where the majority held EPA erred in failing to address comments on standards it had an ongoing duty to update and that were related to the same contaminant at issue in the rulemaking, *Cmty. Voice*, 997 F.3d at 994, Labor Petitioner’s comments here are unrelated to the rulemaking and to any mandatory duty under TSCA.

Instead, Petitioner commented on, and challenges here, EPA’s purported failure to ensure that premanufacture notice submitters provide their workers and union representatives access to certain information on chemical substances. *See* Labor Br. at 23. But this rulemaking did not address, in any way, worker and union access to information from their employers. *See* ACAT-ER-137. In its response to comments, EPA clearly acknowledged and summarized Labor Petitioner’s comments, explained that it deemed Labor Petitioner’s comments outside the scope of the rulemaking, and again clarified the scope of the rulemaking.⁵ *Id.* 134–135, 137. *Contra* Labor Br. at 16 (incorrectly asserting that “nowhere in ... the

⁵ In response to Labor Petitioner’s comments, EPA “acknowledge[d] the desire for improved access to information for workers, unions, and others uniquely impacted,” and stated that it “welcome[d] conversations on how to better provide information to these stakeholders.” ACAT-ER-137. And, in June 2024, entirely independent from the challenged 2024 Rule, EPA took non-rulemaking action to ensure that workers and their representatives have ready access to information in § 2604(e) orders. *See* Boilerplate Language for Orders under Section 5 of TSCA, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/boilerplate-language-orders-under#Updated%20Boilerplate%20Strengthens%20Worker%20Protections> (last updated June 25, 2025) (<https://perma.cc/SZ8L-YSRZ>). Specifically, EPA updated its boilerplate language for § 2604(e) orders to add new requirements for companies to: keep a copy of the order in a clearly visible, readily accessible location in each work area; provide a copy of the order to workers and their representatives upon request; include sufficient information in the provided copy such that workers and their representatives can easily tell which chemical the order applies to and what worker protections it requires; and provide an unredacted copy of the order to any person whose request meets certain requirements. *See id.* (providing downloadable summary of the updates to the boilerplate and copy of current consent order boilerplate).

Response to Comments did EPA ... even mention, the Unions' Comments"), 17, 30. EPA was not required to say more, much less to adopt Labor Petitioner's suggestions raised for the first time in comments. *See Am. Fuel & Petrochemical Mfrs.*, 937 F.3d at 585.

B. TSCA Does Not Require EPA to Adopt Labor Petitioner's Suggestions.

Even if Labor Petitioner's suggestions had been within the scope of the rulemaking, EPA had no obligation to adopt them. Labor Petitioner points to no statutory requirement that EPA's 2024 Rule failed to meet. *See Labor Br.* at 18-23.

First, EPA meets its disclosure obligations under § 2625(j). This provision of TSCA only requires that EPA make certain categories of information "available to the public . . . [s]ubject to section 2613" confidentiality provisions. 15 U.S.C. § 2625(j). The disclosure obligations relevant to the new chemical provisions under § 2604 addressed in this rulemaking are those listed in § 2625(j)(1): "notices, determinations, findings, rules, consent agreements, and orders of the Administrator." *Id.* § 2625(j)(1). EPA meets this requirement by making information available in the Federal Register or the online searchable database ChemView, as applicable. *See, e.g.*, 44 U.S.C. § 1507 (noting that publication in the Federal Register creates a rebuttable presumption that a document was made available for public inspection). Though Labor Petitioner wants EPA to require that a submitter certify that it notified affected workers that it submitted a

premanufacture notice, provided workers with the relevant data, and ensured workers had an opportunity to comment before any action is finalized, Labor Br. at 24, TSCA requires none of this.

Second, Labor Petitioner asks that EPA require premanufacture notice submitters to disclose their confidential information to affected workers, contingent on the requester agreeing to confidentiality protections. Labor Br. at 27-28. But TSCA does not require EPA to mandate such disclosure. In fact, TSCA explicitly requires that EPA not disclose confidential business information except in limited circumstances not applicable here. *See* 15 U.S.C. § 2613; *see also id.* § 2625(j) (providing that EPA make certain information publicly available “[s]ubject to section 2613”). Although Labor Petitioner attempts to import requirements from *other* statutory and regulatory regimes for *other* circumstances to force EPA to create new third-party disclosure requirements as part of the premanufacture notice process, nothing in TSCA requires such disclosure. Labor Br. at 26 (discussing a hazard communication standard promulgated under the Occupational Safety and Health Act of 1970).

In short, EPA did not err in declining to adopt suggestions Labor Petitioner raised for the first time in comments on this unrelated rulemaking. And EPA sufficiently addressed the comments by noting they were out of scope.

C. Labor Petitioner’s Proposed Remedy Is Invalid.

Even if EPA failed to sufficiently address Labor Petitioner’s comment (and it did not), Labor Petitioner’s proposed remedy is outside this Court’s authority. Labor Petitioner appears to seek some sort of mandamus action to require EPA to take additional discretionary action neither proposed nor finalized in the rulemaking regarding premanufacture notices. But Labor Petitioner has only brought this action as a petition for review of an agency rulemaking under 15 U.S.C. § 2618(a), not as a citizen suit under 15 U.S.C. § 2619. *See* Pet., Case No. 25-572, Dkt. No. 1.1; Labor Br. at 3 (asserting jurisdiction under 15 U.S.C. § 2618(a)(1)(A)).

As TSCA makes clear, circuit courts have jurisdiction over challenges to final rules and may “affirm[] or set[] aside, in whole or in part, any rule” under TSCA. 15 U.S.C. § 2618(c)(2). In contrast, district courts have jurisdiction over actions to “compel the Administrator to perform any act or duty under this chapter which is not discretionary.” *Id.* § 2619(a)(2). Because the remedy Labor Petitioner seeks here is an order compelling agency action, this Court lacks original jurisdiction to afford any such remedy. *Id.*; Labor Br. at 30.

Moreover, even if this Court *could* compel EPA’s action in a petition for review, Labor Petitioner could not meet the high standard necessary for that remedy. A court’s ability to compel agency action is limited to circumstances

where the Agency has failed to abide by a specific legislative requirement. *Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 923, 932 (9th Cir. 2010). Here, Labor Petitioner does not allege that EPA failed to take a discrete, non-discretionary agency action. *See* 5 U.S.C. § 706; *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (“a ‘failure to act’ is properly understood to be limited . . . to a *discrete* action”); *Physicians Comm. For Responsible Med. v. Johnson*, 436 F.3d 326, 328 (2d Cir. 2006) (stating that EPA has a nondiscretionary duty to propose a rule for testing a chemical, where the statute stated that “the Administrator *shall* by rule” do so) (citing 15 U.S.C. § 2603(a)). Rather, Labor Petitioner merely provides suggestions for EPA to improve transparency. Labor Br. at 30.

Accordingly, Labor Petitioner’s requested remedy is improper. Should the Court rule in favor of Labor Petitioner, the proper remedy would be remand to the Agency for further proceedings.

CONCLUSION

For the foregoing reasons, the Court should deny the Petition for Review.

Dated: March 2, 2026

Respectfully submitted,

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STATEMENT OF RELATED CASES

Respondents are not aware of any related cases pending in this Court.

CERTIFICATE OF SERVICE

On March 2, 2026, I electronically filed the foregoing Respondents' Answering Brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the Court's Appellate Case Management System.

I certify that counsel for all parties in this case are registered with the Ninth Circuit Appellate Case Management System and that service will be accomplished by that system.

Date: March 2, 2026

/s/ Kimere J. Kimball

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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9th Cir. Case Number(s) 25-158, 25-572, 25-573

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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, *et al.*,

Respondents,

On Petition for Review of
Final Action of the U.S. Environmental Protection Agency

RESPONDENTS' STATUTORY AND REGULATORY ADDENDUM

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Sec.

723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

723.250 Polymers.

AUTHORITY: 15 U.S.C. 2604.

Subpart A [Reserved]

Subpart B—Specific Exemptions

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

(i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.

(ii) Chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.

(ii) Comply with all other provisions of this section.

(3) This section does not apply to microorganisms subject to part 725 of this chapter.

(b) *Definitions.* The following definitions apply to this subpart.

(1) *Act* means the Toxic Substances Control Act (15 U.S.C. 2601 et seq).

(2) *Consumer* means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

(3) *Environment* has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(4) *Environmental transformation product* means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(5) *Metabolite* means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(6) *Serious acute effects* means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(7) *Serious chronic effects* means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(8) *Significant environmental effects* means:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the

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damage persists beyond a single generation of the damaged resource or beyond a single year; or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(9) *Site* means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

(10) The terms *byproduct*, *EPA*, *importer*, *impurity*, *known to or reasonably ascertainable*, *manufacture*, *manufacturer*, *new chemical substance*, *person*, *possession or control*, and *test data* have the same meanings as in § 720.3 of this chapter.

(c) *Exemption categories*. Except as provided in paragraph (d) of this section, this exemption applies to:

(1) Any manufacturer of a new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption.

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) *Consumers and the general population*. For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:

(A) No dermal exposure.

(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section).

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section).

(ii) *Workers*. For exposure of workers to the new chemical substance during all manufacturing, processing, distribution in commerce, use and disposal of the substance:

(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).

(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).

(iii) *Ambient surface water*. For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion, calculated using the methods prescribed in §§ 721.90 and 721.91, unless EPA has approved a higher surface water concentration supported by relevant and scientifically valid data submitted to EPA in a notice under paragraph (e) of this section on the substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration.

(iv) *Incineration*. For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

(kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

(v) *Land or groundwater*. For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential.

(d) *Chemical substances that cannot be manufactured under this exemption*. A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraphs (c)(1) or (c)(2) of

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this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or by-products of the substance, or any reasonably anticipated impurities in the substance may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance:

(1) Serious acute (lethal or sublethal) effects.

(2) Serious chronic (including carcinogenic and teratogenic) effects.

(3) Significant environmental effects.

(e) *Exemption notice.* (1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to EPA at least 30 days before manufacture of the new chemical substance begins. Exemption notices and modifications must be submitted to EPA on EPA Form No. 7710-25 via CDX using e-PMN software in the manner set forth in this paragraph. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Notices and any related support documents, must be generated and completed (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(2) The notice shall contain the information described below, pursuant to the referenced provisions of § 720.45.

(i) Manufacturer identity.

(ii) Chemical identity (§ 720.45(a)).

(iii) Impurities (§ 720.45(b)).

(iv) Known synonyms or trade names (§ 720.45(c)).

(v) Byproducts (§ 720.45(d)).

(vi) Production volume (§ 720.45(e)).

(A) Manufacturers submitting an exemption application under paragraph (c)(1) of this section will be assumed to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000-kilograms level, may so specify by writing the lesser annual production volume in the appropriate box on the

PMN form and marking the adjacent binding option box. Manufacturers who opt to specify annual production levels below 10,000 kilograms and who mark the production volume binding option box shall not manufacture more than the specific annual amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted and approved pursuant to this section.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12-month period during the first 3 years of production.

(vii) Description of intended categories of use (§ 720.45(f)).

(viii) For manufacturer-controlled sites, the manufacturer shall supply identity of manufacturing sites, process descriptions, and worker exposure and environmental release information (§ 720.45(g)); for sites not controlled by the manufacturer, processing and use operation descriptions, estimated number of processing and use sites, and worker exposure/environmental release information (§ 720.45(h)). A manufacturer applying for an exemption under paragraph (c)(1) of this section need not provide information on worker exposure and environmental release referenced in paragraphs (e)(2)(viii) of this section if such information is not known or not readily available to the manufacturer. To assist in reporting this information, manufacturers may obtain a copy of EPA's Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, available from the Environmental Assistance Division at the address listed in paragraph (e)(1) of this section. Where worker exposure and environmental release information is not supplied by the manufacturer, EPA will generally apply "bounding estimates" (i.e., exposure estimates higher than those incurred by persons in the population with the highest exposure) to account for uncertainties in actual exposure and release scenarios.

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(ix) Type and category of notice. The manufacturer must clearly indicate on the first page of the PMN form that the submission is a “TSCA section 5(h)(4) exemption notice,” and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section. Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(x) Test data (§720.50).

(xi) Certification. In addition to the certifications required in EPA form 7710-25, the following certifications shall be included in notices under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30-day review period.

(xii) Sanitized copy of notice. (A) The manufacturer must make all claims of confidentiality in accordance with paragraph (1) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (1)(3) of this section.

(B) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(xiii) Safety Data Sheet (§720.45(i)).

(3) *Incomplete notices.* If EPA receives a submission which does not include all of the information required under this paragraph (e) of this section, the submission will be determined to be incomplete by EPA. When a submission for a new chemical substance has been

determined to be incomplete, a manufacturer reapplying for an exemption for the new chemical substance must submit a new exemption notice containing all the information required under this paragraph (e) of this section including a certification page containing an original dated signature; partial submissions sent to EPA to supplement notices declared incomplete will not be accepted. Photocopied pages from previously submitted exemption forms will be accepted provided that the certifications page contains an original dated signature.

(f) *Multiple exemption holders.* (1) A manufacturer who intends to manufacture a substance for which an exemption under this section was previously approved may apply for an exemption under paragraph (c)(1) or (c)(2) of this section; however, EPA will not approve any subsequent exemption application under paragraph (c)(1) of this section unless it can determine that the potential human exposure to, and environmental release of, the new chemical substance at the higher aggregate production volume will not present an unreasonable risk of injury to human health or the environment.

(2)(i) If EPA proposes to deny an exemption application for a substance for which another manufacturer currently holds an exemption, and that proposed denial is based exclusively on the cumulative human exposure or environmental release of the substance which precludes the EPA from determining that the subsequent applicant’s activities will not present an unreasonable risk of injury to human health or the environment, the EPA will notify the first exemption holder that it must, within 21 days of its receipt of EPA’s notice, either:

(A) Provide a new certification that it has commenced, or that it will commence, manufacture of the new chemical substance under this section within 1 year of the expiration of its exemption review period; or

(B) Withdraw its exemption for the new chemical substance.

(ii) If the first exemption holder does not respond to the EPA’s notice under paragraph (f)(2)(i) of this section within the prescribed time period, EPA shall issue a notice of ineligibility to

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the first exemption holder under the provisions of paragraph (h)(2) of this section.

(g) *Review period.* (1) EPA will review the notice submitted under paragraph (e) of this section to determine whether manufacture of the new chemical substance is eligible for the exemption. The review period will end 30 days after receipt of the notice by the TSCA Document Control Officer. To provide additional time to address any unresolved issues concerning an exemption application, the exemption applicant may, at any time during the review period, request a suspension of the review period pursuant to the provisions of § 720.75(b) of this chapter.

(2) Upon expiration of the 30-day review period, if EPA has taken no action, the manufacturer may consider its exemption approved and begin to manufacture the new chemical substance under the terms described in its notice and in this section.

(h) *Notice of ineligibility*—(1) *During the review period.* If the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30-day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reasons for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act or submitting a new notice under paragraph (e) of this section that satisfies EPA's concerns.

(2) *After the review period.* (i)(A) If at any time after the review period specified in paragraph (g) of this section the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention ("the Assistant Administrator") makes a preliminary determination that manufacture of the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA be-

lieves that the new chemical substance does not meet the terms of the section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (h)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (h)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (h)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (h)(2)(i)(A) of this section may submit, within 15 days of receipt of written notification, detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (h)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that manufacture of the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 7 days of the written notification under paragraph (h)(2)(iii) of this section. The manufacturer may

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not resume manufacture, processing, distribution in commerce, and use of the new chemical substance until it submits a notice under section 5(a)(1) of the Act and part 720 of this chapter and the notice review period has ended.

(vi) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (h)(2)(i)(A) of this section.

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and part 720 of this chapter within 15 days of receipt of the written notification under paragraph (h)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, or 17 of the Act.

(i) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period specified in paragraph (g) of this section, the submitter obtains possession, control, or knowledge of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must send that information to the address listed on the notice form within 10 days of receiving the new information, but no later than 5 days before the end of the notice review period. The new submission must clearly identify the submitter and the exemp-

tion notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(j) *Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.* (1) Except as provided in paragraph (j)(6) of this section, chemical substances manufactured under this section must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice under paragraph (e) of this section.

(2) Where the manufacturer lists a specific physical form in which the new chemical substance will be manufactured, processed, and/or used, the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the notice under paragraph (e), or in a physical form which will not increase the human exposure to or environmental release of the new chemical substance over those exposures or releases resulting from the specified physical form (e.g., a manufacturer which specifies that the new chemical substance will be produced in a non-volatile liquid form generally may not change to a respirable powder form).

(3) The annual production volume of chemical substances manufactured under paragraph (c)(1) of this section for which the manufacturer designated a binding annual production volume pursuant to paragraph (e)(2)(vi) of this section must not exceed that designated volume.

(4) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice for the substance, except as provided in paragraph (j)(6) of this section.

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(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice for the substance.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice for the substance.

(iv) Manufacturing the new chemical substance in a physical form different than that physical form approved in a previous exemption notice for the substance and which form may increase the human exposure to, or environmental release of, the new chemical substance over those exposures or releases resulting from the physical form approved in the previous notice.

(v) Manufacturing the chemical substance in annual production volumes above any volume designated by the manufacturer as binding under paragraph (e)(2)(vi) of this section in a previous exemption notice for the substance.

(5) In an exemption notice informing EPA of a change in site, use, or worker protection, or environmental release controls, the manufacturer is not required to provide all of the same information submitted to EPA in a previous exemption notice for that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, new worker protection or environmental release controls, and new use information. The notice must also include the EPA-designated exemption number assigned to the previous notice and a new certification by the manufacturer, as described in paragraph (e)(2)(xi) of this section.

(6)(i) A manufacturer may, without submitting a new notice, manufacture the new chemical substance at a site not listed in its exemption application under the following conditions:

(A) the magnitude, frequency, and duration of exposure of individual workers to the new chemical substance at the new manufacturing site is equal to, or less than, the magnitude, frequency, and duration of exposure of the individual workers to the new chemical

substance at the manufacturing site for which the EPA performed its original risk-assessment pursuant to the original exemption notice; and

(B) Either (1) at the new manufacturing site, the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or (2) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 part per billion, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described in paragraph (c)(2)(iii) of this section, using the water concentration calculation method described at §§ 721.90 and 721.91.

(ii) The manufacturer shall notify EPA of any new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the exemption at the new manufacturing site as follows:

(A) The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, and a statement that the notification is an amendment to the original exemption application under the terms of this section.

(B) The notification must be submitted electronically to EPA via CDX as a support document to the original notification. Prior to submission to EPA via CDX, such notices must be generated and completed using the e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software.

(k) *Customer notification.* (1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice at paragraph (e) of this section. The manufacturer must also inform processors and industrial

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users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in paragraph (c)(2) of this section are not likely to occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the new substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following:

(i) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in this section and the exemption notice under paragraph (e) of this section.

(ii) That, within 15 working days of notifying the customer of the non-compliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of this section and the exemption notice and will comply with those terms.

(4) If, after receiving a statement of assurance from a customer under paragraph (k)(3)(ii) of this section, the manufacturer obtains knowledge that the customer has again failed to comply with any of the conditions specified in this section or the exemption notice, the manufacturer shall cease supplying the new chemical substance to that customer and shall report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and

under what conditions, distribution of the chemical substance to the customer may resume.

(1) *Confidentiality.* (1) If the manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph (1) must provide a generic chemical name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the manufacturer will be subject to EPA review and approval in accordance with the procedures specified in § 720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice with all information claimed as confidential deleted. EPA will place the second copy in the public file.

(m) *Exemptions granted under superseded regulations.* Manufacturers holding exemptions granted under the superseded requirements of this section (as in effect on May 26, 1995) shall either continue to comply with those requirements (including the production volume limit) or apply for a new exemption pursuant to this section. EPA will not accept requests to amend exemptions granted under the superseded requirements; manufacturers wishing

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to amend such exemptions must submit a new exemption under paragraph (e) of this section. If a new exemption for a new chemical substance is granted under this exemption to the manufacturer holding an exemption under the superseded requirements, the exemption under the superseded requirements for such substance shall be void.

(n) *Recordkeeping.* (1) A manufacturer of a new chemical substance under paragraph (c) of this section must maintain the records described in this paragraph at the manufacturing site or site of importation for a period of 5 years after their preparation.

(2) The records must include the following to demonstrate compliance with this section:

(i) Records of annual production volume and import volume.

(ii) Records documenting compliance with the applicable requirements and restrictions of paragraphs (c), (e), (f), (h), (i), (j), and (k) of this section.

(3) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(2) of this section.

(4) The manufacturer must submit the records listed in paragraph (n)(2) of this section to EPA upon request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) *Compliance.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action

under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

[60 FR 16346, Mar. 29, 1995, as amended at 60 FR 34465, July 3, 1995; 62 FR 17932, Apr. 11, 1997; 64 FR 31989, June 15, 1999; 71 FR 33642, June 12, 2006; 75 FR 787, Jan. 6, 2010; 77 FR 46292, Aug. 3, 2012; 78 FR 72828, Dec. 4, 2013; 80 FR 42746, July 20, 2015; 87 FR 39769, July 5, 2022]

EFFECTIVE DATE NOTE: At 88 FR 37173, June 7, 2023, § 723.50 was amended by revising paragraph (1), effective Aug. 7, 2023. For the convenience of the user, the revised text is set forth as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

* * * * *

(1) *Confidentiality.* Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

* * * * *

§ 723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture and processing of new chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles. This section does not apply to microorganisms subject to part 725 of this chapter.

(2) To manufacture a new chemical substance under the terms of this exemption, a manufacturer of instant photographic or peel-apart film articles must:

(i) Submit an exemption notice when manufacture begins under paragraph (1) of this section.

(ii) Comply with certain requirements to limit exposure to the new chemical substance under paragraphs (e) through (h) of this section.

(iii) Comply with all recordkeeping requirements under paragraph (j) of this section.