FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SAFER CHEMICALS, HEALTHY FAMILIES; ALASKA COMMUNITY ACTION ON TOXICS; ENVIRONMENTAL HEALTH STRATEGY CENTER; ENVIRONMENTAL WORKING GROUP; LEARNING DISABILITIES ASSOCIATION OF AMERICA; SIERRA CLUB; UNION OF CONCERNED SCIENTISTS; UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO/CLC; WE ACT FOR ENVIRONMENTAL JUSTICE; ASBESTOS DISEASE AWARENESS ORGANIZATION; VERMONT PUBLIC INTEREST RESEARCH GROUP, *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY; ANDREW WHEELER,[*]	No. 17-72260

[*] Andrew Wheeler has been substituted for his predecessor, Scott Pruitt, under Fed. R. App. P. 43(c)(2).

Administrator, United States Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL; AMERICAN COATINGS ASSOCIATION; AMERICAN COKE AND COAL CHEMICALS INSTITUTE; AMERICAN FOREST & PAPER ASSOCIATION; AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS; AMERICAN PETROLEUM INSTITUTE; BATTERY COUNCIL INTERNATIONAL; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; EPS INDUSTRY ALLIANCE; IPC INTERNATIONAL, INC., doing business as IPC Association Connecting Electronics Industries; NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS; NATIONAL MINING ASSOCIATION; POLYURETHANE MANUFACTURERS ASSOCIATION; SILVER NANOTECHNOLOGY WORKING GROUP; SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; STYRENE INFORMATION AND RESEARCH CENTER; UTILITY SOLID WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

ENVIRONMENTAL DEFENSE FUND,
Petitioner,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY; ANDREW WHEELER, Administrator, United States Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL; AMERICAN COATINGS ASSOCIATION; AMERICAN COKE AND COAL CHEMICALS INSTITUTE; AMERICAN FOREST & PAPER ASSOCIATION; AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS; AMERICAN PETROLEUM INSTITUTE; BATTERY COUNCIL INTERNATIONAL; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; EPS INDUSTRY ALLIANCE; IPC INTERNATIONAL, INC., doing business as IPC Association Connecting Electronics Industries; NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS; NATIONAL MINING ASSOCIATION; POLYURETHANE MANUFACTURERS ASSOCIATION; SILVER NANOTECHNOLOGY WORKING GROUP; SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; STYRENE INFORMATION AND

No. 17-72501

RESEARCH CENTER; UTILITY SOLID WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS; CAPE FEAR RIVER WATCH; NATURAL RESOURCES DEFENSE COUNCIL,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

AMERICAN CHEMISTRY COUNCIL; AMERICAN COATINGS ASSOCIATION; AMERICAN COKE AND COAL CHEMICALS INSTITUTE; AMERICAN FOREST & PAPER ASSOCIATION; AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS; AMERICAN PETROLEUM INSTITUTE; BATTERY COUNCIL INTERNATIONAL; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; EPS INDUSTRY ALLIANCE; IPC INTERNATIONAL, INC., doing business as IPC Association Connecting Electronics Industries; NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS; NATIONAL MINING ASSOCIATION;

No. 17-72968

EPA No. EPA-HQ-OPPT-2016-0636

POLYURETHANE MANUFACTURERS ASSOCIATION; SILVER NANOTECHNOLOGY WORKING GROUP; SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; STYRENE INFORMATION AND RESEARCH CENTER; UTILITY SOLID WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS; CAPE FEAR RIVER WATCH; NATURAL RESOURCES DEFENSE COUNCIL,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

AMERICAN CHEMISTRY COUNCIL; AMERICAN COATINGS ASSOCIATION; AMERICAN COKE AND COAL CHEMICALS INSTITUTE; AMERICAN FOREST & PAPER ASSOCIATION; AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS; AMERICAN PETROLEUM INSTITUTE; BATTERY COUNCIL INTERNATIONAL; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; EPS INDUSTRY

No. 17-73290

EPA No. EPA-HQ-OPPT-2016-0654

ALLIANCE; IPC INTERNATIONAL, INC., doing business as IPC Association Connecting Electronics Industries; NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS; NATIONAL MINING ASSOCIATION; POLYURETHANE MANUFACTURERS ASSOCIATION; SILVER NANOTECHNOLOGY WORKING GROUP; SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; STYRENE INFORMATION AND RESEARCH CENTER; UTILITY SOLID WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

ENVIRONMENTAL DEFENSE FUND,
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U.S. ENVIRONMENTAL PROTECTION AGENCY; ANDREW WHEELER, Administrator, United States Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL; AMERICAN COATINGS ASSOCIATION; AMERICAN COKE AND COAL CHEMICALS INSTITUTE; AMERICAN FOREST & PAPER ASSOCIATION; AMERICAN FUEL & PETROCHEMICAL

No. 17-73383

EPA No.
EPA-HQ-OPPT-2016-0654

MANUFACTURERS; AMERICAN PETROLEUM INSTITUTE; BATTERY COUNCIL INTERNATIONAL; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; EPS INDUSTRY ALLIANCE; IPC INTERNATIONAL, INC., doing business as IPC Association Connecting Electronics Industries; NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS; NATIONAL MINING ASSOCIATION; POLYURETHANE MANUFACTURERS ASSOCIATION; SILVER NANOTECHNOLOGY WORKING GROUP; SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; STYRENE INFORMATION AND RESEARCH CENTER; UTILITY SOLID WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

SAFER CHEMICALS, HEALTHY FAMILIES; ALASKA COMMUNITY ACTION ON TOXICS; ENVIRONMENTAL HEALTH STRATEGY CENTER; ENVIRONMENTAL WORKING GROUP; LEARNING DISABILITIES ASSOCIATION OF AMERICA; SIERRA CLUB; UNION OF CONCERNED SCIENTISTS; UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS

No. 17-73390

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INTERNATIONAL UNION, AFL-CIO/CLC; WE ACT FOR ENVIRONMENTAL JUSTICE; ASBESTOS DISEASE AWARENESS ORGANIZATION; VERMONT PUBLIC INTEREST RESEARCH GROUP,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY; ANDREW WHEELER, Administrator, United States Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL; AMERICAN COATINGS ASSOCIATION; AMERICAN COKE AND COAL CHEMICALS INSTITUTE; AMERICAN FOREST & PAPER ASSOCIATION; AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS; AMERICAN PETROLEUM INSTITUTE; BATTERY COUNCIL INTERNATIONAL; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; EPS INDUSTRY ALLIANCE; IPC INTERNATIONAL, INC., doing business as IPC Association Connecting Electronics Industries; NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS; NATIONAL MINING ASSOCIATION; POLYURETHANE MANUFACTURERS

ASSOCIATION; SILVER NANOTECHNOLOGY WORKING GROUP; SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; STYRENE INFORMATION AND RESEARCH CENTER; UTILITY SOLID WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

On Petition for Review of an Order of the Environmental Protection Agency

Argued and Submitted May 16, 2019
Seattle, Washington

Filed November 14, 2019

Before: Diarmuid F. O'Scannlain and Michelle T. Friedland, Circuit Judges, and William H. Pauley III,[**] District Judge.

Opinion by Judge Friedland

[**] The Honorable William H. Pauley III, United States District Judge for the Southern District of New York, sitting by designation.

SUMMARY[***]

Environmental Law

The panel dismissed in part, granted in part, and denied in part petitions for review brought by a variety of environmental groups and other organizations, seeking review of a rule promulgated by the United States Environmental Protection Agency ("EPA") establishing a process to evaluate the health and environmental risks of chemical substances.

The EPA promulgated the Risk Evaluation Rule pursuant to the Toxic Substances Control Act ("TSCA").

Petitioners argued that TSCA required EPA to evaluate risks from uses of a chemical substance collectively, and that the Risk Evaluation Rule contradicted this mandate. The panel held that this challenge was not justiciable because petitioners' interpretation of what the EPA intended to do and petitioners' resulting theory of injury were too speculative. The panel further held that because petitioners' theory of injury was dependent upon harm caused by a failure to assess all conditions of use together, and because it was very uncertain whether EPA ever planned to do what petitioners feared, petitioners' alleged injury was too speculative at this time to establish Article III jurisdiction.

Petitioners also argued that the Risk Evaluation Rule expressed an impermissible intent to exclude some

[***] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

conditions of use from the scope of a risk evaluation, thereby contravening TSCA's requirement that EPA consider all of a chemical's conditions of use. With respect to petitioners' challenge to language in the preamble to the Risk Evaluation Rule, the panel held that it was not final agency action, and thus not reviewable under the Administrative Procedure Act. With respect to petitioners' challenges to specific provisions of the Risk Evaluation Rule, the panel held that the challenges were justiciable final agency action. The panel further held that petitioners had standing to challenge these provisions, and that the challenge was ripe. The panel concluded that the Rule's scope provisions failed on the merits because the challenged provisions did not in fact assert discretion to exclude conditions of use from evaluation.

Finally, petitioners challenged EPA's categorical exclusion of legacy activities from the definition of "conditions of use." The panel held that this claim was justiciable. Turning to the merits, the panel held that EPA's exclusion of legacy uses and associated disposals contradicted TSCA's plain language, but that EPA's exclusion of legacy disposals did not.

COUNSEL

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American Coke and Coal Chemicals Institute; American Petroleum Institute; American Forest & Paper Association; American Fuel & Petrochemical Manufacturers; Chamber of Commerce of the United States Of America; EPS Industry Alliance; IPC International, Inc.; National Association of Chemical Distributors; National Mining Association; and Silver Nanotechnology Working Group.

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Paul Olszowka, Barnes & Thornburg LLP, Chicago, Illinois; for Amicus Curiae People for the Ethical Treatment of Animals.

OPINION

FRIEDLAND, Circuit Judge:

Petitioners, a variety of environmental groups and other organizations, seek review of a rule promulgated by the United States Environmental Protection Agency ("EPA" or "the Agency") establishing a process to evaluate the health and environmental risks of chemical substances. EPA promulgated the "Risk Evaluation Rule" under its authority granted by 15 U.S.C. § 2605(b)(4)(B), a provision added in 2016 to the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2601 *et seq.*[1] Petitioners argue that provisions in the Risk Evaluation Rule relating to the Agency's evaluation of the risks from a substance's "conditions of

[1] Unless otherwise specified, all references to TSCA's provisions in title 15 of the United States Code are to the current version, which was amended in 2016.

use" violate several of TSCA's requirements. Specifically, Petitioners argue: (1) that TSCA requires EPA to evaluate risks associated with a chemical's uses collectively before determining that the chemical is safe; (2) that EPA must consider all of a chemical's conditions of use in that evaluation; and (3) that, when considering conditions of use, EPA must evaluate past disposals of all chemicals, as well as the use and subsequent disposal of chemicals not currently or prospectively manufactured or distributed in commerce for that use. Petitioners argue that various provisions of the Risk Evaluation Rule demonstrate that EPA will not do any of these three things.[2]

We hold that we lack jurisdiction to review Petitioners' first challenge, and that their second fails on the merits. But we grant in part the Petition for Review with respect to Petitioners' third challenge.[3]

[2] Petitioners also argue that EPA's simultaneously promulgated "Prioritization Rule" incorporates some of these alleged deficiencies in the Risk Evaluation Rule, and that the provisions doing so are likewise unlawful. Because Petitioners' challenges to the Prioritization Rule are entirely encompassed within their challenges to the Risk Evaluation Rule, the challenges rise or fall together. We thus focus only on the Risk Evaluation Rule.

[3] Petitioners also challenge several information-gathering provisions in both the Risk Evaluation Rule and the Prioritization Rule. *See* 15 U.S.C. § 2625(k). EPA agrees that some of these challenged information-gathering provisions should be reconsidered and therefore requests that they be remanded. We address the information-gathering issues in a concurrently filed memorandum disposition.

I.

A.

Congress enacted TSCA in 1976 "to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491, 4491. TSCA was "designed to fill a number of regulatory gaps" in premarket review, regulation of chemicals themselves (rather than regulation of discharges, emissions, ambient air, or consumer products), and information-gathering responsibility. *Id.* at 1–2. TSCA required EPA to regulate chemical substances that the Agency found to "present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a) (1976). As originally enacted, however, TSCA did not provide a specific process or timeline by which EPA was required to evaluate a substance's risks.

In the decades following TSCA's passage, Congress found that "effective implementation of TSCA by [EPA] ha[d] been challenged by shortcomings in the statute itself, and by several key decisions of Federal Courts and the Agency's interpretation of those decisions." S. Rep. No. 114-67, at 2 (2015). There had "been persistent concerns about the pace of EPA's work under TSCA, the ability of the Agency to use its existing authority, and whether the statute prevent[ed] certain regulatory efforts." H.R. Rep. No. 114-176, at 12–13 (2015), *as reprinted in* 2016 U.S.C.C.A.N. 276, 277. Congress accordingly amended TSCA in 2016. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. § 2601 *et seq.*); *see also generally* S. Rep. No. 114-67; H.R. Rep. No. 114-176.

The 2016 amendments "restructur[ed] the way . . . chemicals are evaluated and regulated," H.R. Rep. No. 114-176, at 13, but Congress's policy goals reflected in the 1976 Act remained "intact," S. Rep. No. 114-67, at 7. Congress intended through the amendments "to provide broad protection of human health and the environment," and "to improve availability of information about chemicals." S. Rep. No. 114-67, at 6.

B.

The 2016 amendments create, among other things, "a separate risk evaluation process for determining whether a chemical substance presents or will present an unreasonable risk of injury," and prescribe statutory deadlines by which EPA is required to complete such evaluations. H.R. Rep. No. 114-176, at 23, 25. The amendments also direct EPA's Administrator to prioritize evaluations of the risks of chemicals considered to be the most dangerous. And once EPA determines that a particular chemical substance is associated with an unreasonable risk, the Agency is required to regulate that substance.

With respect to prioritizing risk evaluations, TSCA requires that the Administrator "designate as a high-priority substance a chemical substance that the Administrator concludes . . . may present an unreasonable risk of injury to health or the environment . . . under the conditions of use." 15 U.S.C. § 2605(b)(1)(B)(i). The Administrator must designate a substance as "low-priority" if "such substance does not meet the standard" to be high-priority. 15 U.S.C. § 2605(b)(1)(B)(ii).

For chemical substances that EPA designates as high-priority, the Agency must initiate and complete a risk evaluation of the chemical within three years, with a possible

six-month extension. 15 U.S.C. § 2605(b)(3)(A), (b)(4)(G). EPA must also conduct some risk evaluations at the request of chemical manufacturers ("manufacturer-requested risk evaluations"). *See* 15 U.S.C. § 2605(b)(4)(C)(ii).

TSCA's risk evaluation provision requires EPA to evaluate chemical substances under their "conditions of use." Specifically, TSCA states:

> The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance 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 to the risk evaluation by the Administrator, under the conditions of use.

15 U.S.C. § 2605(b)(4)(A).

The term "conditions of use" is defined to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4).[4] In the early stages of the risk evaluation process, TSCA requires EPA to list in a published scope document

[4] TSCA provides statutory definitions for the terms "manufacture," "process," and "commerce" (as well as "distribute in commerce" and "distribution in commerce"), but does not define "used" or "disposed of." *See generally* 15 U.S.C. § 2602.

the conditions of use it "expects to consider" for the chemical substance being evaluated. 15 U.S.C. § 2605(b)(4)(D).

Once a risk evaluation is completed, if the Administrator determines based on that evaluation "that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall" promulgate rules regulating that chemical substance so that it "no longer presents such [an unreasonable] risk." 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2605(c)(1).

In order to effectuate TSCA's statutory requirements, Congress instructed EPA to "establish, by rule, a risk-based screening process, including criteria for designating chemical substances as" either high-priority or low-priority for risk evaluation. 15 U.S.C. § 2605(b)(1)(A). EPA was also required to establish by rule "a process to conduct risk evaluations." 15 U.S.C. § 2605(b)(4)(B).

TSCA also contains a judicial review provision. *See* 15 U.S.C. § 2618. It provides that "not later than 60 days after the date on which a rule is promulgated . . . or the date on which an order is issued [under TSCA] any person may file a petition for judicial review of such rule or order." 15 U.S.C. § 2618(a)(1)(A). TSCA specifically authorizes judicial review of EPA's determination that a substance is low-priority or poses no unreasonable risk. 15 U.S.C. § 2618(a)(1)(A), (a)(1)(C)(i).

C.

In accordance with TSCA, EPA issued rules for prioritization and risk evaluation in July 2017. The Risk

Evaluation Rule states, generally, that EPA will evaluate chemical substances under their conditions of use:

> As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

40 C.F.R. § 702.47.

The Risk Evaluation Rule similarly explains that "[t]he scope of the risk evaluation will include," among other things, "[t]he condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation." 40 C.F.R. § 702.41(c). "Conditions of use" is defined in the Risk Evaluation Rule as "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"—the same definition as in TSCA itself. *Compare* 40 C.F.R. § 702.33, *with* 15 U.S.C. § 2602(4).

In the preamble to the Risk Evaluation Rule, EPA states that three categories of uses and activities are excluded from the definition of conditions of use. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,729 (July 20, 2017). These are: (1) "circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution," which the Agency calls "legacy uses"; (2) "disposals from such uses," which the Agency calls "associated disposal"; and (3) "disposals that have already occurred," which the Agency calls "legacy

disposal." *Id.* In this litigation, EPA refers to these uses and activities collectively as "legacy activities."

EPA also states, in the preamble to the Risk Evaluation Rule, that it "intends to exercise discretion in addressing circumstances where [a] chemical substance . . . is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping." 82 Fed. Reg. at 33,730. In some circumstances, EPA states, "it may be most appropriate . . . to evaluate the potential risks arising from a chemical impurity within the scope of the risk evaluations for the impurity itself," while in others it "may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the impurity." *Id.* The preamble further provides that the Agency "may choose not to include [that] impurity within the Scope of any risk evaluation," where "the risk from the presence of the impurity would be '*de minimis*' or otherwise insignificant." *Id.* The preamble also lists several other uses that commenters had suggested should not be considered in risk evaluations, such as misuse and illegal use. *Id.* The preamble ultimately concludes, however, that "it would be premature to definitively exclude a priori specific conditions of use from risk evaluation." *Id.*

D.

Several groups filed petitions for review of the Risk Evaluation Rule pursuant to the judicial review provisions of TSCA, 15 U.S.C. § 2618, and the Administrative Procedure Act, 5 U.S.C. § 706. Those petitions were consolidated.[5] A

[5] Petitioners in this consolidated action are: Safer Chemicals, Healthy Families; Alaska Community Action on Toxics; Environmental Health Strategy Center; Environmental Working Group; Learning

number of industry groups jointly moved to intervene, and a motions panel of our court granted the motion.[6]

Petitioners argue that TSCA requires EPA to evaluate risks from uses of a chemical substance collectively, and that the Risk Evaluation Rule contradicts this mandate. Separately, Petitioners argue that the Risk Evaluation Rule expresses an impermissible intent to exclude some conditions of use from the scope of a risk evaluation. Finally, Petitioners challenge EPA's exclusion of legacy activities from the definition of "conditions of use."

II.

A.

Petitioners first challenge provisions of the Risk Evaluation Rule relating to the process by which EPA will conduct risk determinations. Petitioners argue that several

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Disabilities Association of America; Sierra Club; Union of Concerned Scientists; United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC; WE ACT for Environmental Justice; Asbestos Disease Awareness Organization; Vermont Public Interest Research Group; Alliance of Nurses for Healthy Environments; Cape Fear River Watch; Natural Resources Defense Council; and Environmental Defense Fund.

[6] Intervenors are: American Chemistry Council; American Coatings Association; American Coke and Coal Chemicals Institute; American Forest & Paper Association; American Fuel & Petrochemical Manufacturers; American Petroleum Institute; Battery Council International; Chamber of Commerce of the United States of America; EPS Industry Alliance; IPC International, Inc.; National Association of Chemical Distributors; National Mining Association; Polyurethane Manufacturers Association; Silver Nanotechnology Working Group; Society of Chemical Manufacturers and Affiliates; Styrene Information and Research Center, Inc.; and Utility Solid Waste Activities Group.

provisions in the Rule assert that EPA has authority to determine whether individual conditions of use, in isolation, pose unreasonable risks, rather than to evaluate the risks posed by a chemical substance holistically. Specifically, Petitioners challenge three provisions of the Rule. First is EPA's statement that it "will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use[] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." *See* 40 C.F.R. § 702.47. Second is the Rule's statement that:

> EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation. However, EPA may complete its evaluation of the chemical substance under specific conditions of use or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk to health or the environment under those conditions of use.

40 C.F.R. § 702.41(a)(9).

Finally, Petitioners challenge a provision of the Rule entitled "Final determination of no unreasonable risk," which states:

> A determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable

> risk of injury to health or the environment will be issued by order and considered to be a final Agency action.

40 C.F.R. § 702.49(d).

Petitioners interpret these provisions to mean that EPA plans to conduct use-by-use risk determinations and to declare the safety of individual uses of a chemical standing alone, without first considering whether its conditions of use, viewed together, pose an unreasonable risk. Petitioners argue that this contravenes TSCA's requirement that EPA "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk . . . under the conditions of use." *See* 15 U.S.C. § 2605(b)(4)(A). Petitioners emphasize TSCA's reference to the risk of "*a chemical substance*," arguing that this requires the agency to conduct a holistic assessment of a chemical under all of its conditions of use, rather than to assess risks from individual conditions of use.

Petitioners recognize that when EPA decides that a particular condition of use *does* pose an unreasonable risk, such a determination on its own complies with TSCA's requirement that EPA conduct an evaluation of whether "the substance as a whole poses unreasonable risk." That is because, as Petitioners explain, if any condition of use (or any combination of subsets of the conditions of use) associated with a chemical poses an unreasonable risk of harm, that chemical substance would necessarily pose an unreasonable risk under *all* of its conditions of use considered together. As soon as the Agency determines that any combination of conditions of use pose such a risk, therefore, the Agency may proceed to regulate that chemical under 15 U.S.C. § 2605(a). Petitioners contend that the Risk

Evaluation Rule goes one step further, however, allowing EPA to issue a final determination that a chemical substance does *not* pose an unreasonable risk after having looked at only one or a few of its conditions of use. Petitioners argue that, under TSCA, the Agency may only issue a "no unreasonable risk" determination for a chemical substance after it has considered the risks associated with *all* of that substance's conditions of use.[7]

We hold that this challenge is not justiciable because Petitioners' interpretation of what EPA intends to do and Petitioners' resulting theory of injury are too speculative.

1.

"Article III of the Constitution empowers us to adjudicate only 'live cases or controversies,' not 'to issue advisory opinions [or] to declare rights in hypothetical cases.'" *Clark v. City of Seattle*, 899 F.3d 802, 808 (9th Cir. 2018) (quoting *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000) (en banc)). The requirement of Article III standing "aids the federal judiciary to avoid intruding impermissibly upon the powers vested in the executive and legislative branches, by preventing courts from issuing advisory opinions not founded upon the facts of a controversy between truly adverse parties." *Scott v. Pasadena Unified Sch. Dist.*, 306 F.3d 646, 654 (9th Cir. 2002). For purposes of standing, a plaintiff must establish he or she has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and

[7] No party discusses, so we do not reach, whether a broader evaluation of risks would be required to comply with 15 U.S.C. § 2605(a) at the regulation stage, if the predicate determination of unreasonable risk had been made based on fewer than all of a substance's conditions of use.

(3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

An "injury in fact" is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (citations and quotation marks omitted). A "concrete" injury is one that "actually exist[s]," meaning that it is "real, and not abstract." *Spokeo*, 136 S. Ct. at 1548 (quotation marks omitted). Both "[i]ntangible harms and a 'risk of real harm' can be sufficiently concrete" for these purposes. *Bassett v. ABM Parking Servs., Inc.*, 883 F.3d 776, 779 (9th Cir. 2018) (quoting *Spokeo*, 136 S. Ct. at 1549–50). A "particularized" injury is one that "affect[s] the plaintiff in a personal and individual way." *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560 n.1).

"Ripeness is [another] . . . doctrine[] that we use to determine whether a case presents a live case or controversy" over which we have jurisdiction under Article III. *Clark*, 899 F.3d at 808. Ripeness doctrine

> is designed "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect . . . agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties."

Ohio Forestry Ass'n, Inc. v. Sierra Club, 523 U.S. 726, 732–33 (1998) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967), *abrogated on other grounds by Califano v.*

Sanders, 430 U.S. 99, 105 (1977)). Because ripeness doctrine derived "both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction," *Clark*, 899 F.3d at 809 (quoting *Thomas*, 220 F.3d at 1138), the "ripeness inquiry" has often involved "both 'a constitutional and a prudential component,'" *id.* (quoting *Bishop Paiute Tribe v. Inyo County*, 863 F.3d 1144, 1153 (9th Cir. 2017)).

To satisfy the constitutional ripeness requirement, a case "must present issues that are definite and concrete, not hypothetical or abstract." *Id.* (quoting *Bishop Paiute Tribe*, 863 F.3d at 1153). "[S]orting out where standing ends and ripeness begins is not an easy task," *id.* (quoting *Thomas*, 220 F.3d at 1138), so "[c]onstitutional ripeness is often treated under the rubric of standing because ripeness coincides squarely with standing's injury in fact prong," *id.* (alteration in original) (quoting *Bishop Paiute Tribe*, 863 F.3d at 1153).

Where (as here) there is a judicial review provision in a statute, any prudential ripeness considerations are satisfied for cases brought under that provision.[8] *See Ohio Forestry Ass'n*, 523 U.S. at 737 (citing TSCA's judicial review provision in 15 U.S.C. § 2618 as an example of a statute in which Congress provided for pre-enforcement review, and suggesting that such a provision renders a pre-enforcement challenge prudentially ripe); *see also Shalala v. Ill. Council*

[8] We noted in *Clark* that "[t]he Supreme Court . . . cast doubt on the prudential component of ripeness in *Susan B. Anthony List v. Driehaus*, [573 U.S. 149 (2014)]." 899 F.3d at 809 n.4. In *Clark*, like the Court in *Susan B. Anthony List*, we did not need to "resolve the continuing vitality of the prudential ripeness doctrine." *Id.* (quoting *Susan B. Anthony List*, 573 U.S. at 167). The same is true here because any potential prudential ripeness concerns are resolved by TSCA's judicial review provision.

on Long Term Care, Inc., 529 U.S. 1, 12–13 (2000) (referring to statutorily authorized pre-enforcement review as an exception to ripeness and exhaustion requirements, and likewise citing § 2618 as an example).

Although a judicial review provision like that in 15 U.S.C. § 2618 avoids any *prudential* ripeness concerns about claims brought under that provision, such a provision does not make a claim *constitutionally* ripe. The Supreme Court emphasized in *Spokeo* that Congress cannot confer Article III jurisdiction when it is otherwise lacking. *See Spokeo*, 136 S. Ct. at 1547–48 ("Injury in fact is a constitutional requirement, and '[i]t is settled that Congress cannot erase Article III's standing requirements by statutorily granting the right to sue to a plaintiff who would not otherwise have standing.'" (alteration in original) (quoting *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997))). And while *Spokeo* itself addressed Article III standing, the same is necessarily true of Article III ripeness, which is also a constitutional requirement. *See Stolt-Nielsen S.A. v. AnimalFeeds Int'l Corp.*, 559 U.S. 662, 670 n.2 (2010) ("Ripeness reflects constitutional considerations that implicate 'Article III limitations on judicial power.'" (quoting *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993))); *cf. Barenblatt v. United States*, 360 U.S. 109, 112 (1959) ("Congress . . . must exercise its powers subject to the limitations placed by the Constitution on governmental action."). Petitioners must therefore establish that their case is justiciable under the Article III doctrines of standing and ripeness, with respect to each of their claims.

2.

a.

Petitioners argue that they are injured by the use-by-use approach of the Risk Evaluation Rule in two ways. First, Petitioners contend, the use-by-use approach will lead EPA to underestimate risk where exposure results from multiple activities involving a chemical, which threatens their concrete interests in avoiding harmful exposures to chemicals. Second, they argue that the Rule will deprive them of information about chemical risks to which they are entitled under TSCA and that they need to reduce exposures to toxic chemicals.[9] Petitioners maintain that these injuries are imminent, noting, for example, that their members are currently exposed to a chemical flame retardant that is already undergoing risk evaluation. They also argue that their claims are ripe, pointing to TSCA's judicial review provision and the harm they argue would be caused by

[9] Petitioners further argue that their members are injured by EPA's failure to follow the correct procedures. But Petitioners have not shown that EPA has actually failed to follow any specific procedures—at most, Petitioners' claim is that EPA has indicated, in promulgating the Risk Evaluation Rule, that it intends to not follow correct procedures. Even if that is so, the Agency has not yet taken a specific action that could have violated a procedural or statutory right (*e.g.*, by completing a risk evaluation without following procedures required by TSCA), so this case differs from ones arising out of alleged procedural injuries. *See, e.g.*, *Friends of Santa Clara River v. U.S. Army Corps of Eng'rs*, 887 F.3d 906, 910 (9th Cir. 2018) (challenge under National Environmental Policy Act ("NEPA"), Endangered Species Act, and Clean Water Act to an agency's process in issuing a permit authorizing discharge of materials into a river); *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 970 (9th Cir. 2003) (holding that the plaintiffs "were deprived of the opportunity to comment on the [agency's NEPA documents] at all points in the rulemaking process," and that "[t]his deprivation violated their rights under the regulations implementing NEPA").

delaying the performance of risk evaluations that comply with TSCA.

EPA argues that Petitioners' claim is nonjusticiable because it is based merely on a "hypothes[i]s about how EPA may apply [the Rule] in the future," and therefore Petitioners have not alleged "a concrete or particularized injury." EPA maintains that if it ever *does* take final agency action that Petitioners believe fails to comply with TSCA's requirements, then Petitioners could challenge that action. Intervenors agree with EPA that this claim is not justiciable, because the existence of the Risk Evaluation Rule itself could not possibly cause Petitioners any injury.

b.

We conclude that Petitioners' challenge regarding use-by-use risk evaluations is not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear.

Petitioners rely heavily on the Rule's reference to "whether [a] chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of use*[] within the scope of the risk evaluation." 40 C.F.R. § 702.47 (emphasis added). One reading of this provision (and its use of the term "each") does suggest that EPA will evaluate risks associated with conditions of use individually. But it does not *necessarily* mean that EPA will (or even could) make determinations of "no unreasonable risk" based only on individual use-by-use evaluations, rather than on an evaluation that looks at "each" condition—as in "every one of the" conditions—of use together.

The same is true of the statement in 40 C.F.R. § 702.41(a)(9) that Petitioners challenge, which provides that "EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation." This could well mean EPA will do exactly what Petitioners argue it must: consider all conditions of use before completing a risk determination for a chemical. It also states that "EPA may complete its evaluation of the chemical substance under specific conditions of use or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk." 40 C.F.R. § 702.41(a)(9). But again, although this suggests that EPA plans to conduct some use-by-use risk determinations, it does not clearly mean that EPA will fail to do what Petitioners argue is required under TSCA.

The last provision that Petitioners challenge, 40 C.F.R. § 702.49(d), is no different. There, the Rule states merely that "[a] determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk . . . will be issued by order and considered to be a final Agency action." 40 C.F.R. § 702.49(d). We simply do not know what this provision means either, or how the Agency will apply it in any particular case.

Other provisions in the Rule are similarly ambiguous. One states:

> In general, EPA intends to determine whether a chemical substance does or does not present an unreasonable risk under all of the conditions of use within the scope of the risk

> evaluations, and intends to identify the individual conditions of use or categories of conditions of use that are responsible for such determinations.

40 C.F.R. § 702.41(a)(8). Again, this might well mean that EPA will evaluate whether a substance poses an unreasonable risk under each use individually, or it might mean that the Agency will consider conditions of use collectively, as Petitioners wish. And a provision entitled "Final determination of unreasonable risk," which appears immediately before the challenged § 702.49(d), states that EPA will regulate a substance if it determines that "under one or more of the conditions of use within the scope of the risk evaluation [the substance] presents an unreasonable risk of injury to health or the environment." 40 C.F.R. § 702.49(c). This might comport with Petitioners' understanding of TSCA's requirements: that the relevant question is whether a chemical substance poses an unreasonable risk under any one condition of use, *or* under any combination of uses.

And, in fact, the preamble to the Risk Evaluation Rule weighs against Petitioners' understanding of EPA's plans, as it supports the notion that EPA will evaluate risks collectively, just as Petitioners wish: "[T]he Agency is to exercise [its] discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." Procedures for Chemical Risk Evaluation Under the

Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,729 (July 20, 2017).[10]

The lack of clarity in what the regulations promulgated by EPA mean creates a justiciability problem with Petitioners' claim. To the extent it is not clear how EPA will actually conduct risk evaluations under these rules, there is no concrete, imminent harm to Petitioners' interests that is caused by the challenged provisions. On this point we look to two analogous contexts: pre-enforcement challenges to rules that proscribe certain behavior, and challenges to rules that confer benefits on individuals.

In the context of pre-enforcement challenges to agency rules governing the behavior of regulated parties, we have recognized that "[n]either the 'mere existence of a proscriptive statute' nor a 'generalized threat of prosecution' satisfies the 'case or controversy' requirement." *Wolfson v. Brammer*, 616 F.3d 1045, 1058 (9th Cir. 2010) (quoting *Thomas*, 220 F.3d at 1139). Rather, "for a claim to be ripe, the plaintiff must be subject to a genuine threat of imminent prosecution." *Id*. (quotation marks and emphasis omitted). In evaluating the existence of any such genuine threat, we look at three criteria: "(1) whether the plaintiff has articulated a concrete plan to violate the law in question; (2) whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings; and (3) the history of past prosecution or enforcement under the

[10] By contrast, EPA has asserted in its briefing to our court that it has flexibility, under the Risk Evaluation Rule, to conduct use-by-use "no unreasonable risk" determinations. Elsewhere in its briefs, however, EPA contends that "[u]nder the [Risk Evaluation Rule], EPA will, in fact, issue final risk evaluations for entire chemical substances." These contradictory statements add to the ambiguity about how EPA plans to conduct risk evaluations.

challenged statute." *Id.*; *see also Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) ("[W]e have held that a plaintiff satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979))).

In the context of "benefit-conferring rule[s]," *Mont. Envtl. Info. Ctr. v. Stone-Manning*, 766 F.3d 1184, 1190 (9th Cir. 2014) (quoting *Reno*, 509 U.S. at 69 (O'Connor, J., concurring in the judgment)), we have applied a "firm prediction rule" to determine constitutional ripeness, *id.* Under that rule, drawn from Justice O'Connor's concurring opinion in *Reno v. Catholic Social Services, Inc.* and adopted by our court in *Freedom to Travel Campaign v. Newcomb*, 82 F.3d 1431 (9th Cir. 1996), we ask whether we "can make a firm prediction that the plaintiff will apply for the benefit [at issue], and that the agency will deny the application by virtue of the [challenged] rule." *Id.* at 1436 (quoting *Reno*, 509 U.S. at 69 (O'Connor, J., concurring in the judgment)).

While neither of these lines of cases speaks directly to the issue that we now face, both clearly aim to deduce, in different contexts, the extent to which a claimed injury is actually and non-speculatively impending. Applying the principles underlying each of these tests, we conclude that Petitioners' challenge regarding use-by-use determinations is not justiciable. Because of the ambiguity in the rules, we cannot predict whether Petitioners will be harmed in the way they claim, or whether the Agency will in fact apply these rules as Petitioners wish.

Clark v. City of Seattle is also instructive in this regard. In *Clark*, Seattle's city council passed an ordinance

establishing a multistep collective bargaining process applicable to ride-hailing services. A group of drivers sued, challenging the legality of the ordinance, and we held that the challenge was not ripe under Article III. 899 F.3d at 809 n.4. Among other things, we noted that injury to the drivers was not actual or imminent, because it would occur only if a contract or agreement was in fact reached—and no such contract or agreement was near. *Id.* at 810–11. The assertion of injury was therefore "wholly speculative." *Id.* at 811. Petitioners' theory of injury in this case is even more speculative. In *Clark*, it was clear what the procedures would be but unclear whether they would actually be invoked. Here, it is not even clear what EPA's procedures will be, let alone whether EPA will employ them in a way that injures Petitioners.

Because Petitioners' theory of injury is dependent upon harm caused by a failure to assess all conditions of use together, and because it is very uncertain whether EPA ever plans to do what Petitioners fear, Petitioners' alleged injury is too speculative at this time to establish Article III jurisdiction. *See Clinton v. City of New York*, 524 U.S. 417, 432 (1998) (emphasizing that plaintiffs must establish a "sufficient likelihood of . . . injury to establish standing"). If EPA *does*, in the future, fail to consider all conditions of use together in completing a risk evaluation, and if Petitioners are harmed by that failure, then Petitioners may, under TSCA, seek review of EPA's "no unreasonable risk" determination. *See* 15 U.S.C. §§ 2618(a)(1)(A), 2605(i)(1).[11] Petitioners would at that time have standing to

[11] Likewise, to the extent EPA decides it has discretion under the Prioritization and Risk Evaluation Rules to consider risk on a use-by-use basis, and not holistically, and to the extent that decision affects the Agency's prioritization decisions, Petitioners may challenge EPA's

sue, and such a claim would be ripe for review. And EPA has insisted—both at oral argument and in its briefing here—that Petitioners would be able to challenge an allegedly improper risk determination. *See* 15 U.S.C. § 2618(a)(1)(A).

B.

Petitioners next argue that the Risk Evaluation Rule contravenes TSCA's requirement that EPA consider *all* of a chemical's conditions of use when conducting a risk evaluation—which Petitioners assert is required whether or not Petitioners are correct in their argument, discussed above, that the risk analysis should look at uses collectively. Petitioners' challenge relating to the proper scope of a risk evaluation comes in two forms: a challenge to preambular language, and challenges to provisions of the Risk Evaluation Rule (which we will refer to as the "scope provisions").

First, Petitioners identify language in the preamble to the Risk Evaluation Rule that they contend reflects EPA's intent not to consider every condition of use. For example, Petitioners direct our attention to EPA's suggestion that it may exclude circumstances in which a substance is unintentionally present as an impurity in a second chemical from the risk evaluation of the substance present as the impurity, and may instead evaluate the risks associated with the impurity in the context of the second chemical. *See* 82 Fed. Reg. at 33,730. Petitioners also point to EPA's suggestion that it may disregard the existence of that

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designation of a particular substance as low-priority. *See* 15 U.S.C. §§ 2618(a)(1)(C)(i), 2605(b)(1)(B)(ii).

impurity entirely if its associated risk would be *de minimis*. *Id.*

Second, Petitioners challenge several provisions of the Risk Evaluation Rule itself, relying to some extent on the preamble to support these claims. Specifically, Petitioners challenge the Risk Evaluation Rule's statement that "[t]he scope of the risk evaluation will include . . . [t]he condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation." *See* 40 C.F.R. § 702.41(c). Petitioners also point to EPA's references in the Risk Evaluation Rule to the conditions of use "within the scope of" the evaluation, *see* 40 C.F.R. §§ 702.41(a)(5), (a)(8), (a)(9), (c)(4)(i), (c)(4)(iii), (d)(2); 702.49(b)–(d), arguing that this wording further shows that EPA does not intend to consider all conditions of use. Petitioners express similar concern about the provision on manufacturer-requested risk evaluations:

> EPA will assess whether the circumstances identified in the request constitute condition [sic] of use under [the Risk Evaluation Rule's definition section], and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also assess what, if any, additional conditions of use that [sic] warrant inclusion within the scope of a risk evaluation for the chemical substance.

40 C.F.R. § 702.37(e)(3). Petitioners argue that these provisions demonstrate that not all conditions of use will be in the scope of a risk evaluation, and that EPA is asserting discretion to exclude some conditions of use.

With respect to the challenged preambular language, we hold that it is not final agency action, and thus is not reviewable under the Administrative Procedure Act. We are left, then, with Petitioners' challenges to specific provisions of the Risk Evaluation Rule. Although we conclude that these challenges are justiciable, we hold that they fail on the merits because the provisions that Petitioners point to do not, as Petitioners contend, in fact assert discretion to exclude conditions of use from evaluation.

1.

The Administrative Procedure Act gives courts the authority to review final agency action. *See* 5 U.S.C. § 704; *see also Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 319 (D.C. Cir. 2011) (referring to finality as a "jurisdictional issue[]"). A final agency action is one that "mark[s] the consummation of the agency's decisionmaking process," and one "by which rights or obligations have been determined, or from which legal consequences will flow." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). Formally promulgated rules are the bread and butter of final agency actions. *See Dole v. United Steelworkers of Am.*, 494 U.S. 26, 33 (1990) ("The promulgation of a disclosure rule is a final agency action."); *Cal. Sea Urchin Comm'n v. Bean*, 828 F.3d 1046, 1049 (9th Cir. 2016) ("The 1987 Final Rule was clearly a final agency action."). A regulation's "preamble may under some circumstances be reviewable" as final agency action. *Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1222 (D.C. Cir. 1996); *see also Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1181 n.1 (9th Cir. 2008) ("We do not address this issue since the parties agreed . . . that the preemption

discussion in the preamble of the Final Rule is not final agency action and thus not currently reviewable."). "The question of reviewability hinges upon whether the preamble has independent legal effect, which in turn is a function of the agency's intention to bind either itself or regulated parties." *Kennecott*, 88 F.3d at 1223. Even "[a]bsent an express statement [of intent], we may yet infer that the agency intended the preamble to be binding if what it requires is sufficiently clear." *Id.*

In the preamble to the Risk Evaluation Rule, the Agency noted that based on its reading of TSCA, it "may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern." 82 Fed. Reg. at 33,729. The Agency indicated that it may do so when a risk associated with a use would be *de minimis*, or when another regulatory agency has already assessed that use. *Id.*

In a section of the preamble entitled "Conditions of use that may be excluded from the [s]cope of the risk evaluation," *id.* at 33,730, EPA "elaborate[d] further on this," *id.* at 33,729. There, EPA explained that it "intends to exercise discretion in addressing circumstances where [a] chemical substance . . . is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping." *Id.* at 33,730. In some circumstances, EPA stated, "it may be most appropriate . . . to evaluate the potential risks arising from a chemical impurity within the scope of the risk evaluations for the impurity itself," while in others it "may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the impurity." *Id.* The Agency further provided that it "may choose not to

include [that] impurity within the [s]cope of any risk evaluation," where "the risk from the presence of the impurity would be *'de minimis'* or otherwise insignificant." *Id.* EPA also listed several other uses that commenters had suggested should not be considered in risk evaluations, including: "[u]ses where other agencies hold jurisdiction, misuse, illegal use, speculative future conditions of use, [or] uses that are inconsistent with labeling requirements." *Id.* EPA ultimately concluded, however, that "it would be premature to definitively exclude a priori specific conditions of use from risk evaluation." *Id.*

This is not the sort of language that indicates an agency has intended to bind itself—in fact, it appears to be just the opposite. The preambular language concerning the scope of risk evaluations indicates only that EPA could "exercise discretion" about the context in which it could evaluate a substance that is present as an impurity, and "*may* choose not to" ever consider the impurity when its risk would be *de minimis*. *See id.* (emphasis added); *see also Nat. Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) (emphasizing, in the context of evaluating finality, a distinction between "may" and "will"). The Agency referenced other uses that *commenters* had suggested should be excluded from the scope of a risk evaluation, but explicitly decided *not* to definitively exclude any "specific conditions of use," explaining that it would make "reasonable, technically sound scoping decisions" with respect to each individual substance evaluated. 82 Fed. Reg. at 33,730. The preamble language does not bind the agency to *ever* exclude any conditions of use from consideration. It therefore is not reviewable as final agency action under the Administrative Procedure Act.

2.

We turn next to Petitioners' challenge to the scope provisions. These provisions, as part of the Rule itself, clearly qualify as final agency action, *see Cal. Sea Urchin Comm'n*, 828 F.3d at 1049, and we conclude that Petitioners' challenge to them is justiciable. Nonetheless, Petitioners' challenge fails on the merits. Even assuming TSCA requires EPA to consider all conditions of use within the scope of a chemical substance's risk evaluation, the provisions of the Risk Evaluation Rule that Petitioners challenge do not evince any contrary intent on the part of EPA.

a.

Looking first at Petitioners' standing to challenge the scope provisions of the Risk Evaluation Rule, Petitioners argue that they will imminently be harmed by EPA's exclusion of some conditions of use from consideration, because EPA will systematically understate risks associated with chemicals that are evaluated. Petitioners also argue that because (on their reading) the Risk Evaluation Rule allows EPA to avoid evaluating some potential risks associated with chemical substances, the Rule excludes necessary information from EPA's publications.[12]

As an initial matter, the challenged language here is not ambiguous, so it is not speculative whether the Rule authorizes EPA to do what Petitioners claim. This

[12] Because this challenge is to part of the Rule itself, which, as we have explained, undoubtedly constitutes final agency action, we need not consider whether the challenged language expresses the Agency's intent to bind itself for purposes of deciding whether we may review it. Because that language is in the formally promulgated Rule, rather than a preamble discussion, it by definition binds the Agency.

differentiates it from Petitioners' challenge to use-by-use determinations which, as we explained above, is too speculative to evaluate. Moreover, to the extent Petitioners are correct both that the Risk Evaluation Rule asserts the Agency's discretion to exclude conditions of use and that TSCA forecloses the Agency from asserting such discretion, their alleged injuries would be caused by the challenged provisions. *See Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 319–23 (D.C. Cir. 2011). Although, as we explain, we do not agree with Petitioners that the Rule provisions *actually* have the effect that Petitioners claim, this distinction bears not on Petitioners' standing but on the merits of their claim. *See Kirola v. City and County of San Francisco*, 860 F.3d 1164, 1175 (9th Cir. 2017) (Where a district court held that a plaintiff lacked standing because she "had not been deprived of meaningful access to a challenged service, program, or activity," which was required to establish the claim alleged, the district court had "improperly conflated [the plaintiff's] standing with whether she would prevail on the merits." (quotation marks omitted)); *see also Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) ("Our threshold inquiry into standing 'in no way depends on the merits of the [petitioner's] contention that particular conduct is illegal.'" (alteration in original) (quoting *Warth v. Seldin*, 422 U.S. 490, 500 (1975))). Petitioners therefore have standing to challenge these provisions, and that challenge is ripe.

b.

Petitioners' challenge to the Rule's scope provisions, however, fails on the merits. The problem with Petitioners' theory is that the meaning they attribute to these provisions is inconsistent with the provisions themselves. The phrase "the conditions of use within the scope of" an evaluation simply refers to the conditions of use that are applicable to

any particular substance—and that therefore are included in the scope of that substance's evaluation—without excluding any conditions of use in forming that list. Likewise, the phrase that refers to the conditions of use "that the EPA plans to consider" simply refers to the Agency's role in determining what the conditions of use are for a particular substance. Petitioners effectively acknowledge as much in arguing that the similar language of TSCA itself referring to the conditions of use that the Administrator "expects to consider" *does not* grant EPA discretion to exclude conditions of use. *See* 15 U.S.C. § 2605(b)(4)(D). We see no reason why "plans to consider" should be read differently than "expects to consider."

The provision on manufacturer-requested risk evaluations may lend some support to Petitioners' contrary reading—at least to the extent it suggests that the question whether a circumstance constitutes a condition of use is separable from the question whether that condition of use "warrant[s] inclusion within" a risk evaluation's scope. *See* 40 C.F.R. § 702.37(e)(3). But a more natural reading is that this refers, again, simply to the Agency's discretion (and expertise) in determining what constitutes a condition of use for a particular chemical substance. We therefore conclude that the challenged provisions unambiguously do not grant EPA the discretion Petitioners contend. *See Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1143 (2018) (resolving a question of statutory interpretation based on "the best reading of the statute"); *Nat'l Cable & Telecomms. Ass'n v. Gulf Power Co.*, 534 U.S. 327, 333 (2002) ("This is our own, best reading of the statute, which we find unambiguous.").

We recognize that to the extent a rule is ambiguous, its preamble—even if not itself reviewable as final agency

action—may help explain the promulgating agency's intent. *See City of Las Vegas v. FAA*, 570 F.3d 1109, 1117 (9th Cir. 2009) ("When a regulation is ambiguous, we consult the preamble of the final rule as evidence of context or intent of the agency promulgating the regulations."); *El Comite Para El Bienestar de Earlimart v. Warmerdam*, 539 F.3d 1062, 1070 (9th Cir. 2008) ("[T]he preamble language should not be considered unless the regulation itself is ambiguous."). But because the scope provisions are not ambiguous on their face, reference to the preamble discussion would be improper.

Petitioners also point to the ongoing evaluation of the chemical substance 1,4-dioxane, which is a byproduct created in manufacturing processes and also appears as a contaminant in consumer products. Petitioners contend that EPA's approach to that evaluation is evidence that the Risk Evaluation Rule has the effect they fear.[13] As Petitioners

[13] EPA made the scope document for 1,4 dioxane publicly available online. *1,4-Dioxane Scope Document and Supplemental Files*, EPA, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/14-dioxane-scope-document-and-supplemental-files (last updated June 22, 2017). We take judicial notice of this document. *See* Fed. R. Evid. 201; *Lee v. City of Los Angeles*, 250 F.3d 668, 688–89 (9th Cir. 2001) (explaining that "a court may take judicial notice of matters of public record" under Rule 201 (quotation marks omitted)); *see also Sierra Club v. EPA*, 762 F.3d 971, 975 & n.1 (9th Cir. 2014) (taking judicial notice of EPA "public guidance" under Rule 201). We otherwise deny as moot Petitioners' motion to complete the administrative record. *See TSG Inc. v. EPA*, 538 F.3d 264, 272 n.4 (3d Cir. 2008) (denying as moot a motion to expand the administrative record because the documents at issue did "not alter [the court's] holding"); *Bd. of Regents of Univ. of Wash. v. EPA*, 86 F.3d 1214, 1222 (D.C. Cir. 1996) (dismissing as moot a "Motion to Enlarge the Administrative Record on Review" because it "could have no effect on the outcome" of the case).

emphasize, EPA issued a scope document for 1,4-dioxane indicating that the Agency intends to exclude the production of 1,4-dioxane in a byproduct form from the scope of the risk evaluation for 1,4-dioxane, and intends instead to consider those activities in the scope of risk evaluations for other chemicals. But Petitioners' challenge in this action is to the Rule itself—not to EPA's 1,4-dioxane evaluation—and we do not interpret the language in the Rule to say anything about exclusion of conditions of use.[14] Thus, even assuming the 1,4-dioxane scope document has the flaws Petitioners claim, those flaws would not result from the provisions of the Rule Petitioners challenge here.

We therefore conclude that Petitioners' challenge relating to excluding conditions of use from the scope of risk evaluations fails.

C.

Finally, we turn to Petitioners' challenge to EPA's categorical exclusion of legacy activities from the definition of "conditions of use."

TSCA defines the term "conditions of use" to mean: "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). The definition in the Risk Evaluation Rule parrots the statute. *See* 40 C.F.R. § 702.33. In the preamble to the Risk Evaluation Rule, EPA elaborated on this

[14] As EPA emphasizes, Petitioners could challenge the exclusion of certain forms or uses of 1,4-dioxane in the context of that chemical substance's final risk determination.

definition, however, and stated that it does not consider what it now calls "legacy activities"—consisting of "legacy uses," "associated disposals," and "legacy disposals"—to be conditions of use. *See* 82 Fed. Reg. at 33,729–30.

EPA defines the term "legacy uses" in the preamble as "the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution." *Id.* at 33,729. For example, although asbestos is now infrequently used in making new insulation, it remains in place in previously installed insulation. According to EPA's interpretation, the use of asbestos in insulation is a "legacy use" of that chemical. "Associated disposal[s]" refers to future disposals from legacy uses, *id.*, such as the removal of asbestos-containing insulation to a landfill during a building's renovation. Finally, "legacy disposal[s]" are defined as "disposals that have already occurred," regardless of whether the substance disposed of is still manufactured for its pre-disposal use. *Id.* For example, this could refer to the previous placement of asbestos insulation into a landfill or the previous disposal of a chemical substance in a flame retardant that is still used for that purpose. Petitioners argue that EPA's exclusion of these legacy activities from the definition of "conditions of use" contradicts TSCA's clear statutory definition of the term.

Again addressing jurisdiction first, we agree with both Petitioners and EPA that this claim is justiciable. Proceeding to the merits, we hold that EPA's exclusion of legacy uses and associated disposals contradicts TSCA's plain language, but that EPA's exclusion of legacy disposals does not.

1.

Petitioners argue that their challenge to EPA's exclusion of each of the three types of legacy activities is justiciable.

They contend that it is sufficiently clear that EPA has categorically excluded legacy activities from consideration as conditions of use, and that they will be harmed by these exclusions. As to this claim, EPA agrees with Petitioners that we have jurisdiction—conceding that Petitioners' allegation that they will be harmed by risk determinations that do not include legacy activities "is a sufficient allegation for standing purposes," and that the challenge is ripe because "EPA created a general presumption that it will not prioritize and evaluate existing chemicals under their legacy uses and disposals." We agree.

Petitioners argue that their members are exposed to—and injured by—the use of chemical substances through legacy activities. For example, Petitioner United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union has members who, through their work, are exposed to the known carcinogen asbestos in the form of legacy uses when "equipment or structures are demolished, repaired[,] or refurbished." Petitioners also argue that their members are at risk of exposure to asbestos through its associated disposal. Petitioners similarly claim that their members suffer harmful lead exposures resulting from the "legacy use" of lead paint and water pipes.

Petitioners have standing to challenge this exclusion, and their challenge is ripe. As Petitioners point out, EPA's interpretation here is "definitional," and generally "requir[es] EPA to ignore ongoing exposures from 'legacy activities' in *every* risk evaluation." Petitioners claim that excluding these ongoing exposures from consideration will understate a chemical's health risks, violating Petitioners'

right to risk evaluations that comply with TSCA.[15] They argue that this threatens their concrete interest in the health protections provided by TSCA. EPA's exclusion of legacy activities from the definition of "conditions of use" has the clear, immediate effect of excluding broad categories of activities from EPA's consideration in chemical risk evaluations, and Petitioners' alleged resulting injury is sufficiently clear and concretely tied to the challenged preamble to satisfy the requirements of both standing and ripeness.[16]

2.

In reviewing an agency's interpretation of a statute, we apply the standard articulated by the Supreme Court in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).[17] *See Akhtar v. Burzynski*, 384 F.3d 1193, 1198 (9th Cir. 2004). Under *Chevron* step one, we ask "whether Congress has directly spoken to the precise question at issue." *Id.* At that point, "[i]f the intent of Congress is clear, that is the end of the matter; . . . [we]

[15] Petitioners also argue that these exclusions will infect EPA's prioritization decisions.

[16] Because this alleged injury alone is enough to support standing, we need not decide whether Petitioners could also assert an informational injury.

[17] Because Congress delegated to EPA the authority to promulgate rules establishing a risk evaluation process, and because we conclude that the preamble language at issue here constitutes final agency action, it is evaluated under *Chevron* because "it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001).

must give effect to the unambiguously expressed intent of Congress." *Id.* (quoting *Chevron*, 467 U.S. at 842–43). But if "the statute is silent or ambiguous with respect to the specific issue, we must ask" at *Chevron* step two "whether the regulations promulgated by the agency are based on a permissible construction of the statute." *Id.* If they are, we "must defer to the agency." *Id.* We need not defer to agency regulations, however, "if they construe a statute in a way that is contrary to congressional intent or that frustrates congressional policy." *Id.*

a.

As an initial matter, we note that although EPA's exclusion of legacy activities appears in the preamble to the Risk Evaluation Rule rather than in the text of the rule itself, EPA concedes that its "preamble interpretation regarding legacy activities is reviewable because it is a binding statutory interpretation that EPA stated it intends to apply going forward." We agree. EPA definitively "resolve[d] the [asserted] statutory ambiguity" in the definition of "conditions of use" when it announced in the preamble that it would exclude legacy activities. 82 Fed. Reg. at 33,730. EPA specifically stated that it "interpret[ed] [TSCA's] mandates" to be inapplicable to legacy activities, and accordingly "interpret[ed] the definition" of "conditions of use." *Id.* This interpretation was EPA's final, unequivocal interpretation—there is every reason to believe that the Agency intended to bind itself, and what is required by this interpretation is, as EPA concedes, sufficiently clear to be

reviewable.[18] We therefore may evaluate the preamble's exclusion of legacy activities as final agency action.

b.

TSCA defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Interpreting this statutory text in the preamble to the Rule, EPA relied on what it understood to be TSCA's "focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (*i.e.*, is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal." 82 Fed. Reg. at 33,730. As evidence, EPA pointed to the "to be" phrasing in TSCA's definition of "conditions of use." *Id.* EPA also noted that TSCA's legislative history focuses on the regulation of chemicals "in commerce." *Id.* Finally, the Agency stated that TSCA does not authorize it to regulate uses of chemicals except by regulating chemicals' manufacture, processing, or distribution. For example, although EPA could regulate the production of a flame retardant for use in home furniture, the Agency contends in its briefing here that it could not prevent individuals who already own furniture treated with that flame retardant from

[18] The preamble to the Prioritization Rule similarly stated, in definitive terms: "EPA has determined that certain activities generally should not be considered to be 'conditions of use.'" Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753, 33,755 (July 20, 2017).

continuing to use that furniture. Together, such considerations led EPA to give TSCA a "prospective interpretation" that excludes legacy activities. *Id.*[19]

In defending its interpretation here, EPA draws on these explanations given in the preamble. EPA further argues that the terms "intended" and "reasonably foreseen" as used in TSCA's definition of "conditions of use" "are plainly forward looking"; that "known," when combined with "to be," is a "present tense verb"; and that "intended," "known," and "reasonably foreseen" are all "broad, general terms that plainly require EPA to exercise its judgment." This language, EPA contends, demonstrates that Congress intended EPA to focus on activities for which the manufacturing, processing, or distribution in commerce of a chemical is intended, known, or reasonably foreseen. EPA also argues that it would make little sense to interpret conditions of use to include activities that EPA has little time to evaluate or ability to regulate, and that TSCA should be interpreted to allow the Agency to focus on quickly regulating the worst risks, which it contends do not arise from legacy activities.

Petitioners argue that EPA's interpretation is contradicted by the plain text of TSCA's statutory definition of "conditions of use," and is not saved by any grant of unfettered discretion to the Agency. Petitioners argue that

[19] In the preamble, EPA also concluded that its interpretation finds "support in the general presumption against construing a statute (or implementing regulation) to be retroactive or have retrospective effect." 82 Fed. Reg. at 33,730. It noted that "[w]hile Congress can make a law retroactive, absent clear intent from Congress, courts will not hold a statute to be retroactive, or uphold an agency regulation that seeks to have such an effect." *Id.* EPA does not rely on this argument in responding to this Petition for Review.

EPA's interpretation, which only includes the use and subsequent disposal of chemicals that *also* continue to be manufactured, processed, or distributed in commerce for that same use, fails to give independent meaning to "use" and "disposal" in the statutory definition's disjunctive list ("manufactured, processed, distributed in commerce, used, *or* disposed of"). For instance, Petitioners note, "lead pipes are 'known to be used' in water distribution systems," and "[t]his is true regardless of whether lead pipes continue to be manufactured or distributed." Petitioners also argue that an interpretation that "would result in inconsistent treatment of identical activities based solely on whether manufacture or distribution is ongoing," as EPA's would, does not square with TSCA itself.[20] Petitioners dispute EPA's claim that, when a substance is no longer manufactured or distributed for a particular use, it is unable to evaluate or regulate that use and associated disposal, and argue that even if EPA's assertions to that effect were correct, that would not necessitate a finding that EPA could therefore exclude consideration of such use and disposal from risk evaluations. They further argue that because previously disposed substances continue to be present at disposal sites, their disposal is ongoing, and captured by TSCA's definition. Finally, Petitioners generally contend that EPA's exclusion of legacy activities "undermine[s] TSCA's core aim to prevent unreasonable risks to health and the environment from toxic chemicals."

[20] Petitioners point out that EPA has previously promulgated regulations under TSCA to protect against exposure to legacy uses of asbestos. *See* 40 C.F.R. § 763.120–.123.

c.

EPA's contention that TSCA can reasonably be read to refer to the future use of a product, and disposals associated with such use, *only* when the product will also be manufactured in the future for that use—and not when the product is no longer manufactured for the relevant use—is without merit. TSCA's "conditions of use" definition plainly addresses conditions of use of chemical substances that will be used or disposed of in the future, regardless of whether the substances are still manufactured for the particular use.

Although we agree with EPA that the phrase "to be" in the statutory definition denotes the present or future tense, when "to be" is combined with "used" and "disposed of," two plain meanings result: future uses, and future disposals. And these are precisely the things that EPA has purported to exclude by defining conditions of use to exclude legacy uses and associated disposals: activities (*i.e.*, uses), "that do not reflect ongoing or prospective manufacturing, processing, or distribution,"[21] and "disposals from such uses," such as "the future disposal of insulation that contains a chemical substance that is no longer manufactured, processed, or distributed for use in insulation." *See* 82 Fed. Reg. at 33,729.

[21] Petitioners argue that EPA's own prior definitions of "use" in the context of chemical substances support this understanding, and argue that EPA's exclusion of "legacy use" from conditions of use represents an unexplained departure from these prior interpretations. We need not decide whether EPA's prior definitions of "use" in its regulations are in any way binding on the Agency here, because "use" has a plain meaning within TSCA that, as we explain, clearly encompasses the sorts of things that EPA categorizes as "legacy uses."

The example used by EPA in the Risk Evaluation Rule's preamble—the disposal of insulation previously installed in a building—in fact serves as a useful example for why the Agency's interpretation cannot be upheld: The *future* disposal of asbestos insulation is clearly an example of a chemical substance being "disposed of." To the extent it is "intended" that such a substance be disposed of, or "known" that it will be, or if such disposal is "reasonably foreseen," that circumstance unambiguously falls within TSCA's definition of "conditions of use." Similarly, as Petitioners point out, if lead pipes exist in water distribution systems, they are "known to be used" in those systems. This is so without any regard to whether these substances are *also* intended, known, or reasonably foreseen to be prospectively manufactured (or processed, or distributed in commerce) for those uses. *See* 15 U.S.C. § 2602(4) (referring to substances that will be "manufactured, processed, distributed in commerce, used, *or* disposed of" (emphasis added)); *see also Loughrin v. United States*, 573 U.S. 351, 357 (2014) (noting that the use of the term "or" "is almost always disjunctive, that is, the words it connects are to be given separate meanings" (quoting *United States v. Woods*, 571 U.S. 31, 45 (2013))).

EPA resists this conclusion, arguing that the Agency has broad discretion, granted to it by TSCA, to determine what constitutes a condition of use.[22] We agree that the statute

[22] EPA adds that although it has determined it is not *required* to consider legacy activities in evaluating chemical substances, it *may* do so where appropriate. As Petitioners point out, however, this does not save the legacy exclusion if legacy activities are conditions of use that EPA is required—rather than just permitted—to consider in risk evaluations. Regardless, a plaintiff's challenge to an agency's unambiguous assertion, in the context of a final agency action, of discretion to choose between two alternatives, when one is clearly

grants EPA discretion to determine the conditions of use for each chemical substance, but that discretion may only be exercised within the bounds of the statutory definition itself. *See Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) (explaining that a statute directing an agency to use its "judgment" did not grant the agency "a roving license to ignore the statutory text," but rather directed the agency to "exercise discretion within defined statutory limits"). Where Congress has explicitly provided a definition for a term, and that definition is clear, an agency must follow it. And here, as we have explained, TSCA's definition of "conditions of use" clearly includes uses and future disposals of chemicals even if those chemicals were only historically manufactured for those uses.[23] EPA's exclusion of legacy uses and associated disposals from the definition of "conditions of use" is therefore unlawful.[24]

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disallowed by statute and, if chosen, would injure the plaintiff, is justiciable. *See Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 319–22 (D.C. Cir. 2011). The agency's assertion of discretion would, under those circumstances, be impermissible. *Id.* at 322.

[23] This conclusion is bolstered by the fact that TSCA elsewhere distinguishes between "active" substances—meaning those that have been manufactured or processed since 2006—and "inactive" substances—those that have not. TSCA did not, in calling for chemical risk evaluations, similarly distinguish between active and inactive chemical substances. *Compare* 15 U.S.C. § 2607(b)(4)(A)(ii)–(iii), *with* 15 U.S.C. § 2605. This suggests that Congress intended to make even inactive substances subject to prioritization and risk evaluation.

[24] To the extent the exclusion is incorporated into EPA's Prioritization Rule, it is also unlawful.

d.

We draw a distinction, however, between "legacy uses" and "associated disposals," on the one hand, and "legacy disposals," on the other. EPA uses the term "legacy disposals" to refer to "disposals that have already occurred (*e.g.*, a chemical substance currently in a landfill or in groundwater)." 82 Fed. Reg. at 33,729. As to this issue, EPA's present tense argument has more force, and we hold that its interpretation is permissible under TSCA.

In our view, TSCA unambiguously does not require past disposals to be considered conditions of use. The statutory definition, once again, covers the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). A substance that has already been disposed of will not ordinarily be intended, known, or reasonably foreseen to be prospectively manufactured, processed, distributed in commerce, used, or (again) disposed of. Of course, there may be some substances that already have been disposed of yet are *also* "known . . . to be . . . distributed in commerce" or used. 15 U.S.C. § 2602(4). And TSCA's definition does, as discussed above, clearly cover those substances and those prospective uses. But TSCA does not address a substance that has already been disposed of and remains so.

Petitioners argue that "disposal" in this context "is not a one-time occurrence when the substance . . . is buried or placed in a landfill or other waste facility," but rather that disposal "remains ongoing after the initial act of discard." By way of example, Petitioners note that although TSCA itself does not define the term "disposal," EPA has previously defined the term in the context of regulating

chemicals known as PCBs, under the pre-2016 TSCA. In that context, EPA defines "disposal" to mean "intentionally or accidentally to discard, throw away, or otherwise complete or terminate the useful life of PCBs and PCB Items," and specifically notes that "[d]isposal includes spills, leaks, and other uncontrolled discharges of PCBs as well as actions related to containing, transporting, destroying, degrading, decontaminating, or confining PCBs and PCB Items." 40 C.F.R. § 761.3. EPA takes issue with Petitioners' reliance on this definition, but acknowledges in its briefing here that the term "disposed of" could refer to "the act of putting something in a landfill or other resting place, or it could conceivably refer to the movement of chemicals by natural forces after the initial act of disposal."

We need not wade into any debate over the precise meaning of "disposal." Even accepting Petitioners' asserted definition, we see no reason why "spills, leaks, and other uncontrolled discharges"—or even "actions related to containing . . . or confining" substances as also referenced in 40 C.F.R. § 761.3—would not be considered *independent* disposals. They would thus qualify as "disposals" (and therefore conditions of use) for substances that are currently manufactured for their pre-disposal use, or "associated disposals" for substances that are no longer manufactured for their pre-disposal use. If, under the applicable definition of "disposal," something is in fact *again* disposed of—even if it was disposed of previously—or when a disposal is *in fact ongoing*, we see no reason why that use is not captured as a prospective disposal. But that does not mean that legacy disposals—as used to refer simply to "disposals that have already occurred"—should fall under the statutory definition of "conditions of use."

Because TSCA's statutory definition of "conditions of use" unambiguously does not reach legacy disposals, we hold that the Agency did not err in excluding such disposals from consideration as "conditions of use." *See Chevron*, 467 U.S. at 842–43 ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

III.

For the reasons discussed, the Petition for Review is **DISMISSED** in part, **GRANTED** in part, and **DENIED** in part.[25] The Petition is dismissed with respect to Petitioners' challenge regarding use-by-use determinations. The Petition is granted with respect to Petitioners' challenge to EPA's exclusion of "legacy uses" and "associated disposals" from the definition of "conditions of use," and those portions of the Risk Evaluation Rule's preamble are vacated. The Petition is denied with respect to the alleged exclusion of conditions of use from the scope of risk evaluation and with respect to EPA's exclusion of "legacy disposals" from "conditions of use." The parties shall bear their own costs on appeal.

[25] In the concurrently filed memorandum disposition addressing Petitioners' challenge to information-gathering provisions of the Prioritization and Risk Evaluation Rules, we further deny the Petition in part and remand in part.

Assessing and Managing Chemicals under TSCA

1,4-Dioxane Scope Document and Supplemental Files

Scope document and supplemental files for 1,4-dioxane.

Return to the risk evaluation page for 1,4-dioxane.

You may need a PDF reader to view some of the files on this page. See EPA's About PDF page to learn more.

- Scope of the Risk Evaluation for 1,4-Dioxane (PDF) (58 pp, 818 K)
- Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental Document to the TSCA Scope Document (PDF) (83 pp, 2 MB)
- 1,4-Dioxane (123-91-1) Bibliography: Supplemental File for the TSCA Scope Document (PDF) (449 pp, 7 MB)

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United States
Environmental Protection Agency

EPA Document# EPA-740-R1-7003
June 2017
Office of Chemical Safety and
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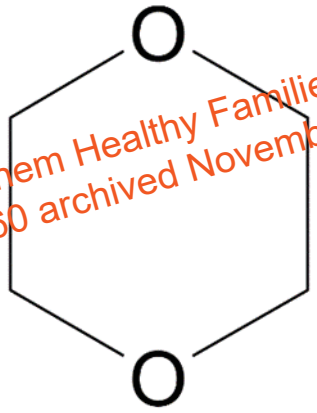
Scope of the Risk Evaluation for 1,4-Dioxane

CASRN: 123-91-1



June 2017

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDIX TABLES

LIST OF APPENDIX FIGURES

ACKNOWLEDGEMENTS

This report was developed by the United States Environmental Protection Agency (U.S. EPA), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT).

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Docket

Supporting information can be found in public docket: EPA-HQ-OPPT-2016-0723.

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ABBREVIATIONS

°C	Degrees Celsius
AAL	Allowable Ambient Level
ACGIH	American Conference of Government Industrial Hygienists
AEGL	Acute Exposure Guideline Level
AES	Alkyl Ethyl Sulphates
AQS	Air Quality System
atm	Atmosphere(s)
ATSDR	Agency for Toxic Substances and Disease Registries
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BSER	Best System of Emission Reduction
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Candidate Contaminant List
CDR	Chemical Data Reporting
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
cm^3	Cubic Centimeter(s)
COC	Concentration of Concern
cP	Centipoise
CPCat	Chemical and Product Categories
CSCL	Chemical Substances Control Law
EC	European Commission
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
g	Gram(s)
GACT	Generally Available Control Technology
HAP	Hazardous Air Pollutant
HPV	High Production Volume
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
kg	Kilogram(s)
kPa	Kilopascal(s)
L	Liter(s)
lb	Pound
Log K_{oc}	Logarithmic Soil Organic Carbon:Water Partitioning Coefficient
Log K_{ow}	Logarithmic Octanol:Water Partition Coefficient
m^3	Cubic Meter(s)
MACT	Maximum Achievable Control Technology
mg	Milligram(s)

µg	Microgram(s)
mmHg	Millimeter(s) of Mercury
MSDS	Material Safety Data Sheet
NAC	National Advisory Committee
NAICS	North American Industry Classification System
NATA	National Air Toxics Assessment
NCEA	National Center for Environmental Assessment
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIH	National Institute of Health
NIOSH	National Institute of Occupational Safety and Health
NOAEL	No-Observed-Adverse-Effect Level
NPRI	National Pollutant Release Inventory
NSPS	New Source Performance Standards
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
PEL	Permissible Exposure Limit
PET	Polyethylene Terephthalate
POD	Point of Departure
POTW	Publicly Owned Treatment Works
ppm	Part(s) per Million
PWS	Public Water System
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Level
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SIDS	Screening Information Data Set
TCA	1,1,1-Trichloroethane
TCCR	Transparent, Clear, Consistent and Reasonable
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time-Weighted Average
UCMR	Unregulated Contaminant Monitoring Rule
U.S.	United States
UV	Ultraviolet
VCCEP	Voluntary Children's Chemical Evaluation Program
VOC	Volatile Organic Compound
WHO	World Health Organisation

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the United States Environmental Protection Agency (U.S. EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). 1,4-Dioxane was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for 1,4-dioxane.

This document presents the scope of the risk evaluation to be conducted for 1,4-dioxane. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA), with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional

interim step, prior to publication of the draft risk evaluation for 1,4-dioxane. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

In 2015, EPA/OPPT published a *Problem Formulation and Initial Assessment for 1,4-Dioxane* (EPA, 2015) and received public comments. As part of this scope, EPA developed an initial life cycle diagram and initial conceptual models for 1,4-dioxane that reconsidered all information under the amended law.

Historically, 90% of 1,4-dioxane production was used as a stabilizer in chlorinated solvents such as 1,1,1-trichloroethane (TCA). Use of 1,4-dioxane has decreased since TCA was phased out by the Montreal Protocol in 1996. 1,4-Dioxane is currently used in industrial processes and for industrial and commercial uses. Industrial processing uses include use as a processing aid and in functional fluids in closed systems. 1,4-Dioxane has uses as a laboratory chemical reagent, in adhesives and sealants and several other identified uses. Based on data from the 2016 Chemical Data Reporting (CDR), the current production volume is approximately 1 million pounds per year (U.S. EPA, 2016b). The most recent data on environmental releases, according to the Toxics Release Inventory (TRI), indicate that approximately 675,000 pounds of 1,4-dioxane were released to the environment in 2015 (U.S. EPA, 2017c). Releases are reported to all types of environmental media: air, water and land. The environmental fate of 1,4-dioxane is characterized by partitioning to the atmosphere, surface water and groundwater, and degradation by atmospheric oxidation or biodegradation. It is expected to be moderately persistent in the environment and have a low bioaccumulation potential.

The initial conceptual models presented in Section 2 identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of the chemical.

This document presents the occupational scenarios in which workers and occupational non-users may be exposed to 1,4-dioxane during conditions of use, such as manufacturing, processing, repackaging and recycling. For 1,4-dioxane, EPA believes that workers and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to workers and/or the general population may occur from industrial releases and industrial and commercial uses. Environmental releases of 1,4-dioxane are reported in the Toxics Release Inventory to air, water or land. 1,4-Dioxane is stable under environmental conditions and does not degrade or react to any appreciable extent in the environment.

1,4-Dioxane has been the subject of several health hazard and risk assessments, based on data in animal studies. Any existing assessments will be a starting point as EPA will conduct a systematic review of the literature, including new literature since the existing assessments, as available in *1,4-*

Dioxane (CASRN 123-91-1) Bibliography: Supplemental File for the TSCA Scope Document (EPA-HQ-OPPT-2016-0723). EPA expects to consider human health hazards of 1,4-dioxane including acute toxicity, non-cancer effects and cancer. Non-cancer effects include irritation of the eyes and respiratory tract, liver toxicity and kidney toxicity. Animals exposed to 1,4-dioxane by inhalation and oral exposure have developed multiple types of cancer.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for 1,4-dioxane. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of 1,4-dioxane.

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for 1,4-dioxane. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the United States Environmental Protection Agency (U.S. EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use."

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for 1,4-dioxane.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination —i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single

unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in currently installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "*de minimis*" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first

10 chemical substances were not subject to the prioritization process that will be used in the future in accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to 1,4-dioxane. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. EPA may evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation.

Federal Laws and Regulations

1,4-Dioxane is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

State Laws and Regulations

1,4-Dioxane is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

Laws and Regulations in Other Countries and International Treaties or Agreements

1,4-Dioxane is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A.3.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected (see *1,4-Dioxane (CASRN 123-91-1) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0723) using the literature search strategy (see *Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0723) to ensure that EPA is considering information that has been made available since these assessments were conducted.

In 2015, EPA/OPPT published a Problem Formulation and Initial Assessment for 1,4-Dioxane (EPA, 2015) and received public comments. As part of this scope, EPA developed an initial life cycle diagram and initial conceptual models for 1,4-dioxane that re-considered all information under the amended law.

Table 1-1. Assessment History of 1,4-Dioxane

Authoring Organization	Assessment
EPA assessments	
EPA, Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT)	TSCA Work Plan Chemical Problem Formulation and Initial Assessment: 1,4-Dioxane (CASRN 123-91-1) (2015b)
EPA, National Center for Environmental Assessment (NCEA)	Toxicological Review of 1,4-Dioxane (With Inhalation Update) (CASRN 123-91-1) (2013)
EPA, NCEA	Toxicological review of 1,4-Dioxane (CAS No. 123-91-1) (2010)
EPA, Office of Water (OW)	Drinking Water Health Advisory (U.S. EPA, 2012a)
Other U.S.-based organizations	
National Toxicology Program (NTP)	Report on Carcinogens, Fourteenth Edition, 1,4-Dioxane (2016)
Agency for Toxic Substances and Disease Registry (ATSDR)	Toxicological Profile for 1,4-Dioxane (2012)
National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee)	Interim Acute Exposure Guideline Levels (AEGL) for 1,4-Dioxane (CAS Reg. No. 123-91-1) (2005b)
International	
International Cooperation on Cosmetics Regulation	Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1.4-Dioxane in Cosmetic Products (2017)

Authoring Organization	Assessment
International Agency for Research on Cancer (IARC)	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 71 (1999)
Government of Canada, Environment Canada, Health Canada	Screening Assessment for the Challenge. 1,4-Dioxane. CASRN 123-91-1 (2010)
Research Center for Chemical Risk Management, National Institute of Advanced Industrial Science and Technology, Japan	Estimating Health Risk from Exposure to 1,4-Dioxane in Japan (2006)
World Health Organisation (WHO)	1,4-Dioxane in Drinking-water (2005)
Employment, Social Affairs, and Inclusion, European Commission (EC)	Recommendation from the Scientific Committee on Occupational Exposure Limits for 1,4-dioxane (2004)
European Chemicals Bureau, Institute for Health and Consumer Protection	European Union Risk Assessment Report. 1,4-dioxane. CASRN 123-91-1. EINECS No: 204-661-8. (2002)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	1,4-Dioxane. Priority Existing Chemical No. 7. Full Public Report (1998)
Organisation for Economic Co-operation and Development (OECD), Screening Information Data Set (SIDS)	1,4-Dioxane. SIDS initial assessment profile (1999)

1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection, (2) data evaluation and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard, human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies

from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the NTP *Report on Carcinogens,* to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0723) provides details about the data sources and search terms that were used in the initial search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in the *Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0723). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) *on-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. *Off-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The *Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0723) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information. For example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in *Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0723) and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *1,4-Dioxane (CASRN 123-91-1) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0723). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for

modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between 1,4-dioxane and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use of 1,4-dioxane. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

Table 2-1. Physical and Chemical Properties of 1,4-Dioxane

Property	Value [a]	References
Molecular formula	$C_4H_8O_2$	
Molecular weight	88.1 g/mole	Howard (1990)
Physical form	Clear liquid	(O'Neil et al., 2001)
Melting point	11.75°C	(Haynes, 2014)
Boiling point	101.1°C	O'Neil et al. (2006)
Density	1.0329 g/cm^3	(O'Neil et al., 2001)
Vapor pressure	40 mm Hg at 25°C	Lewis (2000)
Vapor density	3.03 (relative to air)	(Lewis, 2012)
Water solubility	>8.00 × 10^2 g/L	(Yalkowsky et al., 2010)
Octanol:water partition coefficient (log K_{ow})	-0.27	Hansch et al. (1995)
Henry's Law constant	4.8 × 10^{-6} atm-m^3/mole at 25°C 4.93 X 10^{-4} atm-m^3/mole at 40°C	(Sander, 2017) Howard (1990) Atkins (1986)
Flash point	18.3°C (open cup)	(Lewis, 2012)
Autoflammability	Not readily available	
Viscosity	0.0120 cP at 25°C	(O'Neil, 2013)
Refractive index	1.4224 at 20°C	(Haynes, 2014)

Property	Value [a]	References
Dielectric constant	2.209	Bruno and PDN (2006)
[a] Measured unless otherwise noted		

2.2 Conditions of Use

TSCA § 3(4) defines the conditions of use as ‘‘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.’’

2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g. *Use and Market Profile for 1,4-Dioxane,* (EPA-HQ-OPPT-2016-0723). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 1,4-Dioxane*, EPA-HQ-OPPT-2017-0723-0003) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, consumer; when distinguishable) and disposal. The information is grouped according to CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders) to provide an overview of conditions of use. EPA notes that some subcategories of use may be grouped under multiple CDR categories.

For the purposes of this scope, use categories include the following: “industrial use” means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. “Commercial use” means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. “Consumer use” means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2016b).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting (U.S. EPA, 2016b), when the volume was not claimed confidential business information (CBI). The 2016 CDR reporting data for 1,4-dioxane are provided in Table 2-2 for 1,4-dioxane from EPA's CDR database (U.S. EPA, 2016b).

Table 2-2. Production Volume of 1,4-Dioxane in Chemical Data Reporting (CDR) Reporting Period (2012 to 2015) [a]

Reporting Year	2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	894,505	1,043,627	474,331	1,059,980

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016b). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.

Figure 2-1 depicts the initial life cycle diagram of 1,4-dioxane from manufacture to the point of disposal. The total volume (in lbs) of 1,4-dioxane manufactured (including imported) in the U.S. from 2012 to 2015 indicates that production has varied over that time period. Historically, the main use (90%) of 1,4-dioxane was as a stabilizer of chlorinated solvents such as 1,1,1 trichloroethane (TCA) (ATSDR, 2012). Use of TCA was phased out under the 1995 Montreal Protocol and the use of 1,4-dioxane as a solvent stabilizer was terminated (NTP, 2016; EGIBC, 2002). Lack of recent reports for other previously reported uses (Sapphire Group, 2007) suggest that many other industrial, commercial and consumer uses were also stopped.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR and included in the life cycle diagram are summarized below (U.S. EPA, 2016b). The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting (U.S. EPA, 2016a).

As reflected in the initial life cycle diagram (Figure 2-1), intended, known and reasonably foreseen uses of 1,4-dioxane are primarily associated with industrial and commercial activities. Manufacturing sites produce 1,4-dioxane in liquid form at ≥90% concentration [EPA-HQ-OPPT-2016-0723-0012 (BASF, 2017)]. 1,4-Dioxane is currently used in industrial processes and for industrial and commercial uses. Industrial processing uses include use as a processing aid during wood pulping, pharmaceutical manufacture and etching of fluoropolymers and in functional fluids in closed systems. 1,4-Dioxane uses as a laboratory chemical reagent and in adhesives and sealants may occur in either industrial and/or commercial settings. A search for products containing 1,4-dioxane found several identified laboratory reference materials or standards containing 1,4-dioxane. In addition, two products with >5% of 1,4-dioxane: a professional film cement and a chemiluminescent laboratory reagent were identified. Other uses identified include use in fuels and fuel additives; spray polyurethane foam; and printing and printing compositions.

No consumer uses for 1,4-dioxane were reported in the U.S. in the 2016 CDR (U.S. EPA, 2016b). EPA did not identify any other U.S. sources that stated that 1,4-dioxane is currently used in the production of consumer products and, therefore, assumes that it is not. Other information sources do not differentiate between use of consumer and commercial products (ATSDR, 2012; U.S. EPA, 2006). A European risk assessment stated that 1,4-dioxane is used as a solvent in the production of several products that may be used by consumers like pharmaceuticals, pesticides, magnetic tape and adhesives (ECJRC, 2002). Public comments submitted by an industry coalition group (Public Comment, EPA-HQ-OPPT-2016-0723-0012) assert that 1,4-dioxane is not an intentionally added ingredient in any consumer products in the U.S.

1,4-Dioxane may be produced as a reaction by-product, particularly in chemicals which are produced by ethoxylation. These include alkyl ether sulphates (AES, anionic surfactants) and other ethoxylated substances, such as alkyl, alkylphenol and fatty amine ethoxylates; polyethylene glycols and their esters; and sorbitan ester ethoxylates. Therefore, 1,4-dioxane may be present at residual concentrations in commercial and consumer products that contain ethoxylated chemicals. Examples of products potentially containing 1,4-dioxane as a residual contaminant are paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products (ATSDR, 2012; Health Canada, 2010; FDA, 2007; ECJRC, 2002). Manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process (Public Comment, EPA-HQ-OPPT-2016-0723-0007) (ATSDR, 2012). The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector (ICCR, 2017).

1-4-Dioxane produced as a by-product of reactions in the production of other chemicals is excluded from the scope of the risk evaluation. EPA anticipates that 1,4-dioxane by-product and contaminant issues will be considered in the scope of any risk evaluation of ethoxylated chemicals.

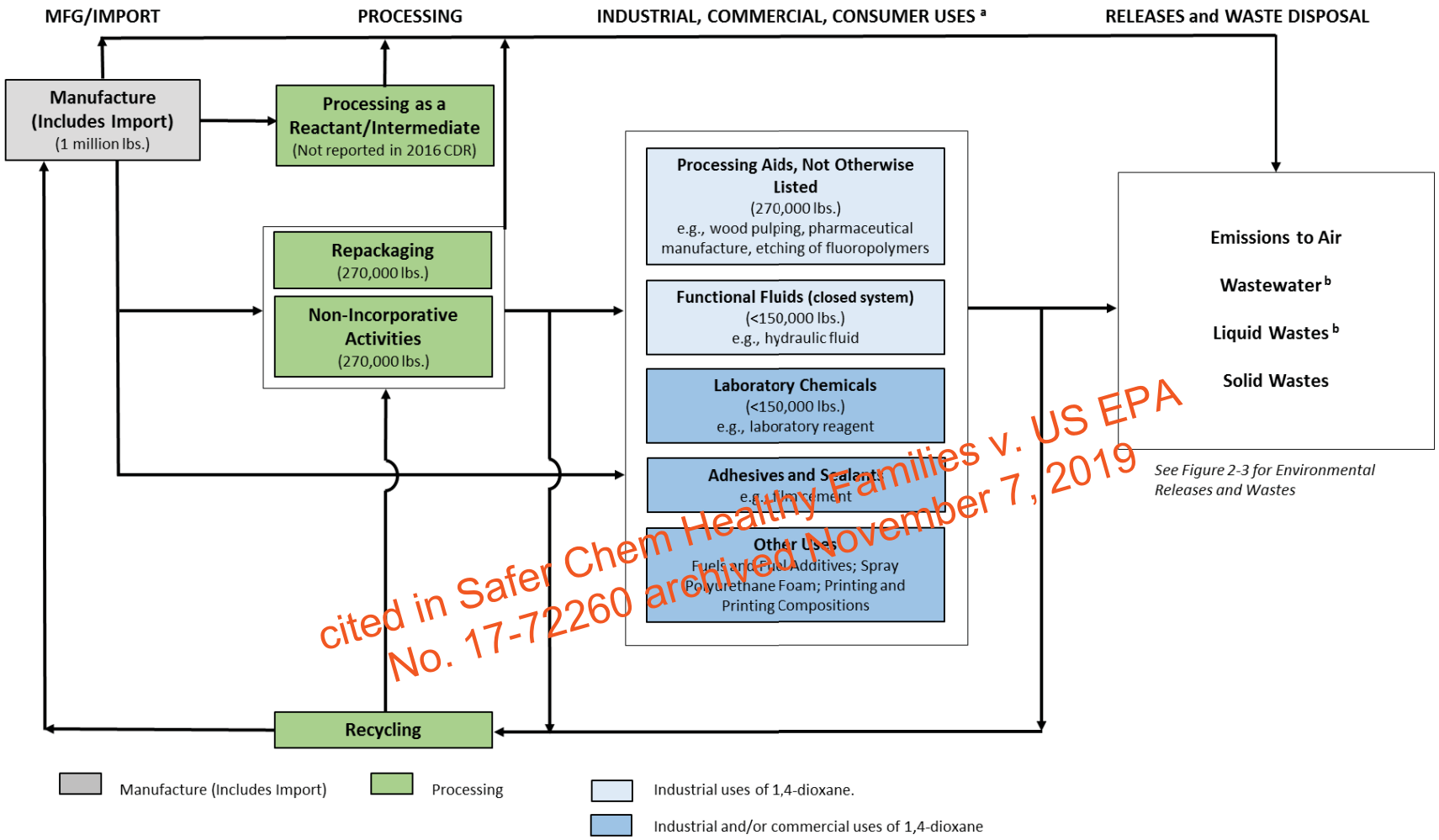

Figure 2-1. Initial 1,4-Dioxane Life Cycle Diagram

The initial life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial or commercial) and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period (U.S. EPA, 2016b). Activities related to distribution (e.g., loading, unloading) will be considered throughout the 1,4-dioxane life cycle, rather than using a single distribution scenario.

[a] See Table 2-3 for additional uses not mentioned specifically in this diagram.

[b] Wastewater: combination of water and organic liquid, where the organic content is <50%. Liquid Wastes: combination of water and organic liquid, where the organic content is >50%.

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for 1,4-dioxane that EPA expects to consider in the risk evaluation. Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

Table 2-3. Categories and Subcategories of Conditions of Use of 1,4-Dioxane

Life Cycle Stage	Category [a]	Subcategory [b]	References
Manufacture	Domestic manufacture	Domestic manufacture	Use document, EPA-HQ-OPPT-2016-0723-0003; Public Comment, EPA-HQ-OPPT-2016-0723-0012
	Import	Import	Use document, EPA-HQ-OPPT-2016-0723-0003
Processing	Processing as a reactant	Pharmaceutical intermediate	Use document, EPA-HQ-OPPT-2016-0723-0003
		Polymerization catalyst	Use document, EPA-HQ-OPPT-2016-0723-0003
	Non-incorporative	Pharmaceutical and medicine manufacturing (process solvent)	Public Comment, EPA-HQ-OPPT-2016-0723-0012
		Basic organic chemical manufacturing (process solvent)	Public Comment, EPA-HQ-OPPT-2016-0723-0012
	Repackaging	Bulk to packages, then distribute	Public Comment, EPA-HQ-OPPT-2016-0723-0012
	Recycling	Recycling	U.S. EPA (2017c)
Distribution in commerce	Distribution	Distribution in commerce	
Industrial use	Intermediate use	Agricultural chemical intermediate	Use document, EPA-HQ-OPPT-2016-0723-0003

Life Cycle Stage	Category [a]	Subcategory [b]	References
		Plasticizer intermediate	Use document, EPA-HQ-OPPT-2016-0723-0003
		Catalysts and reagents for anhydrous acid reactions, brominations and sulfonations	Use document, EPA-HQ-OPPT-2016-0723-0003
	Processing aids, not otherwise listed	Wood pulping	Use document, EPA-HQ-OPPT-2016-0723-0003
		Extraction of animal and vegetable oils	Use document, EPA-HQ-OPPT-2016-0723-0003
		Wetting and dispersing agent in textile processing	Use document, EPA-HQ-OPPT-2016-0723-0003
		Polymerization catalyst	Use document, EPA-HQ-OPPT-2016-0723-0003
		Purification of pharmaceuticals	Use document, EPA-HQ-OPPT-2016-0723-0003
		Etching of fluoropolymers	Public Comment, EPA-HQ-OPPT-2016-0723-0012
	Functional fluids (closed system)	Polyalkylene glycol lubricant	Use document, EPA-HQ-OPPT-2016-0723-0003
		Synthetic metalworking fluid	Use document, EPA-HQ-OPPT-2016-0723-0003
		Cutting and tapping fluid	Use document, EPA-HQ-OPPT-2016-0723-0003
		Hydraulic fluid	Use document, EPA-HQ-OPPT-2016-0723-0003
Industrial use, potential commercial use	Laboratory chemicals	Chemical reagent	Use document, EPA-HQ-OPPT-2016-0723-0003; Public Comment, EPA-HQ-OPPT-2016-0723-0009

Life Cycle Stage	Category [a]	Subcategory [b]	References
		Reference material	Use document, EPA-HQ-OPPT-2016-0723-0003
		Spectroscopic and photometric measurement	Use document, EPA-HQ-OPPT-2016-0723-0003; Public Comment, EPA-HQ-OPPT-2016-0723-0009
		Liquid scintillation counting medium	Use document, EPA-HQ-OPPT-2016-0723-0003
		Stable reaction medium	Use document, EPA-HQ-OPPT-2016-0723-0003
		Cryoscopic solvent for molecular mass determinations	Use document, EPA-HQ-OPPT-2016-0723-0003
		Preparation of histological sections for microscopic examination	Use document, EPA-HQ-OPPT-2016-0723-0003
	Adhesives and sealants	Film cement	Use document, EPA-HQ-OPPT-2016-0723-0003; Public Comment, EPA-HQ-OPPT-2016-0723-0021
	Other uses	Fuels and fuel additives Spray polyurethane foam Printing and printing compositions	Use document, EPA-HQ-OPPT-2016-0723-0003; Public Comment, EPA-HQ-OPPT-2016-0723-0012
Disposal	Emissions to air	Air	U.S. EPA (2017c)
	Wastewater	Industrial pre-treatment	
		Industrial wastewater treatment	
		Publicly owned treatment works (POTW)	
		Underground injection	
	Solid wastes and liquid wastes	Municipal landfill	
		Hazardous landfill	

Life Cycle Stage	Category [a]	Subcategory [b]	References
		Other land disposal	
		Municipal waste incinerator	
		Hazardous waste incinerator	
		Off-site waste transfer	

[a] These categories of conditions of use appear in the initial life cycle diagram (Figure 2-1), reflect CDR codes and broadly represent conditions of use of 1,4-dioxane in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of 1,4-dioxane.

2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to 1,4-dioxane. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of 1,4-dioxane and the exposure to human receptors, including potentially exposed or susceptible subpopulations, and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to 1,4-dioxane.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for 1,4-dioxane.

Table 2-4. Environmental Fate Characteristics of 1,4-Dioxane

Property or Endpoint	Value [a]	References
Direct photodegradation	Not expected to undergo direct photolysis	U.S. EPA (2015b)
Indirect photodegradation	4.6 hours (estimated for atmospheric degradation)	U.S. EPA (2015b)
Hydrolysis half-life	Does not undergo hydrolysis	U.S. EPA (2015b)
Biodegradation	<10% in 29 days (aerobic in water, OECD 301F) <5% in 60 days (aerobic in water, OECD 310) 0% in 120 days, 60% in 300 days (aerobic in soil microcosm)	U.S. EPA (2015b)
Bioconcentration factor (BCF)	0.2-0.7 (OECD 305C)	U.S. EPA (2015b)

Property or Endpoint	Value [a]	References
Bioaccumulation factor (BAF)	0.93 (estimated)	U.S. EPA (2012b)
Organic carbon:water partition coefficient (log K_{oc})	0.4 (estimated)	U.S. EPA (2015b)
[a] Measured unless otherwise noted.		

1,4-Dioxane is expected to volatilize from dry surfaces and dry soil due to its vapor pressure of 40 mm Hg at 25°C (Table 2-1). It reacts with hydroxyl radicals (OH•) in the atmosphere with an estimated indirect photolysis half-life on the order of hours. 1,4-Dioxane is not expected to be susceptible to direct photolysis under environmental conditions since this compound lacks functional groups that absorb light at visible-ultraviolet (UV) light wavelengths.

Due to its water solubility (>800 g/L; Table 2-1) and Henry's Law constant (4.8×10^{-6} atm-m^3/mole at 25°C; Table 2-1), 1,4-dioxane is expected to be slightly volatile from water surfaces and moist soil. Once it enters the environment, 1,4-dioxane is expected to be mobile in soil based on its organic carbon partition coefficient (estimated log K_{oc} = 0.4) and may therefore migrate to surface waters and groundwater. 1,4-Dioxane will not hydrolyze in water because it does not have functional hydrolyzable groups.

In experimental studies, 1,4-dioxane has been demonstrated to be not readily biodegradable and was subject to biodegradation after acclimation in a soil microcosm. Measured bioconcentration factors for 1,4-dioxane are 0.7 or below and the estimated bioaccumulation factor is 0.93. Therefore, 1,4-dioxane has low bioaccumulation potential.

2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

A source of information that EPA expects to consider in evaluating exposure are data reported under the Toxics Release Inventory (TRI) program. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, 1,4-Dioxane is a TRI-reportable substance effective January 1, 1987.

Table 2-5 provides production-related waste managed data (also referred to as waste managed) for 1,4-dioxane reported by industrial facilities to the TRI program for 2015. Table 2-6 provides more detailed information on the quantities released to air or water or disposed of on land.

Table 2-5. Summary of 1,4-Dioxane TRI Production-Related Waste Managed in 2015 (lbs)

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases [a,b,c]	Total Production Related Waste
49	4,292	1,591,064	1,923,623	705,691	4,224,670

Data source: 2015 TRI Data (updated March 2017) U.S. EPA (2017c).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Facilities are required to report if they manufacture (including import) or process more than 25,000 pounds of 1,4-dioxane, or if they otherwise use more than 10,000 pounds of 1,4-dioxane. In 2015, 49 facilities reported a total of 4.2 million pounds of 1,4-dioxane waste managed. Of this total, over 4 thousand pounds were recycled, 1.6 million pounds were recovered for energy, 1.9 million pounds were treated and 700 thousand pounds were released to the environment.

Of the almost 700 thousand pounds of total releases, there were both stack and fugitive air releases, water releases, Class I underground injection, release to Resource Conservation and Recovery Act (RCRA) Subtitle C landfills and other land disposal (Table 2-6).

Table 2-6. Summary of 1,4-Dioxane TRI Releases to the Environment in 2015 (lbs)

	Number of Facilities	Air Releases		Land Releases				Other Releases [a]	Total Releases [b,c]
		Stack Air Releases	Fugitive Air Releases	Water Releases	Class I Under-ground Injection	RCRA Subtitle C Landfills	All other Land Disposal [a]		
Subtotal		46,219	16,377		563,976	13,376	49		
Totals	49	62,596		35,402	577,400			0	675,399

Data source: 2015 TRI Data (updated March 2017) U.S. EPA (2017c).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] These release quantities include releases due to one-time events not associated with production such as remedial actions or earthquakes.
[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-6 include both production-related and non-routine quantities (TRI section 5 and 6 data). As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017c).

One source EPA will use to quantify releases of 1,4-dioxane is EPA's AP-42, *Compilation of Air Pollutant Emission Factors*. AP-42 section 6.13 on pharmaceuticals production provides general process and emissions information and the ultimate disposition of 1,4-dioxane (air, sewer, incineration, solid waste, product) by pharmaceutical manufacturers. Other sources of information provide evidence of releases

of 1,4-dioxane, including National Emission Standards for Hazardous Air Pollutants (NESHAPs) promulgated under the Clean Air Act (CAA) or other EPA standards and regulations that set legal limits on the amount of 1,4-dioxane that can be emitted to a particular media. EPA expects to consider these and other available data in conducting the exposure assessment component of the risk evaluation for 1,4-dioxane.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure. Monitoring data were identified in EPA's data search for 1,4-dioxane.

Monitoring data (measured) from EPA's Air Quality System (AQS) and the open literature, as well as modeled estimates based on the National Air Toxics Assessment (NATA) and TRI emissions data suggest that 1,4-dioxane is present in ambient air. Monitored and modeled air concentrations from these sources suggest that many air concentrations may be low (i.e., <1 µg/m^3) and appear to have been higher in the past, possibly reflecting past uses (U.S. EPA, 2015a, 2011).

Indoor air monitoring data are available. One recent study reported annual average concentrations of 1,4-dioxane ranging from 0.01 to 0.11 µg/m^3 in several hundred homes in Germany (Wissenbach et al., 2016). Older indoor air monitoring studies are summarized in the U.S. EPA Voluntary Children's Chemical Evaluation Program (VCCEP) submission and report slightly higher concentrations, possibly reflecting past uses (Sapphire Group, 2007).

EPA's third Unregulated Contaminant Monitoring Rule (UCMR 3), published in 2012, required monitoring for 1,4-dioxane, along with 29 other contaminants. Over 28,000 drinking water samples were collected for chemicals suspected to be present in drinking water that lack health-based standards under the Safe Drinking Water Act.

Reported levels of 1,4-dioxane in groundwater range from 3 to 31,000 µg/L (ATSDR, 2012; USGS, 2002). Such instances of ground water contamination with 1,4-dioxane are documented in the states of California and Michigan. These data provide a basis for including groundwater in the scope of the 1,4-dioxane risk evaluation from manufacturing, processing, distribution and use unless otherwise regulated or managed.

There are relatively fewer data available on 1,4-dioxane levels in surface water, though some studies of groundwater contamination also reported levels in nearby surface water. 1,4-Dioxane is released into surface water and some studies have examined 1,4-dioxane levels in sewage treatment or chemical plant effluent, combined collection treatments from apartment homes, and in river basin systems (ATSDR, 2012). 1,4-Dioxane has also been detected in landfill leachate. These data are consistent with including releases to surface water within the scope of 1,4-dioxane.

1,4-Dioxane has not been measured and is unlikely to be present in sediment, sludge, soil or dust, based on its physical and chemical properties. 1,4-Dioxane has a low bioaccumulation potential for accumulation in aquatic organisms and is short-lived in humans and few biomonitoring data are available.

2.3.4 Environmental Exposures

The manufacturing, processing, use and disposal of 1,4-dioxane can result in releases to the environment. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-3 in conducting the risk evaluation for 1,4-dioxane.

2.3.5 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

Workers and occupational non-users may be exposed to 1,4-dioxane when performing activities associated with the conditions of use described in Section 2.2, including, but not limited to:

- Unloading and transferring 1,4-dioxane to and from storage containers to process vessels.
- Using 1,4-dioxane in process equipment.
- Cleaning and maintaining equipment.
- Sampling chemical, formulations or products containing 1,4-dioxane for quality control.
- Repackaging chemicals, formulations or products containing 1,4-dioxane.
- Handling, transporting and disposing waste containing 1,4-dioxane.
- Performing other work activities in or near areas where 1,4-dioxane is used.

Based on these activities, EPA expects to consider inhalation exposure to vapors and mists and dermal exposure, including skin contact with vapors, liquids and mists for workers and occupational non-users. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

The United States has several regulatory and non-regulatory exposure limits for 1,4-dioxane: An Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) of 100 ppm 8-hour time-weighted average (TWA) (360 mg/m^3) with a skin notation, a National Institute of Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) of 1 ppm (3.6 mg/m^3) as a 30-minute ceiling and an American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 20 ppm TWA (72 mg/m^3) (OSHA, 2005). The influence of these exposure limits on occupation exposures will be considered in the occupational exposure assessment.

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through

the OSHA Integrated Management Information System (IMIS) at https://www.osha.gov/oshstats/index.html. Table_Apx B-1 in Appendix B.2 provides a summary of industry sectors with 1,4-dioxane personal monitoring air samples obtained from OSHA inspections conducted between 2002 and 2016. NIOSH HHEs are conducted at the request of employees, union officials, or employers and help inform potential hazards at the workplace. HHEs can be downloaded at https://www.cdc.gov/niosh/hhe/. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

2.3.5.2 Consumer Exposures

No consumer uses for 1,4-dioxane were reported to EPA (U.S. EPA, 2017a, 2016b). 1,4-Dioxane may be found as a contaminant in consumer products and/or commercial products that are readily available for public purchase. However, it is present as a result of by-product formation during manufacture of ethoxylated chemicals that are subsequently formulated into products.

EPA does not expect to consider exposures to consumers and bystanders from by-product or contaminant exposure in the risk evaluation for 1,4-dioxane. Rather, EPA anticipates that 1,4-dioxane by-product and contaminant issues will be considered in the scope of any risk evaluation of ethoxylated chemicals.

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of 1,4-dioxane could result in potential pathways for oral, dermal or inhalation exposure to the general population. EPA expects to consider each media, route and pathway to estimate general population exposures.

Inhalation

There is inhalation exposure potential to 1,4-dioxane by breathing ambient air and indoor air. Ambient air exposures may occur from releases from industrial/commercial sources. Indoor air exposures may occur from infiltration from ambient air or emissions from tap water during activities such as showering and bathing. Based on the relatively high water solubility and relatively low Henry's law constant for 1,4-dioxane, 1,4-dioxane is only slightly volatile from water, though water temperature can also influence volatilization.

Based on these potential sources and pathways of exposure, EPA expects to consider inhalation exposures of the general population to 1,4-dioxane in air that may result from the conditions of use of 1,4-dioxane.

Oral

The general population may ingest 1,4-dioxane via contaminated drinking water. Based on reported uses, down-the-drain sources may contribute to surface water and drinking water levels. Therefore, there is potential oral exposure to 1,4-dioxane by ingestion of drinking water from surface water and ground water sources.

Based on these potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the conditions of use of 1,4-dioxane.

Dermal

Dermal exposure via water could occur through contact, such as washing and bathing, with tap water containing 1,4-dioxane. The source of the contaminated water could either be contaminated surface or ground waters.

Based on these potential sources and pathways of exposure, EPA expects to consider dermal exposures to the general population that may result from the conditions of use of 1,4-dioxane.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "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."

In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or disposal sites).

In developing exposure scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or lifestage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006).

In summary, in the risk evaluation for 1,4-dioxane, EPA expects to consider the following potentially exposed groups of human receptors: workers and occupational non-users. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of 1,4-dioxane, as described in *Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0723). Based on initial screening, EPA expects to consider the hazards of 1,4-dioxane identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for 1,4-dioxane: Health Canada (2010); OECD (1999); ECJRC (2002); NICNAS (1998). However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for 1,4-dioxane [*1,4-Dioxane (CASRN 123-91-1) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0723]. The OECD's High Production Volume (HPV) Chemicals program assessed environmental hazards from 1,4-dioxane to fish, aquatic invertebrates and aquatic plants exposed under acute and chronic exposure conditions. Exposure to 1,4-dioxane indicated acute toxicity to aquatic invertebrates, based on mortality and immobilization, chronic toxicity to aquatic invertebrates (growth and reproduction) and toxicity to aquatic plants (growth rate). No chronic effects occurred in fish exposed to 1,4-dioxane.

EPA expects to consider the hazards of 1,4-dioxane to aquatic organisms including fish, aquatic invertebrates and algae exposed to relevant media under acute and chronic exposure conditions. EPA does not expect to consider the hazards of 1,4-dioxane to sediment invertebrates and terrestrial organisms including soil invertebrates, birds and mammals because the physical and chemical properties and high mobility in soil make presence in these media unlikely (see Section 2.3.1).

2.4.2 Human Health Hazards

1,4-Dioxane has an existing EPA IRIS Assessment (U.S. EPA, 2013, 2010), ATSDR Toxicological Profile (ATSDR, 2012), Canada Screening Assessment (Health Canada, 2010), European Union (EU) Risk Assessment Report (ECJRC, 2002) and Interim AEGL (U.S. EPA, 2005b); hence, many of the hazards of 1,4-dioxane have been previously compiled and reviewed. EPA has relied heavily on these comprehensive reviews in preparing this scope. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for 1,4-dioxane [*1,4-Dioxane* (*CASRN 123-91-1*) *Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0723]. EPA expects to consider all potential hazards associated with 1,4-dioxane. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

2.4.2.1 Non-Cancer Hazards

Acute Toxicity

Effects following acute exposures were evaluated (U.S. EPA, 2005b). The Interim AEGLs (U.S. EPA, 2005b) evaluated acute toxicity and irritation and concluded that, in animals, acute toxic effects of 1,4-

dioxane include central nervous system depression, kidney and liver damage and irritation. Humans acutely exposed to 1,4-dioxane experienced irritation of the eyes, nose and throat, nausea and vomiting, coma and death. Also, 1,4-dioxane can cause narcosis in animals inhaling very high concentrations (U.S. EPA, 2005b).

Irritation

Acute inhalation studies in human volunteers noted irritation of the eyes, nose and throat (U.S. EPA, 2005b). In rats, 2 years of inhalation exposure to 1,4-dioxane, resulted in metaplasia, hyperplasia, atrophy, hydropic change, vacuolic change and preneoplastic cell proliferation in the nasal cavity (U.S. EPA, 2013).

Liver Toxicity

In subchronic and chronic repeated exposure studies conducted in rats and mice by the oral (via drinking water) and inhalation routes, evidence shows that 1,4-dioxane is toxic to the liver (U.S. EPA, 2013). Chronic administration of 1,4-dioxane via the drinking water resulted in hepatocellular degeneration and preneoplastic changes. Inhalation exposure to 1,4-dioxane resulted in necrosis of the centrilobular region and preneoplastic changes in the liver.

Kidney Toxicity

In subchronic and chronic repeated exposure studies conducted in rats and mice by the oral (via drinking water) and inhalation routes, evidence shows that 1,4-dioxane is toxic to the kidney (U.S. EPA, 2013). Kidney damage following drinking water exposure to 1,4-dioxane includes degeneration of cortical tubule cells, necrosis with hemorrhage and glomerulonephritis.

2.4.2.2 Genotoxicity and Cancer Hazards

U.S. EPA (2013) concluded that overall, the available literature indicates that 1,4-dioxane is nongenotoxic or weakly genotoxic. Per EPA's Cancer Guidelines (U.S. EPA, 2005a), EPA concluded that "there is insufficient biological support for potential key events and to have reasonable confidence in the sequence of events and how they relate to the development of nasal tumors following exposure to 1,4-dioxane". The mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors was not conclusive, and the available data did not support any hypothesized carcinogenic mode of action for 1,4-dioxane.

EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is "likely to be carcinogenic to humans" based on evidence of carcinogenicity in several 2-year bioassays (oral and inhalation) conducted in four strains of rats, two strains of mice and in guinea pigs (U.S. EPA, 2013). Human occupational studies into the association between 1,4-dioxane exposure and increased cancer risk are inconclusive because they are limited by small cohort size and a small number of reported cancer cases.

2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "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." In developing the hazard assessments, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

The IRIS assessment for 1,4-dioxane U.S. EPA (2013) found no direct evidence that certain populations and lifestages may be more susceptible to 1,4-dioxane. Information on induction of liver enzymes, genetic polymorphisms and gender differences was inadequate to quantitatively assess toxicokinetic or toxicodynamic differences in 1,4-dioxane hazard between animals and humans and the potential variability in human susceptibility.

2.5 Initial Conceptual Models

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for 1,4-dioxane, EPA developed three conceptual models, presented here.

2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial activities and uses of 1,4-dioxane. EPA expects that workers and occupational non-users may be exposed to 1,4-dioxane via dermal and inhalation routes during manufacturing, processing, distribution, use and disposal of 1,4-dioxane. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

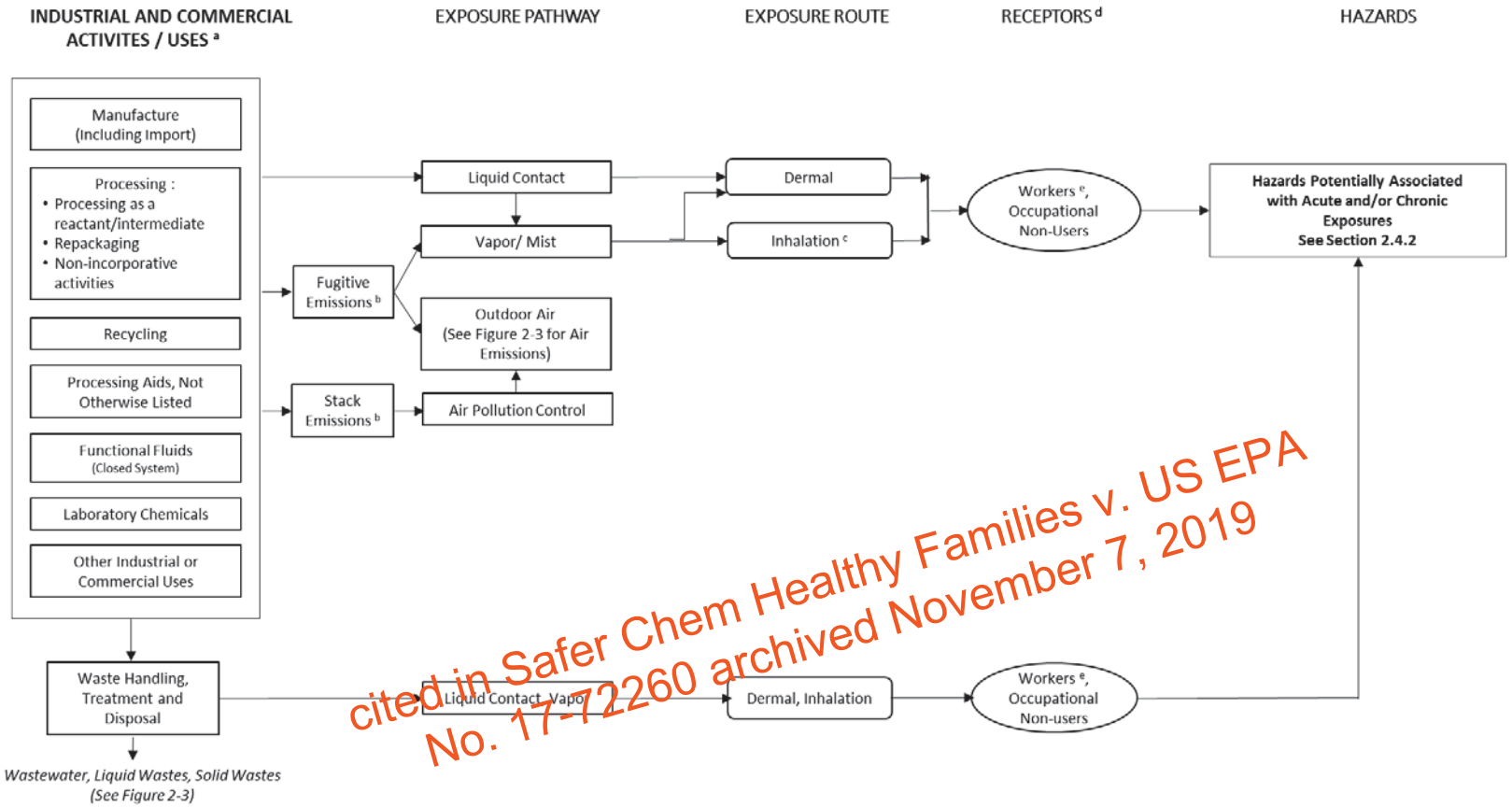

Figure 2-2. Initial 1,4-Dioxane Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of 1,4-dioxane.

[a] Additional uses of 1,4-dioxane are included in Table 2-3.

[b] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions, and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[c] Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed.

[d] Receptors include potentially exposed or susceptible subpopulations.

[e] When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personnel protective equipment have on occupational exposure levels.

2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

As shown in the 1,4-dioxane initial life cycle diagram (Figure 2-1), no uses of 1,4-dioxane in consumer products have been identified.

2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

Figure 2-3 illustrates exposure pathways for human and ecological receptors from environmental releases and waste disposal activities.

As shown in Figure 2-3, the potential pathways from industrial and commercial activities and waste streams reflect the possible exposures to human and ecological receptors. EPA expects the general populations living near industrial and commercial facilities using 1,4-dioxane will be exposed via inhalation of outdoor air. General populations may also be exposed via ingestion of contaminated drinking water, dermal and inhalation exposure from showering/bathing with contaminated drinking water, and inhalation exposure from the migration of vapor in air, soil, or ground water to air. Aquatic and terrestrial life may be exposed to 1,4-dioxane via contaminated surface water.

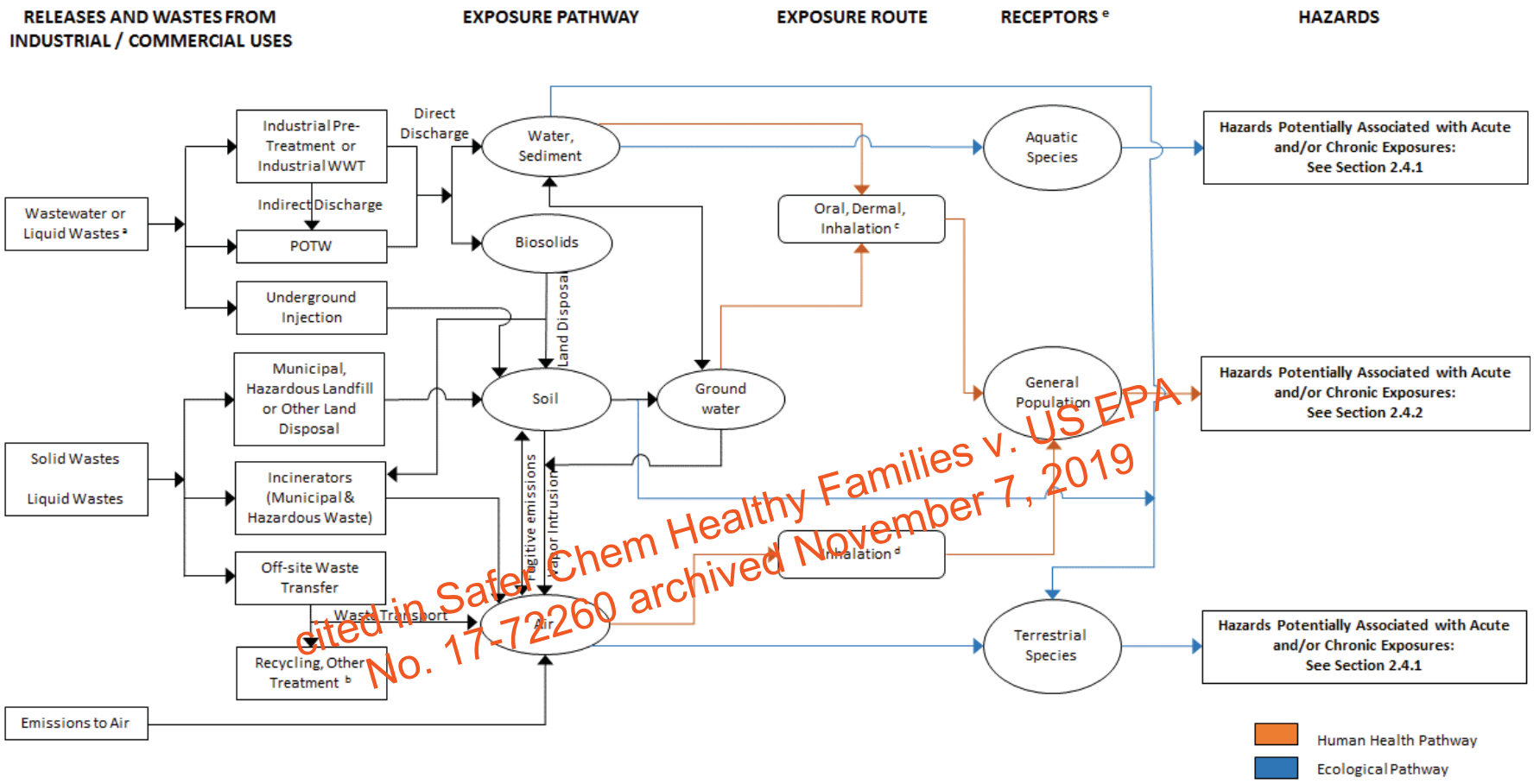

Figure 2-3. Initial 1,4-Dioxane Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of 1,4-dioxane.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). Drinking water will undergo further treatment in drinking water treatment plants. Ground water may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[d] Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.

[e] Presence of mist is not expected; dermal and oral exposure are negligible.

[f] Receptors include potentially exposed or susceptible subpopulations.

2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources as described in Section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of 1,4-dioxane, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the *1,4-Dioxane (CASRN 123-91-1) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0723*).* EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

2.6.1 Exposure

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to environmental media as follows:

1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated.
2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI and National Emissions Inventory [NEI] programs).
3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
4) Understand and consider regulatory limits that may inform estimation of environmental releases.
5) Review and determine applicability of OECD Emission Scenario Documents and EPA Generic Scenarios to estimation of environmental releases.
6) Evaluate the weight of the evidence of environmental release data.
7) Map or group each condition(s) of use to a release assessment scenario.

2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.
2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.
3) Evaluate the weight of the evidence of environmental fate data.

2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its environmental exposure assessment of 1,4-dioxane:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to extent data are available, and characterize exposed aquatic and terrestrial populations.
5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
6) Map or group each condition(s) of use to environmental assessment scenario(s).

2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the NIOSH, and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements).
2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to 1,4-dioxane.
3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
6) Evaluate the weight of the evidence of occupational exposure data.
   Map or group each condition of use to occupational exposure assessment scenario(s).

2.6.1.5 Consumer Exposures

EPA does not expect to consider and analyze consumer exposures in the risk evaluation (see Section 2.3.5.2).

2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
2) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
3) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
7) Evaluate the weight of the evidence of general population exposure data.
8) Map or group each condition of use to general population exposure assessment scenario(s).

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA expects to conduct an environmental hazard assessment of 1,4-dioxane as follows:

1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
3) Derive concentrations of concern (COC) for all identified ecological endpoints.
4) Evaluate the weight of the evidence of environmental hazard data.
5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.

4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
5) Evaluate the weight of the evidence of human health hazard data.
6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent and reasonable (TCCR) (U.S. EPA, 2000). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

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APPENDICES

Appendix A REGULATORY HISTORY

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
TSCA – Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	1,4-Dioxane is on the initial list of chemicals to be evaluated for risk under TSCA (81 FR 91927, December 19, 2016).
TSCA – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	1,4-Dioxane manufacturing (including importing), processing distribution and use information is reported under the CDR rule information about chemicals in commerce in the United States.
TSCA – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured or processed in the United States.	1,4-Dioxane was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process.
TSCA – Section 8(e)	Manufacturers (including importers), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Ten substantial risk reports from 1989 to 2004 (US EPA, ChemView. Accessed April 13, 2017).
EPCRA – Section 313	Requires annual reporting from facilities in specific industry	1,4-Dioxane is a listed substance subject to reporting requirements

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	sectors that employ 10 or more full time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels.	under 40 CFR 372.65 effective as of January 01, 1987.
Federal Food, Drug, and Cosmetic Act (FFDCA) – Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits) or exemptions from the requirement of a tolerance, for all residues of a pesticide (including both active and inert ingredients) that are in or on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is "safe." Sections 408(b) and (c) of the FFDCA define "safe" to mean the Agency has reasonable certainty that no harm will result from aggregate exposures to the pesticide residue, including all dietary exposure and all other exposure (e.g., non-occupational exposures) for which there is reliable information. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation. In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	In 1998, 1,4-dioxane was removed from the list of pesticide product inert ingredients because it was no longer being used in pesticide products. 1,4-Dioxane is also no longer exempt from the requirement of a tolerance (the maximum residue level that can remain on food or feed commodities under 40 CFR Part 180, Subpart D).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
CAA – Section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	1,4-Dioxane is subject to the NSPS for equipment leaks of volatile organic compounds (VOCs) in the synthetic organic chemicals manufacturing industry for which construction, reconstruction or modification began after 1/5/1981 and on or before 11/7/2006 (40 CFR Part 60, Subpart VV).
CAA – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAP). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance.	1,4-Dioxane is listed as a HAP under section 112 (42 U.S.C. § 7412) of the CAA.
CAA – Section 112(d)	Section 112(d) states that the EPA must establish (NESHAPs for each category or subcategory of major sources and area sources of HAPs [listed pursuant to Section 112(c)]. The standards must require the maximum degree of emission reduction that the EPA determines to be	There are a number of source-specific NESHAPs that are applicable to 1,4-dioxane, including: Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry (40 CFR Part 63, Subpart F), Organic Hazardous Air Pollutants from the Synthetic Organic

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	achievable by each particular source category. Different criteria for maximum achievable control technology (MACT) apply for new and existing sources. Less stringent standards, known as generally available control technology (GACT) standards, are allowed at the Administrator's discretion for area sources.	Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater (40 CFR Part 63, Subpart G) Off-Site Waste and Recovery Operations (40 CFR Part 63, Subpart DD), Wood Furniture Manufacturing Operations (40 CFR Part 63, Subpart JJ), Pharmaceuticals Production (40 CFR Part 63, Subpart GGG), Group IV Polymers and Resins (thermoplastic product manufacturing) (40 CFR Part 63, Subpart JJJ), Organic Liquids Distribution (Non-gasoline) (40 CFR Part 63, Subpart EEEE), Miscellaneous Organic Chemical Manufacturing (40 CFR Part 63, Subpart FFFF), Rubber Tire Manufacturing (40 CFR Part 63, Subpart XXXX), Site Remediation (40 CFR Part 63, Subpart GGGGG), and Miscellaneous Coating Manufacturing (40 CFR Part 63, Subpart HHHHH).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release	1,4-Dioxane is a hazardous substance under CERCLA. Releases of 1,4-dioxane in excess of 100 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	
Safe Drinking Water Act (SDWA) – Section 1412(b)	Every 5 years, EPA must publish a list of contaminants that: (1) are currently unregulated, (2) are known or anticipated to occur in public water systems (PWSs) and (3) may require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.	1,4-dioxane was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate List (CCL) (74 FR 51850, October 8, 2009) (81 FR 81099, November 17, 2016).
SDWA – Section 1445(a)	Every 5 years, EPA must issue a new list of no more than 30 unregulated contaminants to be monitored by PWSs. The data obtained must be entered into the National Drinking Water Contaminant Occurrence Database.	1,4-dioxane was identified in the third UCMR, issued in 2012 (77 FR 26072, May 2, 2012).
RCRA – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	In 1980, 1,4-dioxane became a listed hazardous waste in 40 CFR 261.33 - Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof (U108) (45 FR 33084).
Other federal regulations		

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
FFDCA	Provides the U.S. Food and Drug Administration (FDA) with authority to oversee the safety of food, drugs and cosmetics.	FDA established a limit of 10 mg/kg on the amount of 1,4-dioxane that can be present in the food additive glycerides and polyglycides of hydrogenated vegetable oils (21 CFR 172.736 and 71 FR 12618, March 13, 2006).
Occupational Safety and Health Act	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions. Under the Act, OSHA can issue occupational safety and health standards including such provisions as PELs, exposure monitoring, engineering and administrative control measures and respiratory protection.	In 1989, OSHA established a PEL for 1,4-dioxane of 100 ppm or 360 mg/m^3 as an 8-hour, TWA (29 CFR 1910.1001). While OSHA has established a PEL for 1,4-dioxane, OSHA has recognized that many of its PELs are outdated and inadequate for ensuring the protection of worker health. 1,4-Dioxane appears in OSHA's annotated PEL tables, wherein OSHA recommends that employers follow the California OSHA limit of 0.28 ppm, the NIOSH REL of 1 ppm as a 30-minute ceiling or the ACGIH TLV of 20 ppm (8-hour TWA).
Atomic Energy Act	The Atomic Energy Act authorizes the Department of Energy to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL.
Federal Hazardous Materials Transportation Act	Section 5103 of the Act directs the Secretary of Transportation to: Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material and compressed gas) as hazardous when the Secretary determines that transporting the material in	The Department of Transportation (DOT) has designated 1,4-dioxane as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR Part 171, 40 CFR 173.202 and 40 CFR 173.242).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	commerce may pose an unreasonable risk to health and safety or property. Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State PELs	California PEL: 0.28 ppm (Cal Code Regs. Title 8, § 5155).
State Right-to-Know Acts	New Jersey (8:59 N.J. Admin. Code § 9.1), Pennsylvania (34 Pa. Code § 323).
State air regulations	Allowable Ambient Levels (AAL): New Hampshire (RSA 125-I:6, ENV-A Chap. 1400), Rhode Island (12 R.I. Code R. 031-022).
State drinking/groundwater limits	Massachusetts (310 Code Mass. Regs. § 22.00), Michigan (DEQ 2016).
Chemicals of high concern to children	Several states have adopted reporting laws for chemicals in children's products that include 1,4-dioxane, such as Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015) Vermont (Code Vt. R. § 13-140-077) and Washington State (Wash. Admin. Code § 173-334-130).
Other	In California, 1,4-dioxane was added to the Proposition 65 list in 1988 (Cal. Code Regs. title 27, § 27001).

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by other Governments and Tribes

Country/Organization	Requirements and Restrictions
Canada	1,4-Dioxane is on the Cosmetic Ingredient Hotlist as a substance prohibited for use in cosmetics. 1,4-Dioxane is also included in Canada's National Pollutant Release Inventory (NPRI), the publicly-

Country/Organization	Requirements and Restrictions
	accessible inventory of pollutants released, disposed of and sent for recycling by facilities across the country (Government of Canada, 2010. *1,4-Dioxane*. Accessed April 18, 2017).
Australia	In 1994, 1,4-dioxane was assessed. A workplace product containing more than 0.1% 1,4-dioxane is classed as a hazardous substance. 1,4-Dioxane is in Class 3, (Packing Group II) under the Australian Dangerous Goods Code (National Industrial Chemicals Notification and Assessment Scheme, NICNAS, 2013, *Dioxane (1,4-Dioxane)*. Accessed April, 18 2017).
Japan	1,4-dioxane is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law (National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP), Accessed April 18, 2017).
Republic of Korea	The Ministry of the Environment recently adopted a provisional water quality standard for human health of 50 µg/L 1,4-dioxane in drinking water (An et al, 2014).
Australia, Austria, Belgium, Canada, Denmark, European Union (EU), Finland, France, Germany, Hungary, Ireland, Italy, Japan, Latvia, New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, The Netherlands, Turkey, United Kingdom	Occupational exposure limits for 1,4-dioxane (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).
WHO	Established a tolerable daily intake of 16 µg 1,4-dioxane/kg body weight based on a no-observed-adverse-effect level (NOAEL) of 16 mg/kg body weight per day for hepatocellular tumors observed in a long-term drinking-water study in rats. The WHO water quality guideline is 0.05 mg/L 1,4-dioxane in drinking water (WHO 2005).

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

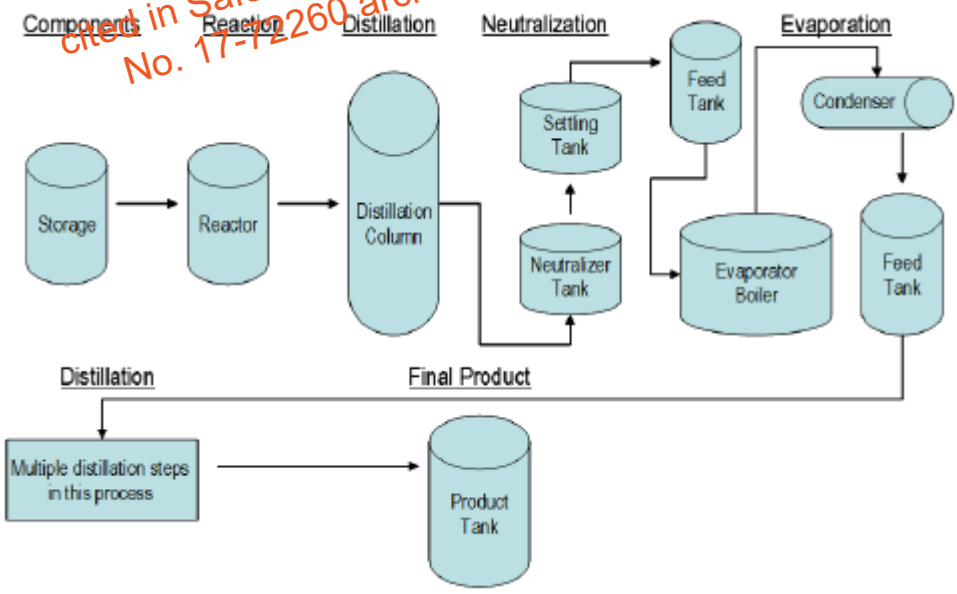
This appendix provides information and data found in preliminary data gathering for 1,4-dioxane.

B.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration.

B.1.1 Manufacture (Including Import)

The primary method for industrial production of 1,4-dioxane involves an acid-catalyzed conversion of ethylene glycol (mono-, di-, tri- and polyethylene glycol may be used) by ring closure in a closed system. The process is carried out at a temperature between 266 and 392°F (130 and 200°C) and a pressure between 0.25 and 1.1 atm (25 and 110 kPa). The synthesis step is performed in a heated vessel. The raw 1,4-dioxane product is then moved to a distillation column to start the purification process. Multiple steps are used to purify the 1,4-dioxane, including separation from water and volatile by-products by extractive distillation, heating with acids, salting out with NaCl, $CaCl_2$ or NaOH, and fine subsequent distillation (ECJRC, 2002). The 1,4-dioxane manufacturing plant in Zachary, Louisiana produces 1,4-dioxane using this reaction with diethylene glycol and concentrated sulfuric acid. Figure_Apx B-1 shows a process flow diagram for the process used by the manufacturer [EPA-HQ-OPPT-2016-0723-0012 (BASF, 2017)].



Figure_Apx B-1: General Process Flow Diagram for 1,4-Dioxane Manufacturing
Source: EPA-HQ-OPPT-2016-0723-0012 (BASF, 2017).

Two other reactions can be used to make 1,4-dioxane, but they are primarily used to make substituted dioxanes and not known to be used for industrial 1,4-dioxane production (ECJRC, 2002).

B.1.2 Processing and Distribution

B.1.2.1 Processing as a Reactant/Intermediate

1,4-Dioxane can be used as a chemical reactant in the production of pharmaceuticals, polyethylene terephthalate (PET) plastics, rubber, insecticides and pesticides, cement, deodorant fumigant, magnetic tape and adhesives [EPA-HQ-OPPT-2017-0723-0003 (U.S. EPA, 2017b)]. Exact process operations involved in the use of 1,4-dioxane as a chemical reactant are dependent on the final product that is being synthesized. For the use of 1,4-dioxane as a chemical reactant, operations would typically involve unloading 1,4-dioxane from transport containers and feeding the 1,4-dioxane into a reaction vessel(s), where the 1,4-dioxane would react either fully or to a lesser extent. Following completion of the reaction, the produced substance may or may not be purified further, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is assumed to be destroyed and is thus not expected to be released or cause potential worker exposures.

B.1.2.2 Processing – Non-Incorporative

1,4-Dioxane is used as a process solvent during the manufacturing of cellulose acetate, resins, waxes and fats [EPA-HQ-OPPT-2017-0723-0003 (U.S. EPA, 2017b)].

B.1.2.3 Repackaging

Typical repackaging operations involve transferring of chemicals into appropriately sized containers to meet customer demands/needs.

B.1.2.4 Recycling

1,4-Dioxane is used as a solvent in several applications. In this capacity, 1,4-dioxane can be regenerated and recycled for reuse.

B.1.3 Uses

B.1.3.1 Processing Aids, Not Otherwise Listed

Processing aids are chemical substances used to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance or mixture, when added to a process or to a substance or mixture to be processed. Processing agents do not become a part of the reaction product and are not intended to affect the function of a substance or article created (U.S. EPA, 2016a). 1,4-Dioxane is used in a number of industrial processes as a processing aid. These processes include wood pulping, extraction of animal and vegetable oils, textile processing, polymerization, pharmaceutical purification and etching of fluoropolymers [EPA-HQ-OPPT-2017-0723-0003 (U.S. EPA, 2017b); EPA-HQ-OPPT-2016-0723-0012 (BASF, 2017)]. Exact process operations involved in the use of 1,4-dioxane as a processing aid are dependent on the final product that is being synthesized.

B.1.3.2 Functional Fluids (Closed System)

Functional fluids are liquid or gaseous chemical substances used for one or more operational properties (U.S. EPA, 2016a). 1,4-Dioxane is used in polyalkylene glycol lubricants, synthetic metalworking fluids, cutting and tapping fluids and hydraulic fluids [EPA-HQ-OPPT-2017-0723-0003 (U.S. EPA, 2017b)]. Exact operations involved in the use of 1,4-dioxane as a functional fluid are dependent on the final product.

B.1.3.3 Laboratory Chemicals

1,4-Dioxane is used in laboratories as a chemical reagent, reference material, stable reaction medium, liquid scintillation counting medium, spectroscopic and photometric measurement, cryoscopic solvent and histological preparation [EPA-HQ-OPPT-2017-0723-0003 (U.S. EPA, 2017b)]. Laboratory procedures are generally done within a fume hood, on a bench with local exhaust ventilation or under general ventilation.

B.1.3.4 Adhesives and Sealants

1,4-Dioxane is found in film cement and as a residual contaminant in two-component glues and adhesives [EPA-HQ-OPPT-2017-0723-0003 (U.S. EPA, 2017b)]. The application procedure depends on the type of adhesive and the type of substrate. After the adhesive is received by the user, it may be diluted or mixed prior to application. The formulation is then loaded into the application reservoir or apparatus and applied to the substrate via spray, roll, curtain or syringe or bead application. Application may be manual or automated. After application, the adhesive or sealant is allowed to dry, usually at ambient temperature, such that the solvent completely evaporates and a bond is formed between the substrates (OECD, 2015).

B.1.3.5 Other Uses

Other conditions of use where 1,4-dioxane may be formulated into a product or used as part of another process may include use in fuels and fuel additives [EPA-HQ-OPPT-2016-0723-0012 (BASF, 2017)], spray polyurethane foam and in printing and printing compositions [EPA-HQ-OPPT-2017-0723-0003 (U.S. EPA, 2017b)].

B.1.4 Disposal

1,4-Dioxane is disposed of to a variety of environmental media: land, water and air. Land disposals include Class I underground injection, RCRA Subtitle C landfills and to other uncategorized land points. 1,4-Dioxane is sometimes discharged to water. Wastewater treatment may or may not precede these water releases. Additionally, 1,4-dioxane is also commonly incinerated (U.S. EPA, 2017c).

B.2 Occupational Exposure Data

EPA presents below an example of occupational exposure-related information from the preliminary data gathering. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

Table_Apx B 1 summarizes OSHA CEHD data by North American Industry Classification System (NAICS) code (OSHA, 2017a, b).

Table_Apx B-1. Summary of Industry Sectors with 1,4-Dioxane Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2002 and 2016

NAICS	NAICS Description
315225	Men's and Boys' Cut and Sew Work Clothing Manufacturing
325199	All Other Basic Organic Chemical Manufacturing
334418	Printed Circuit Assembly (Electronic Assembly) Manufacturing
336399	All Other Motor Vehicle Parts Manufacturing
926150	Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors

United States Court of Appeals for the Ninth Circuit

Office of the Clerk
95 Seventh Street
San Francisco, CA 94103

Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)
Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - ► A material point of fact or law was overlooked in the decision;
  - ► A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - ► An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ► Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ► The proceeding involves a question of exceptional importance; or
- ► The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- *See* Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- An answer, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or answer must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms.*
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms.*

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-7806.

Petition for a Writ of Certiorari

- Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send a letter **in writing within 10 days** to:
  - ► Thomson Reuters; 610 Opperman Drive; PO Box 64526; Eagan, MN 55123 (Attn: Jean Green, Senior Publications Coordinator);
  - ► and electronically file a copy of the letter via the appellate ECF system by using "File Correspondence to Court," or if you are an attorney exempted from using the appellate ECF system, mail the Court one copy of the letter.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 10. Bill of Costs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form10instructions.pdf

9th Cir. Case Number(s)

Case Name

The Clerk is requested to award costs to (*party name(s)*):

I swear under penalty of perjury that the copies for which costs are requested were actually and necessarily produced, and that the requested costs were actually expended.

Signature **Date**

*(use "*s/[typed name]*" to sign electronically-filed documents)*

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