Case No. 25-572
Consolidated with Cases No. 25-158 and 25-573

NOT SCHEDULED FOR ORAL ARGUMENT

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, AFL-CIO,
Petitioner,

v.

ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

On Petitions for Review of a Final Agency Action of the
United States Environmental Protection Agency
89 Fed.Reg. 102,773 (December 18, 2024)

OPENING BRIEF OF PETITIONER INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, AFL-CIO

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INTRODUCTION

The Toxic Substances Control Act (TSCA) requires the Environmental Protection Agency (EPA) to pre-approve the manufacture, import or distribution of new chemicals to ensure the chemicals do not pose unreasonable risks to workers or others. Congress intended this review process to be transparent. Unfortunately, EPA's procedures for approving such applications make it virtually impossible for workers or their representatives to know when their employers apply for premarket authorization or introduce new chemicals at their workplace, or when EPA has imposed occupational exposure controls as a condition of approving the application. Under TSCA, workers have a right to participate in the application review process, to know which chemicals they are exposed to, and to understand the precautions EPA requires their employers to adopt. EPA's current policies impede, rather than enhance, transparency and therefore are inconsistent with this goal.

This case involves EPA's revised procedural rules for approving new chemical and significant new use applications, entitled "Updates to New Chemicals Regulations Under the Toxic Substances Control Act," 89 Fed. Reg. 102773 (Dec. 18, 2024) (the Final Rule); ER-27.[1] In response to EPA's proposed

[1] EPA's rule applies to applications to manufacture a new chemical, referred to as a Pre Manufacture Notice (PMN), as well as notices of an intent to expand the use of the chemical, referred to as a significant new use notice (SNUN). *See* 89 Fed. Reg.

new chemicals rule, Petitioner United Automobile, Aerospace & Agricultural Implement Workers of America, AFL-CIO (UAW), joined with other Unions in submitting comments identifying the obstacles workers face to participate meaningfully in this approval process. The Unions also pointed out that neither EPA's then-existing nor its proposed rules provided workers with any practical means of obtaining information about the chemicals to which they may be exposed, the risks those chemicals may pose, or the occupational exposure controls EPA may require to mitigate those risks. In their comments, the Unions proposed that EPA require employers who submit a PMN to notify workers of that fact and to make a copy of the PMN available to workers or their designated representative, subject to a confidentiality agreement if needed. EPA ignored those comments.

The UAW challenges EPA's failure to consider and respond to the Unions' significant comments, which identified this key omission from EPA's rules and proposed a reasonable means of addressing it. The UAW asks this Court to direct EPA to require PMN submitters to disclose relevant information to potentially exposed workers or their representatives so they can meaningfully participate in EPA's PMN review and can know what occupational exposure controls EPA has mandated.

102773; ER-27. For convenience, we refer throughout this brief to Pre-Manufacture Notices (PMNs). The arguments the UAW raises apply equally to the approval process for both PMNs and SNUNs.

JURISDICTIONAL STATEMENT

This petition challenges EPA's Final Rule, issued on December 18, 2024, amending its procedural rules for processing new chemical applications. 89 Fed. Reg. 102773; ER-27. Jurisdiction over challenges to EPA's final rules lies in the U.S. courts of appeals pursuant to 15 U.S.C. § 2618(a)(1)(A). The UAW filed a timely petition for review in the U.S. Court of Appeals for the District of Columbia Circuit on January 10, 2025. *See* 40 C.F.R. § 23.5 (providing that the date of promulgation is two weeks after publication in the Federal Register). The United States Judicial Panel on Multidistrict Litigation transferred the UAW's petition to this Circuit pursuant to a Consolidation Order. MCP No. 196 (Jan. 27, 2025).

ISSUE FOR REVIEW

Whether the EPA's failure to respond to the Unions' substantive comments regarding the Agency's proposed rules was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," in violation of 5 U.S.C. § 706(2)(A) and 15 U.S.C. § 2618(c)(1)(B).

STATUTES AND REGULATIONS INVOLVED

Pursuant to Ninth Circuit Rule 28-2.7, the relevant statutes and regulations are contained in an addendum bound with this brief. Parallel citations to the addendum are noted as "Add. ___."

STATEMENT OF THE CASE

A. Statutory Background

Congress enacted TSCA to comprehensively regulate chemicals in commerce from their initial manufacture to ultimate disposal 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.'" *Safer Chemicals, Healthy Families v. EPA,* 943 F.3d 397, 406 (9th Cir. 2019) (*quoting* S. Rep. No. 94-698 at 1 (1976)). Of relevance here, TSCA requires companies to apply for EPA approval before they can begin manufacturing a "new chemical," *i.e.,* one that has not previously been made in or imported into the United States. 15 U.S.C. § 2604(a).[2] To enable EPA to determine the potential risks a chemical poses the application must detail how the chemical will be made, used, distributed and disposed of, and include available studies about its health and environmental effects and exposures. *Id.* § 2604(d)(1); 40 C.F.R. §§ 720.45, 720.50.

As enacted in 1976, TSCA gave EPA authority to require manufacturers to submit PMNs and to restrict how the chemicals could be used, if the agency found

[2] An entity that seeks approval to manufacture or import a new chemical must submit a PMN. The PMN submitter may be a parent or subsidiary of the entity that employs the employees who may be exposed to the chemical once it is manufactured. 40 C.F.R. §§ 720.22, 720.40(e). For convenience we refer to manufacturers but intend the term to include any PMN submitter.

a reasonable basis to believe the chemical "presents or will present" an unreasonable risk to health or the environment. Pub. L. No. 94-469 § 5(f)(1), 90 Stat. 2003, 2017 (1976). Under the 1976 TSCA, if, after 90 days, EPA failed to make such a finding – including if it lacked sufficient information to do so – the applicant could proceed to manufacture the chemical without any regulatory restrictions. *Id.*; *see* 15 U.S.C. § 2604 (e)(1), (f)(1) (2015).

Congress enacted comprehensive, bipartisan amendments to TSCA in 2016, in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016). The amendments significantly strengthened the premanufacture review process, making EPA's review of new chemical applications more robust. As amended, the statute requires the Agency to make an affirmative determination on every application before the submitter may begin manufacturing. 15 U.S.C. § 2604(a)(3)(C), (g). Congress also strengthened TSCA's transparency requirements by directing EPA "to make available to the public all notices, determinations, findings, rules, consent agreements and orders of the Administrator issued under this title." 15 U.S.C. § 2625(j)(1). The amended statute also provides limited protection for confidential business information (CBI). 15 U.S.C. § 2613. Congress struck "'a balance between protecting trade secrets and broadening access to information'" to better inform "'the general

public.'" *Environmental Defense Fund v. EPA,* 124 F.4th 1, 12 (D.C. Cir. 2024) (quoting S. Rep. No. 114-67, at 21).

TSCA now requires EPA, in evaluating PMNs, to assess whether the chemical is "likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(a)(3)(A), (C). The statute expressly includes workers as a "potentially exposed or susceptible subpopulation" whose risks the Agency must consider. *Id.* § 2602(12) (defining a potentially exposed subpopulation (PESS) that may be at greater risk due to greater exposure as including workers); *see also* 40 C.F.R. § 720.3 (defining PESS). To enable the Agency to evaluate potential risks posed by a new chemical, EPA requires PMN applications to include detailed information on potential occupational uses and exposures of new chemicals. 40 C.F.R. § 720.45 (g)(1)-(3); (h)(1)-(3).

The statute provides EPA with several options in evaluating PMNs. If the Agency determines, based on available information, that the chemical is "not likely to present an unreasonable risk," the applicant is entitled to "commence manufacture." 15 U.S.C. § 2604(a)(3)(C). If EPA finds that the chemical "presents an unreasonable risk," EPA must issue an order limiting or prohibiting its use "to the extent necessary to protect against such risk." *Id.* § 2604(a)(3)(A), (f). Finally,

if EPA has insufficient information to determine whether the chemical is likely to present an unreasonable risk or the available information suggests the chemical *may* pose an unreasonable risk, the Agency must issue an order, under Section 5(e), specifying the conditions under which the chemical may be manufactured. *Id.* § 2604(a)(3)(B), (e). EPA's "Section 5(e) orders" often specify workplace controls the applicant must implement as a condition of manufacturing the chemical. These orders are commonly referred to as "consent orders," as EPA often negotiates their terms with the PMN applicants.

Congress intended the new chemical review process to be transparent. The review process begins when EPA receives a PMN seeking EPA's approval to manufacture a new chemical. The statute provides that "[i]nformation submitted [as part of these applications] *shall* be made available . . . for examination by interested persons." *Id*. § 2604(b)(3) (emphasis added). To that end, the Agency must, within 5 days of receiving a PMN, publish a Federal Register notice informing the public of its receipt, identifying the chemical substance, listing its uses, and describing the tests performed on the substance. *Id.* § 2604(d)(2). EPA's Federal Register notices list the chemical name, the PNM case number EPA has assigned, the submitter's name (if not claimed as CBI), and the chemical's expected uses, and advise the public of its opportunity to comment on the pending

applications.[3] Although the PMN must identify the locations where the chemical will be produced, that information is not included in the Federal Register notice and, in any event, is often claimed as CBI.[4]

EPA must provide a PMN application to any interested person who wishes to examine it. *Id.* § 2604(d)(1) ("Such [PMN application] shall be made available . . . for examination by interested persons."). EPA regulations provide that "[a]ll information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential." 40 C.F.R. § 720.95. Finally, EPA must publish its findings on the applications in the Federal Register, 15 U.S.C. § 2604(g), and make them available to the public, *id.* §2625(j).

EPA is supposed to post the public file for each PMN on ChemView, the Agency's electronic database of new chemical information, but often fails to do so

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[3] *See, e.g.,* EPA, "Certain New Chemicals; Receipt and Status Information for March 2025," 90 Fed. Reg. 30929, 30931 (July 11, 2025); Add. 74-75; EPA, "Certain New Chemicals; Receipt and Status Information for February 2025," 90 Fed. Reg. 19298, 19300 (May 7, 2025); Add. 71-72. These two notices, neither of which are included in the Administrative Record, are cited for background information. As they are official EPA documents, we urge the Court to take judicial notice of these Federal Register notices and others cited in this brief. We have included all cited Federal Register notices in the Statutory and Regulatory Addendum attached to this brief.

[4] *See* notices listed in footnote 3, *supra.*

in a timely way. After EPA completes its review of the new chemical, if EPA issues a section 5(e) order imposing restrictions on how a chemical may be manufactured or used, that order is also supposed to be posted on ChemView. An individual can only access information on ChemView if they have either the name of the PMN submitter, the assigned case number, the chemical name and/or its proposed use. ChemView information cannot be accessed by facility location.[5]

While Congress mandated robust disclosure of information about new chemical applications, it also recognized the need to protect sensitive commercial information from public disclosure. S. Rep. No. 114-67 at 21; Add. 78.[6] Accordingly, when EPA makes a PMN application available to the public, it must withhold limited categories of CBI. *See* 15 U.S.C. § 2604(d)(1) (making disclosure of a PMN application "subject to section 2613 of this title"). *See also, id.* § 2613. The name of the submitter and the location where manufacture is expected is often denominated as CBI when EPA publishes the Federal Register notice that it has received a PMN and when it posts the information in the ChemView database.[7]

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[5] *See* www.ChemView.epa.gov/ChemView.

[6] S. Rep. 114-67 is the Committee Report that accompanied the version of the Lautenberg Act passed by the Senate in 2015, the relevant provisions of which were virtually identical to the final bill Congress passed in 2016.

[7] For example, of notices EPA listed as having been received in March 2025, the identity of seven of the 12 PMNs and both of the SNUNs were denominated "CBI." 90 Fed. Reg. at 30931; Add. 75 (case numbers beginning with "P" are

B. The Regulatory Process

I. EPA's Proposed Rule

In 2023, EPA published a proposal to "align" its procedural rules for reviewing new chemicals and chemicals with significant new uses with TSCA's 2016 amendments. EPA, "Updates to New Chemical Regulations under the Toxic Substances Control Act (TSCA): Proposed Rule," 88 Fed. Reg. 34100 (May 26, 2023) (Proposed Rule); ER-1. EPA intended the new rules to "improve the effectiveness and efficency [its new chemical] reviews." *Id.* at 34101; ER-2. Recognizing that workers would be the first group exposed to a new chemical's health effects, EPA's proposal required PMN submitters to provide "detailed information about the possible worker exposure at each site controlled by the

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PMNs; those beginning with "SN" are SNUNs). EPA listed the identity of the submitters for eight of the thirteen PMNs and all five of the SNUNs it received in February 2025 as CBI. 90 Fed. Reg. at 19300; Add. 72. EPA also posts lists of PMNs for which EPA received notices that manufacturing commenced and where test information has been received and determined to be complete, but these are listed only by the case number, with no other identifying information. *See* 90 Fed. Reg. at 30932 and 90 Fed. Reg. at 19301; Add. 73, 76.

Many CBI claims may prove overbroad. EPA's review of CBI claims, however, occurs long after the Agency is required to publish notice that it has received a PMN. *Compare* 15 U.S.C. § 2604(d)(2) (requiring publication after 5 days of receipt) w*ith id.* § 2613(g)(1)(A) and (D) (providing 90 days for Administrator to act on CBI request, but providing that failure to act does not constitute a denial). So, even if EPA later reverses the submitter's claim that its identity is CBI, that decision comes too late to allow meaningful participation in the new chemical review process.

submitter . . . and at each site not controlled by the submitter." *Id.* at 34108; ER-9. The detailed information included – for all sites where the chemical would be used – the type of worker activity, the types and duration of potential exposures, engineering controls and protective equipment in place, and the number of workers potentially exposed. *Id.* at 34120-21, ER-21-22; Proposed § 720.45(g)(3) (for sites controlled by the submitter); § 720.45(h)(3) (for sites not controlled by the submitter). EPA invited interested parties to comment on its proposal. 88 Fed. Reg. at 34101; ER-2.

II. The UAW's Experience and the Unions' Comments

The UAW represents approximately 1 million active and retired members in North America, with members in almost every sector of the economy, including corporations of all sizes engaged in manufacturing. These members are routinely exposed to toxic chemicals in their workplaces and are vitally interested in knowing the identity of these chemicals, their potential toxicity, and all legal obligations their employers must follow to ensure their safe use. The UAW is actively involved in monitoring the inventory of chemicals to which their members are exposed and engaging with their employers and public officials in ensuring

they have safe working environments. Declaration of Darius Sivin, PhD. ("Sivin Decl.) ¶ 3; Add. 79.[8]

In response to EPA's proposed rule, the UAW filed comments jointly with the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) and the United Steelworkers (the Union Comments). The comments were informed, in part, by the UAW's experience in attempting to secure information about the health hazards facing the employees in one of its bargaining units.[9]

[8] The Union Comments, Ex. 63 in the Administrative Record filed by EPA (Dckt. No. 14) and included in the Excerpts of Record filed with this brief (ER-55), describe an incident where a union was left in the dark about the filing of a PMN and a "consent order" EPA issued about workplace requirements for the new chemical. Union Comments at 3-4, ER 57-58. The Declaration of Darius Sivin, included in the Addendum to this brief, demonstrates that the UAW was the union involved in the incident described in the Union Comments and is offered for two purposes. First, the declaration establishes that the UAW and its members were injured in fact by EPA's current lack of transparency surrounding new chemicals to which they are exposed. Second, the declaration elaborates on the circumstances, described in Union Comments to EPA included in the record, which precipitated the union's involvement in the new chemical review process under TSCA. Petitioner UAW has separately filed a motion to supplement the record by including Dr. Sivin's declaration in the record before this Court. (Dkt. 21.1).

[9] The UAW ultimately secured information about the chemicals discussed in this section after Dr. Sivin signed a confidentiality agreement insisted upon by the employer. In accord with that agreement, we are not disclosing any information that would identify either the company or the chemicals. *See* Sivin Decl. at ¶ 8; Add. 82.

During a plant walkthrough preceding contract negotiations, a company health and safety official mentioned to a union representative that "consent orders" covered two new chemicals the company had introduced in the process. Sivin Decl. ¶ 5; Add. 80-81.[10] The official described the chemicals but did not disclose their names. Exercising its rights to obtain information relevant to its representational role under the National Labor Relations Act (NLRA), 29 U.S.C. §158, the UAW requested a copy of the consent orders. Sivin Decl. ¶ 6; Add. 81.[11] The company refused, claiming the Section 5(e) orders were confidential. *Id.* As required by the Occupational Safety and Health Administration's (OSHA's) Hazard Communication Standard, 29 C.F.R. § 1910.1200, the company did provide the union with a copy of the chemicals' safety data sheets (SDSs). However, the company redacted the name of one of the chemicals on the SDS, claiming it as CBI. Sivin Decl. ¶ 6; Add. 81.

A UAW representative – an individual with a PhD, far more able to conduct this kind of search than rank-and-file union members – then tried to use

[10] As noted earlier, orders EPA issues under Section 5(e), 15 U.S.C. § 2604(e) – governing how a new chemical may be manufactured, including occupational exposure control requirements – are often referred to as "consent orders."

[11] While an employer's duty to bargain in good faith under the NLRA may provide a union with access to health and safety information necessary for collective bargaining, *see* 29 U.S.C. § 158(a)(5), (d), it provides no access to information for individual workers who are not represented by a union.

ChemView to obtain information on the chemical and a copy of the consent order issued under TSCA section 5(e). When the industrial hygienist searched by the name of the company that employed the UAW members, he got no results. He has since learned that the PMN submitter was not the company that employed the UAW members, but rather, its parent company, and that it had designated its identity as CBI. The search category of "use" proved unhelpful, and he did not have the chemical name. Ultimately, he was unable to find any information about these two chemicals on ChemView. *Id*. ¶ 7; Add. 81-82. [12]

In light of this experience, but also mindful of TSCA's CBI protections, the UAW joined other unions in submitting comments to EPA. In their comments, the Unions proposed specific measures that would readily satisfy Congress' twin goals: EPA could require transparency by mandating that PMN submitters disclose to the affected workers and their representatives (1) the fact that a PMN had been filed; (2) the contents of any PMN application or the PMN number assigned by EPA; and (3) any order EPA issued requiring occupational exposure controls to protect workers from the hazards the new chemical poses. Union Comments at 6; ER-60. These disclosures would provide workers or their representatives with the PMN number, a key piece of information they could use to

[12] A more recent search to help prepare this brief revealed one of the two PMN applications referred to above. *Id.*

search ChemView for additional information about the PMN application. Without timely receipt of such information, workers and their representatives cannot engage with EPA concerning what occupational exposure controls the Agency should require in any Section 5(e) order it may issue. To address the confidentiality interests Congress embedded in TSCA, the Unions proposed that EPA include a provision authorizing a practice routinely followed when employers disclose sensitive information under the NLRA and permitted by OSHA's Hazard Communication standard, 29 C.F.R. § 1910.1200(i)(3): making these disclosures to the union or their employees contingent on their agreeing to confidentiality protections. Union Comments at 8; ER-62. The Unions also urged EPA to require the submitter/employer to post any Section 5(e) order in any workplace where there are potentially exposed employees. *Id*.

The Unions supported their proposals by detailing specific problems they had encountered in securing any information about pending PMNs or resulting Section 5(e) orders – problems that undermined Congress' transparency objective -- and by explaining how their proposal was consistent with TSCA and with practices routinely followed under other statutory schemes. *Id.* at 3-5, 9; ER-57-59, 63. The Unions thus identified a significant problem in the proposed rule that undermined Congress' statutory intent and proposed a solution that satisfied

Congress' interests both in promoting transparency and in preserving confidential business information.

III. The Final Rule

EPA issued its Final Rule on December 18, 2024. The Agency acknowledged receiving 51 public comments on its proposed rule from stakeholders, including unions, and noted that while it was responding to many of the comments in the Rule's preamble, "the more comprehensive version of EPA's response" was "in the Response to Comments document." 89 Fed. Reg. at 102775; ER-29. However, nowhere in either the preamble or the Response to Comments did EPA respond to, or even mention, the Unions' Comments. Nor did EPA in any way modify its proposal to reflect the issues the Unions raised.

STANDARD OF REVIEW

The Court must set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); 15 U.S.C. § 2618(c)(1)(B). Agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm,* 463 U.S. 29, 43 (1983).

SUMMARY OF THE ARGUMENT

TSCA requires manufacturers to secure EPA's approval before they begin manufacturing or using new chemicals. Congress embedded twin goals in TSCA's

new chemical approval provisions: promoting transparency in the review process and protecting the submitters' confidential business information. In response to EPA's proposed new chemical procedures, Petitioner UAW joined with other unions in filing comments with the Agency, pointing out that both its then-existing and its proposed rules failed to satisfy the statute's objective of providing a transparent process for workers potentially exposed to the new chemicals, a group whose exposures TSCA specifically directs EPA to consider in determining whether a new chemical presents an unreasonable risk. 15 U.S.C. §§ 2602, 2604(a)(3). The Union proposal called for EPA to require PMN submitters to disclose that an application had been filed with EPA and, pursuant to a confidentiality agreement, to provide the affected workers and their representatives with relevant information about the application so they could engage with EPA if they chose to do so.

In issuing its Final Rule, EPA completely ignored the Unions' proposals, neither addressing them in responses to the comments the Agency received during the rulemaking process nor in any way modifying its proposal to reflect the concerns the Unions raised. As a result, EPA's current new chemical procedures make worker or union participation in the new chemical review process virtually impossible.

The law is clear that in conducting notice and comment rulemaking, agencies must respond to significant comments that raise relevant points and would require a change in the rule if adopted. *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015); *Safari Aviation Inc. v. Garvey*, 300 F.3d 1144, 1151 (9th Cir. 2002). By ignoring the Unions' relevant, significant points in developing its new chemical regulation, EPA violated the Administrative Procedure Act (APA). This court should remand the Final Rule to EPA and require the Agency to adopt procedures that ensure workers and their representatives have an opportunity for meaningful participation in the review of new chemicals to which they, or their members, will be exposed.

ARGUMENT

A. EPA's Proposed Rules Failed to Satisfy Congress' Intent that New Chemical and Significant New Use Reviews be Transparent.

Congress intended the new chemical review process to be transparent. 15 U.S.C. § 2625(j). As EPA itself acknowledged long ago, "Congress intended information on uses of new substances to be published so that the public can estimate the types and extent of potential human and environmental exposures to substances." EPA, "Premanufacture Notification Requirements and Review Procedures," 44 Fed. Reg. 2242, 2253 (Jan. 10, 1979); Add. 67-68. This disclosure, moreover, was not purely for informational purposes. Instead, Congress intended

that, "[w]ith an understanding of likely exposure, the public more effectively may exercise its opportunities for participating in review of chemical risks." *Id.* Congress' 2016 amendments reinforced that statute's purpose in "maximiz[ing] public availability of health and environmental information relating to chemical substances in commerce." S. Rep. No. 114-67 at 21; Add. 78.

The UAW's experience makes clear that EPA's current procedures fail to make the new chemical review process transparent to workers. EPA's current methods of disclosure – either by publishing a Federal Register notice that it has received a PMN or by including such information in ChemView – do not provide workers with timely access to information and effectively prevent meaningful participation in the new chemical process. Many companies submitting a PMN routinely claim their identity as CBI.[13] The submitter is often not the actual employer whose employees will be exposed to the chemical, either because the submitter is a parent company or the chemical will be produced at a site the submitter does not control. 40 C.F.R. § 720.45(h) (information required "for sites not controlled by the submitter"). Although EPA requires submitters to include that information in the application, 40 C.F.R. § 720.45 (g)(1), (h)(1), it is often

[13] *See* note 7, *supra* (seven of the 12 PMNs and both of the SNUNs submitted in March 2025 and eight of the 13 PMNs and all five of the SNUNs received in February 2025 claimed the submitter's identity as CBI).

claimed as CBI. Moreover, in no case does the Federal Register notice include the location of the facility where the chemical will be produced.

While many workers are concerned about chemical exposures generally, they are particularly concerned about *occupational* exposure in the facility where they work. Without access to information about *who* may produce a new chemical and *where* it may be manufactured, potentially exposed workers and their unions cannot – as a practical matter – engage with EPA before the Agency imposes *occupational* controls that may or may not adequately protect the workers. EPA's disclosures about new chemicals do not routinely include these two key factual components – employer name and location – since the employer is not necessarily the submitter, the submitter's name is often claimed as CBI, and facility location is not among the fields that can be searched in ChemView. As the court observed in *Environmental Defense Fund v. Regan,* Case No. 1:20-cv-762, 2024 WL 3887383, at *7, (D.D.C. Aug. 20, 2024), "the public cannot comment on an application it does not know exists."

The same problem exists with respect to EPA's so-called "Section 5(e) orders," which often include occupational exposure control requirements as a condition of manufacturing a new chemical. As the UAW's experience illustrates, the lack of disclosure means a union's members can be exposed to a chemical, perhaps for years, without knowing the chemical's identity or even that EPA has

mandated worker protections. Thus, although the Section 5(e) order may legally obligate a company to take specific steps to protect its employees from occupational exposures to a chemical, employees are unlikely to learn what protective measures are required unless their employer voluntarily discloses them, even though TSCA requires disclosure of such orders. 15 U.S.C. §2625(j).

Neither workers nor their unions are likely regularly to scour the Federal Register to determine whether their employer is attempting to introduce a new chemical into their manufacturing processes. Even if they did – something we submit would be an unreasonable expectation – the scant and cryptic information in EPA's notices is unlikely to alert workers that their employer is seeking or had secured approval to produce a new chemical at the facility where they are employed. Were factory workers to scan ChemView – also an unrealistic expectation – they would still be unlikely to find information on whether their employer had sought or been granted permission to produce a new chemical at the plant where they work, and most importantly, any occupational controls EPA has mandated. Thus, if workers, or their representative, want to engage with EPA before the Agency decides whether to approve manufacturing or processing of a new chemical and before it decides what, if any, occupational exposure controls are needed to eliminate the risks the chemical may pose to workers, they face insurmountable barriers to doing so.

There can be no doubt that Unions have a particular interest in the identity of the toxic substances to which the workers they represent may be exposed. Unions have the right under the NLRA to bargain with employers over safety and health conditions in their workplaces. *Oil, Chemical & Atomic Workers Local Union No. 6-418 v. NLRB*, 711 F.2d 348, 360 (D.C. Cir. 1983) ("Employee health and safety indisputably are mandatory subjects of collective bargaining"); *NLRB v. Gulf Power Co.,* 384 F.2d 822, 825 (5th Cir. 1967) (same). This includes the right to information about the chemicals manufactured or processed where they represent potentially exposed workers. Unions also routinely engage in regulatory processes to advance their members' interests in ensuring safe work. As the representative of those working in a facility where a new chemical will be used, unions can bring important insights to EPA's new chemicals review process. Even when unions employ professionals who are better equipped than rank-and-file members to peruse the Federal Register or to try to access information through ChemView, the UAW's experience demonstrates that those sources often fail to reveal the information the representatives need to participate in the PMN review process, to monitor workplace conditions, or to exercise their representational rights to request safety and health information from the employer.

EPA has acknowledged that Congress intended "strong citizen involvement" in the new chemical and significant new use review process, which is "impossible

if the maximum amount of information is not made available to the public." EPA, "Reproposal of Premanufacture Notice Form and Provisions of Rules," 44 Fed. Reg. 59764, 59774 (Oct. 16, 1979); Add. 69-70. Instead, it is only "[w]ith an understanding of likely exposure [that] the public more effectively may . . . exercise its opportunities for participating in the review of chemical risks." EPA, "Premanufacture Notification Requirements and Review Procedures," 44 Fed. Reg. at 2253; Add. 68. *Cf., Wilderness Society, Inc. v. Rey,* 622 F.3d 1251, 1259 (9th Cir. 2010) ("Congress's purpose in mandating notice [in a rulemaking proceeding]" is "to allow the public opportunity to comment on the proposals."). Yet, EPA's new chemical review process is nowhere near "transparent" for workers, a population whose exposures EPA is mandated to consider in reviewing new chemical applications, or for the unions that represent those workers.

B. The Unions Filed Significant Comments Alerting EPA that the New Chemical Process Failed to Fulfill TSCA's Statutory Purpose and Proposing a Reasonable Solution.

In their comments on EPA's new chemical proposal, the Unions detailed their concerns about the lack of transparency in EPA's existing procedural rules, problems they believed the proposed amendments did not address. Noting that EPA's new chemical review and evaluation was not intended to be solely a two-way conversation between EPA and the submitter, the Unions proposed a

mechanism through which EPA could require information disclosure to unions or workers without compromising employer confidentiality.

In particular, the Unions proposed that before EPA approves the manufacture of a new chemical, the Agency require any submitter to certify that it

> (1) notif[ied] affected workers and their authorized representative, if there is one, that an application to manufacture . . . a [new] chemical has been filed; (2) ma[de] the application and supporting data available to workers or their authorized representative for review upon request, subject to confidentiality protections . . . ; and (3) ensure[d] that potentially exposed workers and their representatives ha[d] an opportunity to comment on any evaluation or risks or draft Section 5(e) orders before they [were] finalized.

Union Comments at 6; ER-60. The Unions also proposed that EPA require the submitter/employer to post any Section 5(e) order in any workplace where there were affected employees. *Id.*

To ensure the confidentiality of commercially sensitive information, the Unions proposed that, as a condition to this disclosure, EPA permit the employer submitting a PMN application to insist on a non-disclosure agreement from the requesting worker or their designated representative. The Unions explained that their proposed system would further TSCA's goal of making the PMN application and its supporting documentation "available . . . for examination by interested persons," 15 U.S.C. § 2604(b)(3), without putting CBI at risk of disclosure. Union Comments at 6; ER-60. The Union proposal mirrors the existing requirements of OSHA's Hazard Communication standard. 29 C.F.R.§ 1910.1200(i)(3).

TSCA Section 14 prohibits EPA from disclosing CBI submitted to the Agency. 15 U.S.C. § 2613. To be protected as CBI under TSCA, the submitter claiming CBI protection must demonstrate that the information meets both: (1) the test for CBI under Exemption 4 of Freedom of Information Act (FOIA); and (2) the additional CBI requirements of TSCA. 15 U.S.C. § 2613(a), (c) (establishing TSCA's CBI requirements).

While Section 14, like FOIA Exemption 4, allows EPA to withhold confidential information submitted *to the federal government, cf, Center for Investigative Reporting v. DOL,* 145 F.4th 1211, 1217-21 (9th Cir. 2025) (interpreting FOIA exemption 4), neither Exemption 4 nor TSCA Section 14 prohibits EPA from mandating third party disclosure of CBI.[14] Indeed, the Supreme Court has recognized the distinction between reporting rules – which require third parties to provide information to the government – and disclosure rules – which require third parties to disclose information to others. *See Dole v. United Steelworkers,* 494 U.S. 26, 33 (1990) (interpreting the Paperwork Reduction Act). Nothing in TSCA prohibits EPA from adopting a rule requiring PMN submitters to disclose information about their application and any resulting

[14] In fact, TSCA permits EPA to disclose confidential information with non-disclosure agreements to health care professionals. 15 U.S.C. § 2613(d)(5)-(6). And Section 14(d)(8) exempts from the statute's confidentiality requirements information that "is required to be made public under any other provision of Federal law." *Id.* § 2613(d)(8).

occupational exposure control requirements to the affected workers. Indeed, Congress directed that such information be publicly available. 15 U.S.C. § 2625(j).

The Third Circuit was required to balance the need for disclosure of chemical information to exposed workers against their employer's confidentiality concerns when it reviewed OSHA's Hazard Communication Standard. *See United Steelworkers v. Auchter*, 763 F.2d 728, 740 (3d Cir. 1985) (provision barring OSHA from disclosing trade secrets deals only with disclosure by the Agency or its employees). As is the case here, OSHA was required to weigh the interests of chemical manufacturers in maintaining the confidentiality of chemical identity information against a workers' right to know the chemicals to which they may be exposed. OSHA had initially struck that balance by "declin[ing] . . . to authorize direct employee access to specific chemical identities of hazardous substances for which a trade secret is claimed." *Id.* at 742. The Third Circuit rejected that decision, instead directing OSHA to permit direct employee access to claimed trade secret information if the workers signed a confidentiality agreement, writing that "confidentiality agreements are a well-accepted traditional means of allowing access to trade secret information while effectively protecting the owners of that information from irreparable harm." *Id.* at 743.

Workers and their collective bargaining agents routinely have access to or are provided with confidential business information in other contexts as well.

Although EPA may consider process information to be CBI, *see* 15 U.S.C. § 2613(c)(2), workers are usually familiar with the manufacturing processes in the facility where they work. Likewise, although financial information about corporate profits may generally be considered CBI, unions are commonly granted access to such information when employers make costs an issue during collective bargaining. *NLRB v. Truitt Mfg.*, 351 U.S. 149, 152-53 (1956) (employers are obligated to provide financial information relevant to their bargaining positions). Moreover, under the NLRA, unions have a right to information related to their role as the employees' representative in dealing with employers on terms and conditions of employment, including safety and health conditions in the workplace. *Gulf Power Co.,* 384 F.2d at 824 (safety and health conditions are mandatory subjects of bargaining: "It is inescapable that … workers, through their chosen representative, should have the right to bargain with the Company in reference to safe work practices").

In their comments, the Unions pointed out that in all these contexts, they routinely enter into confidentiality agreements with the employers as a condition of receiving the information to which they are entitled. The Unions proposed that EPA take the same approach as part of its procedure for evaluating new chemical applications: requiring the applicants to notify their affected employees that they are submitting the applications and to make the applications, the supporting

studies, EPA's risk evaluation and any resulting Section 5(e) orders available to workers and their unions on request, contingent on the requester agreeing to confidentiality protections. Union Comments at 8; ER-62. The Unions' proposal was consistent with Congress' intent to "strik[e] a balance between protecting trade secrets . . . and broadening access to information on chemicals" to "maximize public availability of health and environmental information relating to chemical substances in commerce." S.Rep. 114-67 at 21; Add. 78.

C. EPA's Failure to Respond to the Union Proposal Is Arbitrary and Capricious.

An agency violates the APA when it ignores an important aspect of a regulatory problem. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (holding that agency rules are arbitrary and capricious where an Agency fails to consider an important aspect of the problem). When engaged in notice-and-comment rulemaking, an agency must respond to significant comments that raise relevant points and would require a change in the rule if adopted. *Perez*, 575 U.S. at 96; *Safari Aviation Inc.*, 300 F.3d at 1151.

Here, the Union Comments highlighted the fact that EPA's new chemical process created an important problem: that despite Congress' intent, the process was completely opaque to affected workers, effectively preventing them and their representatives from participating in agency decisions affecting their workplace.

The Union Comments addressed the problem by proposing a modification of EPA's proposed rule that "would resolve any tension between EPA's interest in bringing greater transparency and public participation into the new chemicals and significant new use approval process and the submitters' legitimate interests in protecting their [CBI]," while also providing affected employees with "information necessary to participate meaningfully in the review process and to monitor implementation of protective processes in their workplaces." Union Comments at 8; ER-62. In particular, the Unions proposed that EPA require submitters to offer to make relevant information about their PMNs available to their workers and/or the workers' unions, with disclosure contingent on confidentiality agreements. And the Unions explained that this system would mirror both existing OSHA requirements and practices unions and employers commonly follow in collective bargaining.

EPA was not entitled to ignore the Unions' proposal. The Unions presented EPA with detailed significant comments that raised a significant problem: that the proposed rule "did not, in fact, serve the purposes . . . set out in the statute." *Altera Corp. & Subsidiaries v. Comm'r*, 926 F.3d 1061, 1082 (9th Cir. 2019) ("An example" of a sufficiently detailed significant comment, which raises a significant problem that requires a response, is if the comment highlights how the proposed rule "did not in fact, serve the purposes . . . set out in the statute.") (citing

American Mining Congress v. EPA, 965 F.2d 759, 771 (9th Cir. 1992)). And the Unions proposed specific, valid measures the Agency could implement to address this problem. Yet, EPA completely ignored the Union Comments. The Agency's failure to respond to the Unions' significant comment was arbitrary and capricious, in violation of the APA.

CONCLUSION

For the foregoing reasons, the UAW asks this Court to direct EPA to require Pre-Manufacture Notice (PMN) submitters to disclose relevant information to potentially exposed workers or their representatives so they can meaningfully participate in EPA's PMN review and know what occupational exposure controls EPA has mandated.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of October, 2025, I caused a true and correct copy of the foregoing Brief of Petitioner International Union, UAW, to be filed electronically with the Clerk of the Court using the Case Management and Electronic Case Files ("CM/ECF") system for the Ninth Circuit. Participants in the case will be served by the CM/ECF system.

/s/ Victoria L. Bor
Victoria L. Bor

ADDENDUM

ADDENDUM

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15 U.S.C.A. § 2602

§ 2602. Definitions

Currentness

As used in this chapter:

(1) the [1] term "Administrator" means the Administrator of the Environmental Protection Agency.

(2)(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including--

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

(B) Such term does not include--

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(3) The term "commerce" means trade, traffic, transportation, or other commerce (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A).

(4) The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(5) The terms "distribute in commerce" and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(6) The term "environment" includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

(7) The term "guidance" means any significant written guidance of general applicability prepared by the Administrator.

(8) The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.

(9) The term "manufacture" means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture.

(10) The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

(11) The term "new chemical substance" means any chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) of this title.

(12) The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

(13) The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce--

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.

(14) The term "processor" means any person who processes a chemical substance or mixture.

(15) The term "protocols and methodologies for the development of information" means a prescription of--

(A) the--

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which information for a chemical substance or mixture are to be developed and any analysis that is to be performed on such information, and

(B) to the extent necessary to assure that information respecting such effects and characteristics are reliable and adequate--

(i) the manner in which such information are [2] to be developed,

(ii) the specification of any test protocol or methodology to be employed in the development of such information, and

(iii) such other requirements as are necessary to provide such assurance.

(16) The term "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(17) The term "United States", when used in the geographic sense, means all of the States.

CREDIT(S)

(Pub.L. 94-469, Title I, § 3, Oct. 11, 1976, 90 Stat. 2004; Pub.L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 100-418, Title I, § 1214(e)(1), Aug. 23, 1988, 102 Stat. 1156; Pub.L. 114-92, Div. A, Title III, § 315, Nov. 25, 2015, 129 Stat. 791; Pub.L. 114-182, Title I, §§ 3, 19(c), June 22, 2016, 130 Stat. 448, 505.)

Notes of Decisions (5)

Footnotes

1 So in original. Probably should be capitalized.

2 So in original. Probably should be "is".

15 U.S.C.A. § 2602, 15 USCA § 2602
Current through P.L. 119-36. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2604

§ 2604. Manufacturing and processing notices

Currentness

(a) In general

(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may--

(i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or

(ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

(B) A person may take the actions described in subparagraph (A) if--

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator--

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including--

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Review and determination

Within the applicable review period, subject to section 2617 of this title, the Administrator shall review such notice and determine--

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) Failure to render determination

(A) Failure to render determination

If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) of this title, and the Administrator shall not be relieved of any requirement to make such determination.

(B) Limitations

(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) Article consideration

The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) Submission of information

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit information for such substance pursuant to a rule, order, or consent agreement under section 2603 of this title before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If--

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule or order under section 2603 of this title before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A)(ii).

(2)(A) If a person--

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule, order, or consent agreement under section 2603 of this title before the submission of such notice to submit information for such substance,

such person may submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes shows that--

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A)(i), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(A)(ii), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) shall be made available, subject to section 2613 of this title, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including--

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of Title 5.

(c) Extension of review period

The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b). Subject to section 2613 of this title, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) Content of notice; publications in the Federal Register

(1) The notice required by subsection (a) shall include--

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information under subsection (b), the Administrator shall publish in the Federal Register a notice which--

(A) identifies the chemical substance for which notice or information has been received;

(B) lists the uses of such substance identified in the notice; and

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 2603 of this title.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the applicable review period has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

(e) Regulation pending development of information

(1)(A) If the Administrator determines that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

(B) An order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the applicable review period, and (ii) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(2) Repealed. Pub.L. 114-182, Title I, § 5(5)(D), June 22, 2016, 130 Stat. 458

(f) Protection against unreasonable risks

(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)--

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(3)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(4) Treatment of nonconforming uses

Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) Workplace exposures

To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

(g) Statement on Administrator finding

If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) Exemptions

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes--

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that--

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information on such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)--

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2613

§ 2613. Confidential information

Currentness

(a) In general

Except as provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of Title 5 by reason of subsection (b)(4) of that section--

(1) that is reported to, or otherwise obtained by, the Administrator under this chapter; and

(2) for which the requirements of subsection (c) are met.

In any proceeding under section 552(a) of Title 5 to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

(b) Information not protected from disclosure

(1) Mixed confidential and nonconfidential information

Information that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure.

(2) Information from health and safety studies

Subsection (a) does not prohibit the disclosure of--

(A) any health and safety study which is submitted under this chapter with respect to--

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or

(ii) any chemical substance or mixture for which testing is required under section 2603 of this title or for which notification is required under section 2604 of this title; and

(B) any information reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the disclosure of any information, including formulas (including molecular structures) of a chemical substance or mixture, that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(3) Other information not protected from disclosure

Subsection (a) does not prohibit the disclosure of--

(A) any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges; or

(B) a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(4) Bans and phase-outs

(A) In general

If the Administrator promulgates a rule pursuant to section 2605(a) of this title that establishes a ban or phase-out of a chemical substance or mixture, the protection from disclosure of any information under this section with respect to the chemical substance or mixture shall be presumed to no longer apply, subject to subsection (g)(1)(E) and subparagraphs (B) and (C) of this paragraph.

(B) Limitations

(i) Critical use

In the case of a chemical substance or mixture for which a specific condition of use is subject to an exemption pursuant to section 2605(g) of this title, if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any conditions of use of the chemical substance or mixture to which the exemption does not apply.

(ii) Export

In the case of a chemical substance or mixture for which there is manufacture, processing, or distribution in commerce that meets the conditions of section 2611(a)(1) of this title, if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any other manufacture, processing, or distribution in commerce of the chemical substance or mixture for the conditions of use subject to the ban or phase-out, unless the Administrator makes the determination in section 2611(a)(2) of this title.

(iii) Specific conditions of use

In the case of a chemical substance or mixture for which the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to a specific condition of use of the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to the condition of use of the chemical substance or mixture for which the ban or phase-out is established.

(C) Request for nondisclosure

(i) In general

A manufacturer or processor of a chemical substance or mixture subject to a ban or phase-out described in this paragraph may submit to the Administrator, within 30 days of receiving a notification under subsection (g)(2)(A), a request, including documentation supporting such request, that some or all of the information to which the notice applies should not be disclosed or that its disclosure should be delayed, and the Administrator shall review the request under subsection (g)(1)(E).

(ii) Effect of no request or denial

If no request for nondisclosure or delay is submitted to the Administrator under this subparagraph, or the Administrator denies such a request under subsection (g)(1)(A), the information shall not be protected from disclosure under this section.

(5) Certain requests

If a request is made to the Administrator under section 552(a) of Title 5 for information reported to or otherwise obtained by the Administrator under this chapter that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of Title 5.

(c) Requirements for confidentiality claims

(1) Assertion of claims

(A) In general

A person seeking to protect from disclosure any information that person submits under this chapter (including information described in paragraph (2)) shall assert to the Administrator a claim for protection from disclosure concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this subchapter.

(B) Inclusion

An assertion of a claim under subparagraph (A) shall include a statement that the person has--

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(C) Additional requirements for claims regarding chemical identity information

In the case of a claim under subparagraph (A) for protection from disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall--

(i) be consistent with guidance developed by the Administrator under paragraph (4)(A); and

(ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure--

(I) that are claimed as confidential; and

(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

(2) Information generally not subject to substantiation requirements

Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(B) Marketing and sales information.

(C) Information identifying a supplier or customer.

(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

(F) Specific production or import volumes of the manufacturer or processor.

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

(3) Substantiation requirements

Except as provided in paragraph (2), a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section.

(4) Guidance

The Administrator shall develop guidance regarding--

(A) the determination of structurally descriptive generic names, in the case of claims for the protection from disclosure of specific chemical identity; and

(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (d).

(5) Certification

An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B), and any information required to substantiate a claim submitted pursuant to paragraph (3), are true and correct.

(d) Exceptions to protection from disclosure

Information described in subsection (a)--

(1) shall be disclosed to an officer or employee of the United States--

(A) in connection with the official duties of that person under any Federal law for the protection of health or the environment; or

(B) for a specific Federal law enforcement purpose;

(2) shall be disclosed to a contractor of the United States and employees of that contractor--

(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this chapter; and

(B) subject to such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use;

(4) shall be disclosed to a State, political subdivision of a State, or tribal government, on written request, for the purpose of administration or enforcement of a law, if such entity has 1 or more applicable agreements with the Administrator that are consistent with the guidance developed under subsection (c)(4)(B) and ensure that the entity will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information;

(5) shall be disclosed to a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation if such person provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that--

(A) the statement of need and confidentiality agreement are consistent with the guidance developed under subsection (c)(4)(B);

(B) the statement of need shall be a statement that the person has a reasonable basis to suspect that--

(i) the information is necessary for, or will assist in--

(I) the diagnosis or treatment of 1 or more individuals; or

(II) responding to an environmental release or exposure; and

(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

(C) the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person who has a claim under this section with respect to the information;

(6) shall be disclosed in the event of an emergency to a treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder (including any individual duly authorized by a Federal agency, State, political subdivision of a State, or tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) if such person requests the information, subject to the conditions that such person shall--

(A) have a reasonable basis to suspect that--

(i) a medical, public health, or environmental emergency exists;

(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

(B) if requested by a person who has a claim with respect to the information under this section--

(i) provide a written statement of need and agree to sign a confidentiality agreement, as described in paragraph (5); and

(ii) submit to the Administrator such statement of need and confidentiality agreement as soon as practicable, but not necessarily before the information is disclosed;

(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this chapter, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding;

(8) shall be disclosed if the information is required to be made public under any other provision of Federal law; and

(9) shall be disclosed as required pursuant to discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law.

(e) Duration of protection from disclosure

(1) In general

Subject to paragraph (2), subsection (f)(3), and section 2607(b) of this title, the Administrator shall protect from disclosure information described in subsection (a)--

(A) in the case of information described in subsection (c)(2), until such time as--

(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or

(ii) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g); and

(B) in the case of information other than information described in subsection (c)(2)--

(i) for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator; or

(ii) if applicable before the expiration of such 10-year period, until such time as--

(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or

(II) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g).

(2) Extensions

(A) In general

In the case of information other than information described in subsection (c)(2), not later than the date that is 60 days before the expiration of the period described in paragraph (1)(B)(i), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

(B) Request

(i) In general

Not later than the date that is 30 days before the expiration of the period described in paragraph (1)(B)(i), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (c)(3), the need to extend the period.

(ii) Action by Administrator

Not later than the date of expiration of the period described in paragraph (1)(B)(i), the Administrator shall, in accordance with subsection (g)(1)--

(I) review the request submitted under clause (i);

(II) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant requirements of this section; and

(III)(aa) grant an extension of 10 years; or

(bb) deny the request.

(C) No limit on number of extensions

There shall be no limit on the number of extensions granted under this paragraph, if the Administrator determines that the relevant request under subparagraph (B)(i)--

(i) establishes the need to extend the period; and

(ii) meets the requirements established by the Administrator.

(f) Review and resubstantiation

(1) Discretion of Administrator

The Administrator may require any person that has claimed protection for information from disclosure under this section, whether before, on, or after June 22, 2016, to reassert and substantiate or resubstantiate the claim in accordance with this section--

(A) after the chemical substance is designated as a high-priority substance under section 2605(b) of this title;

(B) for any chemical substance designated as an active substance under section 2607(b)(5)(B)(iii) of this title; or

(C) if the Administrator determines that disclosure of certain information currently protected from disclosure would be important to assist the Administrator in conducting risk evaluations or promulgating rules under section 2605 of this title.

(2) Review required

The Administrator shall review a claim for protection of information from disclosure under this section and require any person that has claimed protection for that information, whether before, on, or after June 22, 2016, to reassert and substantiate or resubstantiate the claim in accordance with this section--

(A) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of Title 5;

(B) if the Administrator has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section; or

(C) for any chemical substance the Administrator determines under section 2605(b)(4)(A) of this title presents an unreasonable risk of injury to health or the environment.

(3) Period of protection

If the Administrator requires a person to reassert and substantiate or resubstantiate a claim under this subsection, and determines that the claim continues to meet the relevant requirements of this section, the Administrator shall protect the information subject to the claim from disclosure for a period of 10 years from the date of such determination, subject to any subsequent requirement by the Administrator under this subsection.

(g) Duties of Administrator

(1) Determination

(A) In general

Except for claims regarding information described in subsection (c)(2), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (c), and not later than 30 days after the receipt of a request for extension of a claim under subsection (e) or a request under subsection (b)(4)(C), review and approve, approve in part and deny in part, or deny the claim or request.

(B) Reasons for denial

If the Administrator denies or denies in part a claim or request under subparagraph (A) the Administrator shall provide to the person that asserted the claim or submitted the request a written statement of the reasons for the denial or denial in part of the claim or request.

(C) Subsets

The Administrator shall--

(i) except with respect to information described in subsection (c)(2)(G), review all claims or requests under this section for the protection from disclosure of the specific chemical identity of a chemical substance; and

(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection from disclosure under this section.

(D) Effect of failure to act

The failure of the Administrator to make a decision regarding a claim or request for protection from disclosure or extension under this section shall not have the effect of denying or eliminating a claim or request for protection from disclosure.

(E) Determination of requests under subsection (b)(4)(C)

With respect to a request submitted under subsection (b)(4)(C), the Administrator shall, with the objective of ensuring that information relevant to the protection of health and the environment is disclosed to the extent practicable, determine whether the documentation provided by the person rebuts what shall be the presumption of the Administrator that the public interest in the disclosure of the information outweighs the public or proprietary interest in maintaining the protection for all or a portion of the information that the person has requested not be disclosed or for which disclosure be delayed.

(2) Notification

(A) In general

Except as provided in subparagraph (B) and subsections (b), (d), and (e), if the Administrator denies or denies in part a claim or request under paragraph (1), concludes, in accordance with this section, that the information does not qualify for protection from disclosure, intends to disclose information pursuant to subsection (d), or promulgates a rule under section 2605(a) of this title establishing a ban or phase-out with respect to a chemical substance or mixture, the Administrator shall notify, in writing, the person that asserted the claim or submitted the request of the intent of the Administrator to disclose the information or not protect the information from disclosure under this section. The notice shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means that allows verification of the fact and date of receipt.

(B) Disclosure of information

Except as provided in subparagraph (C), the Administrator shall not disclose information under this subsection until the date that is 30 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A).

(C) Exceptions

(i) Fifteen day notification

For information the Administrator intends to disclose under subsections (d)(3), (d)(4), (d)(5), and (j), the Administrator shall not disclose the information until the date that is 15 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A), except that, with respect to information to be disclosed under subsection (d)(3), if the Administrator determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, no prior notification shall be necessary.

(ii) Notification as soon as practicable

For information the Administrator intends to disclose under paragraph (6) of subsection (d), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

(iii) No notification required

Notification shall not be required--

(I) for the disclosure of information under paragraphs (1), (2), (7), or (8) of subsection (d); or

(II) for the disclosure of information for which--

(aa) the Administrator has provided to the person that asserted the claim a notice under subsection (e)(2)(A); and

(bb) such person does not submit to the Administrator a request under subsection (e)(2)(B) on or before the deadline established in subsection (e)(2)(B)(i).

(D) Appeals

(i) Action to restrain disclosure

If a person receives a notification under this paragraph and believes the information is protected from disclosure under this section, before the date on which the information is to be disclosed pursuant to subparagraph (B) or (C) the person may bring an action to restrain disclosure of the information in--

(I) the United States district court of the district in which the complainant resides or has the principal place of business; or

(II) the United States District Court for the District of Columbia.

(ii) No disclosure

(I) In general

Subject to subsection (d), the Administrator shall not disclose information that is the subject of an appeal under this paragraph before the date on which the applicable court rules on an action under clause (i).

(II) Exception

Subclause (I) shall not apply to disclosure of information described under subsections (d)(4) and (j).

(3) Request and notification system

The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).

(4) Unique identifier

The Administrator shall--

(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term; and

(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

(B) annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

(C) ensure that any nonconfidential information received by the Administrator with respect to a chemical substance included on the list published under subparagraph (B) while the specific chemical identity of the chemical substance is protected from disclosure under this section identifies the chemical substance using the unique identifier; and

(D) for each claim for protection of a specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the person who asserted the claim, and for which the Administrator has used a unique identifier

assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such information to the extent practicable.

(h) Criminal penalty for wrongful disclosure

(1) Individuals subject to penalty

(A) In general

Subject to subparagraph (C) and paragraph (2), an individual described in subparagraph (B) shall be fined under Title 18 or imprisoned for not more than 1 year, or both.

(B) Description

An individual referred to in subparagraph (A) is an individual who--

(i) pursuant to this section, obtained possession of, or has access to, information protected from disclosure under this section; and

(ii) knowing that the information is protected from disclosure under this section, willfully discloses the information in any manner to any person not entitled to receive that information.

(C) Exception

This paragraph shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information obtained under paragraph (5) or (6) of subsection (d) to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient.

(2) Other laws

Section 1905 of Title 18 shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported to or otherwise obtained by the Administrator under this chapter.

(i) Applicability

(1) In general

Except as otherwise provided in this section, section 2607 of this title, or any other applicable Federal law, the Administrator shall have no authority--

(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information reported to or otherwise obtained by the Administrator under this chapter prior to June 22, 2016; or

(B) to impose substantiation or resubstantiation requirements, with respect to the protection of information described in subsection (a), under this chapter that are more extensive than those required under this section.

(2) Actions prior to promulgation of rules

Nothing in this chapter prevents the Administrator from reviewing, requiring substantiation or resubstantiation of, or approving, approving in part, or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after June 22, 2016.

(j) Access by Congress

Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this chapter shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

CREDIT(S)

(Pub.L. 94-469, Title I, § 14, Oct. 11, 1976, 90 Stat. 2034; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, § 11, June 22, 2016, 130 Stat. 481.)

Notes of Decisions (8)

15 U.S.C.A. § 2613, 15 USCA § 2613
Current through P.L. 119-36. Some statute sections may be more current, see credits for details.

End of Document

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Proposed Legislation

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2618

§ 2618. Judicial review

Currentness

(a) In general

(1)(A) Except as otherwise provided in this subchapter, not later than 60 days after the date on which a rule is promulgated under this subchapter, subchapter II, or subchapter IV, or the date on which an order is issued under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title,, [1] any person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule or order if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Except as otherwise provided in this subchapter, courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under this subchapter, other than an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(C)(i) Not later than 60 days after the publication of a designation under section 2605(b)(1)(B)(ii) of this title, any person may commence a civil action to challenge the designation.

(ii) The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this subparagraph.

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of Title 28 shall apply to the filing of the record of proceedings on which the Administrator based the rule or order being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(b) Additional submissions and presentations; modifications

If in an action under this section to review a rule, or an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule or order and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule or order being reviewed or make a new rule or order by reason of the additional submissions and presentations and shall file such modified or new rule or order with the return of such submissions and presentations. The court shall thereafter review such new or modified rule or order.

(c) Standard of review

(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of Title 5, and (ii) except as otherwise provided in subparagraph (B), to review such rule or order in accordance with chapter 7 of Title 5.

(B) Section 706 of Title 5 shall apply to review of a rule or order under this section, except that--

(i) in the case of review of--

(I) a rule under section 2603(a), 2604(b)(4), 2605(a) (including review of the associated determination under section 2605(b)(4)(A)), or 2605(e) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole; and

(II) an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such order if the court finds that the order is not supported by substantial evidence in the record taken as a whole; and

(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of Title 5 to be incorporated in the rule or order, except as part of the record, taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of Title 28.

(d) Fees and costs

The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) Other remedies

The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

CREDIT(S)

(Pub.L. 94-469, Title I, § 19, Oct. 11, 1976, 90 Stat. 2039; renumbered Title I and amended Pub.L. 99-519, § 3(b)(2), (c)(1), Oct. 22, 1986, 100 Stat. 2989; Pub.L. 102-550, Title X, § 1021(b)(8), Oct. 28, 1992, 106 Stat. 3923; Pub.L. 114-182, Title I, §§ 14, 19(m), June 22, 2016, 130 Stat. 498, 508.)

Notes of Decisions (17)

Footnotes

1 So in original.

15 U.S.C.A. § 2618, 15 USCA § 2618
Current through P.L. 119-36. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2619

§ 2619. Citizens' civil actions

Currentness

(a) In general

Except as provided in subsection (b), any person may commence a civil action--

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this chapter or any rule promulgated under section 2603, 2604, or 2605 of this title, or subchapter II or IV, or order issued under section 2603 or 2604 of this title or subchapter II or IV to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) Limitation

No civil action may be commenced--

(1) under subsection (a)(1) to restrain a violation of this chapter or rule or order under this chapter--

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 2615(a)(2) of this title to require compliance with this chapter or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) Weight of scientific evidence

The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence.

(j) Availability of information

Subject to section 2613 of this title, the Administrator shall make available to the public--

(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this subchapter;

(2) any information required to be provided to the Administrator under section 2603 of this title;

(3) a nontechnical summary of each risk evaluation conducted under section 2605(b) of this title;

(4) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies; and

(5) each designation of a chemical substance under section 2605(b) of this title, along with an identification of the information, analysis, and basis used to make the designations.

(k) Reasonably available information

flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and safety data sheets.

(2) Information. Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and safety data sheets required by this section.

(3) Training. Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical, health, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system used by their employer; the safety data sheet, including the order of information and how employees can obtain and use the appropriate hazard information.

(i) Trade secrets.

(1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, and/or the exact percentage (concentration) or concentration range of the substance in a mixture, from section 3 of the safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The safety data sheet indicates that the specific chemical identity and/or concentration or concentration range of composition is being withheld as a trade secret;

(iv) If the concentration or concentration range is being claimed as a trade secret then the safety data sheet provides the ingredient's concentration as one of the prescribed ranges below in paragraphs (i)(1)(iv)(A) through (M) of this section.

(A) from 0.1% to 1%;

(B) from 0.5% to 1.5%;

(C) from 1% to 5%;

(D) from 3% to 7%;

(E) from 5% to 10%;

(F) from 7% to 13%;

(G) from 10% to 30%;

(H) from 15% to 40%;

(I) from 30% to 60%;

(J) from 45% to 70%;

(K) from 60% to 80%;

(L) from 65% to 85%; and

(M) from 80% to 100%.

(v) The prescribed concentration range used must be the narrowest range possible. If the exact concentration range falls between 0.1% and 30% and does not fit entirely into one of the prescribed concentration ranges of paragraphs (i)(1)(iv)(A) to (G) of this section, a single range created by the combination of two applicable consecutive ranges between paragraphs (i)(1)(iv)(A) and (G) of this section may be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the exact concentration range in which the ingredient is present.

(vi) Manufacturers may provide a range narrower than those prescribed in (i)(1)(v).

(vii) The specific chemical identity and exact concentration or concentration range is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph (i) of this section.

(2) Where a treating PLHCP determines that a medical emergency exists and the specific chemical identity and/or specific concentration or concentration range of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical identity or percentage composition of a trade secret chemical to that treating PLHCP, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i)(3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity or exact concentration or concentration range, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (e.g., PLHCP, industrial hygienist, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity or percentage composition is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in paragraph (i)(3)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the services of the health professional (i.e. downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(5) Nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(6) If the health professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional, employee, or designated representative prior to, or at the same time as, such disclosure.

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity or percentage composition, the denial must:

(i) Be provided to the health professional, employee, or designated representative, within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity or percent of composition is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the trade secret.

(8) The health professional, employee, or designated representative whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

(9) When a health professional, employee, or designated representative refers the denial to OSHA under paragraph (i)(8) of this section, OSHA shall consider the evidence to determine if:

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity or percentage composition is a trade secret;

(ii) The health professional, employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and,

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(10)(i) If OSHA determines that the specific chemical identity or percentage composition requested under paragraph (i)(3) of this section is not a "bona fide" trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If a citation for a failure to release trade secret information is contested by the chemical manufacturer, importer, or employer, the matter will be adjudicated before the Occupational Safety and Health Review Commission in accordance

with the Act's enforcement scheme and the applicable Commission rules of procedure. In accordance with the Commission rules, when a chemical manufacturer, importer, or employer continues to withhold the information during the contest, the Administrative Law Judge may review the citation and supporting documentation "in camera" or issue appropriate orders to protect the confidentiality of such matters.

(12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process information which is a trade secret.

(j) Dates—

(1) Effective date. This section shall become effective July 19, 2024.

(2) Substances.

(i) Manufacturers, importers, and distributors, evaluating substances shall be in compliance with all modified provisions of this section no later than January 19, 2026.

(ii) For substances, all employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1) of this section, and provide any additional employee training in accordance with paragraph (h)(3) of this section for newly identified physical hazard, or health hazards or other hazards covered under this section no later than July 20, 2026.

(3) Mixtures.

(i) Chemical manufacturers, importers, and distributors evaluating mixtures shall be in compliance with all modified provisions of this section no later than July 19, 2027.

(ii) For mixtures, all employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1) of this section, and provide any additional employee training in accordance with paragraph (h)(3) of this section for newly identified physical hazards, health hazards, or other hazards covered under this section no later than January 19, 2028.

(4) Compliance. Between May 20, 2024 and the dates specified in paragraphs (j)(2) and (3) of this section, as applicable, chemical manufacturers, importers, distributors, and employers may comply with either this section or § 1910.1200 revised as of July 1, 2023, or both during the transition period.

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter A. General
Part 23. Judicial Review Under EPA—Administered Statutes (Refs & Annos)

40 C.F.R. § 23.5

§ 23.5 Timing of Administrator's action under Toxic Substances Control Act.

Currentness

Unless the Administrator otherwise explicitly provides in promulgating a particular rule or issuing a particular order, the time and date of the Administrator's promulgation or issuance for purposes of section 19(a)(1) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is (a) for a Federal Register document, two weeks after the date when the document is published in the Federal Register, or (b) for any other document, two weeks after it is signed.

SOURCE: 50 FR 7270, Feb. 21, 1985; 53 FR 29322, Aug. 3, 1988; 70 FR 33359, June 8, 2005, unless otherwise noted.

AUTHORITY: Clean Water Act, 33 U.S.C. 1361(a), 1369(b); Clean Air Act, 42 U.S.C. 7601(a)(1), 7607(b); Resource, Conservation and Recovery Act, 42 U.S.C. 6912(a), 6976; Toxic Substances Control Act, 15 U.S.C. 2618; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136n(b), 136w(a); Safe Drinking Water Act, 42 U.S.C. 300j–7(a)(2), 300j–9(a); Atomic Energy Act, 42 U.S.C. 2201, 2239; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), 346a, 28 U.S.C. 2112(a), 2343, 2344.

Current through October 8, 2025, 90 FR 48147. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 720. Premanufacture Notification (Refs & Annos)
Subpart A. General Provisions

40 C.F.R. § 720.3

§ 720.3 Definitions.

Currentness

In addition to the definitions under section 3 of the Act, 15 U.S.C. 2602, the following definitions apply to this part.

Act means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

Applicable review period means the period starting on the date EPA receives a complete notice under section 5(a)(1) of the Act and ending 90 days after that date or on such date as is provided for in sections 5(b)(1) or 5(c) of the Act.

Article means a manufactured item:

(1) Which is formed to a specific shape or design during manufacture;

(2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design.

Byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

Byproduct material, source material, and special nuclear material have the meanings contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 et seq. and the regulations issued under it.

Central Data Exchange or CDX means EPA's centralized electronic document receiving system, or its successors.

Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that “chemical substance” does not include:

(1) Any mixture;

(2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide;

(3) Tobacco or any tobacco product;

(4) Any source material, special nuclear material, or byproduct material;

(5) Any pistol, firearm, revolver, shells, or cartridges; or

(6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Commerce means trade, traffic, transportation, or other commerce:

(1) Between a place in a State and any place outside of such State; or

(2) Which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

Cosmetic, device, drug, food, and food additive have the meanings contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., and the regulations issued under it. In addition, the term "food" includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 et seq.; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 et seq.; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 et seq.

Customs territory of the United States means the 50 States, Puerto Rico, and the District of Columbia.

Director means the Director of the EPA Office of Pollution Prevention and Toxics (OPPT).

Distribute in commerce means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after introduction into commerce.

EPA means the U.S. Environmental Protection Agency.

e–PMN software means electronic–PMN software created by EPA for use in preparing and submitting Premanufacture Notices (PMNs) and other TSCA section 5 notices and support documents electronically to the Agency.

Health and safety study or study means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under the Act. Chemical identity is always part of a health and safety study.

(1) Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included.

(2) Examples include:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; acute, subchronic, and chronic effects; and structure/activity analyses.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies of: Biological, photochemical, and chemical degradation; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance.

Importer means any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. “Importer” includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20; or

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with 19 CFR part 144, subpart C. (See “principal importer.”)

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

Inventory means the list of chemical substances manufactured or processed in the United States that EPA compiled and keeps current under section 8(b) of the Act.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Manufacture means to produce or manufacture in the United States or import into the customs territory of the United States.

Manufacture for commercial purposes means:

(1) To manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, “manufacture” of any amount of a chemical substance or mixture.

(2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that

remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes.

Manufacture solely for export means to manufacture for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

(1) Distribution in commerce is limited to purposes of export or processing solely for export as defined in § 721.3 of this chapter.

(2) The manufacturer and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in § 721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with § 720.36.

Manufacturer means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance. A person who contracts with a manufacturer to manufacture or produce a chemical substance is also a manufacturer if:

(1) The manufacturer manufactures or produces the substance exclusively for that person; and

(2) That person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except “mixture” does include:

(1) Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances; and

(2) Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

New chemical substance means any chemical substance which is not included on the Inventory.

Nonisolated intermediate means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

Person means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency or instrumentality of the Federal Government.

Pesticide has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq. and the regulations issued under it.

Possession or control means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner). Information is included within this definition if it is:

(1) In files maintained by submitter's employees who are:

(i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

(ii) Reasonably likely to have such data.

(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, the elderly, or overburdened communities.

Principal importer means the first importer who, knowing that a new chemical substance will be imported rather than manufactured domestically, specifies the identity of the chemical substance and the total amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

Process means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce:

(1) In the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(2) As part of a mixture or article containing the chemical substance or mixture.

Processor means any person who processes a chemical substance or mixture.

Small quantities solely for research and development (or “small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product”) means quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

State means any State of the United States and the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

Support documents means material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence, amendments (if notices for these amendments were submitted prior to January 19, 2016), and test data. The term “support documents” does not include orders under TSCA section 5(e) (either consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)).

Technically qualified individual means a person or persons:

(1) Who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision;

(2) Who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks; and

(3) Who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

Test data means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

United States, when used in the geographic sense, means all of the States.

Credits

[48 FR 41140, Sept. 13, 1983; 51 FR 15101, April 22, 1986; 51 FR 22812, June 23, 1986; 75 FR 784, Jan. 6, 2010; 80 FR 42745, July 20, 2015; 87 FR 39763, July 5, 2022; 89 FR 102789, Dec. 18, 2024]

SOURCE: 48 FR 21742, May 13, 1983; 48 FR 31641, July 11, 1983; 48 FR 41132, Sept. 13, 1983; 51 FR 15101, April 22, 1986, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

Current through October 2, 2025, 90 FR 47963. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 720. Premanufacture Notification (Refs & Annos)
Subpart B. Applicability

40 C.F.R. § 720.22

§ 720.22 Persons who must report.

Currentness

(a)(1) Any person who intends to manufacture a new chemical substance in the United States for commercial purposes must submit a notice unless the substance is excluded under § 720.30.

(2) If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a notice.

(b)(1) Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under § 720.30 or unless the substance is imported as part of an article.

(2) When several persons are involved in an import transaction, the notice must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the notice for that transaction.

SOURCE: 48 FR 21742, May 13, 1983; 48 FR 31641, July 11, 1983; 48 FR 41132, Sept. 13, 1983; 51 FR 15101, April 22, 1986, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

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Part 720. Premanufacture Notification (Refs & Annos)
Subpart C. Notice Form

40 C.F.R. § 720.40

§ 720.40 General.

Currentness

(a) Use of the notice form; electronic submissions.

(1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) All notices must be submitted on EPA Form 7710–25. Notices, and any support documents related to these notices, may only be submitted in a manner set forth in this paragraph.

(i) Submission via CDX. TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710–25 using e–PMN software.

(ii) You can access the e–PMN software as follows:

(A) Website. Go to EPA's TSCA New Chemicals Program website at http://www.epa.gov/oppt/newchems and follow the appropriate links.

(B) Telephone. Call the EPA CDX Help Desk at 1–888–890–1995.

(C) E–mail. HelpDesk@epacdx.net.

(b) When to submit a notice. Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture of the new chemical substance for commercial purposes begins.

(c) Where to submit a notice or support documents. For submitting notices or support documents via CDX, use the e–PMN software.

(d) General notice requirements.

(1) Each person who submits a notice must provide the information described in § 720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the person. In accordance with § 720.50, the notice must also include any test data in the person's possession or control, and descriptions of other data which are known to or reasonably ascertainable by the person and which concern the health and environmental effects of the new chemical substance.

(2) If information is claimed as confidential pursuant to § 720.80, a person who submits a notice to EPA in the manner set forth in § 720.40(a)(2)(i), (ii), or (iii) must also provide EPA with a sanitized copy.

(e) Agency or joint submissions—

(1) A manufacturer (including importer) may designate an agent to assist in submitting the notice. If so, only the manufacturer (including importer), and not the agent, signs the certification on the form.

(2) A manufacturer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. The manufacturer should indicate in a cover letter accompanying the notice which information will be supplied by another person and must identify that other person as a joint submitter where indicated on their notice form. The other person supplying information (i.e., the joint submitter) may submit the information to EPA using either the notice form or a Letter of Support, except that if the joint submitter is not incorporated, licensed, or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, not in a notice form. The joint submitter must indicate in the notice or Letter of Support the identity of the manufacturer. Any person who submits a notice form or Letter of Support for a joint submission must sign and certify the notice form or Letter of Support.

(3) Only the Authorized Official (AO) of a submitting company can certify initial notices and submit all TSCA section 5 documents.

(i) An AO can authorize other persons to be non-certifying AOs who may conduct all section 5 business on behalf of the submitting company except for certifying and submitting initial notices to EPA via CDX.

(ii) An AO may grant access to a support registrant to edit section 5 documents.

(f) New information. During the applicable review period, if the submitter possesses, controls, or knows of new information that materially adds to or changes the information included in the notice, the submitter must submit that information to EPA within ten days of receiving the new information, but no later than five days before the end of the applicable review period. The new information must be submitted electronically to EPA via CDX and must clearly identify the submitter and the notice to which the new information is related. If the new information becomes available during the last five days of the applicable review period, the submitter must immediately inform its EPA contact for that notice by telephone or e-mail and submit the new information electronically to EPA via CDX.

(g) Chemical substances subject to a section 4 test rule.

(1) Except as provided in paragraph (g)(3) of this section, if

(i) A person intends to manufacture a new chemical substance which is subject to the notification requirements of this part, and

(ii) The chemical substance is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with § 720.50. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in § 720.65.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the submitter may not submit a notice until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

(i) The name, title, and address of the person who submitted the test data to EPA.

(ii) The date the test data were submitted to EPA.

(iii) A citation for the test rule.

(iv) A description of the exemption and a reference identifying it.

(h) Chemical substances subject to a section 5(b)(4) rule.

(1) If a person (i) intends to manufacture a new chemical substance which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and (ii) is not required by a rule issued under section 4 of the Act to submit test data for the substance before the submission of a notice, the person must submit to EPA data described in paragraph (h)(2) of this section at the time the notice is submitted.

(2) Data submitted under paragraph (h)(1) of this section must be data which the person submitting the notice believes show that the manufacture, processing, distribution in commerce, use and disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

Credits

[60 FR 16309, March 29, 1995; 75 FR 784, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 80 FR 42746, July 20, 2015; 87 FR 39763, July 5, 2022; 89 FR 102792, Dec. 18, 2024]

SOURCE: 48 FR 21742, May 13, 1983; 48 FR 31641, July 11, 1983; 48 FR 41132, Sept. 13, 1983; 51 FR 15101, April 22, 1986, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

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Subpart C. Notice Form

40 C.F.R. § 720.45

§ 720.45 Information that must be included in the notice form.

Currentness

Each person who submits a notice must include the information specified in the notice form to the extent it is known to or reasonably ascertainable by the submitter. However, no person is required to include information which relates solely to exposure of human or ecological populations outside of the United States. The notice form requires the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance:

(a)(1) The specific chemical identity of the substance that the person intends to manufacture or import, which includes the following:

(i) The currently correct Chemical Abstracts (CA) name for the substance, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on CA 9CI nomenclature rules and conventions). In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Tradenames or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names.

(ii) The currently correct CASRN for the substance if a CASRN already exists for the substance.

(iii) For a Class 1 substance and for any Class 2 substance for which a definite molecular formula is known or reasonably ascertainable, the correct molecular formula.

(iv) For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

(2) For a polymer, the submitter must also report the following:

(i) The specific chemical name and CASRN, if the number is available, of each monomer and other reactant used, at any weight percent, to manufacture the polymer. Tradenames or generic names of chemical reactants or monomers are not acceptable as substitutes for specific chemical names.

(ii) The typical percent by weight of each monomer and other reactant in the polymer (weight of the monomer or other reactant expressed as a percentage of the weight of the polymeric chemical substance manufactured), and the maximum residual amount of each monomer present in the polymer.

(iii) For monomers and other reactants used at 2 weight percent or less (based on the dry weight of the polymer manufactured), indicate on the PMN form any such monomers and other reactants that should be included as part of the polymer description on the Inventory, where the weight percent is based on either

(A) the weight of monomer or other reactant actually charged to the reaction vessel, or

(B) the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer or other reactant molecules or fragments chemically incorporated (chemically combined) in the polymeric substance manufactured.

(iv) For a determination that 2 weight percent or less of a monomer or other reactant is incorporated (chemically combined) in a polymeric substance manufactured, as specified in paragraphs (a)(2)(iii)(B) of this section, analytical data or appropriate theoretical calculations (if it can be documented that analytical measurement is not feasible or not necessary) to support this determination must be maintained at the site of manufacture or import of the polymer.

(v) Measured or estimated values of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight, with a description of how the measured or estimated values were obtained.

(3) The person must use one of the following two methods to develop or obtain the specified chemical identity information reported under paragraphs (a)(1) and (2) of this section and must identify the method used in the notice:

(i) Method 1. Obtain the correct chemical identity information required by paragraphs (a)(1) and (2) of this section directly from the Chemical Abstracts Service (CAS), specifically from the CAS Registry Services Inventory Expert Service, prior to submitting a notice to EPA. A copy of the chemical identification report obtained from CAS must be submitted with the notice.

(ii) Method 2. Obtain the correct chemical identity information required by paragraphs (a)(1) and (2) from any source. The notice will be incomplete according to § 720.65(c)(1)(vi) if the person uses Method 2 and any chemical identity information is determined to be incorrect by EPA.

(4) If an importer submitting the notice cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because it is claimed as confidential by the foreign supplier of the substance, the importer must have the foreign

supplier follow the procedures in paragraph (a)(3) of this section and provide the correct chemical identity information specified in paragraphs (a)(1) and (2) of this section directly to EPA in a joint submission or as a letter of support to the notice, which clearly references the importer's notice and PMN User Fee Identification Number. The applicable review period will commence upon receipt of both the notice and the complete, correct information, in accordance with § 720.65.

(5) If a manufacturer cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because the new chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CASRN, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN Fee Identification Number. The applicable review period will commence upon receipt of the notice, the letter of support, and the complete, correct information, in accordance with § 720.65.

(b) The impurities anticipated to be present in the substance by name, CAS Registry number, and weight percent of the total substance.

(c) Known synonyms or trade names of the new chemical substance.

(d) A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance.

(e) 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 three years of production.

(f)(1) A description of the intended category or categories of consumer or commercial use by function and application, which includes a description of the following:

(i) The estimated percent of production volume devoted to each category of use.

(ii) The percent of the new chemical substance in the formulation for each commercial or consumer use.

(iii) The types of products or articles that would incorporate the new chemical substance (e.g., household cleaners, plastic articles).

(iv) Information related to the use of products or articles containing the new chemical substance by potentially exposed or susceptible subpopulations.

(v) How and where a product or article containing the new chemical substance would be used (e.g., spray applied indoors, brushed on outdoor surfaces).

(vi) Consumption rates and frequency and duration of use of products or articles containing the new chemical substance.

(2) Using the applicable codes listed in Table 1 to paragraph (f)(2), submitters must designate the consumer and commercial product category or categories that best describe the consumer and commercial products in which the new chemical substance is intended or known to be used. When more than 10 codes apply to the consumer or commercial products in which the new chemical substance is intended or known to be used, submitters should only designate the 10 product categories that represent the highest proportion of the anticipated production volume.

Table 1 to Paragraph (f)(2)—Codes for Reporting Consumer and Commercial Product Categories

Code	Category
	Chemical Substances in Furnishing, Cleaning, Treatment Care Products
CC101	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel.
CC102	Furniture & furnishings including plastic articles (soft); leather articles.
CC103	Furniture & furnishings including stone, plaster, cement, glass, and ceramic articles; metal articles; or rubber articles.
CC104	Leather conditioner.
CC105	Leather tanning, dye, finishing, impregnation, and care products.
CC106	Textile (fabric) dyes.
CC107	Textile finishing and impregnating/surface treatment products.
CC108	All-purpose foam spray cleaner.
CC109	All-purpose liquid cleaner/polish.
CC110	All-purpose liquid spray cleaner.
CC111	All-purpose waxes and polishes.
CC112	Appliance cleaners.
CC113	Drain and toilet cleaners (liquid).
CC114	Powder cleaners (floors).
CC115	Powder cleaners (porcelain).
CC116	Dishwashing detergent (liquid/gel).
CC117	Dishwashing detergent (unit dose/granule).
CC118	Dishwashing detergent liquid (hand-wash).
CC119	Dry cleaning and associated products.

CC120.....	Fabric enhancers.
CC121.....	Laundry detergent (unit-dose/granule).
CC122.....	Laundry detergent (liquid).
CC123.....	Stain removers.
CC124.....	Ion exchangers.
CC125.....	Liquid water treatment products.
CC126.....	Solid/Powder water treatment products.
CC127.....	Liquid body soap.
CC128.....	Liquid hand soap.
CC129.....	Solid bar soap.
CC130.....	Air fresheners for motor vehicles.
CC131.....	Continuous action air fresheners.
CC132.....	Instant action air fresheners.
CC133.....	Anti-static spray.
CC134.....	Apparel finishing, and impregnating/surface treatment products.
CC135.....	Insect repellent treatment.
CC136.....	Pre-market waxes, stains, and polishes applied to footwear.
CC137.....	Post-market waxes, and polishes applied to footwear (shoe polish).
CC138.....	Waterproofing and water-resistant sprays.

Chemical Substances in Construction, Paint, Electrical, and Metal Products

CC201.....	Fillers and putties.
CC202.....	Hot-melt adhesives.
CC203.....	One-component caulks.
CC204.....	Solder.
CC205.....	Single-component glues and adhesives.
CC206.....	Two-component caulks.
CC207.....	Two-component glues and adhesives.
CC208.....	Adhesive/Caulk removers.
CC209.....	Aerosol spray paints.

CC210	Lacquers, stains, varnishes, and floor finishes.
CC211	Paint strippers/removers.
CC212	Powder coatings.
CC213	Radiation curable coatings.
CC214	Solvent-based paint.
CC215	Thinners.
CC216	Water-based paint.
CC217	Construction and building materials covering large surface areas, including wood articles.
CC218	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles.
CC219	Machinery, mechanical appliances, electrical/electronic articles.
CC220	Other machinery, mechanical appliances, electronic/electronic articles.
CC221	Construction and building materials covering large surface areas, including metal articles.
CC222	Electrical batteries and accumulators.

Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products

CC301	Packaging (excluding food packaging), including paper articles.
CC302	Other articles with routine direct contact during normal use, including paper articles.
CC303	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft).
CC304	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard).
CC305	Toys intended for children's use (and child dedicated articles), including fabrics, textiles, and apparel; or plastic articles (hard).
CC306	Adhesives applied at elevated temperatures.
CC307	Cement/concrete.
CC308	Crafting glue.
CC309	Crafting paint (applied to body).
CC310	Crafting paint (applied to craft).
CC311	Fixatives and finishing spray coatings.
CC312	Modelling clay.

CC313.....	Correction fluid/tape.
CC314.....	Inks in writing equipment (liquid).
CC315.....	Inks used for stamps.
CC316.....	Toner/Printer cartridge.
CC317.....	Liquid photographic processing solutions.

Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products

CC401.....	Exterior car washes and soaps.
CC402.....	Exterior car waxes, polishes, and coatings.
CC403.....	Interior car care.
CC404.....	Touch up auto paint.
CC405.....	Degreasers.
CC406.....	Liquid lubricants and greases.
CC407.....	Paste lubricants and greases.
CC408.....	Spray lubricants and greases.
CC409.....	Anti-freeze liquids.
CC410.....	De-icing liquids.
CC411.....	De-icing solids.
CC412.....	Lock deicers/releasers.
CC413.....	Cooking and heating fuels.
CC414.....	Fuel additives.
CC415.....	Vehicular or appliance fuels.
CC416.....	Explosive materials.
CC417.....	Agricultural non-pesticidal products.
CC418.....	Lawn and garden care products.

Chemical Substances in Products not Described by Other Codes

CC980.....	Other (specify).
CC990.....	Non-TSCA use.

(g) For sites controlled by the submitter:

(1) The identity and address of each site where the new chemical substance will be manufactured, processed, or used.

(2) A process description of each manufacture, processing, and use operation which includes a diagram of the major unit operations and chemical conversions; indication of whether batch or continuous manufacturing or processing occurs at the site, and the amount manufactured or processed per batch or per day if continuous and per year; the identity, approximate weight per batch or per day for continuous production, and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.); the identity, approximate weight per batch or per day for continuous production, and entry point of all products, recycle streams, and wastes, including frequency of any equipment cleaning; the type of interim storage and transport containers used; and the points of release of the new chemical substance numbered. If the new chemical substance is released to two media at the same step in the process, assign a second number for the second medium.

(3) Worker exposure information for each worker activity anticipated or known to occur during manufacture, processing, or use of the new chemical substance, including worker exposure information from exempt manufacture or related use of the new chemical substance under § 720.30. This information includes:

(i) A description of each worker activity.

(ii) Type of potential worker exposure (e.g., dermal, inhalation).

(iii) Protective equipment in place, if any, including a description of the kind of gloves, protective clothing, goggles, or respirator that limit worker exposure.

(iv) Engineering controls in place, if any.

(v) Physical form of the new chemical substance to which workers may be exposed and moisture content if physical form is solid.

(vi) The percent of new chemical substance in formulation at time of worker exposure.

(vii) The number of workers reasonably likely to be exposed.

(viii) The duration of activities.

(4) Information on known or anticipated release of the new chemical substance to the environment, including releases from the exempt manufacture or related use of the new chemical substance under § 720.30. This information includes the type of release (e.g., transport, interim storage, disposal, equipment cleaning), the quantity of the new chemical substance released directly to the environment, the quantity of the new chemical substance released into control technology, the quantity of the new chemical substance released to the environment after control technology, the media of release, the type of control technology used, and the following additional information based on the type of release:

(i) For equipment cleaning releases, frequency of equipment cleaning and what is used to clean the equipment.

(ii) For transport and storage releases, how the new chemical substance or product containing the new chemical substance is transported from the site and stored, whether dedicated containers are used, whether the cleaning and disposal of the containers is under the submitter's control, the container cleaning method, the frequency of container cleaning, and the amount of release per container cleaning.

(iii) For releases into air, Clean Air Act operating permit numbers, a description of any Leak Detection and Repair program in accordance with 40 CFR parts 60, 61, 63, 65, 264 or 265 (related to the monitoring and management of fugitive releases) the site has implemented, and the type of air pollution control technologies used at the site to treat the stack releases that will contain the new chemical substance.

(iv) For releases into water, the National Pollutant Discharge Elimination System (NPDES) permit number(s), outfall numbers, the name(s) of the waterbody into which the release occurs, and other destination(s) into which the release occurs.

(v) For releases into wastewater treatment plants, the name(s) of the publicly owned treatment works (POTW) or privately owned treatment works into which the release occurs and the corresponding NPDES permit number(s), the type of wastewater treatment technology or technologies employed, and a description of the known or expected treatment efficiency.

(h) For sites not controlled by the submitter:

(1) The identity and address of each site where the new chemical substance will be manufactured, processed, or used.

(2) A description of each type of processing and use operation involving the new chemical substance, including identification of the estimated number of processing or use sites; a process description of each operation which includes a diagram of the major unit operations and chemical conversions; the identity, approximate weight per batch or per day for continuous production, and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.); the identity, approximate weight per batch or per day for continuous production, and entry point of all products, recycle streams, and wastes, including frequency of any equipment cleaning; the type of interim storage and transport containers used; and the points of release of the new chemical substance numbered. If the new chemical substance is released to two media at the same step in the process, assign a second number for the second medium.

(3) Worker exposure information for each worker activity anticipated or known to occur during manufacture, processing, or use of the new chemical substance, including worker exposure information from exempt manufacture or related use of the new chemical substance under § 720.30. This information includes:

(i) A description of each worker activity.

(ii) Type of potential worker exposure (e.g., dermal, inhalation).

(iii) Protective equipment in place, if any, including a description of the kind of gloves, protective clothing, goggles, or respirator that limit worker exposure, if any.

(iv) Engineering controls in place if any.

(v) Physical form of the new chemical substance to which workers may be exposed and moisture content if physical form is solid.

(vi) The percent of the new chemical substance in formulation at time of worker exposure.

(vii) The number of workers reasonably likely to be exposed.

(viii) The duration of activities.

(4) Information on known or anticipated release of the new chemical substance to the environment, including releases from the exempt manufacture or related use of the new chemical substance under § 720.30. This information includes the type of release (e.g., transport, interim storage, disposal, equipment cleaning), the quantity of the new chemical substance released directly to the environment, the quantity of the new chemical substance released into control technology, the quantity of the new chemical substance released to the environment after control technology, the media of release, the type of control technology used, and the following additional information based on the type of release:

(i) For equipment cleaning releases, frequency of equipment cleaning and what is used to clean the equipment.

(ii) For transport and storage releases, how the new chemical substance or product containing the new chemical substance will be transported from the site and stored, whether dedicated containers are used, whether the cleaning and disposal of the containers is under the submitter's control, the container cleaning method, the frequency of container cleaning, and the amount of release of the new chemical substance per container cleaning.

(iii) For releases into air, Clean Air Act operating permit numbers, a description of any Leak Detection and Repair program in accordance with 40 CFR parts 60, 61, 63, 65, 264 or 265 (related to the monitoring and management of fugitive releases) the site has implemented, and the type of air pollution control technologies used at the site to treat the stack releases that will contain the new chemical substance.

(iv) For releases into water, the National Pollutant Discharge Elimination System (NPDES) permit number(s), outfall numbers, the name(s) of the waterbody into which the release occurs, and other destination(s) into which the release occurs.

(v) For releases into wastewater treatment plants, the name(s) of the publicly owned treatment works (POTW) or privately owned treatment works into which the release occurs and the corresponding NPDES permit number(s), the type of wastewater treatment technology or technologies employed, and a description of the known or expected treatment efficiency.

(i) Any safety data sheet already developed for the new chemical substance, including draft safety data sheets.

(j) The physical and chemical properties and environmental fate characteristics of the new chemical substance, which include the following:

(1) For physical and chemical properties, such information includes boiling point, sublimation, density/relative density, dissociation constant, explodability, flammability, melting point, octanol/water partition coefficient, particle size distribution, particle size distribution analysis (i.e., analysis method and data used to develop the particle size distribution), the physical state of the neat substance, pH, solubility, vapor pressure, volatilization from water, volatilization from soil, spectra, UV–VIS absorption data, and surface tension.

(2) For environmental fate characteristics, such information includes hydrolysis, photolysis, aerobic and anaerobic biodegradation, atmospheric oxidation half-lives, Henry's law constant, adsorption/desorption coefficient, bioaccumulation or bioconcentration factor, Incineration Removal Efficiency (Destruction and Removal Efficiencies or DREs), and Sewage Treatment (WWTP) Removals.

(k) Information about pollution prevention efforts, such as using alternative fuel sources, reducing the use of water and chemical inputs, modifying a production process to produce less waste, or implementing water and energy conservation practices, or substituting for riskier existing products. Inclusion of this information is optional.

Credits
[60 FR 16310, March 29, 1995; 83 FR 52719, Oct. 17, 2018; 87 FR 39763, July 5, 2022; 89 FR 102792, Dec. 18, 2024]

SOURCE: 48 FR 21742, May 13, 1983; 48 FR 31641, July 11, 1983; 48 FR 41132, Sept. 13, 1983; 51 FR 15101, April 22, 1986, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

Current through October 8, 2025, 90 FR 48147. Some sections may be more current. See credits for details.

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 720. Premanufacture Notification (Refs & Annos)
Subpart C. Notice Form

40 C.F.R. § 720.50

§ 720.50 Submission of test data and other data concerning the health and environmental effects of a substance.

Currentness

(a) Test data on the new chemical substance in the possession or control of the submitter.

(1) Except as provided in paragraph (d) of this section, each notice must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form.

(2) A full report or standard literature citation must be submitted for the following types of test data:

(i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the chemical substance.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a notice, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the applicable review period ends, the person must submit the study, report, or test data electronically to EPA via CDX, as specified in paragraph (a)(3)(i) of this section, within ten days of receiving it, but no later than five days before the end of the review period. If the test or experiment is completed during the last five days of the review period, the submitter must inform its EPA contact for that notice by telephone or e-mail prior to the end of the review period and submit the study, report, or test data electronically to EPA via CDX.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within ten days of the request, but no later than five days before the end of the review period.

(6) All test data described by paragraph (a) are subject to these requirements, regardless of their age, quality, or results.

(b) Other data concerning the health and environmental effects of the new chemical substance that are known to or reasonably ascertainable by the submitter.

(1) Except as provided in paragraph (d) of this section, any person who submits a notice must describe the following data, including any data from a health and safety study, if the data are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, of any mixture or article containing the new chemical substance, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the substance.

(2) Data that must be described include data concerning the new chemical substance in a pure, technical grade, or formulated form.

(3) The description of data reported under this paragraph must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not contained in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described by this paragraph are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the notice is submitted.

(c) Other information. A person may submit other information, not otherwise required in this section, to facilitate EPA's review of the notice.

(d) Data that need not be submitted—

(1) Data previously submitted to EPA.

(i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the notice includes the office or person to whom the data were submitted, the date of submission, and, if appropriate, a standard literature citation as specified in paragraph (a)(3)(ii) of this section.

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the notice and any claim of confidentiality, under § 720.80.

(2) Efficacy data. This part does not require submission of any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraph (a), (b), or (c) of this section.

(3) Non–U.S. exposure data. This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

Credits

[48 FR 41140, Sept. 13, 1983; 51 FR 15102, April 22, 1986; 51 FR 22812, June 23, 1986; 89 FR 102795, Dec. 18, 2024]

SOURCE: 48 FR 21742, May 13, 1983; 48 FR 31641, July 11, 1983; 48 FR 41132, Sept. 13, 1983; 51 FR 15101, April 22, 1986, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

Current through October 8, 2025, 90 FR 48147. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 720. Premanufacture Notification (Refs & Annos)
Subpart E. Confidentiality and Public Access to Information

40 C.F.R. § 720.95

§ 720.95 Public file.

Currentness

All information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential in accordance with procedures in 40 CFR 703.5. In addition, EPA may add materials to the public file, subject to subpart E of this part. Publicly available materials are available at the docket addresses in § 700.17(b)(1) and (2) of this subchapter and on EPA's website.

Credits
[53 FR 12523, April 15, 1988; 60 FR 16311, March 29, 1995; 60 FR 34464, July 3, 1995; 77 FR 46292, Aug. 3, 2012; 88 FR 37172, June 7, 2023]

SOURCE: 48 FR 21742, May 13, 1983; 48 FR 31641, July 11, 1983; 48 FR 41132, Sept. 13, 1983; 51 FR 15101, April 22, 1986, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

Current through October 2, 2025, 90 FR 47963. Some sections may be more current. See credits for details.

End of Document

federal register

WEDNESDAY, JANUARY 10, 1979
PART II

ENVIRONMENTAL PROTECTION AGENCY

■

TOXIC SUBSTANCES CONTROL

Premanufacture Notification Requirements and Review Procedures

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 720]

[OTS-050002; FRL-1022-6]

TOXIC SUBSTANCES CONTROL

Premanufacture Notification Requirements and Review Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rules and notice forms.

SUMMARY: These proposed rules and notice forms would implement the requirements of section 5 of the Toxic Substances Control Act (TSCA) concerning new chemical substances. TSCA requires each person who intends to manufacture or import a new chemical substance for commerical purposes to submit a notice to EPA at least 90 days before manufacture or import commences. At the end of the notification period, the person may manufacture or import the substance unless EPA has taken regulatory action under section 5(e) or section 5(f) to ban or otherwise regulate the substance.

These proposed rules and forms would define the applicability of these requirements, the information which must be submitted, optional information submissions, and Agency procedures for reviewing notices.

DATES: Interested persons, should comment on these proposed requirements on or before March 26, 1979.

PUBLIC MEETINGS: EPA has scheduled the following public meetings on these proposed rules and forms during the official comment period:

Atlanta, Georgia	January 31, 1979
Dallas, Texas	February 1, 1979
Los Angeles, California	February 2, 1979
Chicago, Illinois	February 6, 1979
Cleveland, Ohio	February 7, 1979
Newark, New Jersey	February 8, 1979
Washington, D.C.	February 13 & 14, 1979

The purpose of these meetings is to enable interested persons to provide oral comments on the proposed rulemaking to EPA officials who are directly responsible for developing the rules and notice forms. See Part VI under "Supplementary Information" below.

ADDRESS: Written comments should bear the document control number OTS-050002 and should be submitted in triplicate to the Document Control Officer (TS-793), Office of Toxic Substances, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

The addresses for the public meetings are provided in Part VI under "Supplementary Information" below.

FOR FURTHER INFORMATION CONTACT:

Mr. John B. Ritch, Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460; 800-424-9065 toll free; in Washington, D.C. call 554-1404.

SUPPLEMENTARY INFORMATION: The remainder of this preamble discusses EPA's approach to implementing the premanufacture notification requirements, the provisions of this proposal, major issues addressed in developing this proposal, and anticipated impact. The Agency also has prepared a Support Document which is available from the Industry Assistance Office. (See "Information Contact" above.) EPA requests comments on any aspect of this proposal and alternative approaches. The Agency has identified specific issues for comment in this preamble and in the Support Document.

Following is an index to the remainder of this preamble.

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I. INTRODUCTION

A. STATUTORY FRAMEWORK

Under § 5 of the Toxic Substances Control Act (TSCA), 15 U.S.C. section 2604, any person who intends to manufacture a new chemical substance for commercial purposes in the United States must submit a notice to the Environmental Protection Agency (EPA) at least 90 days before he commences manufacture. Section 3(7) of the Act defines "manufacture" to include import into this country. Thus section 5 and this proposed rulemaking apply to imports of new chemical substances as well.

Section 3(9) of the Act defines a "new chemical substance" as any chemical substance which is not included on the list, or "inventory," of existing substances published by EPA under section 8(b). The Agency promulgated the inventory reporting rules on December 23, 1977, 40 CFR Part 710, (42 FR 64572) and supplemented these rules on March 6, 1978 (43 FR 9254) and April 17, 1978 (43 FR 16147). The Agency presently is compiling this inventory and intends to publish it during the first half of 1979. Thirty days after this publication, the requirements of section 5 are effective.

Section 5(d)(1) of the Act defines the contents of a premanufacure notice. It requires the manufacturer to report certain information described in § 8(a)(2) of the Act (e.g., chemical identity, uses, and exposure data) plus test data and descriptions of other data related to the effects on health and the environment of the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance. In general, these data and information must be submitted to the extent they are known to or reasonably ascertainable by the submitter.

Section 5(b) of the Act contains additional reporting requirements for chemical substances subject to testing rules under section 4 of the Act and chemicals which the Administrator, by rules under § 5(b)(4) of the Act, has determined may present unreasonable risks of injury to health or the environment. Section 5(h) authorizes exemptions from some or all of the reporting requirements for new chemical substances which are used for certain limited purposes including in small quantities solely for purposes of research and development, for test marketing, or for use as intermediates if there is no exposure to the substances.

tions for data which appear in periodicals listed in Appendix I of the rules. These are periodicals to which EPA has immediate access, and the number of periodicals listed will increase as the Agency's access capacity increases. Second, persons are not required to resubmit any data previously submitted to EPA or another Federal agency, provided EPA is not now prevented from accessing those data because of prior claims of confidentiality. Third, efficacy data need not be submitted. Fourth, test data on exposure to human or ecological populations outside the United States need not be submitted. Finally, persons need not submit data on impurities, byproducts, co-products or other related chemicals which are themselves included on the inventory.

B. EPA'S PROCESSING OF NOTICES

1. *Acknowledgement of Receipt.* Under the procedures proposed in Subpart D, EPA would acknowledge receipt of each premanufacture notice. This receipt would bear the date when the OTS Document Control Officer receives the notice, and the 90-day notice review period would begin on this date. As discussed below, under § 720.34 and § 720.35 EPA may extend the review period for up to 90 additional days.

2. *Confidential Treatment of Information Contained in Premanufacture Notices.* When information is submitted and is covered by a claim of confidentiality asserted in accordance with these rules, EPA will disclose that information only to the extent permitted by the Act, these rules, and EPA's Public Information rules, 40 CFR Part 2. Basically, this means that EPA will not disclose information claimed as confidential without prior notice to the submitter. If a person asserts a claim, but fails to submit any substantiation or, in the case of a health and safety study, fails to submit a sanitized copy, he will be given an opportunity to correct this problem before EPA releases the information.

EPA will review all confidentiality claims asserted for information in health and safety studies, to assure the maximum availability of such information to the public. In addition, the Agency will in every case review a claim with respect to specific chemical identity prior to adding a substance to the inventory. EPA may review claims with respect to other information at any time; however, the Agency will review most claims only upon receipt of Freedom of Information Act requests.

EPA will deny confidentiality claims if it finds that disclosure of the relevant materials would not reveal confidential business information. In general, EPA will grant confidentiality to materials in health and safety studies only if the Agency determines that release would disclose confidential information concerning the manufacturing or processing process for a chemical, or the proportions of a mixture. However, for the period prior to commencement of manufacture, EPA will withhold the chemical identity of a substance as part of a health and safety study if the person shows that release would disclose confidential business information. (EPA's proposed resolution of the question of confidentiality for specific chemical identities is discussed in detail in Section III A of this supplementary information.)

3. *Federal Register Notice.* Under section 5(d)(2) of the Act, five days after EPA receives a premanufacture notice the Agency must publish in the FEDERAL REGISTER, subject to § 14, a notice which includes information identifying the new substance, its "uses or intended uses," and any data developed pursuant to a § 4 rule or to a designation under § 5(b)(4) that the substance may present an unreasonable risk. In implementing § 5(d)(2), EPA faces a conflict between the need to keep certain information confidential, and the need to make information public and thus facilitate public oversight of new substances as intended by Congress. Section 720.32 contains EPA's proposed resolution of this conflict.

As a general rule, EPA will identify the substance in the FEDERAL REGISTER notice by its specific identity. However, if the submitter claims identity to be confidential, the Agency will identify the substance by a generic name.

If a person asserts a valid claim of confidentiality for use information submitted in a notice, EPA will protect this information. However, § 720.42 provides that when a person asserts such a claim, he must at the same time provide non-confidential information concerning the generic uses of the substance and the human and environmental exposure which may occur. This exposure information will focus on identifying the populations which may be exposed to the substance (e.g., consumers, workers), and the extent of the exposure which is likely to occur. In addition, the person would indicate the degree of environmental release of the substance at various stages in its life cycle. This non-confidential data will be published in the § 5(d)(2) FEDERAL REGISTER notice.

EPA believes that Congress intended information on uses of new substances to be published so that the public can estimate the types and extent of potential human and environmental exposures to the substances. With an understanding of likely exposure, the public more effectively may exercise its opportunities for participating in review of chemical risks. By providing for the submittal and publication of exposure information, EPA will address this public need for information without releasing technical use information, which may be the most commercially sensitive type of information included in the premanufacture notice.

Under § 720.32(b)(3), in the section 5(d)(2) notice EPA would list all test data reported as part of a premanufacture notice, and would publish submitter-prepared abstracts for much of this test data. These abstracts would not contain any confidential information. EPA rejected a suggestion that it publish only those data developed in connection with § 4 testing requirements or § 5 (b)(4) designations. Much of the test data submitted with section 5 notices will have been developed independently of the section 4 and section 5(b)(4) requirements, but are relevant to the public's interest in new chemical substances.

Proposed § 720.32 provides that EPA will file this notice with the FEDERAL REGISTER within five days after the Agency receives the premanufacture submittal. Because of this time constraint, the Agency will utilize elements of the notice form for the Federal Register notice, including the submitter's proposed generic chemical identity and use information. However, if any of this information proves inaccurate or significantly more generic than necessary, EPA may publish and amended FEDERAL REGISTER notice, subject to the Agency's confidentiality rules in 40 CFR Part 2.

4. *Deficient Notices.* The information required to be submitted by these rules and the forms is necessary for EPA's effective review of new substances. If a person does not follow these rules, EPA may consider his notice to be deficient.

In §720.34, EPA proposes that its response to a deficient notice would depend upon the nature of the deficiency, distinguishing between those deficiencies of a relatively minor nature for which the Agency may request corrections, and those which are more serious and which will render a notice invalid. Section 720.34(a) provides that within 30 days after receipt of a notice EPA may request a submitter to correct minor or technical deficiencies (e.g., failure to date the notice; typographical errors which render entries unclear or ambiguous.) For thse types of deficiencies, the Agency will suspend the notification period for up to 30 days, pending correction of the notice. If the submitter does not make the correction within this time period, EPA may declare the notice to be invalid.

Section 720.34(b) identifies grounds for invalidation of a notice. These in-

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 720

[FRL—1314-1; OTS-050002E]

Reproposal of Premanufacture Notice Form and Provisions of Rules

AGENCY: Environmental Protection Agency (EPA), Office of Toxic Substances.

ACTION: Reproposal of Toxic Substances Control Act (TSCA) Premanufacture Notice (PMN) forms and provisions of rules; request for public comment.

SUMMARY: On January 10, 1979, EPA proposed rules and notice forms to govern premanufacture notification for new chemical substances in accordance with section 5(a)(1)(A) of TSCA. In response to numerous comments, EPA is reproposing the following: (1) Briefer notice forms for domestic manufacturers, importers, and exporters that require submitters to provide significantly less detailed information, and (2) certain provisions of the rules concerning confidentiality and supplemental reporting.

DATES: Written comments must be submitted by November 30, 1979. EPA will meet with interested members of the public who wish to discuss and comment on this reproposal from October 16, 1979 to November 30, 1979. Following the 45-day period, the Agency will hold at least one public meeting to discuss the comments. Persons who want to meet with Agency representatives either during or after the comment period should refer to the section of this notice entitled "Comments and Public Meetings".

ADDRESS: All comments should bear the identifying notation OTS-050002E and be addressed to Document Control Officer, Office of Toxic Substances (TS-793), EPA, 401 M Street, SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Mr. John B. Ritch, Director, Industry Assistance Office (TS-799), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460; 800-424-9065 toll free; in Washington, D.C., please call 554-1404.

SUPPLEMENTARY INFORMATION: EPA proposed the Premanufacture Notification Requirements and Review Procedures (40 CFR Part 720) on January 10, 1979 (44 FR 2242). Section 5(a)(1)(A) of TSCA requires each person who intends to manufacture or import a new chemical substance for a commercial purpose to submit a PMN to EPA at least 90 days before he commences such manufacture or importation. A "new" chemical substance is one that is not included on the TSCA section 8(b) Inventory of Chemical Substances. At the end of the notification period, the person may manufacture or import the substance unless EPA has taken action to ban or otherwise regulate the substance. The requirement to submit PMN's took effect on July 1, 1979, 30 days after EPA first published the TSCA Inventory (44 FR 28558 May 15, 1979). Thirty days after the Agency publishes the Revised Inventory [see 44 FR 28558, 28561-64] the premanufacture requirements will apply to importers of new chemical substances as a part of mixtures. On May 15, 1979, EPA published a Statement of Interim Policy (44 FR 28564) to govern the submittal and review of premanufacture notices prior to promulgation of the final rules and forms. Under the Interim Policy, a PMN must satisfy the requirements of section 5 of TSCA.

Following is an index to the remainder of this preamble and the major elements of this reproposal.

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Reproposed Premanufacture Rules

I. Confidentiality: 40 CFR 720.40-.45
II. Supplemental Reporting: 40 CFR 720.50 and 720.51

Revised PMN Forms

I. General Premanufacture Notice Form (Form for Domestic Manufacturers)
Appendix A.—Instructions for Asserting and Substantiating Claims of Confidentiality
Appendix B.—Examples of Asserting and Substantiating Claims of Confidentiality
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II. Importers Form
III. Exporters Form

I. The Premanufacture Notice Form

A. January 10 Proposed Form

1. *General Approach.* The January proposal included the following four separate notice forms that were similar in scope and content but designed for different purposes: (1) Domestic manufacturers, (2) importers, (3) processers, and (4) foreign manufacturers/suppliers.

The form for domestic manufacturers and importers contained mandatory and optional parts. The mandatory parts primarily required information on the identity of the manufacturer or importer, the specific identity of the new chemical substance; and production, use, and human and environmental exposure. Submitters were required to provide the information requested in the mandatory parts to the extent it was "known to or reasonably ascertainable by" them. The optional parts identified information concerning engineering and industrial hygiene safeguards, economics, and the assessment of the sufficiency of data submitted on health and environmental effects. If a submitter believed that additional information, other than that requested in the form, would significantly affect EPA's assessment of risk, he could provide it voluntarily. EPA intended for the notice submitter to consider the properties of the new chemical substance, the nature of the business venture, and the costs of completing the optional section(s) when

manufacturer's identity is substantiated by signing a certification statement similar to the one required to substantiate confidentiality claims on the Inventory reporting form. This is all the substantiation that would be required.

For production volume, use data, and process information, in addition to signing the certification statement, the submitter would be required to answer two questions. The first asks whether the submitter's confidentiality concern will be met if the link between the manufacturer's (or importer's) identity and the item claimed confidential is not disclosed. The second asks whether the submitter's confidentiality concern will be met if the link between the specific chemical identity and the item claimed confidential is not disclosed. The two questions are designed to lessen the need for multiple confidentiality claims.

Finally, to substantiate a claim of confidentiality for chemical identity and for the category of "other" claims, the submitter would respond to a series of questions. Detailed substantiation is required for each item in the category "other" because the information does not fall within one of the five categories identified by EPA. In addition, submitters would be required to explain why disclosure of the specific information would disclosure confidential information if the link between the company and the item is not disclosed and if the link between the chemical identity and the item is not disclosed.

In January, EPA proposed in § 720.40(c)(1) that a submitter who asserts a claim of confidentiality for chemical identity or health and safety data must substantiate the claim in his PMN. Under proposed § 720.40(c)(2), if the company does not provide this substantiation, EPA would notify the company and give it ten days to provide the substantiation before the Agency would place the information in the public record. EPA included this latter provision to ensure that submitters who assert claims, but who unintentionally fail to substantiate them, are given an opportunity to correct this error. The Agency did not intend for proposed § 720.40(c)(2) to affect the requirement in § 720.40(c)(1) that companies must substantiate claims for chemical identity and health and safety data at the time they submit their PMN's.

At this time, EPA is not proposing to change section 720.40(c)(2). However, EPA is considering whether it should eliminate this provision in the final rules if the Agency adopts its new scheme for substantiating all claims when PMN's are submitted. A major reason for requiring substantiation when PMN's are submitted is to eliminate delays in giving the public information which is not entitled to confidential treatment. Proposed § 720.40(c)(2) is not entirely consistent with this goal because it requires EPA to go back to submitters in all cases where claims are made but substantiation is missing. Further, in most cases EPA will not need to go back to submitters because they will have adequate notice of the Agency's substantiation requirements and should be expected to undertake reasonable steps to ensure that their PMN's are complete. EPA requests comments on whether it should retain proposed § 720.40(c)(2) in the final rules if it promulgates the reproposed scheme for substantiating claims of confidentiality.

Health and Safety Studies. The January 10 proposal would require the submitter to respond to a list of questions when substantiating confidentiality claims for information included in health and safety studies. This procedure was proposed because of the Act's special provisions for release of data from health and safety studies. EPA is proposing an alternative to the January 10 proposal which is consistent with the new approach described above. Information within a health and safety study may be claimed confidential by linking the information claimed to any of the categories proposed by the Agency. In addition, because of the specific language of section 14(b) of TSCA, a person may claim an item of data from a health and safety study as confidential because it would reveal confidential information on the portions of the substance in a mixture. This is claimed confidential by identifying the item with an "M".

Because of the Act's special provisions for release of data from health and safety studies, EPA will deny any claim of confidentiality that does not establish that disclosure of the information claimed would reveal the following confidential information:

Specific chemical identity of the chemical substance (only until the commencement of manufacture)
Process information
Portions of a mixture
Other information that is unrelated to the effects of the substance on human health and the environment.

Section 3(6) of the Act defines "health and safety study" to include "studies of occupational exposure." Any exposure information provided on the PMN form derived from a "health and safety study" is subject to the special provisions of section 14(b) of the Act and those described in this section for asserting and substantiating claims of confidentiality for health and safety studies. In particular, both section A, subsection 3; and section B, subsection 3 of Part II of the form would require reporting about worker exposure to the extent such information is known to or reasonably ascertainable by the submitter.

EPA specifically invites comment on the extent to which exposure information in PMN's is included in the general definition of "health and safety study". As stated in its January 10 proposal (44 FR 2242, 2258, 2264), EPA interprets the term broadly so that much of the information on exposure included in PMN's could be subject to section 14(b). In addition, the Agency solicits comments on how its proposed scheme for asserting and substantiating claims of confidentiality should be explained and applied to health and safety data contained in the forms themselves.

Analysis of the Revised Proposal for Asserting and Substantiating Confidentiality Claims

EPA's revision of the procedures for asserting and substantiating confidentiality claims is based on a variety of administrative and policy considerations. These include the need to provide non-confidential PMN information to the public, to provide the Agency with information necessary to make judgments under FOIA, and to establish a mechanism for persons to assert claims of confidentiality, with a minimum burden and uncertainty as to the criteria the Agency will use in making its determinations.

EPA's responsibility to provide PMN information to the public is an affirmative one, extending beyond any requirement merely to comply with FOIA. Section 5(d)(1) states explicitly that the PMN must be made available for "examination by interested persons," subject to section 14. Further, section 5(d)(2) requires EPA to publish a **Federal Register** notice which identifies the chemical substance, lists the uses or intended uses, and describes test data. More generally, TSCA includes a variety of provisions whereby citizens can petition the Agency to take particular actions with respect to premanufacture notices. EPA interprets such provisions as indicating that, while the Agency is to be the primary decisionmaker regarding new chemical substances, strong citizen involvement was intended. Effective participation is impossible if the maximum amount of information is not made available to the public.

The proposed scheme serves to increase public information in several ways. First, by focusing submitters' attention on why items are being claimed confidential and by indicating

Filed Date: 5/1/25.
Accession Number: 20250501–5144.
Comment Date: 5 p.m. ET 5/22/25.
Docket Numbers: ER25–2134–000.
Applicants: Entergy Arkansas, LLC, Entergy Louisiana, LLC, Entergy Mississippi, LLC, Entergy New Orleans, LLC, Entergy Texas, Inc.
Description: Annual Informational Filing regarding Prepaid Pension Cost and Accrued Pension Cost of Entergy Arkansas, LLC, et al.
Filed Date: 5/1/25.
Accession Number: 20250501–5157.
Comment Date: 5 p.m. ET 5/22/25.
Docket Numbers: ER25–2135–000.
Applicants: System Energy Resources, Inc.
Description: Annual Informational Filing regarding Prepaid Pension Cost and Accrued Pension Cost of System Energy Resources, Inc.
Filed Date: 5/1/25.
Accession Number: 20250501–5165.
Comment Date: 5 p.m. ET 5/22/25.
Docket Numbers: ER25–2136–000.
Applicants: Oklahoma Gas and Electric Company, Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Oklahoma Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii: Revisions to Formula Rate Template for Oklahoma Gas & Electric Company to be effective 7/1/2025.
Filed Date: 5/1/25.
Accession Number: 20250501–5168.
Comment Date: 5 p.m. ET 5/22/25.
Docket Numbers: ER25–2138–000.
Applicants: Engelhart CTP Energy Marketing, LLC.
Description: Tariff Amendment: MBR Cancellation of Trailstone Energy (Engelhart Energy) to be effective 1/29/2025.
Filed Date: 5/1/25.
Accession Number: 20250501–5239.
Comment Date: 5 p.m. ET 5/22/25.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES25–46–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Tri-State Generation and Transmission Association, Inc.
Filed Date: 4/29/25.
Accession Number: 20250429–5376.
Comment Date: 5 p.m. ET 5/20/25.
Docket Numbers: ES25–47–000.
Applicants: Golden Spread Electric Cooperative.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Golden Spread Electric Cooperative, Inc.
Filed Date: 5/1/25.
Accession Number: 20250501–5189.
Comment Date: 5 p.m. ET 5/22/25.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *https://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organization, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: May 1, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–07953 Filed 5–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15230–002]

Pike Island Hydropower Corporation; Notice of Revised Comment Period for Soliciting Motions To Intervene and Protests

On January 16, 2025, the Commission issued a "Notice of Application Accepted for Filing and Soliciting Motions to Intervene and Protests" (Notice) for the Pike Island Hydroelectric Project (P–15230). The Notice set a deadline of 60 days for filing motions to intervene and protests. Pursuant to 18 CFR 4.32(d)(2), Commission staff submitted the Notice to a local newspaper for publication. Subsequently, Commission staff was notified by the newspaper that the Notice was not published due to a system error. Therefore, the deadline for filing motions to intervene and protests is extended to 60 days from the issuance of this notice, or June 30, 2025. The January 16, 2025, Notice provides additional information on the project and on the process for filing motions to intervene and protests. It can be reviewed at: *https://elibrary.ferc.gov/eLibrary/filelist?accession_number=20250116-3027&optimized=false.*

Questions should be directed to Colleen Corballis, Project Coordinator, Midwest Branch, Division of Hydropower Licensing; telephone at (202) 502–8598; email at *colleen.corballis@ferc.gov.*

Dated: May 2, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–07956 Filed 5–6–25; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2025–0067; FRL–12475–02–OCSPP]

Certain New Chemicals; Receipt and Status Information for February 2025

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt and request for comment.

SUMMARY: This document announces the Agency's receipt of new chemical submissions under the Toxic Substances Control Act (TSCA), including information about the receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN), Microbial Commercial Activity Notice (MCAN), and an amendment to a previously submitted notice; test information; a biotechnology exemption application; an application for a test marketing exemption (TME); and a notice of commencement of manufacture (defined by statute to include import) (NOC) for a new chemical substance. This document also provides a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review. EPA is hereby providing notice of receipt of this information, as required by TSCA,

applications received; the date of receipt; the final EPA determination on the submission; and the effective date of EPA's determination. See *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* In addition, information EPA receives about chemical substances under TSCA, including non-CBI new chemical submissions, can be accessed in ChemView at *https://chemview.epa.gov/chemview.*

III. Receipt Reports

Table 1 provides non-CBI information for the PMNs, SNUNs and MCANs received by EPA during this period that have passed an initial screening and determined to be complete consistent with 40 CFR 720.70(a).

TABLE 1—PMN/SNUN/MCANS RECEIVED AND UNDER REVIEW

Case No.	Received date	Manufacturer	Use(s)	Chemical substance
J–25–0002	01/31/2025	Greenlight Biociences, Inc.	(G) To produce DNA for use in internal manufacturing.	(G) Strain of Escherichia coli modified with genetically stable, plasmid-borne DNA for the production of plasmid-borne DNA.
J–25–0003	02/21/2025	Greenlight Biociences, Inc.	(G) To produce an enzyme for use in internal manufacturing.	(G) Strain of Escherichia coli modified with genetically stable, plasmid-borne DNA for the production of an enzyme.
J–25–0003	02/26/2025	Greenlight Biociences, Inc.	(G) To produce an enzyme for use in internal manufacturing.	(G) Strain of Escherichia coli modified with genetically stable, plasmid-borne DNA for the production of an enzyme.
J–25–0006	01/31/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0006	02/10/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0007	01/31/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0007	02/10/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0008	01/31/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0008	02/10/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0009	01/31/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0009	02/10/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0010	01/31/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
J–25–0010	02/10/2025	CBI	(G) Chemical Production	(G) Chromosomally modified Saccharomyces cerevisiae.
P–22–0149	02/12/2025	Colonial Chemical, Inc.	(S) All-purpose hard surface cleaner; Low foam floor scrubber; Spray Metal Cleaning Concentrate.	(S) Hexanoic acid, 3,5,5-trimethyl-, sodium salt (1:1).
P–24–0027	01/30/2025	Mikros Biochem	(S) Surfactant	(S) Fatty acids, C8–14, 2,3-diesters with rel-(2R, 3S)-2,3,4-trihydroxybutyl Beta-D-mannopyranoside acetate.
P–24–0082	02/12/2025	CBI	(G) Additive used in 3D printing ink formulations.	(S) 2-Propenoic acid, 3-bromo-2,2-bis(bromomethyl)propyl ester.
P–25–0015	02/10/2025	CBI	(G) Additive in paving applications	(G) Modified tall oil fatty acid polyamine condensate.
P–25–0018	02/07/2025	CBI	(G) Paint coating	(S) Graphene platelets.
P–25–0027	02/07/2025	Elemental Advanced Materials, Inc.	(S) The CNOs produced do not require any further treatment for its application on concrete, resins, batteries, paints, asphalt, polyurethanes, etc. Additionally, the CNOs are ready to be combined with other nanostructures to create 2nd generation Li-Ion batteries and antimicrobial materials or composites.	(S) Graphene, Carbon Nano-Onions.
P–25–0029	02/05/2025	CBI	(G) Functional additive in composite; precursor for high-value nanomaterials.	(S) Graphene Oxide.
P–25–0030	02/05/2025	CBI	(G) Precursor for high-value nanomaterials; Functional additive in composite..	(S) Graphene Oxide.
P–25–0035	01/30/2025	W. R. Grace & Co.—Conn.	(G) Used as component in polyethylene production.	(G) Transition metal, carbomonocyclic alkyl-substituted, dialkyl.
P–25–0055*	02/06/2025	Motiva Enterprises, LLC.	(G) Additive used in industrial and commercial applications.	(G) Hydrocarbon, processed.

TABLE 1—PMN/SNUN/MCANS RECEIVED AND UNDER REVIEW—Continued

Case No.	Received date	Manufacturer	Use(s)	Chemical substance
P–25–0064	02/10/2025	CBI	(G) Contained use for microlithography for electronic device manufacturing.	(G) Dibenz thiophenium, 5-phenyl-, salt with fluoroheterosubstitutedalkyl heterosubstitutedhalo substitutedaromatichydro carboncarboxylate (1:1), polymer with 3-ethenylphenol and alkyl cycloalkyl 2-methyl-2-propenoate.
P–25–0066	02/14/2025	CBI	(G) An ingredient used in the manufacture of photoresist.	(G) Sulfonium, bis (dihalo carbomonocycle) carbomonocycle-, salt with dihalo-sulfoalkyl [(alkenylcarbomonocycle)substituted] trisubstituted benzoate, polymer with alkenylcarbomonocycle and alkylcarbomonocycle alkyl alkenoate.
P–25–0067	02/14/2025	CBI	(G) An ingredient used in the manufacture of photoresist.	(G) Sulfonium, bis (dihalo carbomonocycle) carbomonocycle-, salt with trihalobenzoate.
SN–23–0024	01/30/2025	CBI	(G) Component in batteries	(S) Phosphoric acid, iron (2+) lithium salt (1:1:1).
SN–25–0006	02/06/2025	CBI	(S) Substance for use in the manufacture of battery cathodes.	(S) Phosphoric acid, iron (2+) lithium salt (1:1:1).

Table 2 provides non-CBI information on the NOCs received by EPA during this period that have passed an initial screening and determined to be complete:

TABLE 2—NOCS RECEIVED AND UNDER REVIEW

Case No.	Received date	Commencement date	Chemical substance
P–19–0150	02/04/2025	01/22/2025	(G) Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid-2-oxoacetic acid reaction products, sodium salts.
P–20–0101	02/03/2025	01/10/2025	(G) Alkanoic acid, hydroxy-(hydroxyalkyl)-alkyl-, polymer with alpha-[(hydroxyalkyl)alkyl]-omega-alkoxypoly(oxyalkanediyl), (haloalkyl)oxiane polymer (alkylalkylidene)bis[hydroxy-carbomonocycle] alkenoate and isocyanatealkyl-carbomonocycle, hydroxyalkyl acrylate-blocked.
P–21–0215	02/07/2025	02/05/2025	(S) Pyridinium, 3-carboxy-1-methyl-, inner salt.
P–22–0095	02/19/2025	10/14/2024	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.
P–22–0116	02/26/2025	02/25/2025	(G) Carbopolycycle octa-alkene, alkenylaryloxy-.
P–22–0151	02/19/2025	02/19/2025	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.
P–23–0015	02/19/2025	01/24/2025	(G) Amines, polyalkylenepoly, (disubstitutedcarboxy) derivs., alkali metal salts.
P–23–0173	02/10/2025	01/22/2025	(G) Cellulose, alkoxyalkyl ether, alkali metal salt.
P–24–0036	02/11/2025	02/04/2025	(G) Poly(oxy-alkylene), -alkenyl--hydroxy-.

Table 3 provides non-CBI information on the test information that has been received by EPA during this time period:

TABLE 3—TEST INFORMATION RECEIVED AND DETERMINED TO BE COMPLETE

Case No.	Received date	Type of test information	Chemical substance
P–18–0413	02/07/2025	Acute Earthworm OECD 207; Chronic Earthworm study OECD 222; Reproductive study OECD 443; Range finding study.	(G) Haloalkyl alkanoate.

IV. Status Reports

Information about the TSCA section 5 PMNs, SNUNs, MCANs, and exemption applications received, including the date of receipt, the status of EPA's review, the final EPA determination, and the effective date of EPA's determination, is available online at: *https://www.epa.gov/new-chemicals-under-toxic-substances-control-act-tsca/pre-manufacture-notices.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: May 1, 2025.

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2025–07941 Filed 5–6–25; 8:45 am]

BILLING CODE 6560–50–P

through March 31, 2031, or until superseded by another rate schedule, whichever occurs earlier. Notification of the actual effective date will be posted on WAPA–RMR's Rates website and on WAPA–RMR's Open Access Same-Time Information System (OASIS) website.

Applicable

The Incremental Market Efficiency Use (IMEU) accounts for each Western Interconnection Direct Current (West DC) Tie Transmission Owner's expected loss of life of that owner's West DC Tie facilities due to increased utilization of the West DC Ties by the SPP Integrated Marketplace. WAPA–RMR's IMEU Share for the Sidney DC Tie will be calculated using the formula outlined below.

Formula Rate

Define (for each Group of IMEU eligible Sidney DC Tie equipment):

A = Sidney DC Tie Gross Plant Impacted by IMEU ($)

B = Average Service Life of Gross Plant Impacted by IMEU

C = Average Service Life Depreciation Rate of Gross Plant Impacted by IMEU (%)

D = Loss of Service Life Due to Market Use (%)

E = Decreased Average Service Life Depreciation Rate of Gross Plant Impacted by IMEU (%)

IMEU Share for each Group = (E–C)*A, where 1/B=C, and where 1/(B*(1–D))=E

F = Prior period true-up ($)

Total IMEU Share = Sum of IMEU Share for all Groups + F

A recalculated IMEU Share will go into effect every January 1 based on the above formula and updated financial/criteria data. WAPA–RMR will annually notify SPP and make data and information available to interested parties for review and comment related to the recalculated IMEU Share on or shortly after September 1 of the preceding year. This data and information will be posted on the applicable SPP website and on WAPA–RMR's OASIS website.

Rate Schedule LAPT–AS1

United States Department of Energy

Western Area Power Administration

Rocky Mountain Region

Loveland Area Projects

Scheduling, System Control, and Dispatch Service

(Approved Under Rate Order No. WAPA–219)

Effective

The first day of the first full billing period beginning on the later of the following events: (1) when the Western Area Power Administration—Rocky Mountain region (WAPA–RMR) officially becomes a member of, and transfers functional control of Loveland Area Projects (LAP) transmission facilities to, the Southwest Power Pool (SPP); or (2) the go-live date of the expansion of the SPP Regional Transmission Organization (RTO) into the Western Interconnection (scheduled for April 1, 2026, as of the date of the approved Rate Order) and extending through March 31, 2031, or until superseded by another rate schedule, whichever occurs earlier. Notification of the actual effective date will be posted on WAPA–RMR's Rates website and on WAPA–RMR's Open Access Same-Time Information System (OASIS) website.

Applicable

Scheduling, System Control, and Dispatch Service (SSCD) is required to schedule the movement of power through, out of, within, or into one or both of the SPP Balancing Authority Areas (BAA) and certain parts of the transmission system not located within an SPP BAA. WAPA–RMR's annual revenue requirement (ARR) for SSCD will be separated between service provided for LAP transmission facilities in the LAP Zone (LAPZ or Zone 104) and for LAP transmission facilities determined to be in other SPP RTO transmission pricing zones. The ARR and ARR subtotals will be calculated using the formula outlined below.

Formula Rate

Define

A = Operation & Maintenance Expense for SSCD ($)
B = Administrative and General Expense for SSCD ($)
C = Depreciation Expense for SSCD ($)
D = Interest Expense for SSCD ($)
E = Prior Period True-up ($)
F = Applicable ratio share of plant for LAPZ and for other SPP RTO transmission pricing zones (%)
SSCD ARR = (A + B + C + D + E)
ARR Subtotals = (SSCD ARR) * F

A recalculated ARR will go into effect every January 1 based on the above formula and updated financial data. WAPA–RMR will annually notify SPP and make data and information available to interested parties for review and comment related to the recalculated ARR on or shortly after September 1 of the preceding year. This data and information will be posted on the applicable SPP website and on WAPA–RMR's OASIS website.

[FR Doc. 2025–12992 Filed 7–10–25; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2025–0067; FRL–12475–03–OCSPP]

Certain New Chemicals; Receipt and Status Information for March 2025

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt and request for comment.

SUMMARY: This document announces the Agency's receipt of new chemical submissions under the Toxic Substances Control Act (TSCA), including information about the receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN), Microbial Commercial Activity Notice (MCAN), and an amendment to a previously submitted notice; test information; a biotechnology exemption application; an application for a test marketing exemption (TME); and a notice of commencement of manufacture (defined by statute to include import) (NOC) for a new chemical substance. This document also provides a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review. EPA is hereby providing notice of receipt of this information, as required by TSCA, and an opportunity to comment. This document covers the period from 2/27/2025 to 3/31/2025.

DATES: Comments must be received on or before August 11, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2025–0067 and the specific case number provided in this document for the chemical substance related to your comment, online at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you

III. Receipt Reports

Table 1 provides non-CBI information for the PMNs, SNUNs and MCANs received by EPA that have passed an initial screening and determined to be complete consistent with 40 CFR 720.70(a) during this period.

TABLE 1—PMN/SNUN/MCANS RECEIVED AND UNDER REVIEW

Case No.	Received date	Manufacturer	Use(s)	Chemical substance
P–24–0034A ...	03/20/2025	Barentz North America, LLC.	(S) In consumer use cleaning products, the NCS is used as a solvent or cosolvent., For use in laboratories, Elcosol DM is not included in the final article: it is recycled or recuperated for treatment/appropriate disposal, waters are treated through a biological sewage treatment process (STP). There is no consumer use of this NCS for this application. In industrial and commercial cleaning products, Elcosol DM has widespread use as a non-reactive processing aid (no inclusion into or onto article). The substance is not included in the final article it is recycled or recuperated for treatment/appropriate disposal.	(S) 2,5,7,10-Tetraoxaundecane, 4,8-dimethyl-.
P–24–0194	3/31/2025	ERGON, INC	(S) Stabilizer in Asphalt Emulsions	(G) Modified tall oil fatty acid polyamine condensate, hydrochlorides.
P–25–0002A ...	03/21/2025	CBI	(G) Catalyst for polyurethane and polyurethane/epoxy composites.	(G) Poly(oxy-1,2-ethanediyl), alpha, alpha'-[methylenebis(4,1-phenyleneiminocarbonyl)] bis [omega-methoxy-, reaction products with alkali metal salt., Benzene, 1,1'-methylenebis [4-isocyanato-, homopolymer, polyethylene glycol mono-Me ether blocked, reaction products with alkali metal salt.
P–25–0019A ...	03/21/2025	Cytec Industries, Inc.	(G) Additive used in acid production	(G) Dithiophosphate alkyl ester salt.
P–25–0068A ...	03/21/2025	Cytec Industries, Inc.	(G) Additive used in phosphoric acid production.	(G) ether modified polyethyleneimine polymer.
P–25–0069	02/27/2025	CBI	(S) Polymer intermediate	(G) Poly(oxy-1,2-ethanediyl), substituted.
P–25–0070A ...	03/17/2025	CBI	(G) An ingredient used in the manufacture of photoresist.	(G) Sulfonium, bis (dihalo carbomonocycle) (halo carbomonocycle)-, salt with dihalo-sulfoalkyl [(alkenylcarbomonocycle)substituted] trisubstituted benzoate, polymer with alkenylcarbomonocycle and alkylcarbomonocycle alkyl alkenoate.
P–25–0071	03/13/2025	CBI	(G) An ingredient used in the manufacture of photoresist.	(G) Sulfonium, bis (dihalo carbomonocycle) (halocarbomonocycle)-, salt with trihalobenzoate.
P–25–0072A ...	03/19/2025	CBI	(G) Heat transfer fluid, Dielectric testing	(G) 1-Propene, polyfluoro-, trimer, epoxidized.
P–25–0072A ...	03/27/2025	CBI	(G) Heat transfer fluid, Dielectric testing	(G) 1-Propene, polyfluoro-, trimer, epoxidized
P–25–0073A ...	03/25/2025	CBI	(G) Substance for the use in manufacturing of battery components.	(G) Cobalt lithium manganese nickel oxide, metals.
P–25–0074A ...	03/25/2025	Momentive Performance Materials.	(S) The new chemical substance (NCS) will be used as a coupling agent in elastomer-based formulations that will be used in molding operations to manufacture different types of rubber articles.	(G) Ethanol, reaction products with methylated formaldehyde-melamine polymer and substituted alkane modified triethoxysilane.
SN–25–0003A	03/21/2025	CBI	(S) Cathode Active Material in Batteries	(S) Phosphoric acid, iron (2+) lithium salt (1:1:1).
SN–25–0004A	03/24/2025	CBI	(G) Ingredient in the manufacture of consumer cleaning products, Use as monomer in polymer industry, Formulation into cosmetic products.	(S) 1,3-Butanediol, (3R)-.
SN–25–0005A	03/24/2025	CBI	(G) Electronic component manufacturing	(S) 2-Butene, 1,1,1,4,4,4-hexafluoro-, (2Z)-.
SN–25–0006A	03/03/2025	CBI	(S) Substance for use in the manufacture of battery cathodes.	(S) Phosphoric acid, iron (2+) lithium salt (1:1:1).
SN–25–0006A	03/26/2025	CBI	(S) Substance for use in the manufacture of battery cathodes.	(S) Phosphoric acid, iron (2+) lithium salt (1:1:1).

Table 2 provides non-CBI information on the NOCs received by EPA that have passed an initial screening and determined to be complete during this period:

TABLE 2—NOCs RECEIVED AND UNDER REVIEW

Case No.	Received date	Commencement date	Chemical substance
J–24–0015	03/19/2025	02/25/2025	(G) Biopolymer producing modified microorganism, with chromosomally located modifications.
J–25–0001	03/05/2025	02/11/2025	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable.
P–19–0049	03/12/2025	03/11/2025	(G) Fatty acids, polymers with substituted carbomonocycles, dialkanolamine, alkyl substituted alkanediamine and halo-substituted heteromonocycle, formates (salts).
P–19–0171	03/11/2025	03/11/2025	(S) Benzoic acid, 2-chloro-5-fluoro-.
P–19–0176	03/11/2025	03/11/2025	(S) Benzoic acid, 2-chloro-3-methyl-.
P–22–0053	03/19/2025	03/15/2025	(S) Ethanol, 2-amino-, compds. with polyethylene glycol hydrogen sulfate C10-16-alkyl ether.
P–23–0178	03/26/2025	03/26/2025	(S) Benzenamine, 4,4'-(9H-fluoren-9-ylidene) bis-.

Table 3 provides non-CBI information on the test information that has been received by EPA and that have passed an initial screening and determined to be complete during this time period:

TABLE 3.—TEST INFORMATION RECEIVED AND DETERMINED TO BE COMPLETE

Case No.	Received date	Type of test information	Chemical substance
P–14–0712	03/27/2025	Polychlorinated Dibenzodioxins and Polychlorinated dibenzofurans Testing.	(S) Waste plastics, pyrolyzed, C5–55 fraction.
P–16–0543	03/20/2025	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt.
P–21–0036	03/17/2025	Dermal Sensitization Testing Report	(S) 5-Hexen-2-one, 1-bicyclo [2.2.1] hept-2-yl-.
P–21–0079	03/17/2025	Freshwater and Saltwater Fish Acute Toxicity Test (OECD Test Guideline 203); Repeated Dose 28-day Oral Toxicity Study in Rodents (OECD Test Guideline 407); *In Vitro* Mammalian Cell Gene Mutation Tests using the Thymidine Kinase Gene (OECD Test Guideline 490); Dermal Sensitization Testing Report.	(S) 13-Oxabicyclo [10.1.0] trideca-4,8-diene, (4E)-.
P–23–0022	03/28/2025	Skin Sensitization Test Report; Respiratory Sensitization Test Report.	(G) Multi-walled carbon nanotubes.
P–23–0023	03/28/2025	Skin Sensitization Test Report; Respiratory Sensitization Test Report.	(G) Multi-walled carbon nanotubes.
P–23–0024	03/28/2025	Skin Sensitization Test Report; Respiratory Sensitization Test Report.	(G) Multi-walled carbon nanotubes.
P–23–0033	03/28/2025	Skin Sensitization Test Report; Respiratory Sensitization Test Report.	(G) Multi-walled carbon nanotubes.

IV. Status Reports

Information about the TSCA section 5 PMNs, SNUNs, MCANs, and exemption applications received, including the date of receipt, the status of EPA's review, the final EPA determination, and the effective date of EPA's determination, is available online at: *https://www.epa.gov/new-chemicals-under-toxic-substances-control-act-tsca/pre-manufacture-notices.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: July 8, 2025.

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2025–13021 Filed 7–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2025–0067; FRL–12475–04–OCSPP]

Certain New Chemicals; Receipt and Status Information for April 2025

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt and request for comment.

SUMMARY: This document announces the Agency's receipt of new chemical submissions under the Toxic Substances Control Act (TSCA), including information about the receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN), Microbial Commercial Activity Notice (MCAN), and an amendment to a previously submitted notice; test information; a biotechnology exemption application; an application for a test marketing exemption (TME); and a notice of commencement of manufacture (defined by statute to include import) (NOC) for a new chemical substance. This document also provides a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review. EPA is hereby providing notice of receipt of this information, as required by TSCA, and an opportunity to comment. This document covers the period from 4/1/2025 to 4/30/2025.

DATES: Comments must be received on or before August 11, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID)

Calendar No. 121

114TH CONGRESS, 1st Session | SENATE | REPORT 114–67

FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

JUNE 18, 2015.—Ordered to be printed

Mr. INHOFE, from the Committee on Environment and Public Works, submitted the following

REPORT

together with

MINORITY VIEWS

[To accompany S. 697]

[Including cost estimate of the Congressional Budget Office]

The Committee on Environment and Public Works, to which was referred the bill (S. 697) to amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends the bill, as amended, do pass.

GENERAL STATEMENT AND BACKGROUND

S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, amends the Toxic Substances Control Act (TSCA), the fundamental Federal law regulating the manufacture, processing, distribution in commerce, use and disposal of chemical substances.

The Act is named for the late Frank R. Lautenberg, the Senate's long time champion for effective reform of TSCA in order to protect against risks to human health and the environment. Before 2012, Senator Lautenberg (D–NJ) had introduced TSCA reform legislation in five consecutive Congresses. Beginning in early 2013, Senator Lautenberg worked closely with Senator David Vitter (R–LA) to craft the Chemical Safety Improvement Act (CSIA), which was introduced in May, 2013 (S. 1009). The bill represented the very

49–010

Section 11. Relationship to other Federal laws

Section 11 amends section 9 of TSCA, which provides EPA discretionary authority to refer a concern about an unreasonable risk of injury to another Federal Agency, when the authority to address the risk may be more efficiently or effectively regulated by the other Agency. For example, if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information. Section 11 conforms this authority to the provisions of S. 697. It further requires EPA to share information relevant to preventing or mitigating exposures or releases of a chemical substance under another Federal law with any relevant Federal agencies or offices within EPA.

Section 12. Research, development, collection, dissemination, and utilization of data

Section 12 makes a minor conforming amendment to section 10 of TSCA to ensure an appropriate reference to the Department of Health and Human Services.

Section 13. Exports

Section 13 of S. 697 amends the export notification requirements established in section 12 of TSCA. The amendments conform the export notification requirements to the requirements of the Act by requiring prior notice of exports of substances that are not likely to meet, or that do not meet, the safety standard and are subject to proposed or final restrictions. The section requires EPA to promulgate rules to implement the notification requirements.

The substitute strikes the amendments to section 13 of TSCA that were in S. 697 as introduced. Thus, S. 697 makes no changes to the current import requirements under TSCA.

Section 14. Confidential information

Section 14 of S. 697 amends section 14 of TSCA to make several important modifications to the process by which confidential business information (CBI) can be protected against disclosure or disclosed. In general, it is the Committee's intent to balance the need for protection from disclosure for information qualifying under the section b(4) exemption of the Freedom of Information Act (FOIA) (i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential") with the needs to ensure access to such information under appropriate conditions by those who need it to perform their duties, and to maximize public availability of health and environmental information relating to chemical substances in commerce. Striking a balance between protecting trade secrets and sensitive commercial and financial information and broadening access to information on chemicals is essential to encourage innovation and economic competitiveness within the chemical industry and those industries that use chemistry, while better informing the decisions made about chemicals by different levels of government, companies throughout the supply chain, and the general public.

Under this section, all information sought to be protected from disclosure must meet certain criteria, and all such claims must be

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, *Petitioner*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*.	)	Case No. 25-158 Consolidated with Cases No. 25-572, 25-573

DECLARATION OF DARIUS SIVIN, PhD.

1. I, Darius D. Sivin, declare under penalty of perjury that the following statements are true and correct to the best of my knowledge and belief and that they are based upon my personal knowledge.
2. I am an occupational health and safety professional, with extensive experience investigating hazards and making recommendations to improve health and safety in occupational settings. I have a PhD. in Public Health, which I received from Johns Hopkins University in 2002.
3. Since 2002, I have been employed by the United Automobile, Aerospace & Agricultural Implement Workers of America, AFL-CIO (the UAW International Union, UAW) as an International Representative. The UAW represents approximately one million active and retired members in North

America, with members in almost every sector of the economy, including corporations of all sizes engaged in manufacturing. These members are routinely exposed to toxic chemicals in their workplaces and are vitally interested in knowing the identity of these chemicals, their potential toxicity, and all legal obligations their employers must follow to ensure their safe use.

4. In my professional capacity, I provide the International Union, UAW and its local union affiliates with technical support, investigations and recommendations dealing with chemicals and other occupational hazards. In assisting the International Union, UAW and its local unions in their capacity as the exclusive collective bargaining agent for workers in a variety of settings, I have negotiated health and safety provisions in collective bargaining agreements, including securing agreement for the elimination of carcinogens in an auto parts factory. In addition, on behalf of the International Union, UAW, I have developed and delivered testimony to congressional committees and authored and collaborated with other unions on comments to various federal agencies (including the Occupational Safety and Health Administration and the Environmental Protection Agency) on proposed regulations affecting worker health and safety.

5. In February 2023, while participating in a plant walkthrough preceding contract negotiations, I received information from a company health and

safety official that two chemicals in the manufacturing process were covered by an EPA "consent order."[1] Based on my familiarity with EPA's new chemical processes, I knew that a "consent order" issued in connection with a new chemical referred to an order EPA issues under Section 5(e) of the Toxic Substances Control Act, 15 U.S.C. § 2604(e), which governs the manner in which a company is permitted to use a new chemical.

6. Exercising its rights under Section 8(a)(5) of the National Labor Relations Act, 29 U.S.C. § 158(a)(5), which gives a union the right to information relevant to its functions as a collective bargaining representative, the union requested a copy of the consent order. The company's lawyers refused, claiming that it was confidential business information (CBI). The company did provide the union with copies of the safety data sheets (SDSs) for each of the chemicals, as required by OSHA's Hazard Communication Standard, 29 C.F.R. § 1910.1200. One of the ingredients on one of the SDS's was listed only as an "additive," without a chemical name or CAS number.

7. I tried to use EPA's data website, ChemView, to obtain information about these chemicals. ChemView permits searches by the name of the PMN

[1] As I explain below, the UAW subsequently received information about the chemicals under a confidentiality agreement. In compliance with that agreement, I am not disclosing the name or location of the company, nor the identity of the chemicals.

submitter, the assigned case number, the chemical name and/or its proposed use. With only the name and location of the employing company, I was unable to retrieve any information from ChemView. I subsequently learned that the reason my search by name was unsuccessful was that the PMN submitter was not the employer but was instead a parent company or supplier. In preparing this Declaration, I again searched ChemView and was able to find the Pre-Manufacturing Notice (PMN) for one of the two chemicals.

8. The company subsequently provided the UAW with information about the chemicals; under a previously signed confidentiality agreement. Unions and companies routinely enter into these kinds of confidentiality agreements during collective bargaining, to balance the union's NLRA rights to information relevant to its representational role and the employer's rights to protect CBI. OSHA's Hazard Communication Standard similarly permits employers to demand confidentiality agreements as a condition of disclosing safety and health information. 20 C.F.R. § 1910.1200(i)(3).

I declare under penalty of perjury that the foregoing is true and correct to the best of my recollection.

Dated: October 14, 2025

Darius D. Sivin, PhD.