Draft Review of Applications in the American Innovation and Manufacturing (AIM) Act Subsection (e)(4)(B)(4)

Proposed Rule—Phasedown of Hydrofluorocarbons: Review and Renewal of Eligibility for Application-specific Allowances

August 2024

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1. Introduction

The American Innovation and Manufacturing (AIM) Act directs the United States Environmental Protection Agency (EPA) to undertake a review of applications receiving allowances pursuant to subsection (e)(4)(B)(iv) at least every five years. If pursuant to this review EPA determines that the requirements of two statutory criteria are met, EPA shall authorize production or consumption, as applicable, of the exclusive use of regulated substances in the application for renewable periods of not more than five years. EPA refers to this category of allowances as application-specific allowances (ASAs). Specifically, EPA must determine whether (1) no safe or technically achievable substitute will be available during the applicable period for the application; and (2) the supply of the regulated substance that manufacturers or users of the regulated substance for that application are capable of securing from chemical manufacturers is insufficient to accommodate the application. The proposed rule "Phasedown of Hydrofluorocarbons: Review and Renewal of Eligibility for Application-specific Allowances," explains how EPA proposes to interpret these two statutory criteria.

The following chapters in this Technical Support Document (TSD) outline the analysis undertaken by EPA, and the information underlying that analysis, that comprises the review of five of the six applications listed in the AIM Act: propellants in metered dose inhalers, defense sprays, structural composite preformed polyurethane foam for marine use and trailer use, the etching of semiconductor material or wafers and the cleaning of chemical vapor deposition chambers within the semiconductor manufacturing sector, and onboard aerospace fire suppression. For the sixth application listed in the AIM Act, mission-critical military end uses, EPA consulted with DoD and received feedback that informed our analysis. The information contained within this TSD underlies the proposed determinations outlined in the Federal Register notice regarding whether to renew the eligibility for each application to continue to receive ASAs starting in calendar year 2026 based on the two statutory criteria listed above. The TSD chapters contain overviews of each application, analysis of the development and transition to substitutes, and a review of the supply of regulated substances for these applications.

2. Data Sources

In the review of the criterion of available safe or technically achievable substitutes, EPA considered substitutes to include regulated substances (i.e., other hydrofluorocarbons [HFCs]), alternative substances (e.g., hydrofluoroolefins [HFOs], hydrocarbons [HCs], etc.), blends of HFCs and/or HFC alternatives, and not-in-kind (NIK) technologies. Data sources for the information presented in this document include, but are not limited to:

- Manufacturer announcements;
- Information provided by stakeholders under 40 CFR Part 84 reporting requirements and other communications;
- Relevant federal regulations;
- Evaluations carried out under the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) and the Significant New Alternatives Policy (SNAP) Program;

- Standards from industry, standards-setting bodies (e.g., American Society for Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE)), and the U.S. government (e.g., the U.S. Food and Drug Administration's (FDA) standards for metered dose inhalers);
- Peer-reviewed technical reports;
- Montreal Protocol Technology and Economic Assessment Panel (TEAP) reports;
- Scientific journal articles;
- Industry trade groups; and
- International authorities.

In the review of the criterion for the supply of regulated substances, both for currently used and substitute HFCs, EPA looked at several sources of data, including:

- Purification process and requirements that may further limit the quantity and/or sources of HFCs accessible to a particular application, including required regulatory approvals and purity standards or specifications;
- Feasibility of the use of recovered and reprocessed material, which could be a potential source of supply for applications;
- Available supply of HFCs based on 2022 data, the most recent year for which EPA has verified data. This includes the total expected HFC consumption in the United States, global production of individual HFCs used in the applications, and domestic inventory held by suppliers of individual HFCs used in the applications;
- Past and projected market trends for an application that can inform projected demand for the HFC(s) it uses based on a variety of sources, including market reports and academic resources;
- Anticipated regulatory impacts of AIM Act rules; and
- 2022 and 2023 HFC and ASA activity reported to the Agency through biannual reports. These data include inventory of HFCs held by application-specific end users and allowance usage by application, including conferrals, direct imports, and open market purchases by ASA holders, as well as expenditures of allowances conferred by ASA holders to suppliers. Application-specific end users may acquire HFCs in the following ways 1) through a conferral from a producer, importer, or other party in the supply chain, who can then expend that allowance to produce or import HFCs for use in the end user's application; 2) through purchasing HFCs without using ASAs from a supplier, in which the producer/importer expends their own production or consumption allowances to produce or import those HFCs; and (3) through the end user expending their own ASAs to directly import bulk HFCs. Note that EPA intends to take into account 2024 HFC and ASA activity reported to the Agency as available for the final rule.

3. Regulations Impacting All Applications

The Kigali Amendment to the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol) is an international agreement to phase down the production and consumption of HFCs by 80 – 85% by 2047. Regulations and regulatory programs established in the United States and globally could impact use of HFCs in the six applications listed in the AIM Act, development of substitutes in those applications, and the supply of HFCs that entities within a particular application may access. These regulations and regulatory programs include AIM Act rulemakings, HFC phasedown programs in other countries, the CAA Section 612 SNAP program, and regulations related to per- and polyfluoroalkyl substances (PFAS) and are described below as they may impact all five of the applications listed in this TSD. There are additional domestic regulations and standards impacting the use and supply of HFCs, as well as potential substitutes, that are specific to each of the applications and are described in more detail within subsequent chapters.

3.1 AIM Act Rules

The domestic HFC market has been responding to the enactment of the AIM Act in 2020 and the subsequent promulgation of domestic regulations, as well as the global phasedown of HFCs under the Kigali Amendment to the Montreal Protocol. In 2021, EPA promulgated regulations to implement the required phasedown of HFC production and consumption in the United States (*Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act*, 86 FR 55116, October 5, 2021; “Allocation Framework Rule"), including establishing priority access to allowances for the six applications specified in the AIM Act. EPA has issued final rules to address HFCs by facilitating the transition to next-generation technologies through sector-based restrictions on HFCs, specifically *Technology Transitions Restrictions on the Use of Certain HFCs under Subsection (i) of the AIM Act* rulemaking (88 FR 73098, October 24, 2023) (2023 Technology Transitions Rule) and *Technology Transitions Restrictions on the Use of Certain HFCs in the Residential and Light Commercial Air Conditioning and Heat Pump Sector* (88 FR 88825, December 26, 2023). These rulemakings do not regulate the applications while they are receiving ASAs. EPA has also issued a proposed rule addressing maximizing reclamation and minimizing releases from equipment, *Management of Certain Hydrofluorocarbons and Substitutes under Subsection (h) of the American Innovation and Manufacturing Act* (88 FR 72216) (hereafter referred to as the “Emissions Reduction and Reclamation Rule”). Collectively, these rules are expected to affect the demand for and supply of certain individual HFCs within the United States.

EPA anticipates the market will continue to respond to the domestic regulations and global phasedown including by transitioning from higher global warming potential (GWP) HFCs. While the Agency cannot predict specific shifts in chemical production, domestically and internationally, that may occur as the HFC phasedown progresses, EPA anticipates businesses may focus on supplying lower-GWP HFCs, since production and consumption of these lower-GWP HFCs require the expenditure of fewer allowances for the same volume of substance.[1] At

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[1] In the Allocation Framework Rule, EPA established a system whereby allowances are measured on an exchange value equivalent basis. 86 FR at 55142. To determine the total number of allowances needed, producers and

the same time, EPA acknowledges that some sectors and subsectors not covered by the 2023 Technology Transitions Rule may continue to use higher-GWP HFCs in new equipment. HFCs can be used for servicing existing equipment for both covered and not covered sectors and subsectors.

3.1.1 HFC Allocation Framework Rule

The 2021 Allocation Framework Rule was established to achieve the AIM Act-mandated phasedown of HFCs by 85% from historic baseline levels by 2036. The phasedown is implemented through the use of allowances. Entities expend allowances in order to produce or import bulk HFCs. Producing HFCs requires expending both production allowances and consumption allowances at the time of production. Importing HFCs requires expending only consumption allowances at the time of import. This design helps EPA ensure that U.S. production and consumption stay within the limits established under the AIM Act and Montreal Protocol. A third category of allowances, called “ASAs,” can be used to either produce or import bulk HFCs for one of the six listed applications. ASAs are typically conferred by the entity receiving the allowances to their supplier, who expends the allowances at the time they produce or import bulk HFCs. ASA allocations are determined on an annual basis. ASA allowance levels do not decrease consistent with the statutory phasedown schedule, unlike entities receiving general pool allowances. The most recent significant stepdown was in 2024, as the phasedown progressed from 90% to 60% of historic baseline levels. The next stepdown will be in 2029, with a reduction from 60% of historic baseline levels to 30% of the baseline.

3.1.2 Technology Transitions

EPA’s 2023 Technology Transitions Rule restricts the use of HFCs in specific sectors or subsectors, including aerosols, foams, and refrigeration, air conditioning and heat pumps, with compliance dates ranging from January 1, 2025, to January 1, 2028, depending on the subsector. Consistent with the AIM Act, the six applications receiving ASAs are not restricted by the 2023 Technology Transitions Rule while those applications are eligible for ASAs. Many of the sectors and subsectors subject to the 2023 Technology Transitions Rule use the same HFCs as the six applications, and typically have had larger demand for these HFCs. Some of these HFCs have higher GWPs than the restrictions established under the 2023 Technology Transitions Rule, so demand for these HFCs may fall; however, these HFCs may continue to be used in blends that are below the GWP limit established by the rule. For example, overall demand for HFC-134a, which is used in applications including metered dose inhalers and defense sprays, is projected to decrease (EPA, 2023a).

Other HFCs used by the six applications, such as HFC-41 and HFC-23, have little to no use in sectors and subsectors restricted by EPA’s Technology Transitions Program, and continue to have projected demand from non-impacted sectors.[2] Furthermore, for other HFCs the Technology Transitions Program may have countervailing effects on demand, potentially resulting in relatively stable consumption overall despite changes in use. For example, demand for HFC-32 as a component of R-410A (a relatively higher-GWP blend) is anticipated to fall,

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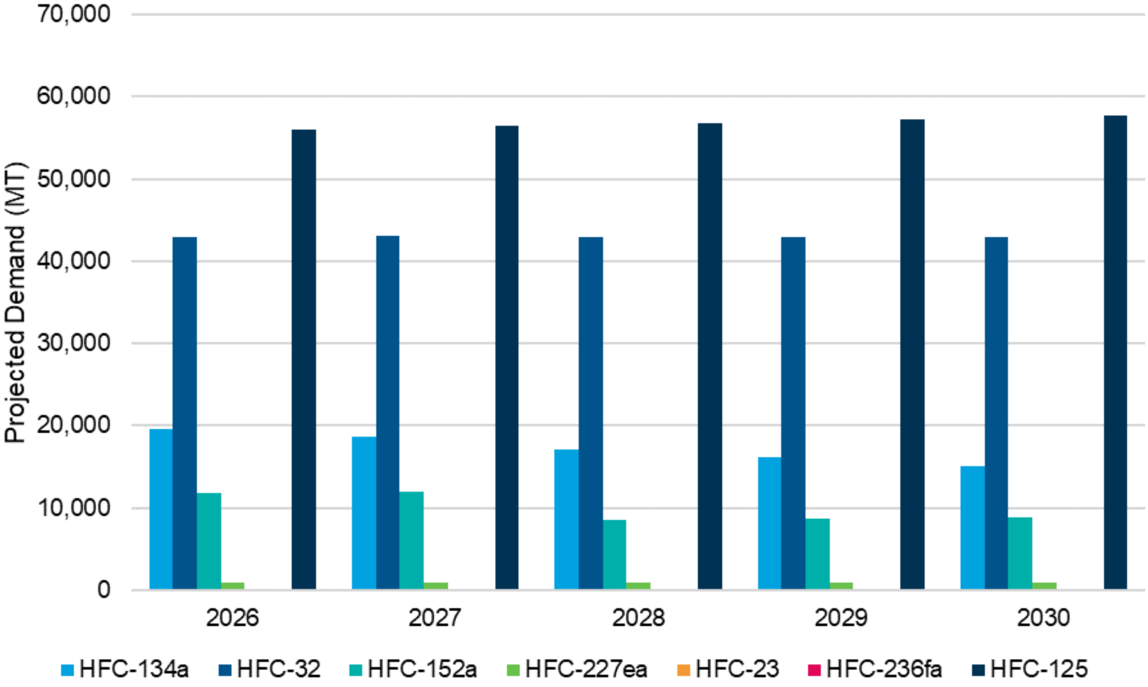
importers multiply the quantity of the HFC they seek to produce or import by its exchange value. For example, an importer would need to expend 143 consumption allowances to import 100 kilograms of HFC-134a. Given the variation in exchange values, one would need to expend 5.3 allowances to import 100 kg of HFC-152a.

[2] HFC-41 is not modeled in EPA’s Vintaging Model.

while demand for neat HFC-32 or HFC-32 in lower-GWP blends is anticipated to increase. Figure 1, which draws on the Technoloy Transitions RIA addendum, presents the resulting projected demand for the HFCs predominantly used by the five applications between 2026 and 2030.

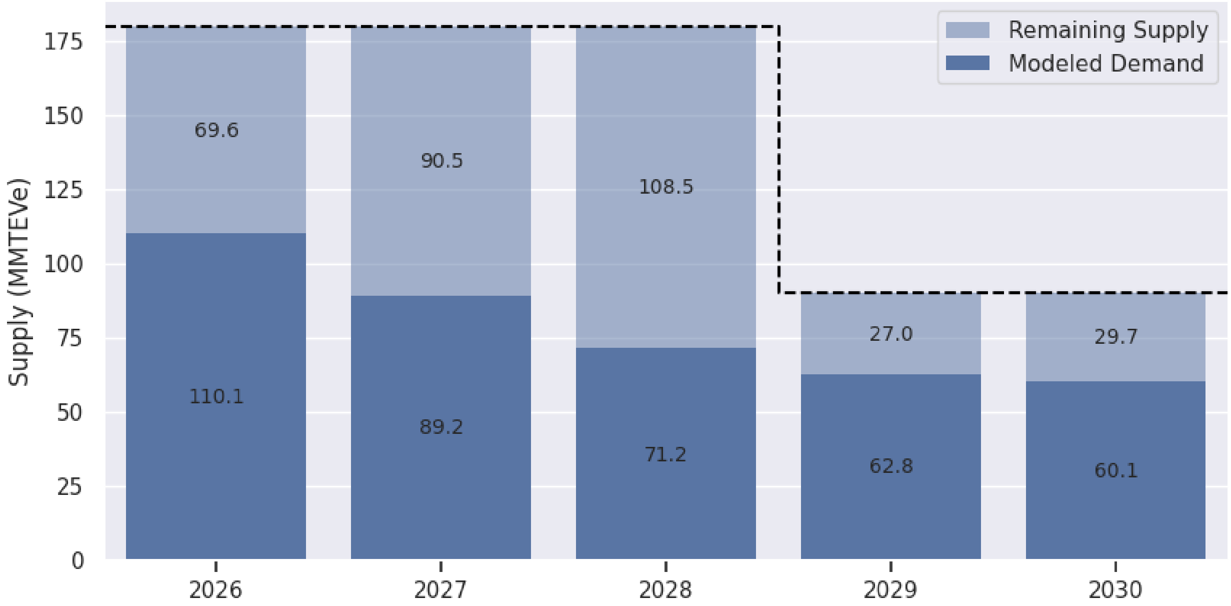
Figure 1. Projected Demand (Metric Tons [MT]) for HFC-134a, HFC-32, HFC-152a, HFC-227ea, HFC-23, HFC-236fa, and HFC-125



Note: HFC-23 and HFC-236fa demand estimates are too small to be shown. Estimates for HFC-23 range from 11 to 12 MT over the time series. Estimates for HFC-236fa range from 190 to 212 MT over the time series. In addition, HFC-41 is not modeled in EPA’s Vintaging Model.

These estimates are uncertain, as they are based on an ex-ante analysis of anticipated industry transitions in response to AIM Act rules and resulting demand. However, assuming future demand for regulated HFCs is consistent with these projections, overall demand may be significantly lower than the limits set out by the statutory phasedown caps (Figure 2). Since HFC production and consumption can continue at the levels allowed under the HFC Allocation Program, i.e., 60% of historic baseline levels through 2028 (181.5 million metric tons of exchange value equivalent (MMTEVe) of consumption) and at 30% of the baseline in 2029-2033 (90.8 MMTEVe of consumption), lower demand for HFCs in some sectors and subsectors could allow for additional available supply of HFC consumption allowances that may be used for the production or import of regulated HFCs. Total demand across all end uses is estimated to be approximately 110.1 MMTEVe in 2026, approximately 69.6 MMTEVe remaining under the cap. In 2030, total demand is estimated to be approximately 60.1 MMTEVe, approximately 29.7 MMTEVe under the cap. By contrast, estimated 2022 use of HFCs for the five applications discussed in this TSD was approximately 2.5 MMTEVe.

Figure 2. Potential Supply of HFCs (MMTEVe), 2026-2030



Note that nothing in EPA's regulations would limit the ability of allowance holders to produce and import HFCs up to the statutory cap on production and consumption. For the reasons described in this chapter and in Section V.A of the accompanying proposed rule, the estimated gap between total allowable consumption and projected demand could be higher or lower than projected. While this overall picture is useful to inform the analysis required in AIM Act subsection (e)(4)(B)(iv), there is uncertainty about how the potential gap would affect the supply of the regulated substance(s) that manufacturers or users of the regulated substance(s) for a specific application are capable of securing from chemical manufacturers. EPA considers this information, as appropriate, when evaluating each application individually.

3.1.3 Emissions Reduction and Reclamation Rule

In a separate action, EPA proposed to establish an Emissions Reduction and Reclamation Program including requirements for leak repair; use of automatic leak detection systems; use of reclaimed HFCs for certain types of equipment in certain refrigeration, air conditioning, and heat pump subsectors and use of recycled HFCs for fire suppression equipment; recovery of HFCs from disposable cylinders before disposal; and use of a container tracking system for certain HFCs. EPA did not propose to extend a requirement to use recycled HFCs in the installation, servicing and/or repair of such fire suppression equipment for the onboard aerospace fire suppression application as long as they qualify for ASAs. This proposed action could reduce the need for virgin production of certain refrigerant and fire suppression agents, which could impact the supply of reclaimed and recycled HFCs available to ASA holders (where the use of reclaimed or recycled HFCs is feasible).

These proposed requirements could also decrease the need for certain virgin HFCs and reduce consumption of virgin HFCs in regulated sectors, i.e., by allowing allowance holders to use allowances for other projected demand. EPA discusses the potential implications in this TSD and the preamble to the proposed ASA Renewal Rule. EPA intends to take into account the final Emissions Reduction and Reclamation rulemaking, when finalizing this action.

3.2 Global Phasedown of HFCs

In addition to the U.S. HFC phasedown program under the AIM Act, HFC phasedown programs in other countries may have additional impacts on the use and development of HFC alternatives and the total supply of HFCs available both domestically and abroad.

The Kigali Amendment to the Montreal Protocol is a global agreement calling for a gradual phasedown in the consumption and production of HFCs to 15 or 20% of their historic levels by 2047. Countries agreed to adopt this amendment in 2016, and those countries that have ratified the Kigali Amendment must develop their own approach to achieve the HFC phasedown targets and may choose to target specific HFCs and/or specific sectors. One hundred and fifty-eight countries have ratified the Kigali Amendment.[3] The United States ratified the Kigali Amendment on October 31, 2022. The global phasedown of HFCs will impact the development of alternatives as countries look to replace HFCs in a tightening HFC market. Some of the applications eligible for ASAs receive additional flexibility or exemptions under other countries' phasedown efforts. For example, semiconductor chips are exempt from the phasedown requirements and import restrictions established in Canada (Government of Canada, 2016). Other countries may instead implement additional restrictions.

Eight countries produce the HFCs used by these applications, including four Article 5 countries[4]: China, India, Republic of Korea, and United Arab Emirates (UAE).[5] China has the largest production capacity for HFCs currently used by entities receiving ASAs (UNEP, n.d.). China produces HFC-134a, HFC-227ea, HFC-32, HFC-125, HFC-152a, and HFC-236fa. The second largest producer of HFCs used in these applications is the United States, which produces HFC-134a, technical and pharmaceutical grade HFC-227ea, HFC-23, HFC-32, HFC-41, HFC-125, and HFC-152a. The United Kingdom produces technical and pharmaceutical grade HFC-134a and HFC-152a, and Germany produces HFC-134a and technical and pharmaceutical grade HFC-227ea. For detailed information on the application-specific HFCs produced by each country, see Table 1.

Table 1. Countries Producing HFCs Used by These Applications

Country	HFC-134a	HFC-227ea	HFC-23	HFC-32	HFC-41	HFC-125	HFC-152a	HFC-236fa
China	X	X		X		X	X	X
Germany	X	X						
India	X			X		X		
Japan	X			X		X		

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[3] As of April 19, 2024. See https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=XXVII-2-f&chapter=27&clang=_en

[4] For a list of Article 5 and non-Article 5 countries see https://ozone.unep.org/classification-parties.

[5] The UAE has legislation in place to regulate the use and distribution of HFCs but has not ratified the Kigali Amendment.

Country	HFC-134a	HFC-227ea	HFC-23	HFC-32	HFC-41	HFC-125	HFC-152a	HFC-236fa
Republic of Korea	X			X				
United Arab Emirates				X				
United Kingdom	X						X	
United States	X	X	X	X	X	X	X	

Sources: EPA (2024), Daikin Industries (n.d.).

3.2.1 European Union

The European Union (EU) has had legislation in place since 2006 to phase down fluorinated gases, including HFCs, and restrict their use in certain sectors (The European Parliament and The Council of the European Union, 2006; The European Parliament and The Council of the European Union, 2014). The 2014 legislation (i.e., (EU) No 517/2014) directed the European Commission to implement an HFC quota allocation system to phase down the addition of HFCs to the EU market (The European Parliament and The Council of the European Union, 2014). In February 2024, the EU amended their regulations to further reduce emissions of fluorinated gases, including HFCs. As outlined in Annex VII of the regulations,[6] the EU will phase out consumption entirely[7] of HFCs by 2050. The agreement also notes that, where suitable HFC alternatives are available, bans should be introduced for new refrigeration, air conditioning, and fire protection equipment, foams, and technical aerosols entering the market that contain or rely upon the use of those HFCs (The European Parliament and The Council of the European Union, 2024). However, the revised F-gas rule allows for renewable four-year exemptions for products and equipment for which alternatives are not available, cannot be used for technical or safety reasons, or where the alternative use would entail disproportionate costs (The European Parliament and The Council of the European Union, 2024). Relevant impacts on the five applications discussed in this TSD are as follows:

- Metered dose inhalers (MDIs) are included in the HFC quota program but, for 2025 and 2026, the regulation guarantees the total allocation necessary to meet market demands. In this system, the MDI subsector will not have to meet phaseout targets until 2030, when it will be on the same phaseout schedule as other sectors in the quota program (The European Parliament and Council of the European Union, 2024).
- Technical aerosols containing HFCs have a phaseout date of January 1, 2030, except for those required to meet safety requirements or used for medical applications (The European Parliament and The Council of the European Union, 2024).

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[6] See https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202400573&qid=1710865333872.

[7] This regulation aims to ensure that the EU comply with its long-term obligations under the Kigali Amendment, including the reduction of consumption and production of HFCs (The European Parliament and The Council of the European Union, 2024). It is assumed that the definition of consumption in the EU regulation is consistent with the definition of consumption in the Montreal Protocol, where it is defined as *production plus imports minus exports of controlled substances* (Ozone Secretariat, 1987).

- All foams containing HFCs have a phaseout date of January 1, 2033, except for those required to meet safety requirements (The European Parliament and The Council of the European Union, 2024). This provision increases the stringency of HFC regulations in the EU foam market, for which market prohibitions had previously only been applied to foams that contain HFCs with GWPs greater than 150 (The European Parliament and The Council of the European Union, 2014).
- Semiconductors are not subject to HFC bans by this regulation and will receive quotas to ensure the necessary HFC supply can be acquired.
- All fire protection equipment containing HFCs have a phaseout date of January 1, 2025, except for those required to meet safety requirements (The European Parliament and The Council of the European Union, 2024).

3.2.2 Canada

In Canada, HFCs are regulated through the *Ozone-depleting Substances and Halocarbon Alternatives Regulations*, introduced in 2016 (Canada Gazette, 2020). The regulation includes prohibitions on the import and manufacture of products that contain certain HFCs. Impacts on the five applications receiving ASAs for the use of HFCs are as follows:

- Health care products and laboratory or analytical uses are exempt from the phasedown requirements and import restrictions in this rule, including bronchial dilators and inhalable steroids (e.g., MDIs) (Government of Canada, 2016).
- As of 2019, the manufacture or import of pressurized container products with 2 kilograms or less of HFCs with a GWP greater than 150, including HFC-134a, is prohibited (Government of Canada, 2016). Exceptions to this rule include, among other products, products used for a permitted essential purpose (Government of Canada, 2016). Defense Technology currently holds an essential purpose permit for imports of law enforcement sprays using HFC-134a (Government of Canada, 2023a).
- As of 2021, the manufacture or import of plastic or rigid foam products containing HFCs with a GWP greater than 150, which includes HFC-134a, is prohibited (Government of Canada, 2016). In these regulations, rigid foam products include, among others, closed-cell rigid polyurethane foam (Government of Canada, 2016). Wabash held an essential purpose permit for imports of refrigerated trailers containing rigid foam blown with HFC-134a through 2023, which exempts the product under this rule, and may still hold this permit (Government of Canada, 2023b; Government of Canada, 2016).
- Semiconductor chips are exempt from the phasedown requirements and import restrictions in this rule (Government of Canada, 2016).
- The regulations' prohibitions on HFCs and HFC-containing products include fire-extinguishing agents/equipment, and essential use permits have not been granted for aircraft fire extinguishing uses. There are, however, exceptions to the prohibition on HFC imports if the importer is granted a consumption allowance, as long as the intended use of the HFC is the same as how any chemical listed in Part 1 of Schedule 1 of the Regulations has previously been used (Government of Canada, 2016); it is unclear whether this applies to onboard aerospace fire suppression.

3.2.3 Other Major Producing Countries

Regulations for HFCs in China, India, Japan, Republic of Korea, and the UAE include:

- China is the world's largest consumer and exporter of HFC products and ratified the Kigali Amendment in July 2021. Later that year, it began officially implementing its licensing system for HFC imports and exports (UNEP, 2021). On November 6, 2023, China released its *2024 Hydrofluorocarbon (HFC) Quota Allocation Plan*, which sets specific limits on HFC production (1.852 billion metric tons CO_2 equivalent [$MTCO_2e$]), domestic use (0.895 billion $MTCO_2e$), and imports (0.01 billion tCO_2e) with the aim of freezing these metrics at these levels in 2024 (Climate Cooperation China, 2023). The plan includes considerations for quota continuity, which has a stated aim to smooth the transition for industries, and market stability, which has a stated aim to prevent disruptions while encouraging responsible practices and fair competition (Climate Cooperation China, 2023). The Kigali Amendment's limits took effect in China in 2024 as well, limiting production and consumption to 100% of the country's baseline (i.e., average HFC production and consumption between 2020 and 2022 plus 65% of the country's hydrochlorofluorocarbon [HCFC] baseline levels) (Ozone Secretariat, 2016). Production and consumption will be phased down to 90% of the baseline in 2029, 70% in 2035, 50% in 2040, and 20% in 2045.
- India ratified the Kigali Amendment in August 2021 and has committed to the Group 2 phasedown schedule for developing countries, with phasedown steps occurring in 2032 onwards with cumulative reduction of 10% percent in 2032, 20% in 2037, 30% in 2042 and 85% in 2047. India's national HFC phasedown strategy is currently under development. (Ministry of Environment, Forest and Climate Change, 2022)
- Japan ratified the Kigali Amendment in December 2018. Japan has had legislation in place since 2013 regulating HFCs. Japan's amended Ozone Protection Law went into effect in December 2018 and contains regulatory measures to control the manufacture and import of HFCs. The Ministry of Economy, Trade, and Industry (METI) along with the Ministry of the Environment (MOE) determines and publishes the limit of production and consumption of HFCs. Manufacturers and importers of HFCs must request METI's permission for a quota for manufacture or imports of HFCs. Target GWP values and years have also been determined for specific product categories within the refrigeration and air-conditioning, foams, and aerosol sectors. (Ministry of Economy, Trade, and Industry and Ministry of the Environment, 2022). Japan's phasedown schedule is the same as that of the United States.
- The Republic of Korea ratified the Kigali Amendment in January 2023. In October 2022, the Korea Ministry of Trade, Industry and Energy amended the "Act on the Management of Specific Substances for the Protection of the Ozone Layer" to implement HFC phasedown regulations. Republic of Korea follows the same phasedown schedule as China.
- The UAE has not ratified the Kigali Amendment. In 2023, the UAE Ministry of Climate Change and Environment implemented Decree No (138) to regulate the distribution and use of HFCs in the country. This decree requires that companies manufacturing, importing, exporting, or transporting HFCs obtain a permit from the Ministry of Climate

Change and Environment, and companies using or selling HFCs report quarterly on HFCs sold, used, and held in stock (Gulf Business, 2023).

3.3 Significant New Alternatives Policy

EPA's SNAP program identifies and evaluates substitutes to ozone-depleting substances (ODS) in certain industrial sectors, including refrigeration and air conditioning, aerosols, and foams.[8] The SNAP Program has an established history evaluating substitutes for ODS, many of which are also substitutes for HFCs. EPA compares these substitutes in a comparative risk framework and looks at overall risks to human health and the environment of existing and new substitutes. The human health risks analyzed include safety, and in particular, flammability, toxicity, and exposure (of workers, consumers, and the general population) to chemicals with direct toxicity; environmental risks include impacts on ecosystems, local air quality, ozone depletion potential (ODP) and GWP. EPA publishes lists of these substitutes as "acceptable," "acceptable, subject to use conditions," "acceptable subject to narrowed use limits," or "unacceptable" (prohibited) for specific uses.

EPA lists substitutes as "unacceptable" under SNAP if the Agency determines that they may increase overall risk to human health and the environment compared to other alternatives that are available or potentially available for the same use. Substitutes listed as unacceptable in an end use are prohibited for that use.

The SNAP Program evaluates substitutes for all of the end-uses that contain the applications discussed in this TSD, with the exception of semiconductor etching and cleaning of CVD chambers.

3.4 Per- and Polyfluoroalkyl Substances

There is no consensus definition of PFAS as a class of chemicals, and different definitions can result in more or fewer chemicals being classified as PFAS. There are several HFCs and HFOs that are defined as PFAS in some jurisdictions and are therefore subject to reporting, restrictions, or other requirements within those jurisdictions. For example, at the federal level, a final rule published in October 2023 (40 CFR part 705, October 11, 2023) under the Toxic Substances Control Act (TSCA) will require PFAS manufacturers and importers from 2011 to 2022 to report certain information to EPA on those substances that meet the structural definition identified in the final rule.[9] In addition, nearly half of U.S. states define PFAS in their own regulations and standards, which, in some states, includes restrictions on products with intentionally added PFAS (e.g., Maine's regulation,[10] July 15, 2021). Maine and Minnesota are examples of states that passed laws defining PFAS as having at least one fully fluorinated carbon atom. HFC-134a and HFC-227ea are examples of HFCs that are both subject to the TSCA 8(a)(7) federal reporting requirements and fall within Maine's and Minnesota's definitions of PFAS and are subject to those states' regulations and restrictions.

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[8] The SNAP program implements Section 612 of the amended Clean Air Act of 1990, which requires EPA to evaluate substitutes for the ozone-depleting substances to reduce overall risk to human health and the environment.

[9] TSCA section 8(a)(7)

[10] See https://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1113&item=5&snum=130

In addition, five EU countries submitted a proposal to the European Chemicals Agency (ECHA) in February 2023 to restrict the manufacture, use, and sale of PFAS under REACH, the EU's chemicals regulation.[11] With one exception,[12] the definition of PFAS proposed by the five countries would cover "any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it)," which includes HFC-134a.[13] The restriction proposal is currently being updated by its submitters and is under review by two ECHA scientific committees.

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[11] See https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea

[12] The proposal notes that "a substance that only contains the following structural elements is excluded from the scope of the proposed restriction: CF_3-X or X-CF_2-X', where X = -OR or -NRR'; X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-)."

[13] See https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea

4. Metered Dose Inhalers

4.1 Overview

In the Allocation Framework Rule, EPA defined a "metered dose inhaler" (MDI) as "a handheld pressurized inhalation system that delivers small, precisely measured therapeutic doses of medication directly to the airways of a patient. MDIs treat health conditions such as asthma and chronic obstructive pulmonary disease and are approved for such use by the U.S. Food and Drug Administration (FDA)" (40 CFR 84.3).

MDI devices include a valve and actuator designed to facilitate, via a propellant, a consistent delivery of a specific dose of a drug to the patient in particles/droplets of a specific size distribution. MDIs require gas propellants with vapor pressures that allow them to be liquefied at ambient temperatures at pressures between 40 and 70 psi inside the canister.

In the United States and worldwide, MDIs constitute a majority of the inhaler market, accounting for 65% of the United States market and 60% of the global market (United Nations Environment Programme [UNEP], 2022).[14] Furthermore, the United States is the largest global market for MDIs, making up 25% of total units sold worldwide (UNEP, 2022).

EPA directly issued ASAs for 2022, 2023, and/or 2024, to nine companies to use hydrofluorocarbons (HFCs) in MDIs: Armstrong Pharmaceuticals, AstraZeneca Pharmaceuticals, Aurobindo Pharma USA, Boehringer Ingelheim, GlaxoSmithKline, InvaGen Pharmaceuticals, Kindeva Drug Delivery, Lupin, and Odin Pharmaceuticals.[15]

4.1.1 Use of Regulated Substances

The pharmaceutical industry historically used chlorofluorocarbons (CFCs), specifically CFC-11, CFC-12, and CFC-114, as a propellant in MDIs. In response to the phaseout of CFCs under both the Clean Air Act and the Montreal Protocol, the pharmaceutical industry introduced HFC propellants for MDIs as replacements for CFCs in the mid-1990s, specifically HFC-134a in 1996 followed by HFC-227ea in 2006.[16] The phaseout of CFC use in MDIs in the United States was a multi-year process, carried out in stages by individual active pharmaceutical ingredient, to allow for manufacturers to reformulate their products. Medication for asthma and chronic obstructive pulmonary disease (COPD) also shifted in part to NIK products that do not use propellants, e.g., dry powder inhalers (DPIs).

MDIs use either pharmaceutical grade HFC-134a or HFC-227ea as a propellant. The average charge sizes for MDIs containing HFC-134a and HFC-227ea are estimated to be 10.5 grams and 9.6 grams, respectively (EPA, 2021). In 2020, approximately 75% of inhaler sales in the United States were HFC-134a MDIs, and 13% were HFC-227ea MDIs.[17] The use of HFC-227ea in MDIs is not as prevalent as the use of HFC-134a as it is costly and has a higher GWP

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[14] Other types of inhalers include DPIs, soft mist inhalers (SMIs), and nebulized liquids. Of the inhaler units sold globally in 2021, 60% were MDIs, 32% were DPIs, and 8% were SMIs or nebulized liquids (UNEP, 2022).

[15] For more information on EPA's HFC allowance allocation program, see here: https://www.epa.gov/climate-hfcs-reduction/hfc-allowances.

[16] In the pharmaceutical industry, HFCs are also referred to as hydrofluoroalkanes (HFAs). Additionally, HFC-134a is occasionally referred to as norflurane and HFC-227ea is occasionally referred to as apaflurane.

[17] The remaining 12% of the market is NIK inhalers (DPIs) as determined by a separate analysis conducted to further investigate the size of the NIK inhaler market (EPA, 2021).

(Noakes, n.d.; UNEP, 2022). However, HFC-227ea has a higher liquid density than HFC-134a, impacting whether certain drug crystals float, are neutrally buoyant, or sink in the propellant. If a drug crystal sinks quickly in the propellant, the drug dose may not be consistent (Noakes, 2015).

HFCs were the preferred propellants as MDIs transitioned from CFCs because they allowed for the continuation of the same MDI therapy without contributing to ozone depletion. By keeping the function of the therapy the same, there was minimal change to the way a patient interacted with the MDI (IPAC, 1999).[18]

The first HFC MDI approved by FDA was for albuterol sulfate utilizing HFC-134a propellant in 1996. When an MDI product is developed using a new propellant, it needs to undergo an FDA review and approval process prior to commercialization. As of 2023, the number of FDA-approved MDI products using HFC propellants has expanded considerably (FDA, 2020b). Current MDI products and their FDA approval dates are shown in Table 2. In 2022, albuterol sulfate[19] MDIs accounted for a significant portion of the United States MDI market and represented more than 60% of the global MDI market (UNEP, 2022).

The pharmaceutical industry also made significant shifts toward NIK inhalers such as DPIs and, more recently, soft mist inhalers (SMIs).[20,21] These NIK inhalers do not contain any propellant so have no ODP and no GWP. DPIs deliver powdered medication that is propelled by the inhalation of the patient (UNEP, 2018), and SMIs are propellent-free devices that release low-velocity aerosol mists of the drug solution over a longer period to maximize lung deposition (Iwanaga et al., 2019; Dalby et al., 2011).

4.1.2 Major Manufacturers and Products

The United States manufactures MDIs domestically in addition to importing MDIs from countries in the EU (e.g., Belgium, France, Germany, Spain, Sweden, and the Netherlands), Asia (e.g., China, India, Japan, and Singapore), and Mexico (SeAir, 2021; Zauba, 2021). Major manufacturers and packagers (i.e., distributors that may be separate from the MDI manufacturer) of some of the HFC MDIs available in the United States are listed in Table 2 by product name, active pharmaceutical ingredient (API), propellant type, and date of FDA approval.[22]

Many of the manufacturers listed in Table 2 also conduct R&D of new products. The primary domestic activities of the major MDI manufacturers are summarized below in Table 3.

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[18] HFC products clog more easily, and the plume has slower velocity and is less cold compared to CFC products. Additionally, there were documented impacts to patient access due to the transition (Jena, 2015; Wouters, 2022).

[19] Internationally, albuterol sulfate is sometimes referred to as salbutamol.

[20] The only manufacturer of FDA-approved SMIs is Boehringer Ingelheim (FDA, 2020d).

[21] The lengthy development and regulatory timescales, the rarity of new technical advancements, as well as the higher costs for new SMIs compared to MDIs and DPIs make SMIs less relevant to the discussion of the current and near future pharmaceutical market and will therefore not be discussed further in this technical support document. (UNEP, 2018). Furthermore, as mentioned in an earlier footnote, sales of SMIs or nebulized liquids constitute a smaller fraction (8%) of the global market (UNEP, 2022).

[22] Several manufacturers of MDIs also produce DPIs under the same product line (EPA, 2021).

Table 2. Major Manufacturers and Packagers of Currently Available HFC MDIs for use in the United States by Propellant

Manufacturer[a]	Packager[a,b]	MDI Product Name[a]	Active Pharmaceutical Ingredient[a]	FDA Approval Date[a]
HFC-227ea				
AstraZeneca	AstraZeneca	Symbicort®	Budesonide; Formoterol Fumarate Dihydrate	7/21/2006
Kindeva Drug Delivery LP	Mylan Pharmaceuticals Inc.	Breyna™	Budesonide; Formoterol Fumarate Dihydrate	3/15/2022
Kindeva Drug Delivery LP[c]	Organon	Asmanex® HFA	Mometasone Furoate	4/25/2014
Kindeva Drug Delivery LP[d]	Organon	Dulera®	Mometasone Furoate; Formoterol Fumarate Dihydrate	6/22/2010
HFC-134a				
Armstrong Pharmaceuticals Inc.	Armstrong Pharmaceuticals Inc.	Primatene® Mist	Epinephrine	11/7/2018
AstraZeneca	AstraZeneca	AirSupra	Albuterol Sulfate; Budesonide	1/10/2023
AstraZeneca	AstraZeneca	Bevespi Aerosphere®	Formoterol Fumarate; Glycopyrrolate	4/25/2016
AstraZeneca	AstraZeneca	Breztri Aerosphere®	Budesonide; Formoterol Fumarate; Glycopyrrolate	7/23/2020
AstraZeneca	AstraZeneca	Symbicort Aerosphere	Budesonide; Formoterol Fumarate	4/28/2023
GlaxoSmithKline	GlaxoSmithKline	Advair®	Fluticasone Propionate; Salmeterol Xinafoate	6/8/2006
GlaxoSmithKline	GlaxoSmithKline	Ventolin HFA®	Albuterol Sulfate	4/19/2001
GlaxoSmithKline	GlaxoSmithKline	Flovent HFA	Fluticasone Propionate	5/14/2004
GlaxoSmithKline	Prasco Laboratories	Authorized Generic Fluticasone Propionate Inhaler	Fluticasone Propionate	5/23/2022
InvaGen Pharmaceuticals	Cipla LTD[k]	Generic Albuterol Sulfate Inhaler	Albuterol Sulfate	4/8/2020
Kindeva Drug Delivery LP	Kindeva Drug Delivery LP	Proventil® HFA	Albuterol Sulfate	8/15/1996

Kindeva Drug Delivery LP[e]	Boehringer Ingelheim	Atrovent®	Ipratropium Bromide	11/17/2004
Kindeva Drug Delivery LP[f]	Covis Pharma B.V.	Alvesco®	Ciclesonide	1/10/2008
Lupin Inc	Lupin Inc.	Generic Albuterol Sulfate Inhaler	Albuterol Sulfate	8/24/2020
Lupin Inc	Lupin Inc.	Xopenex® HFA	Levalbuterol Tartrate	3/11/2005
Teva Pharmaceuticals	Teva Pharmaceuticals	Generic Albuterol Sulfate Inhaler	Albuterol Sulfate	10/29/2004
Teva Pharmaceuticals	Teva Pharmaceuticals	QVAR® Redihaler™	Beclomethasone Dipropionate	8/3/2017
Unspecified				
Catalent Pharmaceuticals[h]	Catalent Pharmaceuticals	NA	NA	NA

NA = Not Applicable.

Note: The companies in this report may not represent an exhaustive list of all HFC MDIs available in the United States or all companies manufacturing within the United States. In addition, there are companies that acquire licensing to commercially distribute MDIs and/or authorizations to produce generic MDIs that are not listed in the table. For example, Sandoz, Inc. has recently acquired licensing of commercial distribution rights to Proventil® HFA and authorized a generic of respiratory inhalation medicine Proventil® HFA (albuterol sulfate) Inhalation Aerosol (Sandoz, 2021).

[a] FDA (2020b).

[b] FDA (2020c).

[c] NIH (2023a).

[d] NIH (2023b).

[e] NIH (2021).

[f] Covis (2020).

[g] InvaGen Pharmaceuticals is a United States-based subsidiary of Cipla LTD.

[h] Catalent Pharmaceuticals manufactures MDI products as a contractor to other pharmaceutical companies, which may include other MDI products listed in this table (Catalent Pharmaceuticals, 2021).

Table 3. MDI Manufacturer Operations (Domestic Manufacture, Import, and/or Domestic R&D)[a] in the United States

Manufacturer
Armstrong Pharmaceuticals Inc.
AstraZeneca
Aurobindo Pharma USA
Catalent Pharmaceuticals
GlaxoSmithKline
InvaGen Pharmaceuticals
Kindeva Drug Delivery LP
Lupin
Odin Pharmaceuticals
Teva Pharmaceuticals

[a] EPA (2024); Determined based on company profiles.

4.2 Availability of Safe, Technically Achievable Substitutes

Based on information available to EPA at this time, EPA is proposing that a safe or technically achievable substitute will not be available during 2026 through 2030 for use as a propellant in MDIs. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

4.2.1 Current Status

There are currently no FDA-approved MDI drug products on the U.S. market that use propellants other than HFC-134a and HFC-227ea. However, EPA is aware of efforts underway to transition to other propellants.

The two most promising potential replacements for HFC-134a and HFC-227ea are HFO-1234ze(E) and HFC-152a (UNEP, 2022). Both have most of the requisite physical properties to function as a propellant in MDIs with significantly lower GWPs than the current HFCs in use; however, neither propellant has significant use in pharmaceuticals today and will require extensive clinical research and FDA evaluation before they could replace the current HFCs (Pritchard, 2020). No other feasible, lower-GWP MDI propellant alternatives have been identified in the United States or abroad (UNEP, 2022).

NIK inhalers are not expected to completely replace HFC MDIs, as NIK inhalers have different mechanisms for the delivery of medication. MDI inhalers may be more appropriate for certain patients based on patient preference or other requirements (e.g., patient inhalation strength and coordination) (GSK, 2019; IPAC, 1999; UNEP, 2018).

Both HFO-1234ze(E) and HFC-152a are listed as acceptable by EPA's SNAP program for use in aerosol products. There are several other aerosol propellants listed as acceptable by SNAP[23] that are commercially available and currently used in consumer and/or technical aerosol products but are not necessarily appropriate for propellants in MDIs. For example, saturated light hydrocarbons (C_3-C_6), which include isobutane, a substance that has historically been investigated for used in MDIs, are listed as acceptable by SNAP for use in propellants. However, isobutane is more flammable than HFC-152a, and studies have cited toxicological concerns for isobutane when used with a beta-agonist, a class of medications used in MDIs. Additionally, isobutane tends to have a particular taste that makes it unfavorable for nasal or oral use (UNEP, 2022).

Table 4 summarizes the atmospheric and flammability characteristics for currently used HFC MDI propellants and potential substitutes.

HFO-1234ze(E) is mainly used in refrigeration, technical aerosols, personal care products (e.g., hairspray, dry shampoo) and some novelty aerosols (e.g., party string), and long-term human safety data would need to be collected before it could be considered for use in MDIs (Honeywell, 2021; Pritchard, 2020). The pharmaceutical industry has submitted a drug master file (DMF) to FDA for HFO-1234ze(E), allowing companies to file Investigational New Drug (IND) applications and initiate clinical trials (Honeywell, 2021). AstraZeneca announced a

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[23] See https://www.epa.gov/snap/substitutes-propellants. There are no additional aerosol propellants currently under SNAP review.

partnership with Honeywell to develop HFO-1234ze(E) MDIs and has begun their Phase III trials (late-stage, large scale) (AstraZeneca, 2022; ClinicalTrials.gov, 2024). At the end of 2022, Honeywell announced that their Baton Rouge facility had doubled its HFO-1234ze(E) production capacity (Honeywell, 2022).

Table 4. Atmospheric and Flammability Characteristics of Currently Used Propellants and Potential Substitutes for MDIs[a]

Propellant	ODP[b]	100-year GWP[c]	Flammability[d]
Currently in Use			
HFC-134a	0	1,430	Nonflammable
HFC-227ea	0	3,220	Nonflammable
Potential Substitutes			
HFC-152a	0	124	Flammable[e]
HFO-1234ze(E)	0	1	Nonflammable[f]

Note: HFC 100-year GWPs are numerically identical to the exchange values used in the AIM Act.

[a] EPA did not review the human health characteristics of these propellants, as this determination would lie with FDA.

[b] WMO (2022).

[c] IPCC (2007), unless otherwise specified. HFC GWP values are numerically equal to the exchange values listed in the AIM Act.

[d] UNEP (2022).

[e] Flammable at concentrations of 3.8 to 18 volume percent in air at room temperature.

[f] Flammable only at concentrations of 8.0-8.5 volume percent in air at one atmosphere and high temperatures (greater than 30°C).

HFC-152a was considered as a possible replacement for CFCs in MDIs along with HFC-134a and HFC-227ea; however, its higher density and flammability would require numerous changes to manufacturing processes and the MDI design to ensure safe and effective use (Pritchard, 2020). Koura considers HFC-152a to be a likely replacement for other HFC propellants because manufacturing sites can be adapted for the safe handling of flammable materials. Propellant-only clinical trials for HFC-152a have been allowed to proceed by FDA, and it is anticipated that program data from these trials will be supported by a DMF that Koura is developing for the commercial use of pharmaceutical grade HFC-152a in the United States (Corr, 2020; Koura, 2023b). GlaxoSmithKline is expected to begin their Phase III trials of MDIs using HFC-152a in the first half of 2024, with regulatory submissions coming in 2025 (GSK, 2023; NIH, 2023c; OINDP News, 2023). [ ] (EPA, 2024), indicating that [ ].

Development of HFC-152a MDIs is also underway in Europe. In 2023, Kindeva announced a partnership with Koura to develop MDIs propelled by HFC-152a with products expected to be available "in-line with the expected commencement of a phase-down of existing pMDI systems containing HFC-134a and HFC-227ea within the European Union." Chiesi, an Italian MDI manufacturer, is also developing MDIs with HFC-152a supplied by Koura (Kindeva, 2023; Chiesi, 2022). To support this expansion of HFC-152a MDI development, Koura opened the first HFC-152a pharmaceutical-grade propellant production facility in early 2022, and it has a production capacity of "several hundred" MT (Koura, 2022; Koura, 2023b).

The timeframe for transitioning to alternative propellants is expected to take place over many years. According to the TEAP's *Report of the Medical and Chemical Technical Options Committee 2022 Assessment Report*, the business-as-usual transition from HFC-134a and HFC-227ea to HFO-1234ze(E) and HFC-152a in MDIs is expected to begin in non-Article 5 countries (i.e., developed countries as defined under the Montreal Protocol) in 2025 and continue through at least 2032 (UNEP, 2022). As mentioned earlier in this section, the use of a new propellant in MDIs will require extensive clinical research and FDA evaluation which could impact the timeframe for transitioning. FDA considers an MDI containing an alternative propellant other than HFC-134a or HFC-227ea as a new drug product that would need to be approved in accordance with FDA's requirements for new drug applications. Additionally, manufacturers of generic MDIs may face difficulty in transitioning to alternative propellants, as generic drug products must be comparable to a previously approved drug product. More information on the FDA approval process for both new and generic drug products is described in Section 4.2.2.

4.2.2 Relevant Regulations and Standards

4.2.2.1 FDA MDI Approval Process

Manufacturers intending to market an MDI containing an alternative propellant are required to submit an application to FDA, which necessitates FDA's review and approval prior to its initial distribution, consistent with section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act). This is the same process as was required during the transition from CFC propellants to HFC-134a and HFC-227ea (FDA, 1995; UNEP, 2022).

4.2.2.1.1 Investigational New Drug (IND) Applications

Generally, FDA regulations require sponsors who wish to evaluate an investigational drug in humans to submit an IND to FDA. To conduct studies in the United States, sponsors (e.g., MDI manufacturer, research institutions, other organizations) developing MDIs with an alternative propellant must have an IND application that is reviewed by FDA and a local institutional review board (IRB). The IND application must contain sufficient preclinical (animal pharmacology and toxicology) data and/or previous human experience with the drug (often foreign use), manufacturing information pertaining to the composition, manufacturer, stability, and controls used for manufacturing and clinical protocols and investigator information. Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA reviews the IND for safety to assure that research participants will not be subjected to unreasonable risk (FDA, 2015; FDA, 2022). Once an IND goes into effect, sponsors can conduct clinical (human) trials to assess the safety and efficacy of the drug product. During development, sponsors can request meetings to seek feedback and guidance from FDA. The clinical development program may take many years to complete, e.g. ranging from over a year to six or more years (FDA, 2018a).

4.2.2.1.2 New Drug Applications

FDA approves NDAs under section 505(c) of the FD&C Act. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical that is not a biologic for sale and marketing in the United States. In approving an NDA, FDA reviewers must determine, among other things, that the drug is safe and effective for its labeled use(s), and that the benefits of the drug outweigh the risks; that the drug's labeling (package insert) is appropriate; and that the methods used in manufacturing the drug and the controls used to maintain the drug's quality comply with FDA *Current Good Manufacturing Practice* (CGMP) requirements to ensure safety, quality, and reliable performance (e.g., drug delivery) of the product (FDA, 2020a).

Under this regulatory pathway, the sponsor will formally request approval for the drug by submitting an NDA, which includes, but is not limited to, all animal and human testing data and analyses, as well as information on how the drug is manufactured. Upon receipt, FDA will conduct a filing review to ensure that the application is sufficiently complete to permit a substantive review. If filed, FDA reviews the NDA in accordance with the applicable statutory requirements for approval. A standard review timeline goal is 10-12 months (FDA, 2017b). As part of its review, FDA may also conduct an inspection of the drug manufacturing facilities to ensure that drugs are manufactured in accordance with CGMP. Once the drug is approved by FDA, the drug sponsor must conduct post-marketing monitoring to monitor safety (FDA, 2015; FDA, 2017a; FDA, 2016).

4.2.2.1.3 Abbreviated New Drug Applications

Applicants request approval for generic drug products, including MDIs, in Abbreviated New Drug Applications (ANDAs).[24] An ANDA is an application submitted and approved under section 505(j) of the FD&C Act for a drug product that, when approved, is presumed to be therapeutically equivalent to a previously approved drug product, i.e., its reference listed drug (RLD). Products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product when administered to patients under the conditions specified in the labeling. An ANDA generally must contain information to show that the proposed generic product (1) is the same as the RLD with respect to the active ingredient(s), conditions of use, route of administration, dosage form, strength, and labeling (with certain permissible differences) and (2) is bioequivalent to the RLD. An ANDA relies on FDA’s finding that the RLD is safe and effective. An ANDA may not be submitted if new clinical investigations are necessary to establish the safety and effectiveness of the proposed product.

FDA provides its recommendations for establishing bioequivalence in its product-specific guidances, which for orally inhaled products like MDIs, have generally included some combination of in vitro and in vivo studies, along with recommendations related to the formulation and device. FDA also provides opportunities for generic developers to consult with the Agency both before and after ANDA submission regarding, among other things, a generic applicant’s quality or bioequivalence related questions, or for clarification regarding received deficiencies following Agency review of the ANDA.

Prior to substantive review of an ANDA, FDA conducts a filing review to determine if the ANDA is substantially complete and can be received. In accordance with the Generic Drug User Fee Amendments Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter), FDA committed to review 90% of standard original

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[24] MDIs approved under ANDAs may also be marketed as brand-name products.

ANDAs within 10 months from the date of submission.[25] This review time can be extended if a site/facility is not ready for inspection. The timing of ANDA approval depends on, among other things, the patent and/or exclusivity protections for the RLD.

4.3 Supply of Regulated Substances

The regulated substances currently used by the MDI market are pharmaceutical grade HFC-134a and HFC-227ea, which are purified from technical grade material.

HFC manufacturers supply industrial HFCs to facilities that purify the propellant(s) to pharmaceutical-grade HFAs (Noakes, 2015). After the propellant(s) are purified, the drug substance(s) are mixed with the HFC propellant(s) and cosolvents (FDA, 2018b). After mixing, MDI canisters are filled with the formulation, the constituent parts of the device are assembled, and the MDIs are packaged (FDA, 2018b).

Based on information available to EPA at this time, EPA has reached a proposed determination that the supply of HFC-134a and HFC-227ea for use as a propellant in MDIs will be insufficient to accommodate the application during 2026 through 2030 based on a number of factors, described in more detail below and in the preamble to the proposed rule.

4.3.1 Purification Process and Requirements

The purity and quality of pharmaceutical grade HFCs are key criteria in FDA's review of an MDI drug product's safety and efficacy. As components of drug products, the use of HFCs in MDIs are subject to certain FDA requirements. CGMP requirements under the statute (21 USC 351(a)) apply to drugs, including their components (21 USC 321(g)(1)), and include requirements related to methods, facilities, controls, manufacturing, processing, packing, and holding to assure that drugs meet requirements for safety, identity, strength, and quality and purity. FDA has also promulgated CGMP regulations for finished pharmaceuticals in 21 CFR 210 and 211. These CGMP regulations also contain requirements for manufacturers in their handling, control, storage, and testing of components used in manufacture of drug products. HFC purification occurs in dedicated facilities that are subject to FDA CGMP requirements for drugs and devices as well as other international quality standards, as MDI manufacturers may serve markets in addition to that of the United States (Daikin Industries, Ltd., n.d.). These facilities may also be periodically inspected to ensure that they meet CGMP requirements, including audits by FDA, and inspections by other non-U.S. health authorities (Koura, n.d.). Additionally, anyone submitting a drug application for FDA's approval should specify the HFC manufacturing facility (FDA, 2018b).

If an MDI manufacturer wanted to change their supplier of pharmaceutical grade HFC, this would trigger FDA review. MDI manufacturers that change suppliers of pharmaceutical grade HFCs would need to provide data to ensure the safety and quality of the new propellant and submit the data to the FDA for review and approval. This data may include pharmacology/toxicology data, product quality data of the new propellant source, a comparison of the current and proposed new propellant sources, and quality data that demonstrates the drug made with the new propellant meets all applicable quality requirements. Depending upon

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[25] Certain prioritized ANDAs receive an 8-month goal date as set forth in the GDUFA III Commitment Letter.

the comparability of the HFA sources, additional data may be requested by FDA (21 CFR 314.70).

FDA has also issued draft guidance to industry on the development and manufacture of inhalation aerosols that describe additional considerations for ensuring product quality and performance for MDIs and DPIs. Per this draft guidance, from a safety standpoint, propellants used in MDIs are recommended (though not required for approval) to have a greater purity of at least 99.99% (FDA, 2018b) compared to other industrial uses (e.g., AHRI 700 requires a purity of 99.5% for refrigerants). FDA has also recommended acceptance criteria for total impurities in these propellants at ≤1,000ppm for HFC-134a and ≤20 ppm for HFC-227ea (FDA, 2018b). When finalized, this guidance will reflect FDA's current thinking on this topic. FDA's guidance documents do not establish legally enforceable responsibilities. They do, however, provide insight into the Agency's interpretation of applicable statute and regulation, and guidance for manufacturers in approaches to comply with statute and regulation. An industry trade association. An industry trade association has told EPA that industry uniformly follows the guidance.

Daikin Industries compared the total impurities of six of their HFC-134a[26] production batches to the FDA limit of ≤1,000 ppm and noted typical total impurity values of 17 ppm on a mass basis (Daikin Industries, Ltd., n.d.). The specifications for Daikin's pharmaceutical grade propellants demonstrate purities of ≥99.9% and ≥99.99% by volume of HFC-134a and HFC-227ea, respectively, and indicate that the difference in purity between technical grade and pharmaceutical grade propellants results from additional manufacturing processes and dedicated manufacturing facilities (Daikin Industries, Ltd., n.d.).

Koura is the largest supplier of pharmaceutical grade HFC propellants globally and in the United States. Koura's global market share of HFC propellants for MDIs is 75% (Koura, 2023a). In the United States, supply of pharmaceutical grade HFC-134a primarily comes from technical grade HFC-134a that is produced at Koura's facility in Saint Gabriel, Louisiana, purified at their United Kingdom facility, and reimported to the United States for consumption (UNEP, 2022; Jeswani and Azapagic, 2019; EPA, 2024). This pharmaceutical grade HFC-134a is also supplied to other pharmaceutical companies globally (UNEP, 2022).

Additionally, four other facilities, one in India, one in Japan, and two in China, produce HFC-134a for purification to pharmaceutical grade (UNEP, 2022). The facility in Japan supplies technical grade HFC-134a to Koura's purification facility in the United Kingdom (Jeswani and Azapagic, 2019). The facilities in India and China supply HFC-134a for purification to facilities within the same country, and material from India is used for MDI manufacture in South Asia [ ] (UNEP, 2022; EPA, 2024).

Pharmaceutical grade HFC-227ea is supplied by Chemours and Daikin Industries (Chemours, 2019; Daikin Industries, Ltd., n.d.). While Chemours' FM-200™ (HFC-227ea) is primarily used as a fire suppressant, the product is also used as a propellant in MDIs (Chemours, 2019). Chemours produces HFC-227ea for subsequent purification to pharmaceutical grade at their El Dorado, Arkansas facility (Chemours, 2023). Daikin Industries' SOLKANE™ 227 pharma is

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[26] Daikin does not supply HFC-134a propellant to MDI manufacturers in the United States (UNEP, 2022).

produced and purified at their Frankfurt, Germany facility and subsequently imported by [ ] (Daikin Industries, Ltd., n.d.; EPA, 2024). Both of these facilities also supply pharmaceutical grade HFC-227ea globally for MDI manufacture (UNEP, 2022).

4.3.2 Use of Recovered and Reprocessed Material

MDI manufacturers indicate that reclaimed HFCs cannot be used in MDIs (EPA, 2024). Reclaimed HFC gas is primarily sourced from the largest users of HFC gas, the refrigeration and air conditioning sector, and may be contaminated with certain impurities including oils, other HFCs, HCFCs, or CFCs (e.g., from equipment that has been retrofitted). Reclaimers process these reclaimed gases to industry standards for refrigeration and air conditioning equipment, which has a higher tolerance for impurities; AHRI sets a maximum allowable level of contaminants at 0.5%,[27] while, as noted above, FDA draft guidance recommends a maximum impurity level of 0.01% for MDI propellants. Daikin has also noted that while their pharmaceutical grade propellants are included in a reclamation program, the reclaimed propellants are unable to be reused in pharmaceutical products or manufacturing (Daikin Industries, Ltd., n.d.).

4.3.3 Available Supply

Due to the purification requirements of this application, this section provides a more targeted discussion on the available supply of HFC-134a and HFC-227ea as of 2022, but a discussion about the overall supply of HFC-134a can be found in Section 5.3.3 and the overall supply of HFC-227ea can be found in Section 8.3.3.

Historically, Chemours, Daikin Industries, SRF, and Mexichem Fluor DBA Koura produce pharmaceutical-grade HFC propellants for use in MDIs in the United States (Chemours, 2019; Daikin Industries, Ltd. n.d; SRF, 2019; Koura, 2019). Pharmaceutical grade HFC-134a is imported, while pharmaceutical grade HFC-227ea can be sourced domestically or imported (UNEP, 2022; EPA, 2024). Since EPA does not have requirements for entities to specify what portion of these quantities are pharmaceutical grade HFC, data on the supply of pharmaceutical grade HFC-134a and HFC-227ea are not available. Subsequently, EPA reviewed the global capacity numbers for facilities where chemicals are purified to provide an upper bound the available supply as of 2022; however, this production would also encompass global MDI manufacturing. Table 5 in Section 4.3.4 also lists the total reported use, as determined by purchases of HFCs, to further approximate the supply of HFCs for this application.

The HFC-134a production capacity at Koura's UK facility is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020).

The combined HFC-227ea production capacity for Chemours and Daikin is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020). Koura also supplies pharmaceutical-grade HFC-227ea from its UK facility (Koura, 2020).

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[27] The Air-Conditioning, Heating & Refrigeration Institute (AHRI) Standard 700 specifies the allowable levels of contaminants for each refrigerant and EPA has established purity requirements for reclaimed refrigerants based on that standard.

4.3.4 Application's Projected Demand of HFCs

Overall, reported HFC-134a use in MDIs in the United States has decreased since 2018, while HFC-227ea use has fluctuated over the years (Table 5). However, their use in MDIs increased significantly in 2020 and 2021,[28] likely as a result of the COVID-19 pandemic (Bloom et al., 2021). These trends are reflected in the three-year average annual growth rate (AAGR)[29] calculated by EPA for the purposes of allowance allocations. From 2018-2020, the MDI AAGR was 11%, the 2019-2022 AAGR was -9%, and the 2020-2023 AAGR was 3% (EPA, 2024).[30,31]

Table 5. Reported Historic HFC-134a and HFC-227ea Use in MDIs (kg), 2018-2023

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
HFC-134a						
Armstrong Pharmaceuticals	[ ]					
AstraZeneca Pharmaceuticals						
Aurobindo Pharma USA						
Boehringer Ingelheim[b,c]						
GlaxoSmithKline						
Invagen Pharmaceuticals						
Kindeva Drug Delivery						
Lupin						
Odin Pharmaceuticals						
Total (kg)	***618,283***	***539,079***	***745,252***	***782,188***	***595,964***	***687,630***
HFC-227ea						
Armstrong Pharmaceuticals	[ ]					
AstraZeneca Pharmaceuticals						
Aurobindo Pharma USA						
Boehringer Ingelheim						
GlaxoSmithKline						
Invagen Pharmaceuticals						
Kindeva Drug Delivery						
Lupin						
Odin Pharmaceuticals						
Total (kg)	***[ ]***	***19,075***	***[ ]***	***78,175***	***39,303***	***40,845***
Total (MTEVe)	***[ ]***	***832,305***	***[ ]***	***1,370,253***	***978,801***	***1,114,832***

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[28] [ ]

[29] AAGR = $[(\frac{Year\ 2\ HFC\ purchases}{Year\ 1\ HFC\ purchases} - 1) + (\frac{Year\ 3\ HFC\ purchases}{Year\ 2\ HFC\ purchases} - 1)] \times \frac{1}{2}$

[30] 2019-2022 spans the second half of 2019 through the first half of 2022 and 2020-2023 spans the second half of 2020 through the first half of 2023.

[31] The AAGRs are derived from reported, verifiable data. Therefore, they do not reflect data from companies with missing reports or documentation.

Company Name	2018	2019	2020	2021	2022[a]	2023[a]

Source: EPA (2024).
NA = Not Available.
[a] Calculated as the sum of HFC held in inventory (previous period) + HFC acquired through conferrals + HFC imported using allowances + other amounts of HFC purchased – HFC held in inventory (current period).
[b] [ ]
[c] Boehringer Ingelheim did not receive 2023 allowances [ ].

Future Market Insights (FMI, 2023) predicts the global MDI market will grow at a compound annual growth rate of 4.5% from 2023-2033, with the United States accounting for 15% of the global market throughout this period. This predicted growth is attributed to the rise in respiratory diseases, increased availability and awareness of effective devices, and growth in research and technological advancements. However, this growth in the overall market may not directly correlate to HFC use.

According to the Centers for Disease Control and Prevention (CDC), in 2021 in the United States, 20.3 million adults and 4.7 million children had asthma while 4.6% of adults (11.9 million) had some form of COPD (CDC, 2021a; CDC, 2021b).[32] Available historical data on asthma and COPD (2001-2022 for asthma, and 2011-2022 for COPD) indicate that their prevalence (i.e., the percentage of the population with a certain medical condition) has been relatively constant, with a slight increase in asthma prevalence in 2022 (CDC, 2021a; CDC, 2021b). However, the growth rate of populations with asthma and COPD both grew by an average of about 1.3% annually (1.31% for asthma and 1.33% for COPD).

To be conservative, EPA calculated the projected HFC use in the U.S. MDI industry using an annual growth rate of 1.35% from EPA's Vintaging Model because it is more suitable than using population growth as a proxy growth rate (Figure 3) (EPA, 2023). Projected HFC demand is conservatively based on average 2021 to 2023 purchases, which were primarily HFC-134a and HFC-227ea.

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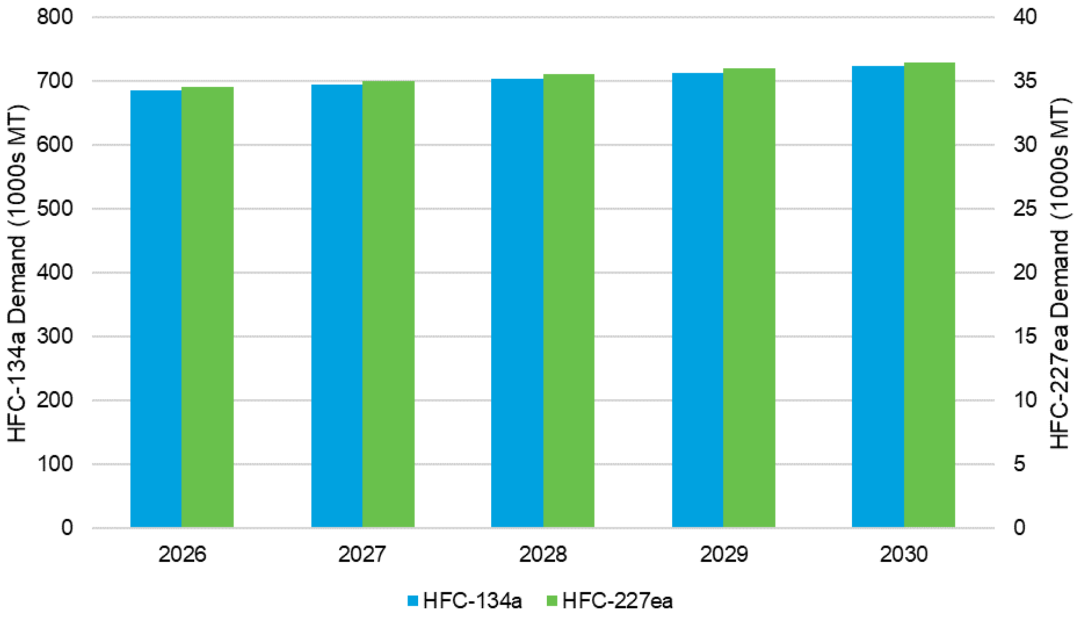
[32] Based on Census data for U.S. adult population in 2021 (Census, 2023).

Figure 3. Projected MDI HFC Demand (MT), 2026-2030



While Figure 3 reflects projected MDI HFC demand on annual basis, MDI use typically fluctuates seasonally due to variations in exacerbations of asthma and COPD and the incidence of respiratory viral illnesses (e.g., respiratory syncytial virus or RSV). For example, rates of COPD exacerbations are generally higher in the winter and lower in the summer (Rabe et al., 2019).

MDI manufacturers have suggested that future therapies may benefit from the delivery of medication by MDIs for patient groups beyond asthma and COPD, including but not limited to the delivery of biologic therapies via the lung. There are numerous therapy areas, both topical and systemic, that pharmaceutical manufacturers may address via MDI for lung or nasal delivery more effectively than by other means (Kindeva, 2021). In addition, medical conditions in which HFC MDIs may be used off label as therapy per the American Thoracic Society include acute viral infections (including COVID-19), bronchiectasis, idiopathic pulmonary fibrosis, non-specific shortness of breath, post-COVID-19 infection, post-infection chronic cough, and sarcoidosis (ATS, 2021).[33]

It is unlikely, however, that these additional medical conditions will significantly alter the growth rate of HFC use in MDIs due to the low prevalence of some of these conditions compared to asthma and COPD (e.g., more than 150 times more people are diagnosed with asthma than with idiopathic pulmonary fibrosis per 100,000 in the United States [CDC, 2019; CDC, 2021c]), the high comorbidity rates of these conditions with COPD and asthma, and the use of alternative treatments. The prevalence of other conditions will be monitored in the future to ensure that the growth rate of HFC use is accurately predicted. In addition, if there is an expansion in the use of MDIs for treatment of medical conditions beyond asthma and COPD,

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[33] Koura commented on the proposed HFC phasedown rule indicating other uses for HFC-based medical propellants such as laser ablation treatment (Koura, 2021). It should be noted, however, that MDIs are the largest application sector for HFC-based medical propellants (Koura, 2021).

propellant use, which may include HFC use, may be higher than what is forecasted using the conservative growth rate established based on the incidence of asthma and COPD only.

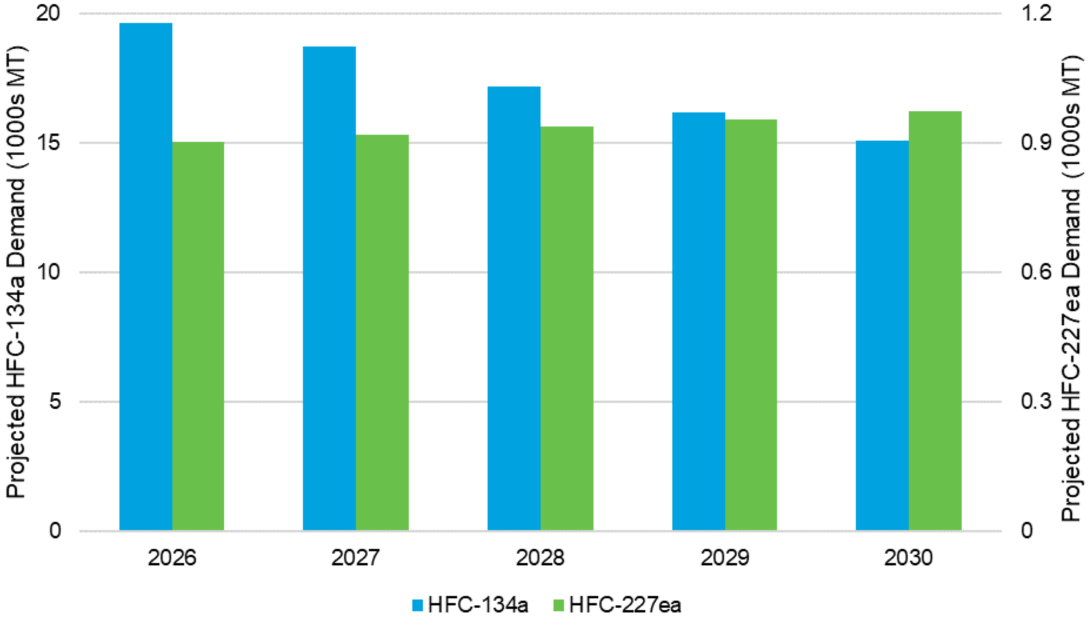
4.3.5 Anticipated Regulatory Impacts on Supply

As noted in Section 3.1.2**Error! Reference source not found.**, EPA's Technology Transitions Program has established GWP limits, which in turn will limit the use of HFC-134a in many sectors and subsectors, including the aerosol sector, as early as 2025. Use of HFCs as a propellant in MDIs is currently exempt from the Technology Transitions requirements, given current eligibility for ASAs. As a result, MDI manufacturers are able to continue using HFC-134a and HFC-227ea for ASA-eligible uses. EPA's Vintaging Model estimates that the aerosol market used 5,209 MT of HFC-134a and 177 MT of HFC-227ea in 2023 (EPA, 2016). ASA holders' use of HFC-134a and HFC-227ea in MDIs constitutes approximately 13% of the aerosol HFC-134a market, at 688 MT or 0.98 MMTEVe of HFC-134a in 2023, and 23% of the aerosol HFC-227ea market, at 41 MT or 0.13 MMTEVe of HFC-227ea in 2023 (EPA, 2024).

EPA regulations under the AIM Act, planned transitions out of HFC-134a, and market trends generally are estimated to reduce demand for HFC-134a through 2030; modeling under existing AIM Act regulations estimates demand for HFC-134a will reduce by approximately 24,800 MT and 28,330 MT in 2026 and 2030, respectively, or a 56% and 66% reduction in projected demand across all uses of HFC-134a, relative to business as usual (BAU) pre-Allocation Rule demand (Figure 4).

HFC-227ea is also primarily used in fire suppression which does not have a GWP limit under EPA's 2023 Technology Transitions Rule. Both fire suppression and MDIs are projected to have continuing demand for HFC-227ea (assuming MDIs continue to be exempt from the Technology Transitions restrictions).

Figure 4. Projected Demand (MT) for HFC-134a and HFC-227ea, 2026-2030



4.3.6 Allowance Usage, Conferrals, and Inventory

As noted below, EPA issued 1,235,562.5 metric tons of exchange value equivalent (MTEVe) of ASAs for MDIs for 2022, 736,450.6 MTEVe of MDI ASAs for 2023, and 1,300,685.9 MTEVe of MDI ASAs for 2024.

MDI allowance holders reported acquisition of HFC-134a and HFC-227ea through conferrals to producers [ ], through direct imports, or through domestic purchases that did not require expending or conferring allowances (see Table 6).

In addition, Table 6 shows the amount of HFC inventory held by MDI ASA holders. Inventory was drawn down for both HFC-134a and HFC-227ea from end-of-year (EOY) 2022 to EOY 2023. Inventory of HFC-134a decreased by about 20% from approximately 252,100 kilograms at the end of 2022 to approximately 200,350 kilograms at the end of 2023. HFC-227ea in inventory decreased by about 40% from 53,400 kilograms to approximately 35,700 kilograms at the end of 2023.

Table 6. Purchases and Inventory (kg) of HFC-134a and HFC-227ea for ASA Holders in 2022 and 2023

Chemical	Report Period	Acquired through Conferrals and Imported Using Allowances	Purchased without Expending or Conferring Allowances	Held in Inventory at End of Period	% of HFC Acquired through Expending or Conferring Allowances
HFC-134a	2022	663,454	37,082	252,081	95%
	2023	595,281	40,240	200,351	94%
HFC-227ea	2022	2,507	[ ]	53,425	[ ]
	2023	221,213	0	35,748	100%

Table 7 summarizes 2022 and 2023 application-wide aggregate allowance balances and activity for MDIs, including BOY levels, EOY levels, quantities of allowances conferred, and quantities of allowances expended. EOY or leftover allowances indicate that 1) application-specific end users did not expend all of their allocated allowances (and may have just purchased from domestic suppliers without expending allowances; Table 6), and/or 2) importers/producers that were conferred allowances did not use them all. End users conferred, transferred, or expended 76% of allocated allowances in 2022 and 83% in 2023. Approximately 75% of ASAs were unexpended for MDIs at the end of 2022, but in 2023 only 44% were expended by the end of the year. Despite the relatively high percentage of allowances that were used by ASA holders (i.e., were conferred, transferred, or expended) in both 2022 and 2023, suppliers and intermediaries did not expend a significant portion of those allowances in 2023. EPA does not have any insight into why this might occur, as we understand suppliers were generally requiring conferral of ASAs for nearly all sales to ensure they could produce or import enough HFC-134a and HFC-227ea.

Table 7. Allowances for MDIs (MTEVe)

	2022	2023
BOY Allowances[a]	1,771,040.50[e]	1,272,818.50
Quantity ASA Holders Conferred and Expended Directly to Import[b]	1,476,350.20	1,154,266.10
Quantity Expended by Supplier[c]	700,372.90	327,234.90
EOY Allowances – End Users[a]	294,690.30	129,413.90
EOY Allowances % Remaining – End Users	17%	10%
EOY Allowances – Suppliers and Intermediaries	26,915.30	285,718.60
EOY Allowances % Remaining – Suppliers and Intermediaries	18%	33%

Source: EPA (2024).

[a] Includes GlaxoSmithKline’s consumption allowances.

[b] Includes GlaxoSmithKline’s consumption allowance transfers and imports using consumption allowances

[c] Includes transferred allowances that were expended.

[e] Includes set-aside allowances.

5. Defense Sprays

5.1 Overview

In the Allocation Framework Rule, EPA defined "defense sprays" as aerosol-based sprays used for self-defense, including pepper spray and animal sprays, and containing the irritant capsaicin and related capsaicinoids derived from oleoresin capsicum (OC), an emulsifier, and an aerosol propellant (40 CFR part 84). Defense sprays are used in a variety of circumstances including for law enforcement and personal protection, primarily when one's personal safety is at risk from human or animal attack.

Commercially available self-defense sprays contain a chemical irritant and a propellant. Self-defense sprays typically contain a lachrymator (i.e., an irritant that causes tearing) as the active ingredient, such as chloroacetophenone (mace), orthochlorobenzylidene malononitrile (tear gas), or a pepper extract (Honeywell, 2018a). Pepper sprays utilize the oil OC which is composed of several different capsaicinoids; the percentage of capsaicinoids determines the potency of the spray. Civilian and law enforcement sprays contain a range of 0.18% to 1.33% capsaicinoids by weight while bear sprays range from 1.0% to 2.0% of capsaicinoids by weight (SABRE, 2021a).

Defense sprays utilize four different delivery methods, including streaming, foam, fog, and vapor sprays:

- **Streaming** defense sprays allow for a precise delivery of the formulation, have less chance to blow back on the consumer and other bystanders in windy conditions, and generally allow for a longer range of defense.
- **Foam** defense sprays are used for indoor security as they are delivered in a semi-stream spray that reduces blow back to users and bystanders, and they stick to the target's face, making it difficult to see, breathe, and wipe away.
- **Fog** formulations are commonly used by law enforcement and in bear sprays and provide area coverage, discharging a cone pattern of spray between the user and assailant to cover a larger area without requiring precise aiming.
- **Vapor** delivery methods work such that propellant evaporates inches from the nozzle, leaving only the active ingredient in flight, which primarily affects a person's respiratory system rather than burning of the eyes and face. Vapor defense sprays are also commonly used by law enforcement and in bear sprays.

Bear sprays are not intended for use against people and are designed to be more potent than pepper sprays designed for personal self-defense. They typically produce larger spray clouds going farther distances and emit from the spray can nozzle at a greater velocity than products for use against dogs or for human defense.

Six manufacturers received ASAs for 2022, 2023, and/or 2024 to use hydrofluorocarbon (HFCs) as propellant in their defense spray products: Defense Technology, Guardian Protective Devices, SABRE, Shamrock Filling, UDAP Industries Inc, and Zarc International Inc.

5.1.1 Use of Regulated Substances

The defense spray industry historically used CFCs as a propellant and, in response to the CAA Section 610 ban on nonessential uses of CFCs and HCFCs, transitioned to a HFC propellant, specifically HFC-134a, as a replacement to CFCs as of January 1, 1994. Concentrations of propellant in a defense spray can range from 15% to 80% by volume. Most civilian canister sizes are approximately 71 grams due to regulatory limitations (e.g., in California), and could therefore contain 11 to 57 grams of propellant (Honeywell, 2018b; Unlawful Use of Tear Gas, California Penal Code § 22810, 2022). SABRE's most popular civilian canister size is 15 grams (i.e., 2.25 grams to 12 grams of propellant per can) (SABRE, 2021a). The United States Forest Service recommends bear spray should be at least 225 grams of net weight, translating to between 33.8 grams and 180 grams of propellant (USFS, n.d.).

HFC-134a is the primary propellant used in defense spray formulations, particularly personal defense sprays, law enforcement sprays, and bear sprays. There is also one bear spray product using HFC-152a.

5.1.2 Major Manufacturers and Products

Defense spray manufacturers procure propellant, e.g., HFC-134a, and, in a highly automated process, fill empty aerosol cans with the propellant and defense spray formulation before the cans are sealed, tested for leaks, and labeled for sale.

There are many manufacturers with defense spray products available in the United States. Table 8 lists major manufacturers in the market but may not encompass every manufacturer with defense spray products available on the U.S. market.

In addition to manufacturers that have received ASAs, Table 8 lists other manufacturers that have not been allocated HFC allowances; therefore, their use of HFCs cannot be confirmed. If they do use HFCs, they would have to purchase the HFCs domestically on the open market.

Table 8. Major Manufacturers of Defense Sprays in the United States

Manufacturer	Type of Defense Spray Manufactured			
	Law	Personal/ Civilian	Bear	Dog
Aerko International/Shamrock Filling[a]	✓	✓	✓	
Adventure Ready Brands DBA Counter Assault			✓	
Defense Technology[b]	✓	✓		
Fox Labs International Inc	✓	✓		
Guardian Protective Devices, Inc	✓	✓	✓	
Mace Security International	✓	✓	✓	✓
SABRE (Security Equipment Corporation)	✓	✓	✓	✓
UDAP Industries Inc	✓	✓	✓	
Zarc International Inc	✓	✓		

[a] Aerko International is a division of Shamrock Filling.

[b] Defense Technology was previously a business segment of The Safariland Group. In June 2020, The Safariland Group entered into an agreement to divest Defense Technology (Safariland, 2020). The testimony given to the Senate Environmental and Public Works Committee by The Safariland Group was given prior to their divestment from Defense Technology.

5.2 Availability of Safe, Technically Achievable Substitutes

Based on information available to EPA at this time, EPA is proposing that a safe or technically achievable substitute will not be immediately available for the entire application but will be available for the entirety of the defense spray application by January 1, 2028. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

5.2.1 Current Status

Because defense sprays are used in a wide variety of scenarios and environments, and particularly for personal protection, they have more technical demands than other aerosols (SEPW, 2020a). The physical and chemical properties of the propellant impacts how the spray performs; these include:

- **Vapor pressure**, which is directly correlated with spray distance and volume (i.e., a lower vapor pressure results in a decreased spray distance and volume);
- **Formulation stability**, which impacts the spray's ability to form an effective fog, foam, or vapor discharge; and
- **Boiling point**, which impacts the temperature range that defense sprays can function at (lower boiling points allow the defense spray to function at lower temperatures).

Manufacturers also note concerns around flammability, particularly in law enforcement and military applications. This is important in law enforcement settings, where defense sprays are often used in conjunction with stun guns (e.g., Tasers), which can ignite (SEPW, 2020a). A transition to a flammable propellant would require training of law enforcement agents, but flammable propellants themselves are not prohibited.

There are several aerosol propellants listed as acceptable[34] by EPA's SNAP Program that are commercially available and currently used in consumer and/or technical aerosol products, including HFO-1234ze(E), HFC-152a, and hydrocarbons. However, these may not all be appropriate for defense sprays (e.g., hydrocarbons, due to flammability concerns) due to the specific technical demands described above. There are no additional aerosol propellants currently under SNAP review. The TEAP's *Report of the Medical and Chemical Technical Options Committee 2022 Assessment Report* (UNEP, 2022) also noted the same substitutes as technically proven and commercially available substitutes to HFC-134a in consumer aerosols but did not identify other alternatives or alternatives specifically for use in defense sprays.

The two most promising replacements for HFC-134a are HFO-1234ze(E) and HFC-152a, which are both listed as acceptable by the SNAP program for use in aerosol products and are both approved for use as inert ingredients for non-food pesticidal use (e.g., animal sprays) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (see Section 5.2.2 for more detail). Both have most of the requisite physical properties to function as a propellant in defense sprays with significantly lower GWPs than the current HFC in use, though EPA notes there are some challenges with regards to required performance parameters, as shown in Table 9. HFC-134a has a higher vapor pressure and lower boiling point than these alternatives. Early manufacturer

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[34] See https://www.epa.gov/snap/substitutes-propellants.

testing has shown a 35% reduction in deployment distance when formulated with HFO-1234ze(E) in place of HFC-134a (SEPW, 2020a, SEPW, 2020b), and some manufacturers have noted HFO-1234ze(E) does not form a stable solution with the formulation ingredients, leading to ineffective discharge characteristics that affect the content, pattern, and discharge of the spray (SEPW, 2020a). In addition, unlike HFC-134a, HFC-152a and HFO-1234ze(E) are mildly flammable and are not fire suppressants, such that the products containing them are considered flammable, which poses some challenges for use in law enforcement settings. HFO-1234ze(E) is more stable at higher temperatures than HFC-134a.

Table 9. Atmospheric, Chemical and Physical Properties, and Human Health Characteristics of Currently Used Propellants and Potential Substitutes in Defense Sprays

Substitute	ODP[a]	100-year GWP[b]	Flammability[c]	Human Health[d]	Boiling Point (°C)[e]	Vapor Pressure at 25°C (kPa)[e]
Currently in Use						
HFC-134a	0	1,430	Nonflammable	• Asphyxiant • Short-term exposure may adversely impact cardiovascular system, potentially resulting in cardiac disorders	-26.5	665
Potential Substitutes						
HFC-152a	0	124	Flammable[f]	• Asphyxiant	-24.0	606
HFO-1234ze(E)	0	1	Non-flammable[g]	• Asphyxiant • Short-term exposure may adversely impact cardiovascular system, potentially resulting in cardiac disorders	-19[h]	499[h]

[a] WMO (2022).
[b] IPCC (2007), unless otherwise specified. HFC GWP values are numerically equal to the exchange values listed in the AIM Act.
[c] UNEP (2022).
[d] NOAA Computer-Aided Management of Emergency Operations (CAMEO) Chemicals Database, International Labour Organization International Chemical Safety Cards (ICSCs), and the Toxin and Toxin Target Database (T3DB), unless otherwise specified.
[e] NIH PubChem Database at https://pubchem.ncbi.nlm.nih.gov, except where noted.
[f] Flammable at concentrations of 3.8 to 18 volume percent in air at room temperature.
[g] Flammable only at concentrations of 8.0-8.5 volume percent in air at one atmosphere and high temperatures (greater than 30°C).
[h] Honeywell (2018a).

Companies have reported mixed success in testing alternatives. Four dog sprays are currently EPA pesticide registered under FIFRA, and all use a non-HFC; dog sprays have never used HFCs. EPA is aware from company communications that three of these dog sprays use compressed nitrogen gas as a propellant. Five bear sprays are currently EPA pesticide registered; two are labelled as flammable. One bear spray uses HFO-1234ze(E), and one bear spray uses HFC-152a. Another company also sells a bear spray that uses HFO-1234ze(E) into the Canadian market. In addition, this company uses HFO-1234ze(E) in fogging defense sprays exported to countries that have restrictions on HFC-134a. Honeywell has also indicated that it indirectly sells HFO-1234ze(E) into the personal defense spray market, and the end customer is in Canada. EPA is not aware which defense spray company Honeywell is supplying to.

Counter Assault sells a bear spray that it notes on its website has a GWP both less than 150 and is less than 90% that of competitor bear sprays, which suggests the propellant is something other than HFC-134a; the product is also labelled as flammable (Counter Assault, 2023).

One company has noted they require a non-flammable propellant with close to the same characteristics as HFC-134a but has not found an alternative that works as well as HFC-134a. This company sells a bear spray into the Canadian market that uses HFO-1234ze(E), and also manufactures fogging defense sprays using HFO-1234ze(E) for export into countries where HFC-134a is not allowed. However, this company has noted deficiencies of HFO-1234ze(E) as compared to HFC-134a, which they have managed to partially remedy. Through email communication, they have shared with EPA that it is their "experience that HFC-134a produces a superior fogging product," and "HFC-134a will continue to be our propellant of choice until an equal to or superior propellant is available".

[ ] (EPA, 2024a). In July 2015, EPA's rulemakings, *Protection of Stratospheric Ozone: Change of Listing Status for Certain Substitutes under the Significant New Alternatives Policy Program* (80 FR 42870; July 20, 2015) prohibited the use of HFCs in personal protection sprays, and [ ] (EPA, 2024a). A partial vacatur was issued in 2018 indicating that EPA will not apply the HFC listings in the 2015 Rule, pending a rulemaking (EPA, 2018). This allows the continued use of HFCs in personal protection sprays, after which [ ] (EPA, 2024a).

[ ] (EPA, 2024a).

[ ] (EPA, 2024a).

[ ], several companies indicated they are researching mixtures of HFO-1234ze(E) but did not specify the additional components under consideration. Honeywell International indicates that HFO-1234ze(E) propellant can be blended with HFC-134a, HFC-152a, or hydrocarbons (HCs) (Honeywell International, 2017). In personal care products, an HFO-1234ze(E)/HFC-134a blend (90%/10%) is specifically formulated to meet the non-flammability requirements for consumer aerosols in Europe (Climalife, n.d.). For various propellant applications, including personal care products and technical and novelty aerosols, Honeywell International formulates HFO-1234ze(E), which is registered in Europe, Canada, Japan, China, Republic of Korea, and Australia (Honeywell, 2015).

Safariland tested other propellants, such as HCs and compressed gases, for use in defense sprays but deemed both unsuitable due to flammability in the case of HCs and inability to provide sufficient pressure and spray pattern in the case of compressed gases (Safariland, 2017b).

As noted above, there are some commercially available products, namely animal sprays, using alternative propellants. However, the technology has not yet been widely adopted across the industry, and testing is still ongoing.

5.2.2 Relevant Regulations and Standards

EPA regulates bear spray and dog spray as pesticides under FIFRA[35] and requires registration and labeling consistent with 40 CFR 156.70[36] for human and environmental hazards associated with a product. The entire formulation must meet the registration standard under FIFRA Section 3, including the lack of unreasonable adverse effects on humans and the environment. In addition, each ingredient (active or inert) in the formulation must be individually approved for pesticide use. For inert ingredients for non-food use, EPA performs a non-dietary risk assessment (focusing on other routes of exposure) and will approve or deny the chemical for the uses proposed (EPA, 2023). As noted above, HFC-134a, HFC-152a, and HFO-1234ze(E) are approved by EPA for non-food pesticidal use (e.g., in animal sprays).

Defense sprays used by law enforcement may follow ASTM International's *Standard Specification for Less Lethal Aerosol Devices Used by Law Enforcement, Corrections, and Other Public Safety Officers* (E3187/E3187M), which provides performance requirements and test methods for the evaluation of chemical irritant sprays (i.e., pepper spray) used by law enforcement, corrections, and other public safety officers (ASTM International, 2022). The standard sets performance requirements and test methods for both the final product and the chemical formulation of the product, including the propellant, but is not mandatory or written into law. The manufacturer must list all ingredients, including the propellant, when applying for certification under E3187/E3187M, but no other requirements for the propellant are listed (ASTM International, 2019). As applicable, the performance requirements include tests for spray pattern, parameters preventing carcinogen solvents and other harmful additives, and resistance to damage from dropping, crushing, and extreme temperatures. ASTM International's *Standard Practice for Certification of Less Lethal Aerosol Devices Used by Law Enforcement, Corrections, and Other Public Safety Officers* (E3215) defines the requirements for certification of such products to E3187/E3187M. However, defense spray products do not need to meet these standards or be certified to be sold or used by law enforcement.[37]

EPA did not identify regulations or standards for other defense sprays (e.g., personal defense sprays).

5.3 Supply of Regulated Substances

HFC-134a is the primary propellant used in defense sprays outside of dog sprays.

Defense spray manufacturers procure propellant, e.g., HFC-134a, and, in a highly automated process, fill empty aerosol cans with the propellant and defense spray formulation before the cans are sealed, tested for leaks, and labeled for sale.

Based on information available to EPA at this time, EPA is proposing that either (1) the supply of HFC-134a is not insufficient to accommodate the application as of January 1, 2026, or (2) the supply of HFC-134a is not insufficient to accommodate this application as of January 1, 2028.

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[35] Not all uses of defense sprays are regulated under FIFRA, including pepper spray designed for human-to-human self-defense.

[36] See https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-156/subpart-D/section-156.70

[37] Safety Equipment Institute, an affiliate of ASTM International, tracks certified products under various ASTM International standards. SABRE is the only defense spray manufacturer with certified products under ASTM E3187/E3187M (SEI, N.d.).

EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

5.3.1 Purification Process and Requirements

Specific purity requirements for the propellants in defense sprays were not identified.

5.3.2 Use of Recovered and Reprocessed Material

ASAs holders were required to discuss feasibility of recovered, recycled, or reclaimed material in their initial applications for HFC allowances in 2021 but have not been required to report an update on progress as of 2023, nor has new information been identified publicly.

[ ] (EPA, 2024a).

Two defense spray manufacturers, Aerko (a division of Shamrock Filling) and UDAP, have indicated they are considering reclaimed HFC-134a in defense spray manufacturing as an alternative to the use of virgin HFCs (Aerko, 2021; UDAP, 2021a).

EPA has defined reclaim as “the reprocessing of regulated substances to all of the specifications in appendix A to 40 CFR part 82, subpart F (based on Air-Conditioning, Heating, and Refrigeration Institute (AHRI) Standard 700–2016) that are applicable to that regulated substance and to verify that the regulated substance meets these specifications using the analytical methodology prescribed in section 5 of appendix A to 40 CFR part 82, subpart F” (40 CFR 84.3). Thus, HFC-134a refrigerant that is reclaimed and used by a different user than the one recovering the refrigerant must meet the purity requirements of AHRI 700, *Standard for Specifications for Refrigerants*. That standard, among other things, requires that reclaimed HFC-134a must be visibly clean (that is, no visible solids or particulate), no more than 1.5 percent by volume of air in the vapor phase, no more than 10 parts per million of water by weight, and no more than 0.5 percent by weight of other volatile impurities. Since there are no federal purity requirements or industry purity standards for HFCs used in aerosols, the purity of reclaimed HFCs is likely the same or higher than the virgin HFCs used in this application.

If reclaimed HFCs were to be used in defense sprays, the reclaimed refrigerant market could offer a significant supply. For example, in 2022, approximately 1,036.8 MT of HFC-134a refrigerant (i.e., 1,482,624 MTEVe) were reportedly reclaimed in the United States (Table A1); however, as discussed further in Section 3.1.3, EPA’s Emissions Reduction and Reclamation rulemaking could impact the availability of reclaimed HFCs for defense sprays.

5.3.3 Available Supply

The regulated substance primarily used by the defense sprays market is HFC-134a. The only producers of HFC-134a in the United States are Chemours and Mexichem Fluor DBA Koura. In 2022, there were also 28 importers of HFC-134a (Table A2). Arkema also produced HFC-134a in 2022; however, they are in the process of completing their retrofit of the HFC-134a production line to a new hydrochlorofluoroolefin (HCFO)-1233zd(E) unit (Arkema, 2022). [ ] are the current known suppliers of HFC-134a to defense spray ASA holders.

There is one defense spray product that uses HFC-152a. The sole domestic producer, [ ], of HFC-152a is Chemours. There were also seven importers of HFC-152a in 2022.

EPA identified that in 2022, 61,377 MT of HFC-134a were produced in the United States, 7,363.1 MT were imported, 17,220.2 MT were exported, and 1,036.8 MT were reclaimed (Table A1). Additionally, 51,902.9 MT of HFC-134a were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022,[38] resulting in an available supply of 104,459.6 MT of HFC-134a in the United States that year (EPA, 2024b). The global production capacity for HFC-134a in 2020 is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020).

EPA identified that in 2022, 29,654.9 MT of HFC-152a were produced in the United States, 5,810.1 MT were imported, 3,763.9 MT were exported, and [ ] were reclaimed (Table A1). Additionally, 5,076.3 MT of HFC-152a were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022,[39] resulting in an available supply of 36,777.3 MT of HFC152a in the United States that year (EPA, 2024b).[40] The global production capacity for HFC152a is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020). Chemours is currently increasing production capacity of HFC-152a by 20% at its Corpus Christi facility and expects to be completed by mid-2024 with the primary goal of meeting demands for lower GWP propellants and foam blowing agents (Chemours, 2023).

5.3.4 Application's Projected Demand of HFCs

Overall, reported HFC-134a use in defense sprays increased between 2018 and 2021, but has since been decreasing annually (Table 10). This decrease is further illustrated by the change in the defense sprays three-year AAGR calculated by EPA for the purposes of allowance allocations.[41] The 2018–2020 defense sprays AAGR was 31%, the 2019–2022 AAGR was 7%, and the 2020–2023 AAGR was -32% (EPA, 2024a).[42,43]

Fact.MR (2023) predicts the North American defense spray market will grow at a compound annual growth rate of 12.5% from 2023–2033, led by the United States market. However, this growth in the overall market may not directly correlate to HFC use.

In early 2020, industry estimated that demand for HFC-134a in defense sprays would experience modest growth over the next 15 years. Specifically, they estimated law enforcement and military usage of products would remain relatively constant or experience modest increases

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[38] Includes HFC blend components as HFC blends are disaggregated in inventory reporting under current EPA reporting requirements.

[39] Includes neat HFC-152a and HFC-152a as a component in a blend, as HFC blends are disaggregated in inventory reporting under current EPA reporting requirements. However, in 2022, EPA's Vintaging Model estimated 100% of HFC-152a demand was for neat HFC-152a.

[40] Any quantities reclaimed in 2022 are not included in the calculation of available supply for HFC-152a.

[41] AAGR = $[(\frac{Year\ 2\ HFC\ purchases}{Year\ 1\ HFC\ purchases} - 1) + (\frac{Year\ 3\ HFC\ purchases}{Year\ 2\ HFC\ purchases} - 1)] \times \frac{1}{2}$

[42] 2019–2022 spans the second half of 2019 through the first half of 2022, and 2020–2023 spans the second half of 2020 through the first half of 2023.

[43] The AAGRs are derived from reported, verifiable data. Therefore, they do not reflect data from companies with missing reports or documentation.

in demand, and the usage of bear spray would increase over time as populations continue to encroach on bear habitats, increasing the incidence of encounters with bears (SEPW, 2020c).

In 2020, there was a large increase in HFC-134a use in defense sprays, likely due in part to an increase in demand for bear sprays associated with a large uptick in the number of people hiking and going to national parks (i.e., 7.1 million more Americans went hiking in 2020 compared to 2019, representing a 7.3% increase) as well as an increase in demand for law enforcement sprays due to higher than average levels of civil unrest (i.e., in 2020, protests reached a cumulative size of more than 1,011,700 people and lasted for more than a year, compared to approximately 600,000 people and only one week of duration in 2019, representing a nearly 70% increase, in participant size) (Outdoor Foundation, 2021; Press & Carothers, 2020; Carnegie Endowment for International Peace, 2024). Defense spray manufacturers subsequently modified their growth projections to 10–15% over the next several years (SABRE, 2021b; UDAP, 2021; Safariland, 2021b). In 2021, civil unrest also remained high, and outdoor recreation continued to grow, albeit at a much more modest rate, such that defense sprays' purchases of HFCs further increased that year (Press & Carothers, 2022; Outdoor Foundation, 2022). Since then, however, this trend has not been sustained, and purchases have been on a decline since 2021. As noted, the spike in outdoor recreation participants has not been sustained, with growth rates of only 2.2% and 2.3% in 2021 and 2022, respectively, and levels of civil unrest have also decreased (Outdoor Foundation, 2021; Outdoor Foundation, 2022; Outdoor Foundation, 2023; Carnegie Endowment for International Peace, 2024). Data reported by defense spray companies in 2022 and 2023 also indicates that elevated HFC-134 use in 2020 and 2021 may have been an anomaly, with 2022 use approximately 17% lower than in 2020, as shown in Table 10.

Table 10. Historic HFC-134a Use in Defense Sprays (kg), 2018-2023

Company Name	2018	2019	2020	2021[a]	2022[a]	2023[a]
Defense Technology, LLC	[ ]					
Guardian Protective Devices						
Security Equipment Corporation (SABRE)						
Shamrock Filling LLC						
UDAP Industries Inc						
Zarc International Inc[g]						
Total (kg)	***113,660***	***136,300***	***209,294***	***266,292***	***174,387***	***112,643***
Total (MTEVe)	***162,534***	***194,908***	***299,291***	***380,798***	***249,373***	***161,079***

Source: EPA (2024a).
NA = Not Available.
[a] Calculated as the sum of HFC held in inventory (previous period) + HFC acquired through conferrals + HFC imported using allowances + HFC purchased – HFC held in inventory (current period). For 2021, HFC held in inventory is not available for these manufacturers as it was only required to be reported by companies requesting set-aside allowances.
[b] Not all data is verified due to missing documentation. In addition, some reports are missing. [This number may be incomplete or inaccurate, due to missing reports and/or unverified purchase data.]
[g] [ ]

EPA is projecting demand for HFCs in the U.S. defense spray industry to be relatively stable in the coming years. As explained above, 2020 and 2021 were anomalously high purchase years for the industry, and the market appears to have receded from these high years; in 2023, purchase levels were nearly identical to those in 2018. While there could be moderate growth or contraction of the market through 2030, at this time, the Agency does not have reliable growth estimates off which to base calculations. AAGRs have been inconsistent in the various three-year periods between 2018 to 2023, such that none can reasonably be considered to be representative of projected demand for the market. At the time of the final rule, EPA will have data for 2024, which may provide insight on projected HFC demand within the application.

In addition, there is an ongoing transition out of HFC-134a, so demand for HFC-134a is likely to continue falling. If the industry largely transitions to HFC-152a, it is uncertain how demand for HFCs in total will change, as it will depend on if HFC-152a substitutes for HFC-134a on a one-for-one basis or if more or less HFC-152a is needed to achieve the same results. If the industry largely transitions to HFO-1234ze(E), demand for HFCs will approach zero.

5.3.5 Anticipated Regulatory Impacts on Supply

As noted in Section 3.1.2, EPA's Technology Transitions Program is establishing GWP limits, which in turn will limit the use of HFC-134a in many sectors and subsectors as early as 2025, including consumer aerosols (excluding defense sprays) as of January 1, 2025, and most technical aerosols as of January 1, 2028. EPA's Vintaging Model estimates that the aerosol market used 5,209 MT of HFC-134a and 19,493 MT of HFC-152a in 2023 (EPA, 2016). ASA holders' use of HFC-134a defense sprays constitute approximately 2% of the aerosol HFC-134a market, at 113 MT or 0.16 MMTEVe of HFC-134a in 2023 (EPA, 2024a).

EPA regulations under the AIM Act, planned transitions out of HFC-134a, and market trends generally are estimated to reduce demand for HFC-134a through 2030; modeling under existing AIM Act regulations estimates demand for HFC-134a will be reduced by approximately 24,800 MT and 28,330 MT in 2026 and 2030, respectively, or a 56% and 66% reduction in projected demand across all uses of HFC-134a, relative to BAU pre-Allocation Rule demand (Figure 5). This reduction in projected demand may free up additional available supply, which could be used to help meet future demand for HFC-134a in defense sprays.

HFC-152a projected demand is less clear. Overall demand for HFC-152a compared to BAU pre-AIM Act regulations is projected to decrease by 16,120 MT and MT in 2026 and 2030, respectively, or a 58% and 71% reduction in projected demand across all uses of HFC-152a (Figure 5). However, HFC-152a has a GWP (and EV) of 124, which is below the lowest GWP limit established by the Technology Transitions program and is also one of the lowest EVs of all regulated substances under the AIM Act. HFC-152a is an available or potentially available substitute for multiple subsectors subject to the Technology Transitions restrictions, including all foam subsectors, aerosol propellants, motor vehicle air conditioning, and household refrigerators and freezers.[44] However, all of these subsectors have multiple other acceptable

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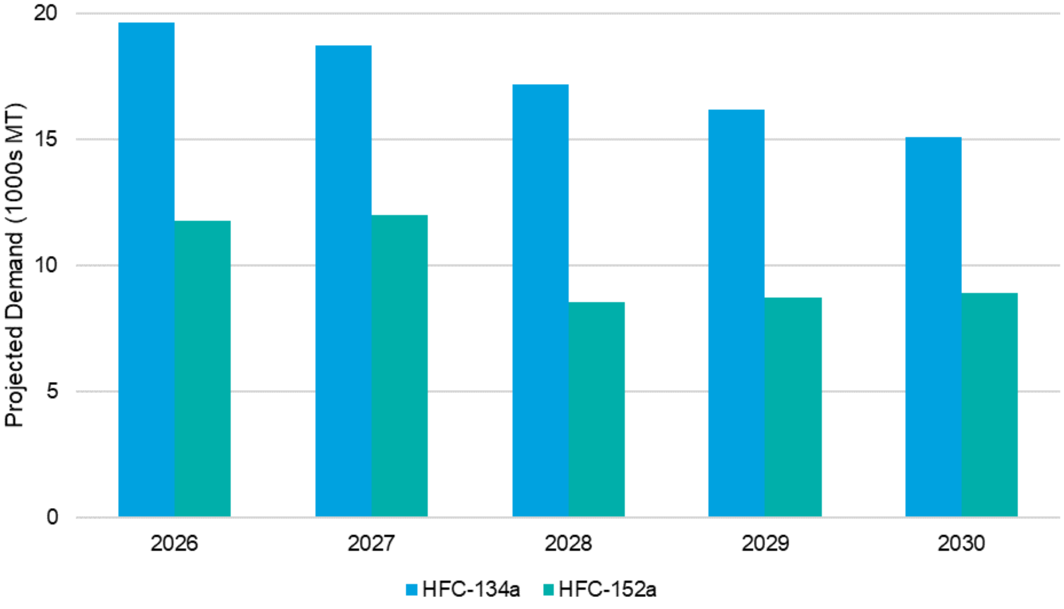
[44] See 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) TSD "American Innovation and Manufacturing Act of 2020 – Subsection (i)(4) Factors for Determination: List of Substitutes." This list is not exhaustive, so it is possible HFC-152a is an available alternative for other subsectors. In addition, EPA did not identify information for products or equipment containing certain substitutes, which may indicate a lack of current commercial demands for the substitutes in those products or equipment. However, this did not automatically remove those substitutes from the list of available substitutes, as commercial demands is only one subfactor that needed to be considered under subsection (i)(4)(B).

alternatives, including non-HFCs, and many of these subsectors have already transitioned to another substitute (e.g., motor vehicle air conditioning, household refrigerators and freezers), so it is highly unlikely that a new transition to HFC-152a would be considered. For subsectors where HFC-152a neat or in blends is likely under consideration, it is not yet known if there will be any significant shift toward use of HFC-152a, particularly as many relevant subsector (e.g., foams and aerosols) have begun to move out of HFCs entirely (UNEP, 2022; UNEP, 2023). In addition, given its lower EV, fewer allowances are needed to import or produce HFC-152a in comparison to the same volume of higher-EV HFCs. For example, an importer would need to expend 143 consumption allowances to import 100 kg of HFC-134a compared to 12.4 allowances to import 100 kg of HFC-152a—a greater than 90% reduction.

As mentioned in Section 3.1.3, potential increased use of reclaimed HFCs in other applications due to the Emissions Reduction and Reclamation Rule could free up additional supply of virgin HFC-134a available to meet future demand in defense sprays.

In addition, EPA intends to finalize the rulemaking "*Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA)"* (88 FR 74712, October 31, 2023), which has proposed to ban the use of TCE due to unreasonable risk of injury to human health. The proposed rule would prohibit TCE from being used as a feedstock to manufacture HFC-134a within eight and a half years from when that rule is finalized; EPA recognizes that provisions may be different in the final rulemaking and will update this document and related analysis accordingly. While there are other pathways to produce HFC-134a, it is EPA's understanding that the pathway using TCE is the primary pathways utilized in the United States, and it is costly to change production pathways. Thus, this rulemaking could likely affect domestic production of HFC-134a, though it will not impact global production and, relatedly, imports of HFC-134a.

Figure 5. Projected Demand (MT) for HFC-134a and HFC-152a, 2026–2030



5.3.6 Allowance Usage, Conferrals, and Inventory

As noted below, EPA issued 603,579.1 MTEVe of ASAs for defense sprays for 2022, 185,368.5 MTEVe of defense spray ASAs for 2023, and 100,285.8 MTEVe of defense spray ASAs for 2024.

Defense spray allowance holders reported acquisition of HFC-134a through both conferrals to producers ([ ]) and domestic purchases that did not require expending or conferring allowances (Table 11).

Table 11. Purchases and Inventory (kg) of HFC-134a for ASA Holders in 2022 and 2023

Report Period	Acquired through Conferrals and Imported Using Allowances	Purchased without Expending or Conferring Allowances	Held in Inventory at End of Period	% of HFC Acquired through Expending or Conferring Allowances
2022	54,883[ ]	139,131	15,346	28%
2023	91,757[ ]	26,636	21,096	78%

Source: EPA (2024a).

[ ]

In addition, Table 11 shows the amount of HFC inventory held by defense spray ASA holders. Inventory was built up for HFC-134a from EOY 2022 to EOY 2023. Inventory increased by about 37% from approximately 15,300 kilograms of HFC-134a at the end of 2022 to approximately 21,100 kilograms of HFC-134a at the end of 2023.

Table 12 summarizes 2022 and 2023 aggregate allowances and activity for defense sprays, including BOY levels, EOY levels, quantities of allowances conferred, and quantities of allowances expended. At the end of 2022, end users conferred, transferred, or expended 49% of allocated allowances, [ ]. At the end of 2023, [ ] end users conferred, transferred, or expended 79% of allocated allowances. EOY or leftover allowances indicate that 1) application-specific end users did not expend all of their allocated allowances (and may have just purchased from domestic suppliers without expending allowances; Table 11) and/or 2) importers/producers that were conferred allowances did not use them all.

Table 12. Allowances for Defense Sprays (MTEVe)

	2022	2023
BOY Allowances	603,579.1[a]	185,368.50
Quantity ASA Holders Conferred and Expended Directly to Import	295,377.50	145,579.40
Quantity Expended by Supplier	[ ]	
EOY Allowances – End Users	308,201.60	39,789.10
EOY Allowances % Remaining – End Users	51%	21%
EOY Allowances – Suppliers and Intermediaries	[ ]	
EOY Allowances % Remaining – Suppliers and Intermediaries	[ ]	

Source: EPA (2024a).

[a] Include set-aside allowances.

6. Structural Composite Preformed Polyurethane Foam for Marine and Trailer Uses

6.1 Overview

In the Allocation Framework Rule, EPA defined structural composite preformed polyurethane (SCPPU) foam as “a foam blown from polyurethane that is reinforced with fibers and with polymer resin during the blowing process, and is preformed into the required shape (*e.g.,* specific boat or trailer design) to increase structural strength while reducing the weight of such structures” (40 CFR Part 84). SCPPU foam is a specific type of polyurethane (PU) foam that is used for structural and insulation purposes and offers reduced weight, increased thermal efficiency, and cost savings (Composites World, 2019; Compsys, 2023a; Compsys, 2023c) and includes the characteristics described in the definition above.

In general, PU foam products are manufactured with chemical or physical blowing agents that expand the plastic resin matrix to create a cellular structure when it solidifies (UNEP, 2023). In the case of foam used for insulation (e.g., refrigerated trailers), the blowing agent also functions as an insulating component of the foam. There are three major types of PU foam, namely rigid, flexible, and integral skin/expanded elastomers (UNEP, 2023). PU foams can be sprayed, injected, poured into molds, or purchased as panels or laminated boardstock (UNEP, 2023).

6.1.1 Marine

In the marine industry, a variety of foams are utilized for comfort, insulation, structure, and flotation in both recreational and non-recreational uses. Historically, the blowing agents for sound and vibration reduction foams and flotation foams accounted for roughly 80–90% of HFC use in the marine foams subsector (SEPW, 2020f; SEPW, 2020g). However, HFCs in these types of foams have since been eliminated and replaced with methyl formate and HFO formulations (SEPW, 2020f). The remaining 10–20% of the industry’s HFC use is for SCPPU foams, which are typically used in internal structures of the boat, particularly stringers and bulkheads (SEPW, 2020f; SEPW, 2020g; Composites World, 2013). Stringers are structures that run parallel along the boat’s hull and provide structural integrity, e.g., keeping the boat from bending, especially when going over waves. Bulkheads are vertical walls that provide structural integrity and partition the boat into watertight compartments to reduce damage in the case of an accident.

Historically, stringers and bulkheads were made of plywood and, more recently, sandwich foam cores (Composites Manufacturing, 2015; Composites World, 2013). The sandwich foam cores typically use HFCs, HCs, and HFOs as blowing agents. In the late 1980s, SCPPU foams were developed and employed for marine uses (e.g., recreational boats, commercial fishing boats), which provided a lighter-weight and more durable alternative, which resulted in the ability to use less powerful engines and reduce fuel consumption, thus decreasing the overall purchase and operation cost of boats (SEPW, 2020; SEPW, 2020f). BASF, a supplier of formulations and systems for blowing PU foam, estimates that marine applications of SCPPU foams make up the majority of the overall SCPPU foam market (EPA, 2021).

6.1.2 Trailers

In trailers, foams are used for structure and insulation in two different applications: intermodal containers and reefer trailers. Intermodal containers are refrigerated containers that allow for uninterrupted refrigerated storage during transport. Reefer trailers are insulated cargo space that are designed with a refrigeration system to maintain a certain temperature during transit. These trailers can be found on trucks or trailer-mounted systems. Normally, these trailers are used to transport perishable or frozen goods (Zandstra, 2020). Reefer trailers are moveable on their own while intermodal containers require shipment on a trailer.

Traditionally, both trailer types have used PU foam to provide insulation for their refrigerated system and metal to provide structure to the trailer or intermodal container. For example, a truck may feature a fully aluminum roof, floor, and sidewalls, with injected polyurethane expanded foam insultation (Rockport Trucks, 2023). Conversely, SCPPU foam has specific properties that eliminate the need for metal frames found in typical trailer structures (Composites World, 2019). Thus, SCPPU foam panels would make up the walls and floor of the trailer itself (Compsys, 2023b). For trailer floors, instead of a steel structure with an attached insulated floor, trailers utilizing SCPPU foam have assemblies of hollow aluminum extrusions and preformed foam beams that are laminated directly onto the metal (Compsys, 2023b). SCPPU technology spread to the manufacturing of truck trailers (e.g., refrigerated trailers for transportation of perishable goods) in 2016 with Wabash's molded structural composite (MSC) technology (Wabash National, 2016). Wabash's MSC technology, now referred to as its EcoNex technology, is built off of PRISMA preforms, Compsys' SCPPU foam technology, with the addition of resins and gel coats (Wabash National, 2022; Trailer/Body Builders, 2018).

SCPPU foam has been used in both intermodal containers and reefer trailers to a limited extent (Composites World, 2019). Certain trailer manufacturers have begun transitioning to trailer bodies within the last five years that replace traditional PU foam completely with SCPPU foam (Composites World, 2019; Wabash, 2019). SCPPU foams are estimated to improve thermal efficiency of trailers up to 28% and reduce overall weight up to 10%, compared to traditional foam and aluminum insulation (Composites World, 2019).

6.1.3 Use of Regulated Substances

SCPPU foam was first developed for marine applications using HCFC-22 as the blowing agent, which then transitioned to HFC-134a for SCPPU foams in both the marine and trailer end uses (SEPW, 2020a; SEPW, 2020b; SEPW, 2020f; SEPW, 2020h; EPA, 2007). The quantity of blowing agent used depends on the application and size of the SCPPU foam.

6.1.4 Major Manufacturers and Products

There are typically three entities involved in the SCPPU foam product supply chain: systems houses (i.e., chemical companies), structural composite preform PU foam suppliers, and boat and trailer manufacturers. Systems houses develop formulations for foam blowing, such as the HFC-134a formulation currently in use, for manufacturing of SCPPU foams. The systems house then sells these formulations for foam blowing to structural composite preform foam suppliers who work directly with boat and trailer manufacturers to create specific molds for their intended application. Finally, boat and trailer manufacturers install structural composite preforms into the specific boat and trailer models for sale to consumers (SEPW, 2020c; SEPW, 2020d; SEPW, 2020e; SEPW, 2020f; SEPW, 2020h). In some cases, the boat and trailer manufacturers buy directly from the systems houses, bypassing the SCPPU foam manufacturer (EPA, 2021). For example, BASF and Wabash, a major trailer manufacturer, worked together directly to develop Wabash's all-composite refrigerated trailer and all-composite reefer trailer in 2016 (BASF, 2016; FleetOwner, 2016).

6.1.4.1 Structural Composite Foam Manufacturers

BASF is the major systems house for the SCPPU foam market (SEPW, 2020f; SEPW, 2020h; EPA, 2024a). SCPPU foam applications are highly specialized, particularly for marine end uses which typically involve custom-manufactured molds, and the HFC supply chain involves a limited number of companies. Companies such as Compsys and Structural Composites, both subsidiaries of The Composites Company, buy formulations for foam blowing from a systems house to create SCPPU foam which is then installed in boats and trailers (SEPW, 2020a; SEPW, 2020b; SEPW, 2020h).

6.1.4.2 Marine Manufacturers

Major boat manufacturers that have confirmed the utilization of SCPPU foam in their boats are Grady White Boats, HCB Center Console Yachts, and Parks Manufacturing, LLC (SEPW, 2020c; SEPW, 2020d; SEPW, 2020e; SEPW, 2020g). As discussed above, these companies do not manufacture the structural composite preforms themselves but source them from preform suppliers, such as Compsys (SEPW, 2020c; SEPW, 2020d; SEPW, 2020e). Additional major boat manufacturers include, but are not limited to, Boston Whaler, Mastercraft, Sea Ray, Chaparral, Ranger, Cobalt, Contender, and Malibu (Boat Trader, 2022). These manufacturers are assumed to use SCPPU foam as systems houses indicated that the majority of the recreational boating market utilizes SCPPU foam (EPA, 2021).

6.1.4.3 Trailer Manufacturers

There are multiple domestic trailer manufacturers (Table 13), but only Wabash is known to use SCPPU foams (SEPW, 2020i).

Table 13. Major Manufacturers of Trailers in the United States

Manufacturer	Estimated Market Share[a]
Utility Trailer Manufacturing	31%
Wabash	16%
Kidron Inc.	13%
Great Dane	14%
Morgan Corporation	9%
Hyundai Trailers	4%
Other	15%[b]

Source: Skeist (2004), Refrigerated Transporter (2010), and Wabash National (2019).

[a] Totals may not sum due to independent rounding.

[b] Estimated to be comprised of equal shares of Maersk Container Ind. (5%), Danteco (5%), and Vanguard National Trailer Corp. (5%).

6.2 Availability of Safe, Technically Achievable Substitutes

Based on information available to EPA at this time, multiple possible outcomes could occur regarding whether a safe or technically achievable substitute will be available during 2026 through 2030 for HFC use in SCPPU foam for marine and trailer uses. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

6.2.1 Current Status

There are several foam blowing agents listed as acceptable by EPA's SNAP Program that are commercially available and currently used in rigid polyurethane marine flotation foam[45] and commercial refrigeration[46] (e.g., refrigerated transport vehicles), but many may not be appropriate for SCPPU foam applications (e.g., due to structural instability, as discussed below). Some of these substitutes were also noted as viable and commercially available substitutes to HFCs in the foam sector in the TEAP's *Flexible and Rigid Foams Technical Options Committee 2022 Assessment Report* (UNEP, 2023). However, this report did not explicitly discuss SCPPU foams. There are no additional foam blowing agents currently under SNAP review for rigid polyurethane marine flotation foam or commercial refrigeration.

Table 14 below summarizes the atmospheric, flammability, and human health characteristics, including ODP and GWP, for HFC-134a, which is the blowing agent currently used in marine and trailer SCPPU foam markets, as well as potential SCPPU foam blowing agent substitutes.

Globally, many traditional PU foam systems, such as sprayed foam or sandwich panels, for transport refrigeration applications (e.g., trailers) are manufactured using HCs as the foam blowing agent, especially those manufactured by medium and large enterprises (UNEP, 2023). For those medium and large manufacturers that have transitioned away from HCFCs/HFCs, there is also some continued use of HFOs and HCFOs, either alone or in blends with hydrocarbons, in addition to the use of hydrocarbons as indicated above (UNEP, 2023). In Latin America, refrigerated transport, trucks, and trailers are generally manufactured using formulated polyols with HFCs or blends with oxygenated foam blowing agents, with limited use of HFOs/HCFCs due to high prices and lack of availability (UNEP, 2023).

In the United States, trailers using traditional PU foam typically use HFCs, hydrocarbons, and, more recently, HFOs as blowing agents. Most foams used in the marine industry in the United States, with the exception of SCPPU foams, have transitioned from HFC-134a to methyl formate and HFO formulations (SEPW, 2020f). In the marine end use, SCPPU foam is the only foam use that has not commercialized an HFC alternative (SEPW, 2020f). In 2015, manufacturers began research and development programs to establish alternative foam blowing agents for marine and trailer SCPPU foams (SEPW, 2020a; SEPW, 2020f).

As noted above, SCPPU foams have different requirements than other PU foams, so these alternatives may not all be appropriate for this application. The most promising options to date are an HFC-152a/cyclopentane blend and HFOs.

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[45] See https://www.epa.gov/snap/substitutes-rigid-polyurethane-marine-flotation-foam.

[46] See https://www.epa.gov/snap/substitutes-rigid-polyurethane-commercial-refrigeration.

Table 14. Atmospheric, Flammability, and Human Health Characteristics of Currently Used Blowing Agents and Potential Substitutes in Marine and Trailer Structural Composite Preformed Polyurethane Foam

Substitute	ODP[a]	100-year GWP	Flammability[b]	Human Health[c]
Blowing Agent Currently in Use				
HFC-134a[d]	0	1,430[e]	Nonflammable[d]	• Asphyxiant • Short-term exposure may adversely impact cardiovascular system, potentially resulting in cardiac disorders
Potential Blowing Agent Substitutes				
Methyl formate[f]	0	13[g]	Flammable	• No relevant toxicity concerns
HCFO-1233zd(E)[f]	<0.0004	4[g]	Nonflammable[d]	• No relevant toxicity concerns[h]
HFO-1234ze(E)[i]	0	1[g]	Mildly Flammable[h]	• Asphyxiant • Short-term exposure may adversely impact cardiovascular system, potentially resulting in cardiac disorders
HFO-1336mzz(Z)[d]	0	2[g]	Nonflammable[d]	• Not classified[h]
HFC-152a[j]	0	124[e]	Mildly Flammable	• Asphyxiant
Cyclopentane	0	<<1[a]	Highly flammable	• Asphyxiant

[a] WMO (2022).

[b] NOAA Computer-Aided Management of Emergency Operations (CAMEO) Chemicals Database, unless otherwise specified.

[c] NOAA CAMEO Chemicals Database, International Labour Organization International Chemical Safety Cards (ICSCs), and the Toxin and Toxin Target Database (T3DB), unless otherwise specified.

[d] Classified by ASHRAE Standard 34 as a Class A1 refrigerant, meaning it does not propagate a flame and has lower toxicity (ASHRAE, 2022).

[e] IPCC (2007). Values are numerically equal to the exchange values listed in the AIM Act.

[f] Classified by ASHRAE Standard 34 as a Class B2 refrigerant, meaning it has lower flammability and higher toxicity (ASHRAE, 2022).

[g] 40 CFR Part 84.64.

[h] ECHA (2024).

[i] Classified by ASHRAE Standard 34 as a Class A2L refrigerant, meaning it has lower flammability, a slow burning velocity, and lower toxicity (ASHRAE, 2022).

[j] Classified by ASHRAE Standard 34 as a Class A2 refrigerant, meaning it has lower flammability and lower toxicity (ASHRAE, 2022).

Initial research into HFO blowing agents by both companies that receive ASAs for SCPPU foam was unsuccessful (SEPW, 2020a; SEPW, 2020h). Early trials by Structural Composites and Wabash with HFO-blown SCPPU foams showed instability, including shrinkage in the product after 14 days in Structural Composites' trial, which could cause safety concerns (SEPW, 2020a; SEPW, 2020h). Since then, one company has continued to experiment with HFO blowing agents and expects to transition from HFC-134a as a blowing agent by the end of 2025 (EPA, 2024a). The other company also expects to transition out of HFC-134a before 2026, but to an HFC-152a/cyclopentane blend. This blend would not require SNAP approval, as HFC-152a and cyclopentane have previously each been approved for marine flotation and commercial refrigeration (e.g., refrigerated transport vehicles) use. For both marine flotation and commercial refrigeration, SNAP permits the blending of blowing agents that are already listed as acceptable without an additional submission for the blend (EPA, 2020).

The other company has noted that, after extensive trials, they did not believe HFOs or HFO blends are feasible alternatives for SCPPU foam for their product (EPA, 2024a). Wabash received an air permit in August 2023 from the Minnesota Pollution Control Agency for use of an HFC-152a/cyclopentane blend [ ] (Minnesota Pollution Control Agency, 2023).

6.2.2 Relevant Regulations and Standards

EPA did not identify any relevant federal regulations or standards for SCPPU foam use in marine or trailer applications.

6.3 Supply of Regulated Substances

The regulated substance currently used by the SCPPU foam market is HFC-134a. As explained in more detail in Section 5.3, HFC-134a is produced domestically, and there are also multiple importers.

Based on information available to EPA at this time regarding HFC-134a, EPA is proposing that either (1) the supply of HFC-134a for use in SCPPU foam for marine and trailer uses is not insufficient to accommodate the application as of January 1, 2026; or (2) the supply of HFC-134a is not insufficient to accommodate this application as of January 1, 2028. With regards to HFC-152a, EPA could determine (1) the supply of HFC-152a for use in SCPPU foam for marine and trailer uses is not insufficient to accommodate the application as of January 1, 2026; (2) the supply of HFC-134a is not insufficient to accommodate this application as of January 1, 2028; or (3) the supply of HFC-152a is insufficient to accommodate this application for the entire five-year period from 2026–2030. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

6.3.1 Purification Process and Requirements

Specific purity standards for blowing agents were not identified. However, the efficacy of blowing agents is determined by interactions with the blend, which may be influenced by the blowing agent's composition and purity.

6.3.2 Use of Recovered and Reprocessed Material

ASAs holders were required to discuss feasibility of recovered, recycled, or reclaimed material in their initial applications for HFC allowances in 2021 but have not been required to report an update on progress as of 2023, nor has new information been identified publicly.

[ ] (EPA, 2024a). If reclaimed HFCs were to be used in SCPPU foam, the reclaimed refrigerant market could offer a significant supply of HFC-134a, as discussed above in Section 5.3.2.

6.3.3 Available Supply

There is substantial domestic and global production of HFC-134a that is supplied to the United States, as well as a large amount of inventory held by suppliers, as explained in more detail in Section 5.3.3.

In the United States, [ ] supplier of foam blowing agent formulations to Compsys and Wabash. [ ] bulk HFC-134a from [ ] to produce the blowing agent formulations. In 2022, [ ] conferred allowances to [ ], who in turn conferred those allowances to [ ]. The bulk HFC-134a is produced at [ ] (EPA, 2024a).

HFC-152a is also produced and imported in large quantities, as well as held in inventory by suppliers (see Section 6.3.3 for more information).

6.3.4 Application's Projected Demand of HFCs

Table 15 summarizes quantities of HFC-134a used, as determined from reported use and purchases of HFCs, by ASA holders in 2018–2023 (reported use data were only reported for 2018–2020), showing [ ]. [ ].

[ ] (EPA, 2024a). [ ]. Wabash announced in 2021 that it was launching a grocery delivery vehicle in 2022 utilizing SCPPU foam (Wabash, 2021). [ ]

Table 15. Historic HFC-134a Use in SCPPU Foams (kg), 2018-2023

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
Compsys[b]	[ ]					
Wabash National Corporation[c]						
Total (kg)	[ ]					
Total (MTEVe)	[ ]					

Source: EPA (2024a).

[a] Calculated as the sum of HFC held in inventory (previous period) + HFC acquired through conferrals + HFC imported using allowances + HFC purchased – HFC held in inventory (current period).

[b] [ ]

[c] [ ]

The recreational boat market, the majority of which utilizes SCPPU foam (EPA, 2021), is expected to grow in the United States in the next several years, increasing from a valuation of 17.31 billion USD in 2022 to a projected 28.54 billion USD by 2028, growing at a compound annual growth rate (CAGR) of 8.69% (Arizton, 2023). Contributors to this growth include a rising number of middle-class families and more participation in outdoor recreational activities (Arizton 2023). However, over the last two decades, recreational boat registration decreased at an average of 0.42% annually from 12.9 million registrations in 2002 to 11.8 million registrations in 2022, though this number has fluctuated annually (USCG, 2022). Projections of HFC-134a use in SCPPU foams for marine use were based on these historical registration trends. In these projections, however, it was assumed that HFC-134a use remains constant, which is a more conservative assumption than what is indicated by historical registrations.

The refrigerated trailer market is expected to grow from 5.9 billion USD in 2021 to 8.8 billion USD in 2027, growing at a CAGR of over 6% during that time (Research and Markets, 2022). Importantly, the growth in both the recreational boat and refrigerated trailer markets may not directly correlate to HFC use. HFC-134a use in structural composite preformed trailer foams is assumed to grow at an average rate of 4.8% between 2026 and 2030, in line with the growth rate of intermodal containers (EPA, 2022).

Projected HFC demand in the U.S. SCPPU foams industry is uncertain given that the transition to alternatives is underway (as described in Section 6.2.1). While EPA recognizes the limitations of the data, we still find it valuable to estimate projected demand for the industry. Assuming no growth for SCPPU foams for marine uses and 4.8% growth for SCPPU foams for trailer uses and no transition (i.e., the entire industry continues using HFC-134a), demand for HFC-134a over the five-year period of 2026–2030 could be on the order of 27–31 MT. However, given the ongoing transition out of HFC-134a, this value is likely high. If the industry largely transitions to HFC-152a, it is uncertain how demand will change, as it will depend on if HFC-152a substitutes for HFC-134a on a one-for-one basis or if more or less HFC-152a is needed to achieve the same results. At the same time, SCPPU foams for marine uses is planning to transition to an HFO, so demand for HFC-152a will likely not grow for this sub-application; however, given the assumed 0% growth rate for SCPPU foams for marine uses, the overall demand for HFC-152a by this application would not be substantially impacted by which alternative marine uses transitions into.

Industry stakeholders have noted the potential for use of reclaimed HFCs in the market, which could also impact projected use of virgin HFCs (Structural Composites, 2021).

6.3.5 Anticipated Regulatory Impacts on Supply

As noted in Section 3.1.2, EPA's Technology Transitions Program is establishing GWP limits, which in turn will limit the use of HFC-134a in many sectors and subsectors as early as January 1, 2025. All foam subsectors, except SCPPU foam for marine and trailer uses (given its current status as an ASA holder), will be subject to a GWP limit of 150 as of January 1, 2025; neat HFC-134a thereby cannot be used, given its GWP of 1,430, but HFC-152a, with a GWP of 124, is acceptable. EPA's Vintaging Model estimates that the foams market used 6,359 MT of HFC-134a and 2,336 MT of HFC-152a in 2023 (EPA, 2016). ASA holders' use of HFC-134a blowing agent for SCPPU foam constitutes approximately [ ] of the foam HFC-134a market, at [ ] MT or [ ] MMTEVe of HFC-134a in 2023 (EPA, 2024a).

The Technology Transitions Program, the Allocation Rule, and other AIM Act regulations, as well as market trends writ large are estimated to reduce demand for HFC-134a and HFC-152a, though HFC-152a demand projections are less clear (see Section 5.3.5 for further discussion).

6.3.6 Allowance Usage, Conferrals, and Inventory

As noted below, EPA issued 83,935.2 MTEVe of ASAs for SCPPU foam for 2022, 87,695.8 MTEVe SCPPU foam ASAs for 2023, and 86,268.6 MTEVe of SCPPU foam ASAs for 2024.

SCPPU foam allowance holders reported acquisition of HFC-134a through conferrals to suppliers of foam blowing formulations, who then conferred those allowances to chemical producers [ ], or through domestic purchases that did not require expending or conferring allowances (Table 16).

Table 16. Purchases and Inventory (kg) of HFC-134a for ASA Holders in 2022 and 2023

Report Period	Acquired through Conferrals and Imported Using Allowances	Purchased without Expending or Conferring Allowances	Held in Inventory at End of Period	% of HFC Acquired through Expending or Conferring Allowances
2022	[ ]			
2023				

Source: EPA (2024a).

Table 16 also shows the amount of HFC inventory held by SCPPU foam ASA holders. Inventory was [ ] for HFC-134a from EOY 2022 to EOY 2023. Inventory [ ] from [ ] kilograms of HFC-134a at the end of 2022 to [ ] kilograms of HFC-134a at the end of 2023.

Table 17 summarizes 2022 and 2023 application-wide allowance balances and activity for SCPPU foam, including BOY levels, EOY levels, quantities of allowances conferred, and quantities of allowances expended. At the end of 2022, [ ] end users conferred, transferred, or expended 99% of allocated allowances. At the end of 2023, end users conferred, transferred, or expended 84% of allocated allowances, [ ]. EOY or leftover allowances indicate that 1) application-specific end users did not expend all of their allocated allowances (and may have just purchased from domestic suppliers without expending allowances; Table 16) and/or 2) importers/producers that were conferred allowances did not use them all.

Table 17. Allowances for SCPPU Foam (MTEVe)

	2022	2023
BOY Allowances	83,935.2[a]	87,695.80
Quantity ASA Holders Conferred and Expended Directly to Import	83,037	73,543
Quantity Expended by Supplier	[ ]	
EOY Allowances – End Users	898	14,153
EOY Allowances % Remaining – End Users	1%	16%
EOY Allowances – Suppliers and Intermediaries	[ ]	
EOY Allowances % Remaining – Suppliers and Intermediaries	[ ]	

Source: EPA (2024a).

[a] 2022 BOY allowances include set-aside allowances.

7. Etching of Semiconductor Material or Wafers and the Cleaning of Chemical Vapor Deposition Chambers Within the Semiconductor Manufacturing Sector

7.1 Overview

The AIM Act instructed EPA to provide ASAs for HFC use in “the etching of semiconductor material or wafers and the cleaning of chemical vapor deposition chambers within the semiconductor manufacturing sector” through 2025. In the Allocation Framework Rule, EPA defined “etching” in the context of semiconductor manufacturing as “a process type that uses plasma-generated fluorine atoms and other reactive fluorine-containing fragments that chemically react with exposed thin films (*e.g.,* dielectric, metals) or substrate (*e.g.,* silicon) to selectively remove portions of material. This includes semiconductor production processes using fluorinated GHG reagents to clean wafers.” EPA defined “chemical vapor deposition chamber cleaning” in the context of semiconductor manufacturing as “a process type in which chambers used for depositing thin films are cleaned periodically using plasma-generated fluorine atoms and other reactive fluorine-containing fragments” (40 CFR 84.3).

HFCs have physical properties that make them well suited for certain aspects of the semiconductor manufacturing process. They are used primarily to create intricate circuitry patterns upon silicon wafers (i.e., dry etching, hereafter referred to as etching), but also minimally to clean chemical vapor deposition (CVD) chambers (UNEP, 2022). Depending on the complexity of the product, the manufacturing process for semiconductors may require upwards of 100 steps utilizing HFCs and other gases (EPA, 2023). Two steps of the semiconductor manufacture process that use HFCs are etching and CVD chamber cleaning; these are the only two uses eligible for ASAs. While HFCs are used during the manufacture of semiconductors, the finished product does not contain HFCs.

Semiconductor devices are critical to the functioning of electronic equipment. They are used to provide logic and memory functions in many electronic appliances as well as social infrastructure (e.g., cellphones, computers, data servers) that support everyday life.

Semiconductors can be classified into four major product groups, primarily based on their function. Some semiconductors have broad functionality, while others are designed for specific use.

- **Microprocessors and logic devices** are used for the interchange and manipulation of data in computers, communication devices, and consumer electronics (CRS, 2020). Microprocessors and logic boards account for 42% of total semiconductor sales worldwide (SIA, 2022a).
- **Memory devices** are used to store information. This segment includes NAND flash memory and dynamic random-access memory (RAM or DRAM) that stores temporary bits of information and is found in smartphones, computers, and flash drives. Memory devices accounted for 28% of global semiconductor sales (SIA, 2022a).
- **Analog devices** are used to translate analog signals, such as light, touch, and voice, into digital signals. For example, they are used to convert the analog sound of musical

performances into a digital recording stored online or on a compact disc (CRS, 2020). Analog devices account for 13% of global semiconductor sales (SIA, 2022a).

- **Optoelectronics, sensors, and discrete** (commonly referred to as O-S-D). Optoelectronics and sensors are used for generating or sensing light while discrete are designed to perform a single electrical function O-S-D account for 17% of total semiconductor sales worldwide (SIA, 2022a).

Since the 1990s, the U.S. semiconductor industry has accounted for a substantial share of global semiconductor sales. In 2022, the United States accounted for 48% of global semiconductor sales, ahead of Republic of Korea (19%), Japan (9%), Europe (9%), Taiwan (8%), and China (7%) (SIA, 2023). However, the United States only produces roughly 12% of the world's semiconductors, compared to 37% in the 1990s. This is fifth in the world, behind Taiwan (22%), Republic of Korea (21%), China (15%), and Japan (15%) in terms of semiconductor manufacturing capacity (Varas et al., 2020). Reasons for this discrepancy include the fact that, as of 2021, U.S. chip exports were the highest price per chip (Hufbauer and Hogan, 2022) and only 43% of U.S.-headquartered firms' front-end semiconductor wafer manufacturing capacity was in the United States (SIA, 2022d).

Thirty-six semiconductor manufacturers received ASAs for 2022, 2023, and/or 2024 to use hydrofluorocarbon (HFCs) in etching/cleaning.[47]

7.1.1 Use of Regulated Substances

The semiconductor industry uses a variety of fluorinated gases during etching and chamber cleaning, including perfluorocarbons (e.g., CF_4, C_2F_6, C_3F_8, and C_4F_8), sulfur hexafluoride (SF_6), nitrogen trifluoride (NF_3), HFCs, and fluorinated heat transfer fluids (EPA, 2023). Semiconductor manufacturers began using three HFCs for semiconductor etching in the mid-1980s with the development of dry etching—HFC-23 (CHF_3), HFC-32 (CH_2F_2), and HFC-41 (CH_3F). Prior to this, wet etching with aqueous chemicals such as HF was the primary method to form chip patterns.

The etching and CVD chamber cleaning processes have both historically utilized HFCs and other fluorinated gases. HFC-23 is commonly used for selective dry etching of silicon dioxide (SiO_2) and silicon nitride (SiN), while HFC-32 and HFC-41 are used in high aspect hole etching (e.g, production of DRAM or NAND) (UNEP, 2022). HFC-23, HFC-32, and HFC-41 may also be minimally used in chamber cleaning processes (IPCC, 2019). These HFCs may be used in recipes with other fluorinated gases, and they may also be used in both the etching and cleaning processes. For example, HFC-32 may be used as an etching and cleaning gas. However, as manufacturing steps are optimized for specific gases, individual HFCs cannot typically be used as drop-in replacements for other HFCs. The percentage of fluorine per molecule and the hydrogen to fluorine ratio are critical factors when determining which chemicals to use, and HFCs are not chemically equivalent in this regard (Peng and Loh, 2014).

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[47] For more information on EPA's HFC allowance allocation program, see here: https://www.epa.gov/climate-hfcs-reduction/hfc-allowances.

HFCs account for 8.9% of GWP-weighted emissions from U.S. semiconductor manufacturing, behind perfluorocarbons (57.8%), sulfur hexafluoride (20%), and nitrogen trifluoride (13.3%) (EPA, 2023).

The physical and chemical characteristics of single-carbon HFCs make them well suited for use in semiconductor etching processes. The carbon and fluorine that these compounds deliver in a plasma are essential when etching advanced integrated circuits because, in addition to etching, they form polymers, which allow for highly selective and anisotropic (directional) film removal (Bartos and Burton, 2000). Single-carbon HFCs have a particularly high fluorine-carbon ratio, which allows for greater etching efficiency of the substrate (Rueger et al., 1997). Additionally, the hydrogen in the HFC input gas may react with the fluorinated silicon substrate, forming a volatile species that enhances etching (Metzler et al., 2016). The high fluorine content of HFCs is also advantageous during CVD chamber cleaning.

7.1.2 Major Manufacturers and Products

A number of domestically headquartered or foreign-owned semiconductor companies currently operate over 90 semiconductor fabrication plants (commonly known as fabs) in the United States (SIA, 2023). The manufacturing output has remained stable for many years (SIA, 2022). Table 18 lists some of the major manufacturers of semiconductors in the United States. Semiconductor fabs are classified as either 300-millimeter (mm) diameter wafer production facilities or 200-mm diameter wafer production facilities (CRS, 2020). Currently, there are more 200-mm fabs than 300-mm fabs within the United States (WFF, 2021).

Table 18. Some Major Manufactures of Semiconductors in the United States[a]

Company[b]	Number of Fabs	Products
Intel Corporation	8	Logic/Microprocessor Unit
Samsung	2	Foundry/IDM
TSMC	1	Foundry
Micron Technology	4	Memory/Flash/DRAM
GlobalFoundries	4	Foundry/Dedicated
Texas Instruments	2	Analog/Linear

Sources: CSR (2020); SIA (2023)

[a] As of December 2023, many of the companies in this table are among the top 15 largest semiconductor suppliers worldwide by market cap, and all are ASA holders (companiesmarketcap.com, 2023).

7.2 Availability of Safe, Technically Achievable Substitutes

Based on information available to EPA at this time, EPA is proposing that a safe or technically achievable substitute will not be available during 2026 through 2030 for HFC use in the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

7.2.1 Current Status

In addition to HFCs, the semiconductor manufacturing processes of etching and chamber cleaning also commercially utilize other fluorinated gases, such as saturated perfluorocarbons (PFCs), sulfur hexafluoride (SF_6), and nitrogen trifluoride (NF_3), many of which have higher

GWPs and lower utilization rates (i.e., higher emission rate) than HFCs (UNEP, 2022). In etching processes, HFCs are commonly used alongside other fluorinated gases (Peng and Loh, 2014). In chamber cleaning, NF_3, hexafluoroethane (C_2F_6), and SF_6 are the primary gases used due to their high fluorine content, but some companies have reported the use of HFCs in these processes (GHGRP, 2023).

The TEAP’s Medical and Chemical Technical Options Committee assessed these gases, along with new gases, to provide information on the technological feasibility, environmental impact, economic viability, among other factors, of alternatives to HFCs (see Table 19). However, these alternative gases are not drop-in replacements for HFCs and require significant investments from fabs to substitute existing chemicals. In addition, these alternative gases also have specific use cases (e.g., etching of different substrate materials) and multiple different alternatives might be required to replace the function of a single HFC gas (UNEP, 2022). Similarly, fabs have highly unique processes, which makes the adoption of specific chemicals across the industry difficult. Table 19 summarizes the HFCs currently in use in semiconductor manufacturing and lists potential alternatives, along with their atmospheric, flammability, and human health impacts.

Several challenges to developing or identifying new substitutes to HFCs persist, including the chemical selectivity HFCs offer in manufacturing processes and the effort and cost associated with research and development. In order to switch input gases for etching processes, several systems have to be specifically installed for each gas type, including piping, flow controllers, and exhausts (Sarangan, 2016). Industry has noted that semiconductor technologies may require at least 10 years from fundamental research to high volume manufacturing to innovate and implement new technologies and their associated raw materials (SIA, 2022c; McKinsey, 2022). Additionally, technologies are typically tailored for use by individual manufacturers, and sales between industry competitors are rare (IRDS, 2020).

Table 19. Atmospheric, Flammability, and Human Health Characteristics of HFCs and Potential Substitutes in Semiconductor Manufacturing

Chemical	ODP[a]	100-year GWP[b]	Flammability[c]	Human Health[d]	Description of Use and Challenges
HFC Currently in Use					
HFC-23 (CHF_3)[e]	0	14,800	Nonflammable	• Asphyxiant • Short-term exposure may adversely impact cardiovascular system, potentially resulting in cardiac disorders	Used in etching of SiO_2, and SiNX. Used minimally in chamber cleaning.
HFC-32 (CH_2F_2)[f]	0	675	Mildly flammable	• Asphyxiant	Used in etching of SiO_2, and SiNX. Used minimally in chamber cleaning.
HFC-41 (CH_3F)	0	92	Flammable	• Asphyxiant	Used in high-aspect hole etching. Not used in chamber cleaning.
Commercially Available and Technically Proven Alternatives					
SF_6	0	22,800	Flammable[g]	• Asphyxiant	Used in etching of Si, SiO_2, and SiNX, and chamber cleaning.
NF_3	0	17,200	May cause or intensify fire; oxidizer[h]	• No relevant toxicity concerns	Used in etching of Si and Si_3N_4, and chamber cleaning.
Saturated PFCs (CF_4, C_2F_6, c-C_4F_8)	0	7,390-12,200	Flammable[g]	• Asphyxiants • Short-term exposure may adversely impact cardiovascular system, potentially resulting in cardiac disorders[i]	Used in etching of Si, TiN, organics (e.g., CF_4, c-C_4F_8) and chamber cleaning (e.g., C_2F_6); Difficult to abate and issues with utilization rate.
HFC-125 (CF_3CHF_2)[j]	0	3,500	Nonflammable[g]	• Asphyxiant	Used minimally in high aspect hole etching.
HFC-134a (CH_2FCF_3)[j]	0	1,430	Flammable[g]	• Asphyxiant • Short-term exposure may adversely impact cardiovascular system	Used minimally in high aspect hole etching.
Unsaturated PFCs (C_4F_6, C_5F_8)	0	<2	Highly Flammable[k]	• Asphyxiants • C4F6: fatal if inhaled[k]	Used in high aspect hole etching. Not widely adopted.
Not Technically Proven Alternatives					
Trifluoroiodomethane (CF_3I)	0	0.4	No data[i]	• Suspected of causing genetic damage to human germ cells[i]	Used for etching of SiO2 and SiNx. Not widely adopted.

Carbonyl Sulfide (COS)	0	27	Highly Flammable	- Inhalation or absorption through skin may be fatal	Etching for NAND and DRAM; Issues with safety and ease of use; Very flammable and toxic.
HFO-1336mzz(E) ($CF_3CH=CHCF_3$)	0	18	Nonflammable	- No relevant toxicity concerns	Studied as replacement to CF_4 in etching; Not technically proven.
PFC-1216 (C_3F_6)	0	<1	Flammable[g]	- Asphyxiant - Suspected carcinogen[k]	Studied for use in etching SiO_2; Not technically proven.
Chlorine trifluoride (ClF_3)	0	0	May cause or intensify fire; oxidizer[h]	- No relevant toxicity concerns	Chamber cleaning in low pressure systems; Extremely flammable.
Hexafluoroisobutylene (HFIB) ($CH_2=C(CF_3)_2$)	0	~3	Not classified[k]	- Suspected of causing genetic damage to human germ cells - Toxic if inhaled[k]	Studied for use in etching of trench holes, trench gates, etc. of Si substrates; Not technically proven.[l]
Fluorine (F_2)	0	0	May react with combustible materials to cause fire.	- Inhalation may be fatal - Contact with skin may cause injury - Chronic absorption through skin may cause osteosclerosis and ligament calcification - Vapors are extreme skin and eye irritants	Explored as replacement to NF_3 in chamber cleaning; Very aggressive and low selectivity; Challenges with transport, storage, and use due to high reactivity and toxicity.[m]

Adapted from UNEP (2022), unless otherwise specified.

[a] WMO (2022).

[b] IPCC (2007). Values are numerically equal to the exchange values listed in the AIM Act.

[c] NOAA CAMEO Chemicals Database, unless otherwise specified.

[d] NOAA CAMEO Chemicals Database, International Labour Organization ICSCs, and T3DB, unless otherwise specialized.

[e] Classified by ASHRAE Standard 34 as a Class A1 refrigerant, meaning it does not propagate a flame and has lower toxicity (ASHRAE, 2022).

[f] Classified by ASHRAE Standard 34 as a Class A2 refrigerant, meaning it has lower flammability and lower toxicity (ASHRAE, 2022).

[g] May burn but does not readily ignite.

[h] Nonflammable but increases flammability of other substances. Vessels may explode when heated.

[i] Human health impacts were assumed to be the same for all saturated PFCs.

[j] Bartos and Burton (2000); Tsai (2005); Hudson and Roberts (2017).

[k] ECHA (2024).

[l] Choi et al. (2023).

[m] Cigal et al. (2016).

7.2.2 Relevant Regulations and Standards

EPA has identified some applicable regulations and standards in the semiconductor industry at the different steps in the supply chain. The Occupational Safety and Health Administration (OSHA) establishes standards to protect workers. For example, while HFCs are not considered hazardous, OSHA Standard 29 CFR 1910.119: Process Safety Management of Highly Hazardous Chemicals contains requirements for the management of hazards associated with highly hazardous chemicals and may be applicable to the etching and CVD chamber cleaning manufacturing processes (OSHA, 2023). Similarly, the National Fire Protection Association (NFPA) Standard 318-2022: Standard for The Protection of Semiconductor Fabrication Facilities, establishes protocols for protection against fire and related hazards in areas where hazardous chemicals are used (NFPA, 2022).

7.3 Supply of Regulated Substances

Etching and chamber cleaning processes require the use of technical grade HFCs, which are purified from raw material (e.g., HFC-23, HFC-32, and HFC-41) and supplied to semiconductor manufacturers.

Based on information available to EPA at this time, EPA is proposing the supply of both HFC-23 and HFC-41 for use in the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector are insufficient to accommodate the application during 2026 through 2030. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

7.3.1 Purification Process and Requirements

Semiconductor etching and CBD chamber cleaning requires HFCs to be used in precise quantities, high purity, and under carefully controlled process conditions to achieve the desired results. The raw HFC material is produced at a grade of around 95–97% purity at 30,000–50,000 parts per million (ppm) of impurities (SIA, 2021). This raw product is then passed downstream to purifiers and refiners in the supply chain. The HFC typically needs to be purified to 99.999–99.9999% or 1–10 ppm of impurities before it can be used by semiconductor manufacturers; however, this varies by company as there is no set industry standard.

Some testing standards have been established to ensure compliance for a variety of manufacturing steps and equipment components. ASTM International *Standard F1398-93(2020): Standard Test Method for Determination of Total Hydrocarbon Contribution by Gas Distribution System Components*, establishes protocols for contamination control within gas delivery systems (ASTM International, 2020). Gas delivery systems are crucial during the etching and CVD chamber cleaning steps, both of which may use HFCs.

Neither the producers of HFCs nor the end users (i.e., semiconductor manufacturers) are capable of purifying HFCs to the necessary level. Supplying refined HFCs to end users can take up to one year, as purifiers require long lead times. There are few current domestic refiners that supply purified HFCs to semiconductor manufacturers (Electronic Fluorocarbons, 2021). The purification process also necessarily results in losses of HFCs. One refiner estimates that 1.06 kilograms of raw HFCs are required to produce 1.0 kilograms of semiconductor grade HFC

(Adams, 2021), which represents 5.7% in losses. Another HFC producer estimated HFC purification loss rates above 10% (EPA, 2021).

7.3.2 Use of Recovered and Reprocessed Material

Semiconductor manufacturers indicated that it might be possible to use reclaimed HFCs in the future, though they did not indicate that reclaim is currently happening or feasible (EPA, 2024a). Purity standards for HFCs used for etching and chamber cleaning set by semiconductor manufacturers are generally stricter than those for the air conditioning and refrigeration industry. Reclaimed HFC gas is primarily sourced from the largest users of HFC gas, the refrigeration and air conditioning sector, and is often contaminated with certain impurities like oils, other HFCs, HCFCs, or CFCs (e.g., from equipment that has been retrofitted). Reclaimers process these reclaimed gases to industry standards for refrigeration and air conditioning equipment, which has a relatively high tolerance for impurities. As explained in Section 5.3.2, AHRI has standards that EPA has adopted as part of its regulatory requirements (40 CFR 84.3 and 40 CFR 84.5(i)(3)(ii)). AHRI and EPA have set a maximum allowable level of contaminants at 0.5%;[48] as noted above, tolerance levels in the semiconductor industry are significantly lower (i.e., 0.001–0.0001%). However, EPA is currently unaware of a reason why recovered and reprocessed HFCs could not be purified to this level. In addition, although it is possible to capture the unreacted process gases used in semiconductor manufacturing, the reclamation of fluorinated gases from the semiconductor manufacturing process is not currently economically viable (UNEP, 2022).

7.3.3 Available Supply

The producers of these HFCs in the United States are Chemours (HFC-23), Arkema (HFC-32), and Iofina Chemical (HFC-41). In 2022, there were also seven importers of HFC-23, 16 importers of HFC-32, and five importers of HFC-41 (Table A2).

HFCs for semiconductor etching and chamber cleaning in the United States are currently supplied and/or purified by multiple companies located in the United States and abroad, namely Air Liquide, Electronic Fluorocarbons, Iofina, Linde, Matheson Tri-Gas, Resonac, and Versum Materials (Air Liquide, 2024; Electronic Fluorocarbons, 2024; Iofina, 2024; Linde, 2024; Matheson Tri-Gas, 2024; Resonac, 2024; EMD Electronics, 2024). Table 20 shows these companies' roles in the United States HFC supply chain.

Table 20. Companies Supplying HFCs for Use in U.S. Semiconductor Manufacturing

Company	Role	Company Headquarters
Iofina[a]	[ ]	U.S.
Matheson Tri-Gas	[ ]	U.S. (Global subsidiary)
Air-Liquide	[ ]	France
Linde	[ ]	Germany
Resonac	[ ]	Japan
Versum	[ ]	U.S. (Global subsidiary)

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[48] The Air-Conditioning, Heating & Refrigeration Institute (AHRI) Standard 700 specifies the allowable levels of contaminants for each refrigerant and EPA has established purity requirements for refrigerants based on that standard. The specifications can be found in appendix A to 40 CFR part 82, subpart F.

Electronic Fluorocarbons	[ ]	U.S.

Source: Air Liquide (2024); Electronic Fluorocarbons (2024); EPA (2024a); Iofina (2024); Linde (2024); Matheson Tri-Gas (2024); Resonac (2024); EMD Electronics (2024).
[a] [ ]

These companies also participate in the global HFC supply chain for semiconductor manufacturing, exporting HFC-23, HFC-32, and HFC-41 to Argentina, Belgium, Brazil, Canada, China, Ireland, Israel, Mexico, Netherlands, Singapore, Republic of Korea, Taiwan, and Vietnam (EPA, 2024a).[49,50,51]

EPA identified that in 2022, 5.2 MT of HFC-23 were produced in the United States, 125.6 MT were imported, 26.9 MT were exported, and [ ] were reclaimed. Additionally, 304 MT of HFC-23 were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022,[52] resulting in an available supply of 407.9 MT of HFC-23 in the United States that year (Table A1).[53]

For HFC-32, 17,744.3 MT were produced in the United States, 9,885.3 MT were imported, 964.2 MT were exported, and [ ] were reclaimed in 2022. Additionally, 21,435 MT of HFC-32 were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022, [54] resulting in an available supply of 48,100.4 MT of HFC-32 in the United States in 2022 (Table A1).[55]

For HFC-41, 22.2 MT were produced in the United States, 38.3 MT were imported, 15.9 MT were exported, and no material was reclaimed in 2022. Additionally, 26.7 MT of HFC-41 were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022, resulting in an available supply of 71.3 MT of HFC-41 in the United States in 2022 (Table A1). The global production capacity for HFC-41, HFC-32, and HFC-23 in 2020 is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020). Data on the availability of purified HFC-41, HFC-32, and HFC-23 are not available.

7.3.4 Application's Projected Demand of HFCs

Overall, reported HFC-23, HFC-32, and HFC-41 use in semiconductor etching and chamber cleaning each increased between 2018 and 2021, but decreased in 2022 and 2023 (see Table 21 for a summary of HFC use in kilograms). This trend is reflected by the change in the

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[49] HFC-23 and HFC-41 are primarily used in semiconductor manufacturing; therefore, it is presumed that export of these HFCs is for the semiconductor sector. HFC-32 can also be used as a refrigerant, so export data were analyzed to determine which companies receiving HFC-32 are likely in the semiconductor sector.

[50] In addition to exporting directly to semiconductor companies, [ ] export to their own facilities abroad (EPA, 2024a). EPA is unaware how these HFCs are used; however, it is possible that they are being exported as raw material for purification and sold for semiconductor manufacturing abroad.

[51] Includes blends in which HFC-23 is the only HFC component.

[52] Includes HFC blend components as HFC blends are disaggregated in inventory reporting under current EPA reporting requirements.

[53] Any quantities reclaimed in 2022 are not included in the calculation of available supply for HFC-23 given confidentiality considerations.

[54] Includes HFC blend components as HFC blends are disaggregated in inventory reporting under current EPA reporting requirements.

[55] Any quantities reclaimed in 2022 are not included in the calculation of available supply for HFC-32 given confidentiality considerations.

semiconductor manufacture three-year AAGR[56] calculated by EPA for the purposes of allowance allocations. The 2018–2020 semiconductor etching and chamber cleaning AAGR was 12%, the 2019–2022 AAGR was 20%, and the 2020–2023 AAGR was 3% (EPA, 2024a).[57,58]

Table 21. Historic HFC-23, HFC-32, and HFC-41 Use in Semiconductor Manufacture (kg), 2018-2023

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
HFC-23						
Analog Devices	[ ]					
Apple Inc.						
Applied Materials						
ASML US LLC						
Broadcom						
Diodes Incorporated						
General Electric						
GlobalFoundries						
Hitachi High-Tech America, Inc.						
IBM Corporation						
Intel Corporation						
Jireh Semiconductor						
Keysight Technologies						
LA Semiconductor						
Lam Research Corp.						
Medtronic Tempe Campus						
Microchip Technology, Inc.						
Micron Technology						
Newport Fab DBA TowerJazz						
Northrop Grumman Corporation						
NXP Semiconductor						
Polar Semiconductor						
Qorvo Texas						
Renesas Electronics America Inc.						
Samsung Austin Semiconductor						
Semiconductor Components Industries DBA ON Semiconductor						
SkyWater Technology						

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[56] AAGR = $[(\frac{Year\ 2\ HFC\ purchases}{Year\ 1\ HFC\ purchases} - 1) + (\frac{Year\ 3\ HFC\ purchases}{Year\ 2\ HFC\ purchases} - 1)] \times \frac{1}{2}$

[57] 2019–2022 spans the second half of 2019 through the first half of 2022, and 2020–2023 spans the second half of 2020 through the first half of 2023.

[58] The AAGRs are derived from reported, verifiable data. Therefore, they do not reflect data from companies with missing reports or documentation.

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
Skyworks Solutions						
Taiwan Semiconductor Manufacturing Company Arizona Corporation (TSMC Arizona Corporation)						
Texas Instruments						
The Research Foundation for The State University of New York OBO SUNY Polytechnic Institute						
Tokyo Electron America						
Tower Semiconductor San Antonio						
WaferTech						
Wolfspeed, Inc.						
X-FAB Texas						
Total (kg)	***45,504***	***51,746***	***59,842***	***90,469***	***84,129***	***69,304***
HFC-32						
Analog Devices				[ ]		
Apple Inc.						
Applied Materials						
ASML US LLC						
Broadcom						
Diodes Incorporated						
General Electric						
GlobalFoundries						
Hitachi High-Tech America, Inc.						
IBM Corporation						
Intel Corporation						
Jireh Semiconductor						
Keysight Technologies						
LA Semiconductor						
Lam Research Corp.						
Medtronic Tempe Campus						
Microchip Technology, Inc.						
Micron Technology						
Newport Fab DBA TowerJazz						
Northrop Grumman Corporation						
NXP Semiconductor						
Polar Semiconductor						
Qorvo Texas						
Renesas Electronics America Inc.						

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
Samsung Austin Semiconductor						
Semiconductor Components Industries DBA ON Semiconductor						
SkyWater Technology						
Skyworks Solutions						
Taiwan Semiconductor Manufacturing Company Arizona Corporation (TSMC Arizona Corporation)						
Texas Instruments						
The Research Foundation for The State University of New York OBO SUNY Polytechnic Institute						
Tokyo Electron America						
Tower Semiconductor San Antonio						
WaferTech						
Wolfspeed, Inc.						
X-FAB Texas						
Total (kg)	***5,558***	***6,576***	***7,202***	***9,764***	***8,144***	***6,958***
HFC-41						
Analog Devices	[ ]					
Apple Inc.						
Applied Materials						
ASML US LLC						
Broadcom						
Diodes Incorporated						
General Electric						
GlobalFoundries						
Hitachi High-Tech America, Inc.						
IBM Corporation						
Intel Corporation						
Jireh Semiconductor						
Keysight Technologies						
LA Semiconductor						
Lam Research Corp.						
Medtronic Tempe Campus						
Microchip Technology, Inc.						
Micron Technology						
Newport Fab DBA TowerJazz						
Northrop Grumman Corporation						

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
NXP Semiconductor						
Polar Semiconductor						
Qorvo Texas						
Renesas Electronics America Inc.						
Samsung Austin Semiconductor						
Semiconductor Components Industries DBA ON Semiconductor						
SkyWater Technology						
Skyworks Solutions						
Taiwan Semiconductor Manufacturing Company Arizona Corporation (TSMC Arizona Corporation)						
Texas Instruments						
The Research Foundation for The State University of New York OBO SUNY Polytechnic Institute						
Tokyo Electron America						
Tower Semiconductor San Antonio						
WaferTech						
Wolfspeed, Inc.						
X-FAB Texas						
Total (kg)	***6,113***	***7,133***	***8,890***	***11,437***	***9,619***	***7,869***
Total (MTEVe)	***677,772***	***770,978***	***891,341***	***1,346,586***	***1,251,487***	***1,031,122***

Source: EPA (2024a).

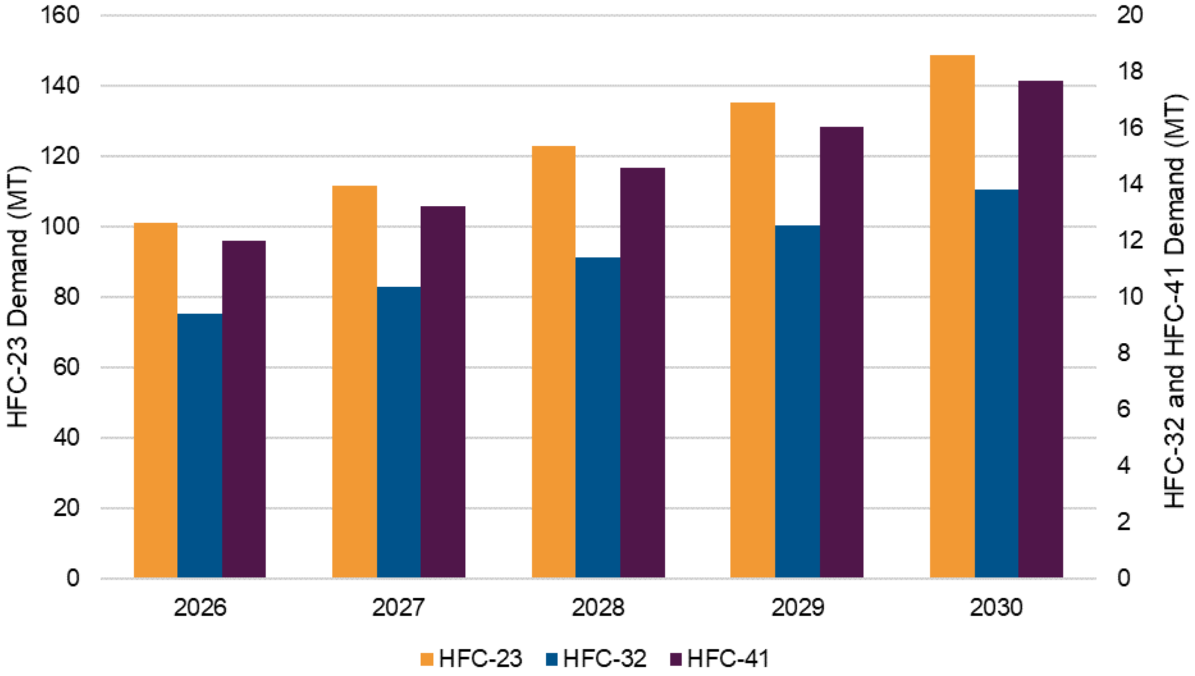
[a] Calculated as the sum of HFC held in inventory (previous period) + HFC acquired through conferrals + HFC imported using allowances + HFC purchased – HFC held in inventory (current period).

As discussed above, HFC use in semiconductor etching and CVD chamber cleaning is projected to continue. Between 2013 and 2020, global consumption of HFC-23 had an AAGR of 15% (UNEP, 2022). The use of HFCs and other fluorinated GHGs in semiconductor etching and chamber cleaning has two main drivers: the production of semiconductors and the complexity of semiconductor devices (e.g., the number of mask layers per wafer). Similarly, the consumption of both HFC-32 and HFC-41 is expected to increase rapidly due to their use in high aspect hole etching (e.g., manufacturing of DRAM, NAND). Production of semiconductors is expected to increase because of their fundamental role in enabling technological innovation throughout the economy. Many growth areas for the U.S. economy, including electric vehicles, Internet of Things, clean energy, and others, are enabled by semiconductor technology (SIA, 2021).

The Creating Helpful Incentives to Produce Semiconductors (CHIPS) Act of 2022 has allocated over 50 billion dollars to semiconductor research, development, manufacturing, and workforce development in the United States, which has spurred additional investment by semiconductor manufacturers (White House, 2022a). The Semiconductor Industry Association (SIA), a semiconductor trade association, lists the number of U.S.-based semiconductor projects that are under way, announced, or under consideration, totaling them at over 190 billion dollars through 2030 and distributed among over 35 new fabs and facility expansions (SIA, 2023).

Investment spurred by the CHIPS Act is expected to increase the global market share of U.S. semiconductor manufacturing. For example, the U.S. market share of memory chip production is projected to grow from less than 2% to up to 10% over the next decade. Worldwide, it is predicted that demand will continue to grow and that semiconductors will become a 1 trillion-dollar industry by 2030 (White House, 2022b; McKinsey, 2023). EPA projected future HFC use in the United States by using reported average 2021 to 2023 HFC purchases and the average annual growth in HFC usage in semiconductor production over the period of 2011 to 2019 of 10.1 % (SIA, 2021; Figure 6).

Figure 6. Projected Semiconductor HFC Demand (MT), 2026-2030



As transistor technology improves, the number of mask layers per wafer has increased, which leads to an increase in process steps that require fluorinated gases, including HFCs (SIA, 2021). The introduction of 450mm wafers in the United States has also been under consideration by the industry for many years, which could change the industry's current patterns of fluorinated GHG use. However, due to its significantly higher costs and need for specialized equipment, it is not anticipated that widespread U.S. manufacturing of 450mm will occur in the near future (Hruska, 2017; Robinson, 2022).

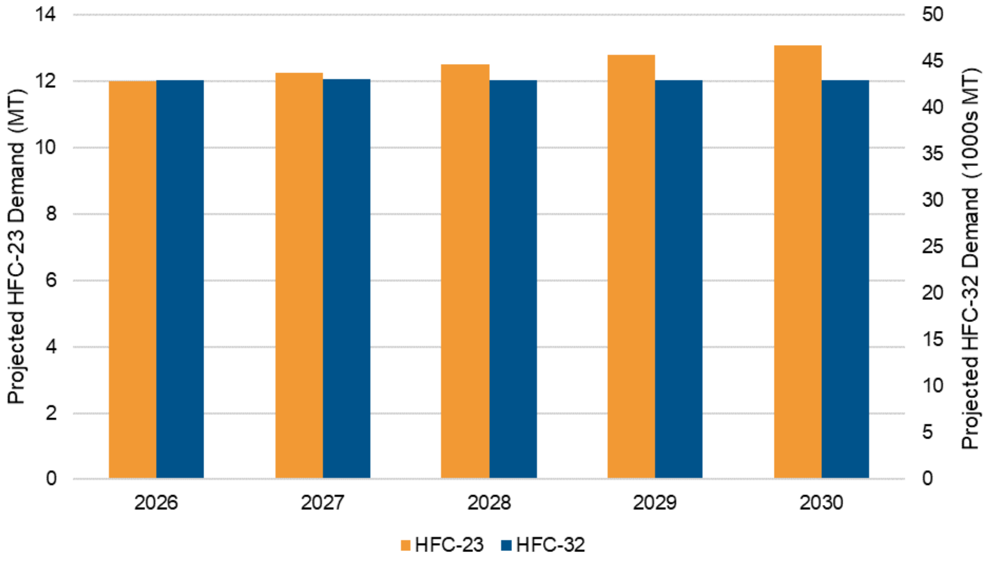
National security interests and global competition within the semiconductor industry has resulted in recent regulations limiting the trade of domestic product. In October 2023, the U.S. Commerce Department announced two new rules that update and expand the Export Administration Regulations (EAR) controls, which restrict the export of semiconductor products and components (e.g., certain equipment designed for epitaxial growth, advanced fabrication equipment designed for metal deposition of the barrier layer, and equipment designed for ion-beam or physical vapor deposition), particularly to China (Covington, 2023). Rules such as these may impact future growth of the semiconductor industry in the United States.

7.3.5 Anticipated Regulatory Impacts on Supply

As noted in Section 3.1.2, EPA's Technology Transitions Program is establishing GWP limits, which in turn will limit the use of certain refrigerant blends that include HFC-32 (e.g., R-410A, R-407A, R-407C) in many end uses as early as January 1, 2025; however, HFC-32 has a GWP below certain regulatory limits and likely will be used in certain sectors and subsectors. HFC-23 is used primarily in fire suppression and very low temperature refrigeration. Demand for HFC-23 is less likely to be influenced by the 2023 Technology Transitions Rule. EPA's Vintaging Model estimates that the refrigeration and air-conditioning market used 40,423 MT of HFC-32 and the fire suppression sector used 11 MT of HFC-23 in 2023 (EPA, 2016). ASA holders' use of HFC-32 in semiconductor manufacturing constitutes approximately 0.02% of the refrigeration and air-conditioning HFC-32 market, at 7 MT or 0.05 MMTEVe of HFC-32 in 2023 (EPA, 2024a). ASA holders' use of HFC-23 in semiconductor manufacturing is significantly larger than the fire suppression HFC-23 market, at 69 MT or 1.0 MMTEVe of HFC-23 in 2023 (EPA, 2024a). HFC-41 is almost exclusively being used for semiconductor etching and cleaning. Demand for this chemical is not expected to be affected by the 2023 Technology Transitions Rule.

The 2023 Technology Transitions Rule together with expected reductions associated with the HFC consumption and production phasedown under the AIM Act and market trends and planned transitions more generally are estimated to prevent approximately 530 MT and 1,357 MT of HFC-32 demand from impacted products in 2026 and 2030, respectively, or 1.2% and 3.1% reduction in projected demand across all uses of HFC-32, relative to the BAU pre-Allocation Rule demand. This reduction in projected demand may lead to an increase in available supply, which could be used to help meet future demand for HFC-32 in semiconductor etching and chamber cleaning. The 2023 Technology Transitions Rule is not expected to significantly affect the use of HFC-23 or HFC-41, as noted above. Figure 7 presents projected demand of HFC-32 and HFC-23.

Figure 7. Projected Demand (MT) for HFC-32 and HFC-23, 2026-2030



As mentioned in Section 3.1.3, increased use of reclaimed HFCs in other applications due to the proposed Emissions Reduction and Reclamation Rule could also make an additional supply of virgin HFC-32 or HFC-23 available to meet future demand in semiconductor manufacturing (where reclaim is feasible).

7.3.6 Allowance Usage, Conferrals, and Inventory

As noted below, EPA issued 1,580,677.2 MTEVe of ASAs for semiconductor manufacture for 2022, 1,898,622.7 MTEVe of semiconductor ASAs for 2023, and 1,830,343.7 MTEVe of semiconductor ASAs for 2024.

ASA holders reported acquisition of HFC-23, HFC-32, and HFC-41 through conferrals to producers [ ] or through domestic purchases that did not require expending or conferring allowances (Table 22).

Table 22. Purchases and Inventory (kg) of HFC-23, HFC-32, and HFC-41 to ASA Holders in 2022 and 2023

HFC	Report Period	Acquired through Conferrals and Imported Using Allowances	Purchased without Expending or Conferring Allowances	Held in Inventory at End of Period	% of HFC Acquired through Expending or Conferring Allowances
HFC-23	2022	59,228	22,789	10,682	72%
	2023	59,089	5,616	10,324	91%
HFC-32	2022	3,599	4,337	2,378	45%
	2023	2,812	3,293	2,175	46%
HFC-41	2022	9,236	407	970	96%
	2023	7,447	210	1,126	97%

Source: EPA (2024a).

In addition, Table 22 shows the amount of HFC inventory held by semiconductor ASA holders. Between EOY 2022 and EOY 2023, inventory was drawn down for HFC-23 and HFC-32 but built up for HFC-41. Inventory of HFC-23 decreased by about 3% from approximately 10,700 kilograms at the end of 2022 to approximately 10,300 kilograms at the end of 2023. Inventory of HFC-32 decreased by about 9% from approximately 2,400 kilograms at the end of 2022 to approximately 2,200 kilograms at the end of 2023. Inventory of HFC-41 increased by about 16% from approximately 970 kilograms at the end of 2022 to approximately 1,126 kilograms at the end of 2023. Table 23 summarizes 2022 and 2023 application-wide aggregate allowances balance and activity for semiconductors, including BOY levels, EOY levels, quantities of allowances conferred, and quantities of allowances expended. Approximately 39% of ASAs remained unexpended for semiconductors at the end of 2022, and 39% remained unexpended at the end of 2023. End users conferred, transferred, or expended approximately 61% of allocated allowances in both 2022 and 2023. EOY or leftover allowances indicate that 1) application-specific end users did not expend all of their allocated allowances (and may have just purchased from domestic suppliers without expending allowances; Table 23) and/or 2) importers/producers that were conferred allowances did not use them all.

Table 23. Allowances for Semiconductor Manufacture (MTEVe)

	2022	2023
BOY Allowances	1,580,677.2[a]	1,898,622.70
Quantity ASA Holders Conferred and Expended Directly to Import	956,740.10	1,160,565.30
Quantity Expended by Supplier	999,760.40	1,284,466.60
EOY Allowances – End Users	623,937.20	738,057.40
EOY Allowances % Remaining – End Users	39%	39%
EOY Allowances – Suppliers and Intermediaries	-43,020.4[b]	-123,901.3[b]
EOY Allowances % Remaining – Suppliers and Intermediaries	20%[c]	5%[c]

Source: EPA (2024a, 2023).

[a] 2022 BOY allowances include set-aside allowances.

[b] EPA has issued administrative consequences and taken enforcement action for entities that imported without allowances for semiconductor use without having the requisite ASAs.

[c] Removing quantities of HFCs that were imported without the requisite number of ASAs.

8. Onboard Aerospace Fire Suppression

8.1 Overview

In the Allocation Framework Rule, EPA defined onboard aerospace fire suppression as “use of a regulated substance in fire suppression equipment used on board commercial and general aviation aircraft, including commercial-derivative aircraft for military use; rotorcraft; and space vehicles.” Onboard commercial aviation fire suppression systems are installed throughout mainline and regional passenger and freighter aircraft, including engine nacelles, auxiliary power units (APUs), lavatory trash receptacles, baggage/crew compartments, and handheld extinguishers (40 CFR 84.3).

Onboard commercial aviation fire suppression systems, which have historically used halons, are installed to protect valuable and sensitive assets (International Civil Aviation Organization [ICAO], 2016; ICAO, 2019a). Commercial-derivative aircraft include those aircraft intended for sale to military customers that are built using commercial aircraft designs modified for military use, or those aircraft built to commercial specifications and then modified for military use (Boeing, 2021b).

Fire suppression systems on board aircraft have historically used halons, namely halon 1301 and halon 1211, and the majority of these systems continue to do so; however, some onboard aircraft fire suppression systems have transitioned to HFCs, specifically HFC-227ea, HFC-236fa, and HFC-125 (UNEP, 2018; Robin, 2011; and UNEP, 2022).

Fire suppression systems on board aircraft can be divided into two main product categories:

- **Total flooding systems** are designed to automatically discharge a fire extinguishing agent by detection and related controls (or manually by a system operator) and achieve a specified minimum agent concentration throughout a confined space (i.e., volume percentage of the agent in air).
- **Streaming applications** use portable fire extinguishers that can be manually manipulated to discharge an agent in a specific direction and release a specific quantity of extinguishing agent at the time of a fire.

Fires caused by fuels found on aircraft (i.e., ordinary combustibles, flammable liquids, energized electrical equipment) are classified as Class A, B, or C, as defined in Table 24 (FEMA, 2015).

Table 24. Relevant Classifications of Fire Types in the United States Based on Fuel Hazard

Symbol	Fire Type Classification	Fuel
	Class A	Ordinary combustibles (e.g., wood, paper, plastics)

Symbol	Fire Type Classification	Fuel
	Class B	Flammable liquids (e.g., gasoline, petroleum oil and paint) and flammable gases (e.g., propane, butane)
	Class C	Energized electrical equipment (e.g., motors, transformers, appliances)

Source: FEMA (2015).

Total flooding systems are used in both normally occupied and unoccupied areas in onboard aerospace fire suppression. Total flooding systems on aircraft include engine nacelles, APUs,[59] cargo compartments, and lavatory trash receptacles (Robin, 2011):

- **Engine nacelles and APUs**: Total flooding systems in engine nacelles and APUs typically protect against Class B fires. Due to the proximity to fuels and other volatile fluids, the requirements for fire suppression systems for engine nacelles and APUs are especially challenging (UNEP, 2018b). These fire suppression systems are often deployed at high altitudes (and low temperatures), so the suppression agent must be highly volatile at low temperatures. These unique operating requirements are especially stringent for fire suppression systems for engine nacelles and APUs (UNEP, 2022). Engine fire suppression systems involve two bottles of high-pressure fire extinguishing agent that can serve two different engines, though there are models that have independent bottles that serve each engine. They are typically located in the wing, fuselage, strut, or pylon, and are connected to the engine via distribution tubing (Hariram, Phillipp, and Dummeyer, 2010). APU fire extinguishing systems are comprised of a bottle of extinguishing agent located on the other side of a firewall that isolates the APU from the rest of the aircraft, which discharges the agent into the APU through tubing. Both engine and APU fire suppression systems are controlled from the flight deck (Hariram, Phillipp, and Dummeyer, 2010).
- **Cargo compartments**: Total flooding systems in cargo compartments must be able to suppress Class A and Class B fires and must have sufficient ability to continue to provide fire suppression and safety from the initial fire warning through landing, often over 350 minutes. A rapid discharge of fire extinguishing agent is deployed to suppress the fire when first detected and is followed up by a slow-release discharge to maintain a steady concentration of suppressant until the plane lands (UNEP, 2022). These systems

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[59] The APU is a small turbine engine installed near the rear of an aircraft and serves as an additional energy source normally used to start one of the main engines on an airliner or business jet. The APU is equipped with an extra electrical generator to create enough power to operate onboard lighting, galley electrics, and cockpit avionics, usually while the aircraft is parked at the gate (FlyingMag, 2018).

are activated by the flight crew when detectors indicate that there is a fire in the cargo compartment (Federal Aviation Administration [FAA], 2008; Aircraft Systems Tech, N.d.). Additionally, performance standards are being updated to require that total flooding systems in cargo compartments be able to suppress fires caused by the transport of lithium-ion batteries, liquid fuel, ethanol, and cardboard boxes with shredded office paper (UNEP, 2022). EPA is not aware when these updates will be finalized.

- **Lavatory trash receptacles**: Total flooding systems in lavatory trash receptacles are meant to extinguish trash receptacle fires in pressurized cabins' lavatories in the case of a Class A fire (ICAO, 2016; ICAO, 2019a; UNEP, 2022). These systems traditionally involve a bottle filled with pressurized fire extinguishing agent that is discharged when a certain heat threshold is reached. The heat melts the solder that seals the nozzles of the bottle, discharging the agent. Charge sizes for lavatory trash receptacle fire extinguishing systems are small, with one bottle containing between 115 to 150 grams of HFC-227ea (Kidde, n.d.; FFE Limited, n.d.).

Streaming applications in onboard aerospace fire suppression include portable fire extinguishers designed to protect against specific hazards. Portable fire extinguishers are intended as a first line of defense for fires of limited size. The selection and installation of extinguishers is independent of whether an area is equipped with a total flooding fire suppression system (NFPA, 2013). The amount of fire extinguishing agent in streaming applications ranges depending on the size of the extinguisher. For example, handheld extinguishers manufactured by Amerex range from a capacity of 87 grams to 567 grams of 2-bromo-3,3,3-trifluoropropene (2-BTP) (Amerex, 2022).

EPA directly issued ASAs to two companies for 2022, 2023, and 2024 to use HFCs in onboard aerospace fire suppression: Proteng Distribution and RTX Corporation (formerly known as Raytheon Technologies).[60]

8.1.1 Use of Regulated Substances

Onboard fire suppression systems have historically used and predominantly still use halons, a class of halogenated chemicals containing bromine, as clean extinguishing agents (i.e., those that do not leave residue following system discharge) to protect valuable and sensitive assets (UNEP, 2018; ICAO, 2016; ICAO, 2019a). Halons have a combination of characteristics that make them good fire suppressants, including being electrically non-conductive, dissipating rapidly without residue (i.e., clean), efficiently extinguishing most types of fires, and having low toxicity. Historically, halon 1301 has been used in total flooding systems and halon 1211 in streaming agents. However, the United States phased out the production and import of virgin halons in 1994 due to their high ODP. Recycled halons have been the only supply of halons in the United States for over 30 years and still comprise the majority of installed fire suppression capacity on most aircraft. Industry has made extensive efforts to identify alternatives to halons particularly with recent estimates from the TEAP's FSTOC that the dwindling supply of recycled halons could lead to shortages in the next decade (UNEP, 2022).

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[60] For more information on EPA's HFC allowance allocation program, see here: https://www.epa.gov/climate-hfcs-reduction/hfc-allowances.

Halons are still widely used in onboard aerospace fire suppression systems; however, between 2006 and 2020, HFCs, specifically HFC-227ea and HFC-236fa, replaced all halon 1301 lavatory trash receptacle systems in new and existing commercial aircraft. These HFCs were suitable substitutes for this specific end use as they are chemical-for-chemical replacements from a space and weight perspective (UNEP, 2022).

Due to perceived weight and volume restrictions or certain tradeoffs (e.g., increased fuel consumption), HFCs have not been popularized in other fire suppression systems on board commercial aircraft (ICAO, 2016; ICAO, 2019a), and halons are therefore still used in engine nacelles and APUs, cargo compartments, and sporadically in portable fire extinguishers (UNEP, 2022). However, HFC-125 is used in engine nacelles and APUs on board commercial-derivative aircraft by the U.S. military (UNEP, 2022). Additionally, the U.S. military uses HFC-236fa in portable fire extinguishers on commercial-derivative aircraft (Boeing, 2020).

While larger commercial aircraft currently use HFCs in their lavatory trash receptacle systems, some older legacy platforms have not transitioned away from halons in this use (UNEP, 2022). As discussed in detail in Section 8.2.1, the transition away from halons is currently taking place for portable extinguishers, primarily using a non-HFC replacement agent (2-BTP); however, some new installations still use halon 1211 (UNEP, 2022). [ ] (EPA, 2024b). Aside from lavatory trash receptacle systems and some portable fire extinguishers, there have been no large-scale retrofits of halon systems or portable extinguishers with halon alternatives globally (UNEP, 2022). Thus, all new installations of engine and cargo compartment fire extinguishing systems still use halon 1301 in commercial aircraft (UNEP, 2022). It is not known when the transition to halon substitutes, which could include HFCs, will occur across all applications. As discussed above, the U.S. military uses HFC-125 for engine nacelle and APU fire suppression in commercial-derivative aircraft (UNEP, 2022).

Proteng Distribution manufactures a fire suppression system containing HFC-227ea called THIA (“Tube+Heat = InstantAction”) that may be used in some general aviation aircraft (Proteng Distribution, 2023; Experimental Aircraft Association [EAA], 2019). [ ] (EPA, 2024b).

8.1.2 Major Manufacturers and Products

Manufacturers of fire suppression systems for aircraft manufacture numerous types of total flooding and/or streaming systems for a wide range of applications and fire suppression agents. The fire suppression equipment manufacturers purchase gases directly from the supplier and fill them into cans or bottles. For new equipment in aircraft, these equipment manufacturers then provide the fire suppression equipment directly to the aircraft manufacturer for installation onto the aircraft.

Fire suppression systems on board commercial aircraft are regularly tested but are not necessarily serviced on-site. For example, lavatory trash receptacle fire extinguishing systems are hermetically sealed and must be punctured to remove the fire suppressant agent and, thus, are not serviceable. At the end of the equipment lifetime (e.g., when the suppression system is utilized), the lavatory system bottle is removed from the system and shipped to the manufacturer for replacement (EPA, 2021). HFCs from lavatory trash receptacle systems (which contain approximately 0.1 kilograms of HFC-227ea or HFC-236fa per system) are removed and stored but are not currently used to fill new lavatory trash receptacle systems (see Section 8.3.2 for more information about fire suppression recycling).Table 25 lists some, but not all, of the major manufacturers of total flooding systems and portable fire extinguishers for aircraft in the United States.

Table 25. Some Manufacturers of Total Flooding Systems and Portable Fire Extinguishers for Aircraft in the United States

Manufacturer[a]	Total Flooding Systems	Portable Fire Extinguishers
BFPE International	✓	✓
FFE, Ltd.	✓	
Fike Corporation	✓	
FireBoy-Xintex	✓	✓
Firetrace International	✓	
Gielle		✓
H3R Aviation, Inc.		✓
Kidde Technologies[b]	✓	✓
Meggitt	✓	
Minimax	✓	
Proteng Distribution	✓	
PyroChem		✓
TYCO (Ansul)		✓

[a] Manufacturers in bold manufacture HFC lavatory trash receptacle fire extinguishing systems.

[b] Kidde Technologies is a part of Collins Aerospace, which is an RTX Corporation (formerly known as Raytheon Technologies) company.

Table 26. Estimated Size of Airplane and Rotorcraft Fleet in the United States and Number of Onboard Fire Suppression Systems in 2020[a]

Aircraft Type	Number of Aircraft Vehicles in 2020	Number of Onboard Fire Suppression Systems				
		Engine Nacelle	APU	Cargo Compartment	Lavatory	Portable
Mainline Passenger Aircraft	18,703	2-4	1	1-9	3-18	3-6
Regional Passenger Aircraft	1,577	2-3	1	1-5	3-5	1-4
Mainline Freighter Aircraft	692	2-4	1	1-9	1-3	1-4
Regional Freighter Aircraft	133	1-2	1	1-5	1-2	1-2
Rotorcraft[b]	24	1	1	1-3	0-1	1-3
Private Planes[c]	22,000	1-2	1	1-2	0-3	1-4

Source: Estimates were developed based on fleet and delivery estimates from Boeing (2017, 2020a) and Airbus (2017, 2019).

[a] Commercial-derivative aircraft are considered in this estimate, no other military aircraft are included.

[b] The commercial rotorcraft estimate was derived from global revenue breakdowns by region and major manufacturer market shares (Airbus, 2021a; Airbus, 2021b; Leonardo, 2021).

[c] Number of private planes estimated for 2022. Estimated number includes turboprop data (Hendry, 2023).

As discussed above, onboard commercial aviation fire suppression systems are installed throughout mainline and regional passenger and freighter aircraft, including engine nacelles, APUs, lavatory trash receptacles, baggage/crew compartments, and handheld extinguishers (UNEP, 2022).

Table 26 shows the total number of commercial aircraft vehicles, including commercial rotorcraft and commercial-derivative aircraft,[61] in the United States in 2020 by type and the estimated number of onboard fire suppression systems per aircraft type (which varies by aircraft size). Onboard aerospace fire suppression systems are consistent in all aircraft types for a given manufacturer and do not differ by country.

Airbus, Boeing, and Embraer are the three largest aircraft manufacturers worldwide, representing 97.8% of the market (Businesswire, 2022). The majority of airlines worldwide utilize a combination of both Boeing and Airbus aircraft for their long-haul operations, while the aircraft from all three manufactures are used for short-haul operations.

Gulfstream, Beechcraft, Bombardier, Cessna, Dassault, Honda, and Embraer are all manufacturers of private planes. Private planes can range from transcontinental business jets to twin-seater turboprop engine planes. Private plane manufacturers are expected to manufacture an additional 7,875 new aircraft from 2023 through 2032, and the annual rate of private planes manufactured is anticipated to increase by approximately 25% by 2029 (Jaworowski, 2023).

Aircraft manufacturers utilize different fire suppression equipment manufacturers, and therefore different HFCs. For example, Kidde Technologies (RTX Corporation) is the main supplier of lavatory trash receptacle systems to Boeing (ICAO, 2016) and utilizes HFC-227ea in their systems. Lavatory trash receptacles installed in Airbus aircraft, on the other hand, contain HFC-236fa and are manufactured by FFE Ltd., a UK-based company (EPA, 2021).[62] Embraer and Bombardier started replacing halon with HFCs in lavatory trash receptacle systems on newly produced aircraft starting in 2013 (ICAO, 2016); however, EPA is unaware which fire suppression agent is currently being used in lavatory trash receptacle systems on Embraer and Bombardier aircraft. The U.S. military utilizes HFC-236fa in onboard aircraft portable fire extinguishers and uses a military derivative of a Boeing aircraft that utilizes HFC-125 for engine nacelle and APU fire suppression (SEPW, 2020; UNEP, 2022).

8.2 Availability of Safe, Technically Achievable Substitutes

Based on information available to EPA at this time, EPA is proposing that a safe or technically achievable substitute will not be available during 2026 through 2030 for all HFC uses in onboard aerospace fire suppression. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

8.2.1 Current Status

The majority of onboard aerospace fire suppression systems still use halons. Halon alternatives include HCFCs, HFCs (specifically HFC-236fa, HFC-227ea, and HFC-125), 2-BTP, and NIK extinguishing agents (Dinesh et al., 2023). HFCs are used as a replacement in lavatory trash

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[61] This analysis assumes that commercial-derivative aircraft are included in the commercial aircraft analysis. In addition, this analysis also assumes that the number of commercial-derivative aircraft vehicles is negligible compared to the commercial aircraft fleet. This analysis does not consider other military aircraft vehicles.

[62] As this fire suppression system is not manufactured within the United States, no allowances are allocated to FFE Ltd. However, as U.S. airlines have a large, combined fleet of Airbus aircraft, this HFC-236fa lavatory trash receptacle fire suppression system is utilized within the United States.

receptacle systems. There are currently no suitable non-HFC alternatives for this use. 2-BTP is currently utilized as a non-HFC substitute for onboard aerospace streaming agents.

Table 27. Atmospheric and Human Health Characteristics of Halon Onboard Aerospace Fire Suppressants and Available and Potential Substitutes in Onboard Aerospace Fire Suppression

Substitute	ODP[a]	100-year GWP[a]	Human Health[b]
Halons Currently Used			
Halon 1301	17	7,430	• Asphyxiant
Halon 1211	7.1	1,990	• Asphyxiant • Short-term exposure may adversely impact cardiovascular system, potentially resulting in cardiac disorders
Potential and Currently Used Halon Substitutes			
HFC-125[c,d,e]	0	3,500[i]	• Asphyxiant[j]
HFC-227ea[d,e]	0	3,220[i]	• Asphyxiant[k]
HFC-236fa[d,e]	0	9,810[i]	• Asphyxiant[l]
2-BTP	<0.05	<<1	• Suspected of causing genetic damage to human germ cells[m]
Trifluoroiodomethane (CF_3I)[d]	<0.09	<1	• Suspected of causing genetic damage to human germ cells[m]
FK-5-1-12	0	<1	• No data[m]
HCFC Blend B[f,g,h]	0.0098	77	• Short-term exposure may adversely impact cardiovascular system
IG-100 (N_2)[d]	0	0	• Asphyxiant
Powdered Aerosol F	0	0	• No data identified

[a] WMO (2022), unless otherwise specified.

[b] NOAA CAMEO Chemicals Database, International Labour Organization ICSCs, and T3DB, unless otherwise specified.

[c] HFC-125 is used in engine nacelles and APUs in a commercial-derivative aircraft for military use (UNEP, 2022).

[d] Classified by ASHRAE Standard 34 as a Class A1 refrigerant, meaning it does not propagate a flame and has lower toxicity (ASHRAE, 2022).

[e] HFC-125, HFC-227ea, and HFC-236fa are currently used in onboard aerospace fire suppression.

[f] HCFC Blend B contains greater than 93% HCFC-123 and less than 7% proprietary gas mixture (AMPAC, 2016). Flammability and health properties included in this table are for HCFC-123.

[g] HCFCs are scheduled for phaseout under the Montreal Protocol. Starting in 2020, production and import of bulk HCFCs is limited to servicing refrigeration, air-conditioning, and fire suppression equipment manufactured prior to January 1, 2020.

[h] HCFC-123 is classified by ASHRAE Standard 34 as a Class B1 refrigerant, meaning it does not propagate a flame and has higher toxicity (ASHRAE, 2022).

[i] IPCC (2007). HFC GWPs are numerically equal to the exchange values listed in the AIM Act.

[j] National Center for Biotechnology Information (2024a).

[k] National Center for Biotechnology Information (2024b).

[l] National Center for Biotechnology Information (2024c).

[m] ECHA (2024).

EPA's SNAP program has listed as acceptable non-HFC substitutes for total flooding agents[63] and streaming agents,[64] but many of these substitutes may not be appropriate for onboard aerospace fire suppression applications because they have not been technically proven, have toxicity concerns in occupied areas, are deemed unsafe to use in a pressurized cabin environment, or may require increased space and weight on the aircraft.

Table 27 summarizes the currently used onboard aerospace fire suppressants, their available and potential substitutes, and their atmospheric and human health characteristics. As noted in the table, halons have very high ODPs because they contain bromine, which has a higher reactivity with ozone than chlorine. Thus, halons have higher ODPs than chlorine-containing compounds, such as CFCs and HCFCs, and also have high GWPs.

Alternatives specific to total flooding and streaming uses are discussed in more detail in Sections 8.2.1.1 and 8.2.1.2, respectively.

International Civil Aviation Organization (ICAO) Standards and Recommended Practices (SARPs) currently recommend the phase-out of halons in aircraft produced on or after December 31, 2011, for lavatory trash receptacle systems and December 31, 2018, for hand-held fire extinguishers (ICAO, 2021). ICAO SARPs also recommend the use of a halon alternative in engine nacelle and APU fire suppression systems for aircraft type certification applications submitted after December 31, 2014 (ICAO, 2021). An alternative for the cargo compartment fire suppression system is recommended for type certification after November 28, 2024 (ICAO, 2021).

8.2.1.1 Total Flooding Agent Alternatives

Alternatives to halon 1301 for use in total flooding systems onboard aircraft include several HFCs. There are also several non-HFC agents which are considered potential alternatives, but these agents may not be technically proven or available because they have not met the FAA minimum performance standard (MPS) for use in certain onboard aerospace applications. These standards are described in greater detail in Section 8.2.2. Table 28 summarizes the availability of alternatives for the total flooding systems in use in onboard aviation applications.

Table 28. Halon 1301 Alternatives for Total Flooding Systems in Onboard Aerospace Applications

Location	Halon 1301[a] Alternative
Cargo Hold	Water mist and IG-100 mixture[b]
Engine Nacelles & APUs	**HFC-125**,[c] 2-BTP,[d] CF_3I, Powdered Aerosol F,[e] FK-5-1-12
Lavatory Trash Receptacles	**HFC-227ea**, **HFC-236fa**

Source: UNEP (2022).

Bold text indicates the alternative is currently in use.

[a] The production of Halon 1301 and Halon 2402 was phased out in the United States in 1994 in compliance with the Montreal Protocol. Ongoing halon use is limited to recycled halon.

[b] A mixture of water mist and IG-100 has passed the FAA MPS for cargo compartments; however, further development of fire suppression systems using these fire suppressants is necessary as they require the use of large heavy equipment that is not currently well-suited to aircraft (UNEP, 2022; ICAO, 2016; NIST, n.d.)

[c] HFC-125 is used in engine nacelles and APUs in a commercial-derivative aircraft for military use (UNEP, 2022).

[d] 2-BTP is listed by SNAP as acceptable with use conditions for engine nacelles and APUs; however, the FAA has not approved 2-BTP for use as a total flooding agent. The SNAP program is currently reviewing a blend of 2-BTP and CO_2 as an alternative total flooding agent for use in cargo hold, engine nacelle, and APU fire suppression

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[63] https://www.epa.gov/snap/substitutes-total-flooding-agents

[64] https://www.epa.gov/snap/substitutes-streaming-agents

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systems. The FAA is also reviewing a blend of 2-BTP and CO_2 for use in cargo hold fire suppression systems, having passed proof-of-concept and MPS testing (UNEP, 2022).

[e] Powdered Aerosol F is listed by SNAP as acceptable with use conditions for use in normally unoccupied areas; however, the FAA has not approved Powdered Aerosol F for use as a total flooding agent. The FAA is currently testing Powdered Aerosol F against the MPS for aircraft engine nacelles, but it has not yet been technically proven (UNEP, 2022).

At present, HFC-227ea is not considered to be a viable alternative in cargo holds or engine nacelle/APUs in a total flooding system. However, as previously discussed, Proteng Distribution manufactures an HFC-227ea fire suppression system called THIA [ ] (EPA, 2024b). [ ] (EPA, 2024b).

Lavatory Trash Receptacles

Research and testing have shown that HFC-227ea and HFC-236fa are suitable chemical-for-chemical replacements for halon 1301 in lavatory trash receptacles from a space, weight, and cost perspective and meet all the relevant toxicological requirements (UNEP, 2022). Boeing and Airbus began using HFC-227ea and HFC-236fa alternatives in 2011, and manufacturers of smaller aircraft followed shortly after in January 2013 (ICAO, 2016). Virtually all lavatory trash receptacle systems on new aircraft are outfitted with HFC fire suppression agents. Specifically, Boeing utilizes HFC-227ea, and Airbus utilizes HFC-236fa (IACO, 2016). EPA is not aware why Boeing and Airbus utilize different substitutes in their fire protection systems. Several airlines are also replacing the existing halon 1301 lavatory trash receptacle systems in older aircraft with these two HFC alternatives (UNEP, 2022).

RTX Corporation currently utilizes HFC-227ea for lavatory trash receptacles (Kidde, n.d.). [ ] (EPA, 2024b).

Currently, there are no approved lower-GWP alternatives for fire suppression agents in lavatory trash receptacle systems (UNEP, 2022).

Engine Nacelles and APUs

HFC-125 has been used as an alternative for engine nacelles and APU fire suppression by the U.S. military since the 1990s, including on a military derivative of large commercial aircraft. However, due to the increased weight and space requirements of HFC-125 compared to halon 1301, commercial aircraft manufacturers have chosen not to pursue qualification and installation certification for HFC-125 in engine nacelles and APUs fire suppression (UNEP, 2022).

CF_3I (trifluoroiodomethane) has been considered as an alternative for halon 1301, but it has not been commercialized. CF_3I is the closest chemical-for-chemical replacement for halon 1301; however, given its toxicity there are concerns with exposure and CF_3I has an ODP that is similar to class II ODS. The commercial aviation industry is continuing to research CF_3I as a suitable alternative for unoccupied spaces, however it has not passed the FAA MPS test (UNEP, 2022).

FK-5-1-12 was developed for use as a fire suppression agent in engine nacelles but failed a FAA required live fire test (FAA, 2011b). Furthermore, as noted in Section 3.4, an EU proposal is undergoing review by ECHA to restrict PFAS, which would include FK-5-1-12. 3M, the original patent holder for FK-5-1-12 under the name Novec™ 1230, announced in December 2022 that they will discontinue manufacturing of PFAS by the end of 2025, including production of FK-5-1-12 (3M, 2022). However, 3M's patent expired in 2020 which led to the manufacture of FK-5-1-12 by other manufacturers, including in China and Singapore (Firetrace International, 2021). EPA is not aware of any manufacturers of FK-5-1-12 located in the United States at this time.

2-BTP, a non-HFC clean agent, was listed as acceptable by the SNAP program for use in engine nacelles and APUs (EPA, 2016a) but does not appear to have been pursued as a replacement agent in this end use at this time. 2-BTP has not been approved by the FAA for use as a total flooding agent, including in engine nacelles and APUs at this time.

Powdered Aerosol F, an NIK dry chemical agent, is listed by SNAP as acceptable in normally unoccupied areas only. It has not yet passed the FAA MPS test for engine and APU compartments, having failed the required FAA full-scale engine fire test as of 2016 (ICAO, 2016). In addition to not yet being technically proven, it is unclear if it is commercially available (UNEP, 2022).

Cargo Compartment

To date, there are no suitable halon 1301 alternatives for cargo compartment fire suppression (UNEP, 2022). Various single component vaporizing liquid agents, including HFC-125, 2-BTP, and FK-5-1-12, were evaluated but did not pass the exploding aerosol can MPS test, causing an "undesired increase in the test compartment pressure if discharged at a concentration below which the agent will suppress a fire or deflagration event" (UNEP, 2022). However, a blend of 2-BTP and CO_2 has successfully undergone proof-of-concept and MPS testing as a cargo compartment fire suppression agent, though there are still concerns related to agent toxicity and/or reduced oxygen concentration (UNEP, 2022). Furthermore, some inert gases (e.g., IG-100 [N_2]) are being tested against the FAA MPS for cargo compartments. A mixture of IG-100 met FAA MPS requirements for cargo compartment fire suppression; however, this system is still being commercially developed, and fire suppression systems using inert gases require large heavy steel cylinders and pipes. Additionally, inert gas systems have the potential to cause anoxia at high elevations (UNEP, 2022; NIST, n.d.).

8.2.1.2 Streaming Agent Alternatives

Currently, there are four halon 1211 alternatives that have been approved by the EPA SNAP program and FAA, have met all MPS tests, and are commercially available: HFC-227ea, HFC-236fa, HCFC Blend B, and 2-BTP (Table 29).

Table 29. Halon 1211 Alternatives for Streaming Agents (Portable Extinguishers)

Location	Halon 1211[a] Alternatives
Flight Deck & Passenger Compartment	HFC-227ea, **HFC-236fa**, HCFC Blend B,[b,c] **2-BTP**

Source: UNEP (2022), EPA (2024a).
Bold text indicates alternative is currently in use.
[a] The production of halon 1211 was phased out in the United States in 1994 in compliance with the Montreal Protocol.
[b] HCFC Blend B contains greater than 93% HCFC-123 and less than 7% proprietary gas mixture (AMPAC, 2016).
[c] HCFCs are scheduled for phaseout under the Montreal Protocol. Starting in 2020, production and import of bulk HCFCs is limited to servicing refrigeration, air-conditioning, and fire suppression equipment manufactured prior to January 1, 2020.

Commercial aircraft manufacturers have chosen not to pursue HFC-227ea or HFC-236fa for use as streaming agents due to the increased space and weight characteristics relative to halon 1211 and the higher GWP of both HFCs (UNEP, 2022).

HCFC Blend B has been approved by FAA as a replacement agent for halon 1211, however, HCFC Blend B does not have the fire extinguishing performance of halon 1211, meaning that greater quantities of HCFC Blend B and larger units would be required to replace halon 1211 as an onboard streaming agent (FAA, 2011a; UNEP, 2022). Therefore, it has not been pursued as an onboard streaming agent. Furthermore, the agent's main component, HCFC-123, is a Class II ODS. In keeping with its obligations under the Clean Air Act and the Montreal Protocol, the United States has phased out the production and import of most ODS and HCFC-123 is subject to a complete phaseout in 2030.

Aircraft manufacturers are considering 2-BTP, which is the closest direct replacement based on size and weight (ICAO, 2019a). As a SNAP-listed and FAA approved alternative, the transition to 2-BTP in portable extinguishers for newly produced cargo aircraft is underway (UNEP, 2022). All new commercial aircraft are now fitted with 2-BTP streaming agents as the fire suppression agent (UNEP, 2022). [ ] (EPA, 2024b).

Dry chemical, dry powder, and CO_2 handheld extinguishers have also been considered for replacement of halon 1211 for general streaming applications; however, according to FAA, these alternatives should not be used in aircraft due to their corrosive and toxicological properties (FAA, 2013).

8.2.2 Relevant Regulations and Standards

A fire suppression equipment manufacturer's development of an alternative chemical for use in total flooding and/or streaming fire suppression begins with the chemical's approval as a substitute under EPA's SNAP program. Once approved by SNAP, the manufacturer tests the alternative to assess whether it meets MPS as set forth by the FAA. Alternatives must be able to meet MPS that includes the ability to extinguish a fire while not creating an environment that exceeds the chemical agent's maximum acceptable level for toxicity (UNEP, 2022). Table 30 summarizes the MPS requirements.

Table 30. Minimum Performance Standards for Fire Suppression Products Aboard Airplanes and Rotorcraft[a]

Standard	Title	Description
FAA MPS (DOT/FAA/AR-01/37)	Handheld Fire Extinguishers as a Replacement for Halon 1211 on Civilian Transport Category Aircraft	• Specifies two extinguisher tests that replacement agents must pass in addition to requiring national certifications to ensure that replacement agents will meet or exceed performance of halon 1211 both in fighting fires and maintaining a safe breathing environment in aircraft cabins
FAA MPS (DOT/FAA/TC-TN12/11)	Aircraft Cargo Compartment Halon Replacement Fire Suppression Systems	• Establishes the MPS that a halon 1301 replacement aircraft cargo compartment fire suppression system must meet as

Standard	Title	Description
		part of the aircraft certification procedures
FAA MPS	Fire Extinguishing Agents/Systems of Civil Aircraft Engine and APU Compartments	• Establishes the MPS that engine and APU compartment fire extinguishing systems must meet
FAA MPS (DOT/FAA/AR-96/122)	Lavatory Trash Receptacle Automatic Fire Extinguishers	• Establishes the MPS that an agent must meet and provides an equivalent level of safety to that of halon • Establishes the fire load, trash disposal receptacle test article, test procedures, and pass/fail criteria for built-in extinguishers for lavatory disposal receptacles

Sources: NFPA (2017), FAA (1997, 2002, 2012).

[a] FAA MPS for hand fire extinguishers for use in aircraft consider both onboard airplanes and rotorcraft (FAA, 2011a) and address requirements for 14 CFR parts 29 and 127, among others.

If the alternative meets the MPS required, then it can be submitted to FAA for consideration. The FAA has full discretion and can indicate if any additional testing needs to be conducted before aircraft type certification.[65] There is no predetermined timeframe for FAA approval.

Standards for handheld extinguishers aboard commercial aircraft require the unit to be able to suppress fires while not causing unsuitable visual obscuration, discomfort, or toxic effects where the space is occupied (UNEP, 2018). The FAA Advisory Circular (AC) 20-42D indicates that hand fire extinguishers must meet Underwriters Laboratories' (UL) standard 5B:C and UL standard 2B:C for large aircraft and small airplanes or rotorcraft, respectively (FAA, 2011a). AC 20-42D also specifies that hand fire extinguishers be maintained and inspected in accordance with inspections and testing specified in the applicable NFPA standards, including NFPA 10, Standard for Portable Extinguishers (FAA, 2011a).

In AC 20-42D (FAA, 2011a), the FAA requires clean agents replacing halon 1211 to meet the following ASTM International specifications:[66]

- HCFC Blend B – ASTM D 7122-05, Standard Specifications for HCFC Blend B[67]
- HFC-227ea – ASTM D 6064-03, Standard Specifications for HFC-227ea, 1,1,1,2,3,3,3-1-Heptafluoropropane (CF_3CHFCF_3)[68]
- HFC-236fa – ASTM D 6541-05, Standard Specification for HFC-236fa, 1.1,1.3.3,3-Hexafluoropropane ($CF_3CH_2CF_3$)[69]
- Other Halon 1211 replacement agents must have and meet applicable ASTM or other specifications.

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[65] A type certificate designates that a general aircraft design meets design and safety requirements. The aircraft design must then also gain a certificate of airworthiness which designates a specific aircraft meets all additional requirements (ICAO, 2019b).

[66] For these replacement agents, whether new or recycled, FAA AC 20-42D indicates that the validation of agent purity is the responsibility of the fire extinguisher manufacturers (FAA, 2011a).

[67] See https://www.astm.org/d7122-05.html.

[68] See https://www.astm.org/d6064-03.html.

[69] See https://www.astm.org/d6541-05.html.

These ASTM specifications outline requirements for these agents as firefighting mediums, including tests to determine chemical and physical properties such as purity and component content.

Although there were no requirements to meet ASTM standards for halon 1301 substitutes identified, [ ] (EPA, 2024b).

After these approvals, aircraft manufacturers ultimately will make the final decision on whether these alternatives will be included on their aircraft. In many cases, due to factors such as weight and space constraints, halon alternatives are not deployed.

8.3 Supply of Regulated Substances

Currently, HFC-227ea, HFC-236fa, and HFC-125 are used in onboard aerospace fire suppression. As discussed in Section 8.1.1, HFC-227ea and HFC-236fa are commonly used in lavatory trash receptacle systems in new and existing commercial aircraft. Lavatory trash receptacle systems manufactured in the United States are made only using HFC-227ea, and lavatory trash receptacle systems containing HFC-236fa are imported. As described in Section 8.1.1, the U.S. military uses HFC-125 as a halon alternative for engine nacelles and APU fire suppression in commercial-derivative aircraft. The U.S. military also uses HFC-236fa in portable aircraft fire extinguishers (Boeing, 2020).

Kidde was the original manufacturer of halon 1301 lavatory trash receptacle fire extinguishing systems but now uses HFC-227ea. Before the adoption of the AIM Act, Kidde sourced bulk HFC-227ea from Chemours. [ ] (EPA, 2024b).

Proteng Distribution [ ] (EPA, 2024b).

Based on information available to EPA at this time, EPA is proposing that the supply of HFC-227ea and the supply of HFC-236fa for use in onboard aerospace fire suppression are insufficient to accommodate the application during 2026 through 2030. EPA has reached this proposed determination after considering a number of factors, described in more detail below and in the preamble to the proposed rule.

8.3.1 Purification Process and Requirements

As described in Section 8.2.2, FAA AC 20-42D establishes that halon, HFC, and other fire suppression agents used in handheld fire extinguishers must meet ASTM or ISO standards for purity (FAA, 2011a). Specifically, the following standards must be met.

- Halons:
    - Halon 1211: ASTM D7673-10, *Standard Specification for Halon 1211-Bromochlorodifluoromethane* (*CF_2ClBr*), or ISO 7201-1:1989, *Fire protection – Fire extinguishing media – Halogenated Hydrocarbons – Part 1: Specifications for Halon 1211 and Halon 1301*[70]
    - Halon 1301: ASTM D5632-08, *Standard Specification for Halon I 301-Bromotrifluoromethane* (*CF_3Br*), or ISO 7201-1: 1989[71]

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[70] See https://www.astm.org/d7673-10.html and https://www.iso.org/standard/13821.html.

[71] See https://www.astm.org/d5632-08.html and https://www.iso.org/standard/13821.html.

- Halon 1211-Replacing Streaming Agents:
    - HCFC Blend B: ASTM 7122-05, *Standard Specifications for HCFC Blend B*[72]
    - HFC-227ea: ASTM D 6404-03, *Standard Specifications for HFC-227ea, 1,1,1,2,3,3,3-Heptafluoropropane* (CF_3CHFCF_3)[73]
    - HFC-236fa: ASTM D 6541-05, *Standard Specifications for HFC-236fa, 1,1,1,3,3,3-Hexafluoropropane* ($CF_3CH_2CF_3$)[74]
    - Other fire suppressants must meet an applicable ASTM or other relevant purity standard.

Manufacturers of handheld fire extinguishers are responsible for ensuring the agents' purity for both new and recycled agents (FAA, 2011a).

As noted in Section 8.2.2, while there were no requirements to meet ASTM standards for halon 1301 substitutes identified, [ ] (EPA, 2024b).

8.3.2 Use of Recovered and Reprocessed Material

There is historical precedent within the fire suppression industry for utilizing recycled material. As noted above, manufacturers of handheld fire extinguishers that utilize halon 1211 or its substitutes, whether the agent is virgin or recycled, are responsible for the validation of the agent's purity against the ASTM specifications (FAA, 2011a). Advisory Circular 20-42D notes that handheld fire extinguishers using halon agents are acceptable for continued use as long as the recycled halon meets ASTM or ISO specifications (FAA, 2011a). The fire suppression industry has met these ASTM and ISO purity specifications and been utilizing recycled halon 1211 for portable extinguishers for over 20 years (A-Gas, 2022).

[ ] (EPA, 2024b).

Table 31. Recycled HFC-227ea Use in Onboard Aerospace Fire Suppression (kg), 2018-2020

Company Name	2018	2019	2020
[ ]			

Source: EPA (2024b).

In 2015, data on recycling of HFC fire suppression agents were collected as part of the HFC Emissions Estimating Program (HEEP), which is a voluntary data collection effort implemented by the fire suppression industry. HEEP collects data on sales of fire suppression agents for recharge in order to estimate annual emissions of HFCs. These data showed that HFC-227ea, HFC-125, HFC-236fa and HFC-23 are all recycled for fire suppression use (Halon Alternatives Research Corporation [HARC], 2022). The HEEP data provide a rough estimate of recycled HFC sales between approximately 150,000 and 230,000 kilograms annually since 2012 and an estimated 80 percent of agent coming from recyclers (HARC, 2022).

UL listings and testing and certification by FM Approvals present typical commercial hurdles to using recycled HFCs but similar barriers were overcome with the use of recycled halon 1211 (A-

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[72] See https://www.astm.org/d7122-05.html.

[73] See https://www.astm.org/d6064-03.html.

[74] See https://www.astm.org/d6541-05.html.

Gas, 2022). In 2023, A-Gas and Chemours announced a partnership to market UL-listed and FM approved recycled HFC-227ea for fire suppression (Newswire, 2023).

The recycled fire suppressant market could serve as a source of supply. For example, in 2022, approximately 210.8 MT of HFC-227ea (i.e., 599,886 MTEVe) were reportedly reclaimed or recycled in the United States (Table A1). As discussed further in Section 3.1.3, EPA's Emissions Reduction and Reclamation Rule proposed requiring the use of reclaimed HFCs for certain types of equipment in certain refrigeration, air conditioning, and heat pump subsectors and use of recycled HFCs for fire suppression equipment. EPA did not propose to extend the requirement to use recycled HFCs in onboard aerospace fire suppression equipment as long as the application continues to qualify for ASAs; however, the requirement to use recycled HFCs in other fire suppression applications could impact the availability of recycled HFCs for the onboard aerospace fire suppression application.

8.3.3 Available Supply

The only producer, [ ], of HFC-227ea in the United States is Chemours. In 2022, there were also nine importers of HFC-227ea. For HFC-236fa, there are no producers in the United States, and there were seven importers of HFC-236fa in 2022 (Table A2). The only producer of HFC-125 in the United States is Honeywell International, and there were 19 importers of HFC-125.

EPA identified that in 2022, of HFC-227ea were produced in the United States, 454.2 MT were imported, 1,466.2 MT were exported, and 210.8 MT were reclaimed or recycled. Additionally, 1,008.3 MT were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022,[75] resulting in an available supply of 1,507.3 MT of HFC-227ea in the United States that year (Table A1). The global production capacity for HFC-227ea in 2020 is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020).

EPA identified that in 2022, no HFC-236fa was produced in the United States, 301.4 MT were imported, 32.9 MT were exported, and 14.4 MT were reclaimed or recycled. Additionally, 127.5 MT were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022,[76] resulting in an available supply of 410.4 MT of HFC-236fa in the United States that year (Table A1). The global HFC-236fa production capacity in 2020 is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020).

In 2022, EPA identified that 19,175.7 MT of HFC-125 were produced in the United States, 23,849 MT were imported, 3,047.6 MT were exported, and 58.4 MT were reclaimed or recycled. Additionally, 56,208.2 MT were held in inventory by producers, importers, exporters, fire suppression agent recyclers, and reclaimers as of December 31, 2022,[77] resulting in an

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[75] Includes HFC blend components as HFC blends are disaggregated in inventory reporting under current EPA reporting requirements.

[76] Includes HFC blend components as HFC blends are disaggregated in inventory reporting under current EPA reporting requirements.

[77] Includes HFC blend components as HFC blends are disaggregated in inventory reporting under current EPA reporting requirements.

available supply of 96,243.8 MT of HFC-125 in the United States that year (Table A1). The global production capacity for HFC-125 in 2020 is included in a memo summarizing copyrighted information, to comply with the licensing requirements of the *Chemical Economics Handbook: Fluorocarbons* report (IHS, 2020).

8.3.4 Application's Projected Demand of HFCs

As noted above, HFC use in commercial aviation fire suppression applications is primarily limited to lavatory trash receptacle systems. Lavatory trash receptacle systems are estimated to make up less than 0.5% of the total installed base of fire suppression chemical on aircraft (UNEP, 2022).

Table 32 summarizes reported quantities of HFC-227ea used by ASA holders in 2018-2023, showing [ ]. This is illustrated by the change in the three-year AAGR,[78] which is calculated by EPA based on company-reported data for the purposes of allowance allocations. The 2018-2020 onboard aerospace fire suppression AAGR was [ ], the 2019-2022 AAGR was [ ], and the 2020-2023 AAGR was [ ].[79,80] However, it is noted that most onboard aerospace fire suppression systems are still using halons; it is unclear when a larger scale transition to halon substitutes will occur and whether transition to HFCs would occur at all.

Table 32. Historic HFC-227ea Use in Onboard Aerospace Fire Suppression (kg), 2018-2023

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
Proteng Distribution	[ ]					
RTX Corporation						
Total (kg)						
Total (MTEVe)						

Source: EPA (2024b).

[a] Calculated as the sum of HFC held in inventory (previous period) + HFC acquired through conferrals + HFC imported using allowances + HFC purchased – HFC held in inventory (current period).

Boeing predicts that the global aviation market will grow at a compound annual growth rate of 2.5% from 2022-2042 with the Americas and Europe accounting for 24% and 23% of the market, respectively (Boeing, 2023b). However, even if this estimate were taken at face value, this growth in the overall market may not directly correlate with HFC use in onboard aerospace fire suppression systems given that the majority of fire suppression systems are still using halons, and the timeline of industry phaseout of halons remains unclear.

For projections in HFC use in onboard aerospace fire suppression, EPA used these growth rates provided by industry to conservatively estimate that HFC use on commercial jets grows at an annual rate of 3.5%, while HFC use on single-engine aircraft grows at an annual rate of 13% (Boeing, 2023a; Embraer, 2024). EPA calculated projected HFC use in onboard aerospace fire suppression using an annual growth rate of 8.25%, which is the average of the growth rates

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[78] AAGR = $[(\frac{Year\ 2\ HFC\ purchases}{Year\ 1\ HFC\ purchases} - 1) + (\frac{Year\ 3\ HFC\ purchases}{Year\ 2\ HFC\ purchases} - 1)] \times \frac{1}{2}$

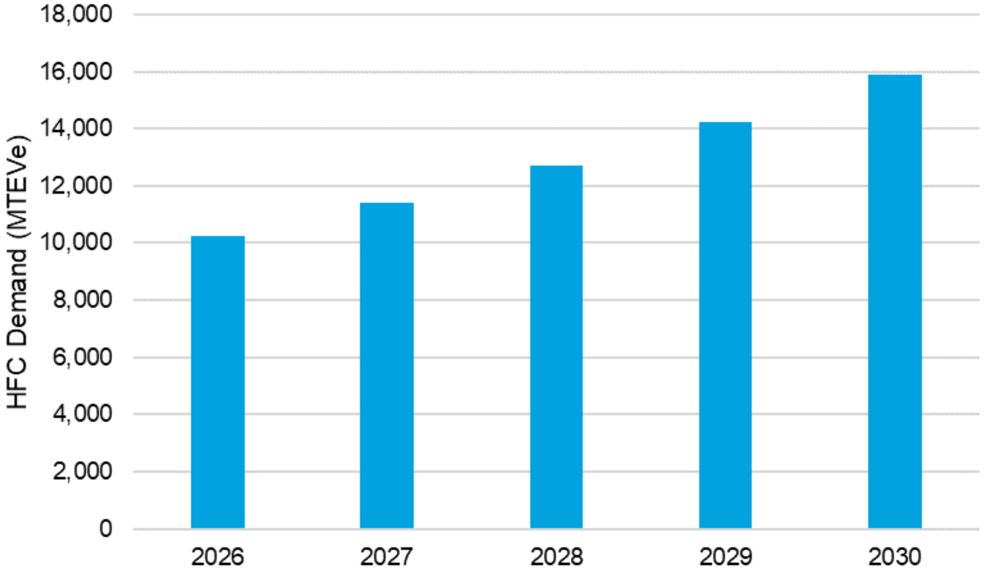
[79] 2019-2022 spans the second half of 2019 through the first half of 2022 and 2020-2023 spans the second half of 2020 through the first half of 2023.

[80] The AAGRs are derived from reported, verifiable data. Therefore, they do not reflect data from companies with missing reports or documentation. Additionally, given that there are only two allowance holders for this specific application, the reported AAGR may not be fully representative of actual market trends.

above for commercial jets and single-engine aircraft. Projected demand is based on 1) reported average 2021 to 2023 purchases of HFC-227ea (Figure 8) and 2) 2024 allowance allocations for the application (Figure 9).

[ ]

Figure 9. Projected Onboard Aerospace Fire Suppression HFC Demand (MTEVe), 2026-2030[a]



[a] Projections are based on 2024 allowance allocations.

As the aviation industry continues to transition away from halons and additional alternatives are tested for engine nacelle, APU, and cargo compartment use, use of HFCs could increase (ICAO, 2016; ICAO, 2019a). For example, industry notes that HFC-125 may be used for engine nacelle and APU fire suppression if another halon alternative is not identified (Boeing, 2021a; Collins, 2021). HFC use in lavatory trash receptacle systems could decrease if alternatives became available. Given the low quantities of fire extinguishing agent used in lavatory trash receptacle systems, as well as the low emission rates, finding alternatives to these agents is viewed as a low priority by industry at this time (UNEP, 2022).

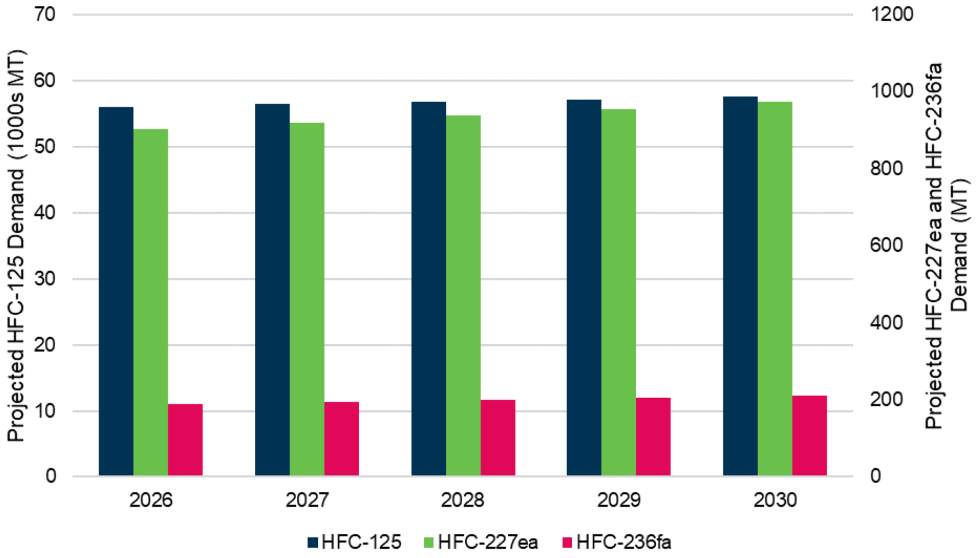
8.3.5 Anticipated Regulatory Impacts on Supply

As noted in Section 3.1.2, EPA's 2023 Technology Transitions Rule established GWP limits, which in turn will limit the use of HFC-236fa and blends containing HFC-125 (e.g., R-410A, R-404A) in many sectors and subsectors as early as 2025. As noted in Section 4.3.5, HFC-227ea is used primarily in MDIs and fire suppression, neither of which have a GWP limit under EPA's 2023 Technology Transitions Rule. Both uses are projected to have continuing demand for HFCs. EPA's Vintaging Model estimates that the fire suppression market used 679 MT of HFC-227ea, 172 MT of HFC-236fa, and 540 MT of HFC-125 in 2023 (EPA, 2016b). ASA holders' use of HFC-227ea in onboard aerospace fire suppression constitutes approximately [ ] of the fire suppression HFC-227ea market, at [ ] MT or [ ] MMTEVe of HFC-227ea in 2023 (EPA, 2024b). As previously noted, while ASA holders did not report use of HFC-236fa or HFC-125 for onboard aerospace fire suppression, the U.S. military uses both for fire suppression on commercial-derivative aircraft.

The Technology Transitions Program together with expected reductions associated with the HFC consumption and production phasedown under the AIM Act and market trends and planned transitions more generally are estimated to prevent approximately 28,300 MT and 36,900 MT of HFC-125 demand from impacted products in 2026 and 2030, respectively, or a 51% and 64% reduction in projected demand across all uses of HFC-125. This reduction in projected demand may free up available supply, which could be used to help meet future demand for HFC-125 in onboard aerospace fire suppression. Figure 10 presents projected demand for HFC-227ea, HFC-236fa, and HFC-125.

As mentioned in Section 3.1.3, there may be increased use of reclaimed HFCs in other applications due to the Emissions Reduction and Reclamation Rule, which could also make an additional supply of virgin HFC-227ea available to meet future demand in onboard aerospace fire suppression where the use of recycled HFCs is feasible.

Figure 10. Projected Demand (MT) for HFC-227ea, HFC-236fa, and HFC-125, 2026-2030



8.3.6 Allowance Usage, Conferrals, and Inventory

As noted below, EPA issued 56,180.4 MTEVe of ASAs for onboard aerospace fire suppression for 2022, 5,013.0 MTEVe of onboard aerospace fire suppression ASAs for 2023, and 8,258.8 MTEVe of onboard aerospace fire suppression ASAs for 2024.

Onboard aerospace fire suppression allowance holders reported acquisition of HFC-227ea through conferrals to producers [ ] or through domestic purchases that did not require expending or conferring allowances (see Table 33).

Table 33. Purchases and Inventory of HFC-227ea (kg) for ASA Holders in 2022 and 2023

Report Period	Acquired through Conferrals and Imported Using Allowances	Purchased without Expending or Conferring Allowances	Held in Inventory at End of Period	% HFCs Acquired through Expending or Conferring Allowances
2022	[ ]			
2023				

Source: EPA (2024b).
[ ]

In addition, Table 33 shows the amount of HFC inventory held by onboard aerospace fire suppression ASA holders. Inventory was [ ] for HFC-227ea from EOY 2022 to EOY 2023. Inventory of HFC-227ea [ ] from [ ] kilograms at the end of 2022 to [ ] kilograms at the end of 2023.

Table 34 summarizes 2022 and 2023 application-wide allowance balances and activity for onboard fire suppression, including BOY levels, EOY levels, quantities of allowances conferred, and quantities of allowances expended. End users conferred, transferred, or expended 24% of allocated allowances in 2022 and 0% in 2023. [ ]. EOY or leftover allowances indicate that 1) application-specific end users did not expend all of their allocated allowances (and may have just purchased from domestic suppliers without expending allowances; see Table 34) and/or 2) importers/producers that were conferred allowances did not use them all.

Table 34. Allowances for Onboard Aerospace Fire Suppression (MTEVe)

	2022	2023
BOY Allowances	56,180.4[a]	5,013.00
Quantity ASA Holders Conferred and Expended Directly to Import	13,535.60	-
Quantity Expended by Supplier	[ ]	-
EOY Allowances – End Users	42,644.80	5,013.0
EOY Allowances % Remaining – End Users	3%	100%
EOY Allowances – Suppliers and Intermediaries	[ ]	-
EOY Allowances % Remaining – Suppliers and Intermediaries	[ ]	-

Source: EPA (2024b).
[a] 2022 BOY allowances include set-aside allowances.

Appendix A. Supply of Regulated Substances Used in Application-specific End Uses

Table A1. United States Available Supply and Use of Regulated Substances in Application-specific End Uses (MT), 2022

Regulated Substance	Calculated Production[a]	Imports for Consumptive Use[b]	Exports[c]	Quantity Reclaimed[d]	Quantity Held in Inventory[e]	Available Supply[f]	Application-Specific Use				
							Defense Sprays	MDIs	Fire Suppression	Semiconductor	SCPPU Foam
HFC-134a	61,377.0	7,363.1	17,220.2	1,036.8	51,902.9	104,459.6	174.4	596.0	[ ]	[ ]	[ ]
HFC-227ea	1,324.7	454.2	1,466.2	210.8[g]	1,008.3	1,507.3	-	39.3		-	
HFC-23	5.2	125.6	26.9	[ ]	304.0	407.9[h]	-	-		84.1	
HFC-32	17,744.3	9,885.3	964.2	[ ]	21,435.0	48,100.4[h]	-	-		8.1	
HFC-41	22.2	38.3	15.9	-	26.7	71.3	-	-		9.6	
HFC-152a	29,654.9	5,810.1	3,763.9	[ ]	5,076.3	36,777.3[h]	-	[ ]		-	
HFC-125	19,175.7	23,849.0	3,047.6	58.4[g]	56,208.2	96,243.8	-	-		-	
HFC-236fa	-	301.4	32.9	14.4[g]	127.5	410.4	-	-		-	

Source: EPA (2024).

[a] Excludes production for transformation or destruction.

[b] Includes imports of virgin and used HFCs that are not used as feedstock. Does not include imports for transformation or destruction.

[c] Excludes transshipments.

[d] Excludes quantities of HFCs reclaimed that are contained within blends.

[e] Includes HFC components of blends held in inventory.

[f] Calculated as (Calculated Production) + (Imports for Consumptive Use) – (Exports) + (Quantity Reclaimed) + (Quantity Held in Inventory).

[g] Includes quantity of recycled fire suppression agents.

[h] Any quantities reclaimed in 2022 are not included in the calculation of available supply for HFC-23, HFC-32, and HFC-152a given confidentiality considerations.

Table A2. 2022 Importers of Regulated Substances Used in Application-Specific End Uses

Regulated Substance	Number of Importers
HFC-134a	28
HFC-227ea	9
HFC-23	7
HFC-32	16
HFC-41	5
HFC-152a	7
HFC-125	19
HFC-236fa	7

Source: EPA (2024).

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