Graff, Michelle (she/her/hers)

From: Miller, Sofie E. EOP/OMB <Sofie.E.Miller@omb.eop.gov>
Sent: Wednesday, July 31, 2024 1:32 PM
To: Graff, Michelle (she/her/hers)
Cc: Hall-Jordan, Luke; Pordesimo, Kristine
Subject: Passback #3 - EPA NPRM Phasedown of HFCs: Review and Renewal of Eligibility for Application-specific Allowances (2060-AV98)

Following up with a corrected email subject line, and also confirming that EPA has all comments for the 3rd round of review—nothing further is coming. Thanks!

From: Miller, Sofie E. EOP/OMB
Sent: Wednesday, July 31, 2024 12:58 PM
To: 'Graff, Michelle (she/her/hers)' <graff.michelle@epa.gov>
Cc: Hall-Jordan, Luke <Hall-Jordan.Luke@epa.gov>; Pordesimo, Kristine <Pordesimo.Kristine@epa.gov>
Subject: RE: Passback #2 - EPA NPRM Phasedown of HFCs: Review and Renewal of Eligibility for Application-specific Allowances (2060-AV98)

Hi Michelle & team,

3rd round passback is attached on the preamble and TSD for EPA's draft proposed rule, "Phasedown of Hydrofluorocarbons: Review and Renewal of Eligibility for Application-specific Allowances," RIN 2060-AV98. All new comments/edits are labeled Round 3.

Chat soon,

Sofie

EO12866_42 USC 7675 2060-AV98 FRM 20250502

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 84

EPA-HQ-OAR-2024-0196; FRL-10782-01-OAR

RIN 2060-AV98

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Environmental Protection Agency is undertaking this rulemaking to assess the eligibility of six applications to receive priority access to allowances allocated pursuant to the American Innovation and Manufacturing Act of 2020. This rulemaking proposes the framework for how EPA will assess whether to renew the eligibility of applications to receive application-specific allowances; decisions to renew or not renew each of the six applications that currently receive application-specific allowances; revisions to the Technology Transitions regulations as relevant to the specific applications under review; a procedural process for submitting a petition to designate a new application as eligible for priority access to allowances; narrow revisions to the methodology used to allocate allowances to application-specific allowance holders for calendar years 2026 and beyond; and limited revisions to existing regulations. EPA is also proposing to authorize an entity to produce regulated substances for export. Lastly, EPA is proposing certain confidentiality determinations for newly reported information if this rule were finalized as proposed.

Commented [Round 21]: In looking at some previous AIM Act-related rules, we noticed that a few have been published in the Federal Register without a RIN, which makes it especially difficult to track EPA's rulemakings over time. Thanks for including the RIN here and please ensure this is also included in the document as published in the FR

Commented [EPA2R1]: Thank you for this comment. We acknowledge the commenter's concerns, and intend to include the RIN in the document we send to OFR for publication. Ultimately EPA cannot control decisions made by OFR in the process of publication.

Commented [EO 128663]: Interagency reviewer appreciates EPA's efforts in finalizing this rule. This rule is an important piece of implementation of the American Innovation and Manufacturing (AIM) Act, which is the primary law giving the United States domestic authority to implement the Kigali Amendment to the Montreal Protocol. U.S. ratification of the Kigali Amendment was an important achievement of the Biden Administration as full implementation of the Kigali Amendment could result in preventing up to half a degree Celsius of warming by 2100. Under the Kigali Amendment, in 2024 the United States is obligated to take a significant reduction in its HFC consumption, reducing from 90% of baseline levels required in 2023 to 65% of baseline levels, which is a significant domestic implementation challenge. EPA's effective and timely promulgation of AIM Act rules is what will allow the United States to meet its compliance target this year and in future years. With this in mind, we strongly support the prompt finalization of this rule."

Commented [Round 24R3]: 2nd round comment: Reviewing agency has no concerns about the passback for this rule and we support this rule's finalization as soon as possible to support the effective implementation of the AIM Act and through that implementation of U.S. obligations under the Kigali Amendment to the Montreal Protocol. The Kigali Amendment was ratified under the Biden Administration and its implementation is a major foreign policy priority for the Administration and many U.S. stakeholders.

DATES: Comments must be received on or before **[INSERT DATE ~~45~~ 6045 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Any party requesting a public hearing must notify the contact listed below under FOR FURTHER INFORMATION CONTACT by 5 p.m. Eastern Daylight Time on **[INSERT DATE 5 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**. If a virtual public hearing is held, it will take place on or before **[INSERT DATE 15 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]** and further information will be provided at https://www.epa.gov/climate-hfcs-reduction.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA-HQ-OAR-2024-0196. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard-copy form. Publicly available docket materials are available electronically through http://www.regulations.gov or in hard copy at the EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Michelle Graff, U.S. Environmental Protection Agency, Stratospheric Protection Division, telephone number: 202-564-5387; or

Commented [EO 128665]: Consistent with EO 12866 section 6, EPA should seek public comment for no fewer than 60 days:

"Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days."

Commented [EPA6R5]: As noted elsewhere, EPA has a statutory deadline to finalize this rule and have it take effect prior to the allocation of calendar year 2026 (by October 1, 2025) in order for any entity to be eligible for application-specific allowances. To ensure adequate time to review and fully respond to comments in the final rule and meet the statutory deadline, there is a need to move this rule expeditiously. EPA intends to post a pre-publication version of the proposal on its website, which we estimate will provide interested stakeholders with close to 60 days to review the rule. If there is a willingness to conclude review on this rule by mid-July, EPA could consider a 60-day comment period.

Commented [Round 27R5]: The 90 days of review contemplated in EO 12866 are not intended to be mutually exclusive with a full 60-day comment period for NPRMs. Both serve important purposes. EPA should reconsider whether it can offer the public more than a 45-day window for public comments—particularly given the significant number of unknowns, which EPA recognizes throughout, and the great degree of uncertainty regarding what direction EPA intends to go with various application-specific allowances.

Commented [EPA8R5]: Thank you for the additional comment. EPA has given this significant consideration, but has ultimately determined it is necessary in this instance to maintain a public comment period of 45 days from publication. As explained elsewhere in this notice, EPA has done significant public outreach and engagement in the development of this proposal and has provided meaningful opportunity for stakeholder input as this proposal was developed. As noted in our prior response, we also plan to post this proposal on our website upon signature and notify interested stakeholders via email ahead of publication to allow as much time as possible for stakeholders to consider the proposal. When we balance these facts against the timing pressures we face (which are outlined in more detail in response to an interagency comment on page 66), we have ultimately decided to maintain a 45 day comment period in this instance.

email address: graff.michelle@epa.gov. You may also visit EPA's Web site at https://www.epa.gov/climate-hfcs-reduction for further information.

SUPPLEMENTARY INFORMATION: Throughout this document, whenever "we," "us," "the Agency," or "our" is used, we mean EPA. Acronyms and abbreviations that are used in this rulemaking that may be helpful include:

2-BTP – 2-bromo-3,3,3-trifluoropropene
AAGR – Average Annual Growth Rate
AES – Automated Export System
AIM Act – American Innovation and Manufacturing Act of 2020
AHRI – Air-Conditioning, Heating, and Refrigeration Institute
APU – Auxiliary Power Unit
ASHRAE – American Society for Heating, Refrigerating, and Air-Conditioning Engineers
ASA – Application-specific Allowance
CAA – Clean Air Act
CBI – Confidential Business Information
CBP – U.S. Customs and Border Protection
CF_3I – Trifluoroiodomethane
CFR – Code of Federal Regulations
CGMP – Current Good Manufacturing Practice
CHIPS Act – Creating Helpful Incentives to Produce Semiconductors Act of 2022
ClF_3 – Chlorine Trifluoride
CO_2 – Carbon Dioxide
COVID – Coronavirus Disease
CVD – Chemical Vapor Deposition
DFARS – Defense Federal Acquisition Regulation Supplement
DOD – U.S. Department of Defense
DOJ – U.S. Department of Justice
EEI – Electronic Export Information
EV – Exchange Value
EVe – Exchange Value Equivalent
EPA – U.S. Environmental Protection Agency
FAA – Federal Aviation Administration
FAR – Federal Acquisition Regulation
FDA – U.S. Food and Drug Administration
FIFRA – Federal Insecticide, Fungicide, and Rodenticide Act
FSTOC – Fire Suppression Technical Options Committee
FTOC – Flexible and Rigid Foams Technical Options Committee
FR – *Federal Register*
GHG – Greenhouse Gas
GWP – Global Warming Potential
HCFO – Hydrochlorofluoroolefin

HFC – Hydrofluorocarbon
HFIB – Hexafluoroisobutylene
HFO – Hydrofluoroolefin
ICAO – International Civil Aviation Organization
ICR – Information Collection Request
IPCC – Intergovernmental Panel on Climate Change
ITN – Internal Transaction Number
Kg – Kilogram
MCMEU – Mission-Critical Military End Uses
MCTOC – Medical and Chemicals Technical Options Committee
MDI – Metered Dose Inhaler
MT – Metric Ton
MTEVe – Metric Tons of Exchange Value Equivalent
NAICS – North American Industry Classification System
NF_3 – Nitrogen Trifluoride
ODP – Ozone Depletion Potential
ODS – Ozone-Depleting Substances
OMB – U.S. Office of Management and Budget
PFC – Perfluorocarbon
PII – Personally Identifiable Information
PRA – Paperwork Reduction Act
PU – Polyurethane
RACA – Requests for Additional Consumption Allowance
RFA – Regulatory Flexibility Act
RIA – Regulatory Impact Analysis
RSV – Respiratory Syncytial Virus
SCPPU – Structural Composite Preformed Polyurethane
SF_6 – Sulfur Hexafluoride
SiN – Silicon Nitride
SiO_2 – Silicon Dioxide
SNAP – Significant New Alternatives Policy
SISNOSE – Significant Economic Impact on a Substantial Number of Small Entities
TCE – Trichloroethylene
TEAP – Technology and Economic Assessment Panel
TSCA – Toxic Substances Control Act
TSD – Technical Support Document
UMRA – Unfunded Mandates Reform Act

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Regulatory Action

The U.S. Environmental Protection Agency (EPA) is undertaking this action to implement certain provisions of the American Innovation and Manufacturing Act of 2020, codified at 42 U.S.C. 7675 (AIM Act or the Act). The Act directs EPA to implement the phasedown of hydrofluorocarbons (HFCs) by issuing a limited quantity of transferrable production and consumption allowances, which entities must expend to produce or import HFCs. In addition, subsection (e)(4)(B) of the Act authorizes EPA to allocate allowances exclusively for the use in specific applications for which there is (1) no safe or technically achievable substitute and (2) an insufficient supply of the HFCs used in the application that can be secured from chemical manufacturers. The Act listed six applications that would receive priority access to allowances for a five-year period beginning on December 27, 2020: propellants in metered dose inhalers (MDIs), defense sprays, structural composite preformed polyurethane (SCPPU) foam for marine use and trailer use (hereafter referred to as SCPPU foam for marine and trailer uses), the etching of semiconductor material or wafers and the cleaning of chemical vapor deposition (CVD) chambers within the semiconductor manufacturing sector, mission-critical military end uses (MCMEU), and onboard aerospace fire suppression. EPA intends to finalize this rule ahead of the allocation of calendar year 2026 allowances. Without finalization of this rule, all applications would be ineligible for allowances for calendar year 2026.[1] EPA has created a category of allowances to provide this priority access, which EPA refers to as application-

Commented [EO 128669]: EPA uses this term several times but doesn't really explain what it means (i.e., whatever the appropriate wording is to explain how ASAs get taken first out of the general pool, and the remainder of the general pool gets allocated proportionally to entities based on their relative market share). Could EPA provide an explanation wherever appropriate, perhaps here or further down in II.B?

Commented [EPA10R9]: Thank you for this suggestion. Additional clarification on this priority access has been added here.

[1] EPA first codified the allocation methodology for general pool and ASA holders in "*Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act"* (hereafter referred to as the "Allocation Framework Rule") (86 FR 55116, October 5, 2021). The methodology for general pool allowance holders was subsequently updated in "*Phasedown of Hydrofluorocarbons: Allowance Allocation Methodology for 2024 and Later Years*" (hereafter referred to as the "2024 Allocation Rule" (88 FR 46836, July 20, 2023); the ASA methodology was not updated in the 2024 Allocation Rule.

specific allowances (ASAs). ASAs are allocated ahead of general pool allowances based on a methodology intended to determine eligible entities' needs for regulated substances (see Section VII of this preamble and the Allocation Framework Rule (86 FR 55116, October 5, 2021) for more information). After the total ASA quantity is determined, the remaining allowances are distributed to general pool allowance recipients using a different methodology.

Subsection (e)(4)(B)(v) of the AIM Act directs EPA to review applications receiving priority access to allowances not less frequently than once every five years, and, if the application meets the criteria above, authorize the eligibility of the application to receive priority access to allowances for a period of not more than five years. EPA is proposing how the Agency will interpret these two criteria to review applications receiving ASAs. EPA is also proposing decisions to renew or not renew each of the six applications that currently receive ASAs.

Separately, subsection (i) of the Act authorizes EPA, by rulemaking, to restrict the use of HFCs in sectors or subsectors where the regulated substances are used. Under the authority of this provision, EPA finalized the rule "*Phasedown of Hydrofluorocarbons: Restrictions on the Use of Certain Hydrofluorocarbons Under the American Innovation and Manufacturing Act of 2020*" (hereafter referred to as the "2023 Technology Transitions Rule"; 88 FR 73098, October 24, 2023), which established restrictions for three sectors and 39 subsectors. The rule exempted applications with a current qualification for ASAs. As such, if an application is no longer eligible to receive ASAs, it would become subject to the restrictions established in the 2023 Technology Transitions Rule. EPA is therefore proposing how the Technology Transitions regulations would apply to applications if EPA were to determine that those applications are not eligible for renewal for the full five-year period.

The Act also includes a provision for the public to petition EPA to designate an application as eligible for priority access to allowances. EPA is proposing a procedural process for submitting a petition under this provision and to define minimum required elements of such a petition. In addition, this rulemaking proposes narrow revisions to the methodology used to allocate allowances to ASA holders for calendar years 2026 and beyond as well as other limited revisions to the existing 40 CFR part 84 regulations. EPA is also proposing to authorize an entity to produce regulated substances for export for application-specific uses pursuant to subsection (e)(5). Lastly, EPA is proposing certain confidentiality determinations for newly reported information if this rule were finalized as proposed.

B. Summary of Proposed Actions

Application-specific allowance holder review: EPA is describing how it proposes to interpret the criteria under subsection (e)(4)(B) of the AIM Act and evaluate the six categories of ASA holders listed in subsection (e)(4)(B)(v) of the Act. EPA is proposing to renew the following applications for the full five-year period from 2026–2030: propellants in MDIs, the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector, MCMEU, and onboard aerospace fire suppression. EPA is co-proposing two options for defense sprays: do not renew or renew for a two-year period through 2027. EPA is co-proposing three options for SCPPU foams for marine and trailer uses: do not renew, renew for a two-year period through 2027, or renew for the full five-year period from 2026–2030 with allowance amounts determined based on the exchange value (EV) of a substitute HFC. In cases where EPA is proposing to change the status of ASA holders, this proposal also details how the Technology Transitions regulations would apply to those applications.

Application-specific allowance holder petitions: EPA is proposing the process and information requirements for submitting petitions under subsection (e)(4)(B) of the AIM Act which seek the designation of an application as an essential use.

Application-specific allowance methodology ~~and other revisions~~: EPA is proposing targeted revisions to the existing ASA methodology: to require companies to provide a total request for allowances for the calendar year, to expand permissible scenarios that could qualify as unique circumstances, to use a different allocation methodology for certain very small users of HFCs and entities with irregular purchasing history, how to account for inventory in allocation decisions, to establish a set-aside of allowances for situations that meet the criteria for unique circumstances related to medical conditions treated by MDIs, and to allow ASA holders to return a portion of their allowances voluntarily if they do not intend to use them. EPA is also proposing new requirements for conferrals of MCMEU allowances and an opportunity to return unneeded ASAs.

Other regulatory revisions: EPA is ~~also~~ proposing other specific regulatory changes to: clarify the ability of the federal government to pursue, if appropriate, auctioning illegally imported HFCs that are seized by enforcement officials, require exporting companies to report "Internal Transaction Numbers" (ITNs) quarterly, and simplify the reporting on "date of purchase" for a Request for Additional Consumption Allowances (RACA).

Authorization of production for export: EPA is proposing to authorize an entity to produce for export for application-specific uses abroad.

Handling of confidentiality for newly reported information: EPA is proposing certain confidentiality determinations for newly reported information if this rule were finalized as proposed.

Commented [EO 1286611]: Do these items fit into the rest of this category, or should they be separated out as "Other Revisions"?

Commented [EPA12R11]: Accepted.

II. General Information

A. Does this action apply to me?

You may be potentially affected by this proposal if you use HFCs in one of the six applications eligible for an allocation under section (e)(4)(B)(iv) of the AIM Act. You may also potentially be affected if you produce, import, export, purify, destroy, reclaim, package, or otherwise distribute HFCs for end users in one of these six applications or are a current HFC allowance holder. Potentially affected categories, North American Industry Classification System (NAICS) codes, and examples of potentially affected entities are included in Table 1.

Table 1: NAICS Classification of Potentially Affected Entities

NAICS Code	NAICS Industry Description
325120	Industrial Gas Manufacturing
325199	All Other Basic Organic Chemical Manufacturing
325211	Plastics Material and Resin Manufacturing
325412	Pharmaceutical Preparation Manufacturing
325414	Biological Product (except Diagnostic) Manufacturing
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing
326220	Rubber and Plastics Hoses and Belting Manufacturing
326150	Urethane and Other Foam Product
326299	All Other Rubber Product Manufacturing
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing
333511	Industrial Mold Manufacturing
334413	Semiconductor and Related Device Manufacturing
334419	Other Electronic Component Manufacturing
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing
336212	Truck Trailer Manufacturing
336214	Travel Trailer and Camper Manufacturing
336411	Aircraft Manufacturing
336611	Ship Building and Repairing
336612	Boat Building
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing
SIC 373102	Military Ships, Building, and Repairing.
339112	Surgical and Medical Instrument Manufacturing

423720	Plumbing and Heating Equipment and Supplies (Hydronics) Merchant Wholesalers
423730	Warm Air Heating and Air-Conditioning Equipment and Supplies Merchant Wholesalers
423740	Refrigeration Equipment and Supplies Merchant Wholesalers
423830	Industrial Machinery and Equipment Merchant Wholesalers
423840	Industrial Supplies Merchant Wholesalers
423860	Transportation Equipment and Supplies (except Motor Vehicle) Merchant Wholesalers
424690	Other Chemical and Allied Products Merchant Wholesalers
488510	Freight Transportation Arrangement
541380	Testing Laboratories
541714	Research and Technology in Biotechnology (except Nanobiotechnology)
562111	Solid Waste Collection
562211	Hazardous Waste Treatment and Disposal
562920	Materials Recovery Facilities
922160	Fire Protection

This table is not intended to be exhaustive, but rather provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this section could also be affected. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under "**FOR FURTHER INFORMATION CONTACT**."

B. What is EPA's authority for taking this action?

On December 27, 2020, the AIM Act was enacted as section 103 in Division S, Innovation for the Environment, of the Consolidated Appropriations Act, 2021 (codified at 42 U.S.C. 7675). In subsection (k)(1)(A), the AIM Act provides EPA with the authority to promulgate necessary regulations to carry out EPA's functions under the Act, including its obligations to ensure that the Act's requirements are satisfied (42 U.S.C. 7675(k)(1)(A)). Subsection (k)(1)(C) of the Act also provides that Clean Air Act (CAA) sections 113, 114, 304, and 307 apply to the AIM Act and any regulations EPA promulgates under the AIM Act as

though the AIM Act were part of title VI of the CAA. Accordingly, this rulemaking is subject to CAA section 307(d) (see 42 U.S.C. 7607(d)(1)(I)) (CAA section 307(d) applies to "promulgation or revision of regulations under subchapter VI of this chapter (relating to stratosphere and ozone protection)").

The AIM Act authorizes EPA to address HFCs in three main ways: phasing down HFC production and consumption through an allowance allocation program, facilitating the transition to next-generation technologies by restricting use of these HFCs in the sector or subsectors in which they are used, and promulgating certain regulations for purposes of maximizing reclaiming and minimizing releases of HFCs from equipment and ensuring the safety of technicians and consumers. This proposal relates to the first area and addresses restrictions in the second area for impacted subsectors.

The Act required EPA, for the five-year period beginning on December 27, 2020, to allocate the full quantity of allowances necessary, based on projected, current, and historical trends, for the production or consumption of regulated substances for the exclusive use in six applications: propellants in MDIs, defense sprays, SCPPU foam for marine and trailer uses, the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector, MCMEU, and onboard aerospace fire suppression (42 U.S.C. 7675(e)(4)(B)(iv)(I)). EPA has defined these allowances as ASAs. EPA intends to finalize this rule ahead of the allocation of calendar year 2026 allowances. Without finalization of this rule, all applications would be ineligible for allowances for calendar year 2026.

Subsection (e)(4)(B)(v) of the AIM Act requires EPA to review applications receiving allocations 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. 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.

Separately, an entity may file a petition for an application to receive ASAs. The AIM Act outlines timeframes and deadlines for EPA to act on such a petition and how the Agency should assess such a petition (42 U.S.C. 7675(e)(4)(B)(ii)). Specifically, not later than 180 days after receiving a petition, EPA must propose and seek public comment on whether to provide ASAs for the application. Not later than 270 days after EPA receives a petition, the Agency must take final action on the petition. Any application determined to be eligible for ASAs would also be subject to the review requirements in subsection (e)(4)(B)(v).

Subsection (i) of the AIM Act, "Technology Transitions," provides that "the Administrator may by rule restrict, fully, partially, or on a graduated schedule, the use of a regulated substance in the sector or subsector in which the regulated substance is used" (42 U.S.C. 7675(i)(1)). However, rules promulgated under subsection (i) "shall not apply to . . . an essential use under clause (i) or (iv) of subsection (e)(4)(B), including any use for which the production or consumption of the regulated substance is extended under clause (v)(II) of that subsection" (42 U.S.C. 7675(i)(7)(B)(i)). Therefore, per subsection (i)(7)(B)(i), the restrictions promulgated under the Technology Transitions Program are not currently applicable to any application receiving an ASA (40 CFR 84.56(a)(2)). To the extent that this proposal would result in an application no longer receiving an ASA, this action also proposes the Technology

Transitions Program restrictions that would apply to that application, if any, based on EPA's consideration of the factors listed in subsection (i)(4) of the AIM Act, should EPA finalize a determination that an application can no longer receive an ASA.

Prior to proposing a rule, subsection (i)(2)(A) of the Act directs EPA to consider negotiating with stakeholders in the sector or subsector subject to the potential rule in accordance with negotiated rulemaking procedures established under subchapter III of chapter 5 of title 5, United States Code (commonly known as the "Negotiated Rulemaking Act of 1990"). If EPA makes a determination to use the negotiated rulemaking procedures, subsection (i)(2)(B) requires that EPA, to the extent practicable, give priority to completing that rulemaking over completing rulemakings under subsection (i) that are not using that procedure. If EPA does not use the negotiated rulemaking process, subsection (i)(2)(C) requires the Agency to publish an explanation of the decision not to use that procedure before commencement of the rulemaking process. The Negotiated Rulemaking Act of 1990 (5 U.S.C. 563) provides seven criteria that the head of an agency should consider when determining whether a negotiated rulemaking is in the public interest, namely, whether: (1) There is a need for a rule; (2) there are a limited number of identifiable interests that will be significantly affected by the rule; (3) there is a reasonable likelihood that a committee can be convened with a balanced representation of persons who can adequately represent the identified interests and are willing to negotiate in good faith to reach a consensus on the proposed rule; (4) there is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed period of time; (5) the negotiated rulemaking procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of the final rule; (6) the agency has adequate resources and is willing to commit such resources, including technical assistance, to the committee; and (7) the agency, to the maximum extent

possible consistent with the legal obligations of the agency, will use the consensus of the committee with respect to the proposed rule as the basis for the rule proposed by the agency for notice and comment.

If a head of agency determines that the use of the negotiated rulemaking procedure is in the public interest, an agency may convene a federally chartered advisory committee, and may rely on an appointed convener under 5 U.S.C. 563(b) to assist with ascertaining the names of persons who are willing and qualified to represent interests that will be significantly affected by the proposed rule. If the agency decides to establish a negotiated rulemaking committee, the agency must publish in the *Federal Register* and in relevant publications a notice announcing the agency's intention to establish a negotiated rulemaking committee, a description of the subject and scope of the rule, a list of the interests which are likely to be significantly affected by the rule, a list of the persons proposed to represent such interests and the proposed agency representatives, a proposed agenda and schedule for completing the committee's work, a description of the administrative and technical support to be provided to the committee by the agency, a solicitation for comments on the proposal to establish the committee and on the proposed membership of the committee, and an explanation of how a person may apply or nominate another person for membership on the committee. The agency must provide at least 30 calendar days for the submission of comments and applications related to the membership of the committee. In establishing and administering such a committee, the agency shall comply with the Federal Advisory Committee Act, unless an exception applies. If the committee reaches consensus on a proposed rule, the committee shall transmit a report containing the proposed rule to the federal agency. If the committee does not reach a consensus on a proposed rule, the committee may transmit a report specifying any areas upon which consensus was reached. The

proposed rule is still subject to public comment, and for purposes of a rulemaking developed under the AIM Act, the requirements of CAA section 307(d).

Before proposing the 2023 Technology Transitions Rule, consistent with AIM Act subsection (i)(2)(A) and (C), EPA considered whether to negotiate with stakeholders using the negotiated rulemaking procedure provided for in the Negotiated Rulemaking Act of 1990, decided not to use such procedures, and published its explanation of that decision in the *Federal Register* (86 FR 74080, December 29, 2021).

EPA noted in the final 2023 Technology Transitions Rule that, where appropriate, EPA will consider recent Agency actions and decisions related to restrictions on the use of HFCs in sectors and subsectors for its consideration on using negotiated rulemaking procedures. EPA did not, for example, separately consider using negotiated rulemaking for four petitions that were received after a rulemaking process had already been commenced regarding the same sectors and subsectors, nor did EPA consider anew whether or not to use negotiated rulemaking in an interim final rule (88 FR 88825, December 26, 2023) that amended one provision of the 2023 Technology Transitions Rule for one subsector.

Similarly, the proposed changes to the Technology Transitions regulations contemplated in this action would be targeted at a subset of applications within a subsector subject to those restrictions. EPA is not addressing a new subsector in this proposal, nor even proposing a different level of stringency from already promulgated restrictions; rather, this action proposes only to establish deadlines by which applications would need to comply with Technology Transitions regulations in the event that those applications no longer receive ASAs. EPA does not believe that the public interest would be served by using the negotiated rulemaking procedure

for this limited adjustment to the Technology Transitions regulations, especially because timeliness is a concern.

III. Background

HFCs are anthropogenic[2] fluorinated chemicals that have no known natural sources. HFCs are used in a variety of applications such as refrigeration and air conditioning, foam blowing agents, solvents, aerosols, and fire suppression. HFCs are potent greenhouse gases (GHGs) with 100-year global warming potentials (GWPs) (a measure of the relative climatic impact of a GHG) that can be hundreds to thousands of times that of carbon dioxide (CO_2).

HFC use and emissions have been growing worldwide due to the global phaseout of ozone-depleting substances (ODS) under the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol), and the increasing use of refrigeration and air-conditioning equipment globally. HFC emissions had previously been projected to increase substantially over the next several decades. In 2016, in Kigali, Rwanda, countries agreed to adopt an amendment to the Montreal Protocol, known as the Kigali Amendment, which provides for a global phasedown of the production and consumption of HFCs. The United States ratified the Kigali Amendment on October 31, 2022. Global adherence to the Kigali Amendment would substantially reduce future emissions, leading to a peaking of HFC emissions before 2040.

There are hundreds of possible HFC compounds. The 18 HFCs listed as regulated substances by the AIM Act are some of the most commonly used HFCs (neat and in blends) and have high impacts as measured by the quantity of each substance emitted multiplied by their respective GWPs. These 18 HFCs are all saturated, meaning they have only single bonds

[2] While the overwhelming majority of HFC production is intentional, EPA is aware that HFC-23 can be a byproduct associated with the production of other chemicals, including but not limited to hydrochlorofluorocarbon (HCFC)-22 and other fluorinated gases.

between their atoms, and therefore have longer atmospheric lifetimes than fluorinated compounds that are unsaturated. ~~Some HFCs ((e.g. those that contain at least one fully fluorinated methyl or methylene carbon atom) meet existing scientific criteria to be considered per- and polyfluoroalkyl substances (PFAS).~~ More detailed information on HFCs, their uses, and their impacts is available in the Allocation Framework Rule (86 FR 55116, October 5, 2021).

Commented [EO 1286613]: Consider mentioning that certain HFCs are PFAS and therefore decreasing production and reducing emissions of HFCs supports the Administration's commitment to protecting human health and ecosystems from the harmful effects of "forever chemicals."

Commented [EPA14R13]: While we agree that PFAS is an Administration and EPA priority, we do not think it is appropriate to suggest that there's an agreed definition of PFAS that includes HFCs. There is no consensus definition of PFAS as a class of chemicals. Most existing regulations on PFAS, including those in the United States, focus on individual, longer chain, non-polymeric PFAS for which the most data on their occurrence in the environment and their human health and environmental impacts are available. These existing regulatory efforts have typically not focused either on substances controlled under the AIM Act and Montreal Protocol or their most likely substitutes. We are aware that more recent regional, non-US national, and subnational regulatory efforts agreed to or under development have or would address PFAS more categorically.

Commented [Round 215R13]: Reviewer agrees that it would not be accurate to suggest that there is an agreed upon definition of PFAS at this time. Please consider these readline edits that simply acknowledge that some HFCs meet the criteria set forth by several scientific bodies to be considered PFAS.

Commented [EPA16R13]: Per discussion, deleting the added sentence.

IV. How is EPA assessing whether to extend eligibility for application-specific allowances?

As noted in Section II.B of this preamble, the AIM Act directs EPA to undertake a review of applications receiving allowances pursuant to subsection (e)(4)(B)(iv) at least every five years. The statute says that access to ASAs shall be authorized for a renewed period if two statutory criteria are met. Specifically: (1) "no safe or technically achievable substitute will be available during the applicable period for that 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…including any quantities of a regulated substance available from production or import, is insufficient to accommodate the application" (42 U.S.C. 7675(e)(4)(B)(1)). In this section, we outline how EPA interprets these criteria, what information the Agency will consider in assessing these criteria, and a proposed framework for evaluating if an application is eligible for renewal for up to five years. EPA notes that under the statute, these criteria also apply to new applications that may be listed, but, aside from Section VI addressing the petition process, this proposed rulemaking is primarily focused on the renewal of existing applications. However, EPA's interpretations of the criteria discussed in this section would apply to future actions to add new applications. The AIM Act includes additional evaluation considerations for new applications in subsection (e)(4)(B)(i), but the Agency is not addressing their interpretation in this rulemaking.

A. How is EPA interpreting the "no safe or technically achievable substitute will be available" criterion?

In order for an application to continue to be eligible to receive ASAs, EPA must determine "no safe or technically achievable substitute will be available" for the application during the time period under review (42 U.S.C. 7675(e)(4)(B)(i)(I)). EPA is proposing that the best interpretation of this criterion is that if there is an available substitute that is both safe and technically achievable, an application would not meet this criterion for renewal. EPA acknowledges that the statutory language could be ambiguous as to whether a substitute must be both safe and technically achievable. However, reading the statutory language differently than proposed would seem to create a perverse outcome. In such a scenario, an application would become ineligible for ASAs if EPA identified a substitute that was technically achievable, but not safe. EPA reads the context of subsection (e)(4) as indicating that Congress intended that listed applications continue to receive priority access to allowances as long as the application needed to use regulated substances. In a situation where an identified substitute is not safe, EPA believes that it would be Congress's intent to continue to provide priority access to allowances such that the application was not prematurely forced to transition to an unsafe substitute. Similarly, it does not seem reasonable to take away access to ASAs when an identified substitute is safe, but not technically achievable. If the application cannot technically implement the transition to a substitute, it seems unrealistic to think that there could be a transition away from regulated substances. Accordingly, EPA proposes to interpret the statutory text and surrounding framework such that if EPA determines there is no safe substitute that is technically achievable for an application, or a technically achievable substitute is not safe, the application would meet the first criterion for renewal.

In looking at potential substitutes for an application under subsection (e)(4)(B)(i)(I), EPA is proposing to consider regulated substances (*i.e.,* other HFCs), alternative substances (*e.g.*, hydrofluoroolefins (HFOs), hydrocarbons), and blends of HFCs and/or HFC alternatives that can perform the same general function as the current HFC in use. EPA is proposing that such an interpretation of the term "substitute" is most consistent with the statutory language of subsection (e)(4)(B) as a whole. Specifically, in its direction to EPA to review applications receiving ASAs every five years, Congress directed EPA to "review the availability of substitutes, including any quantities of the regulated substance available." This sentence structure, indicating that ~~says~~ examination of quantities of regulated substances available would be included as part of analyzing what substitutes are available, suggests that regulated substances are part of the universe of substitutes that Congress intended EPA to include in its review. In addition to EPA's determination that such an approach is more consistent with the statutory language than an approach of only looking at non-regulated substances as substitutes, EPA has also identified other benefits of this interpretation. For example, it would seem to be a perverse outcome if EPA renewed an application's eligibility for ASAs at historic quantities where there was an available substitute that did not require any or required fewer allowances to procure. Non-HFCs may be able to fill the same role as the HFC, often functioning as a chemical-for-chemical replacement or requiring limited design changes.

EPA is proposing, as part of its assessment of what chemicals may be determined to be safe as a substitute for applications under review, to only include substances, including blends of substances, with a lower GWP than the regulated substance currently in use. As explained in the Allocation Framework Rule (86 FR 55116, October 5, 2021), the HFC phasedown's significant benefits are derived from the reduction of production and consumption of certain chemicals on a

Commented [EO 1286617]: Suggesting readability edits

Commented [EPA18R17]: Accepted.

Commented [EO 1286619]: This seems to be the only explicit statement of how EPA defines safe for this statutory criterion i.e. has a lower GWP. Further clarity on how safe determinations will be made would provide stakeholders the means to anticipate and/or evaluate public health impacts.

Commented [EPA20R19]: We added a sentence at the end of this paragraph to connect to the later discussion regarding our interpretation of "safe," which commenter noted is clearer.

GWP-weighted basis.[3] Considering higher-GWP substances or blends of substances would run against this overall objective and could reduce the benefits of the HFC phasedown, especially if this rule led to the uptake of higher-GWP non-HFC technologies (*e.g.*, semiconductor manufacturers transitioning back to using higher-GWP perfluorocarbons (PFCs)). In addition, this proposed interpretation aligns with the approach under the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023), which established GWP limits for subsectors and considered substitutes as only those with lower GWPs. Further discussion regarding the sources EPA is relying on to determine if a substitute is safe (*e.g.*, listed by EPA's Significant New Alternatives Policy (SNAP) Program) can be found below.

In addition to looking at chemicals that could serve as substitutes, EPA is also including in its analysis any potentially available not-in-kind technologies (*e.g.,* finger-pump bottles that would not use any chemical propellant in lieu of aerosol cans) for purposes of subsection (e)(4)(B)(i)(I). Such an approach is consistent with the common understanding of the plain language definition of "substitute." For example, Merriam Webster defines substitute as a thing that "takes the place of function of another" and the Oxford dictionary similarly notes a substitute is a "thing acting or serving in place of another." In general, not-in-kind technologies can serve the need of some applications, so it is appropriate to include them within the scope of assessing safe and technically achievable substitutes. It would be unnecessarily limiting to exclude from the scope of the analysis a technology that performs the same general function for the application as the current HFC in use does. EPA also acknowledges that market pressure from the HFC phasedown may encourage a transition into not-in-kind technologies (and non-

[3] While the AIM Act calls for reduction of HFC production and consumption on an EV-weighted basis, EV and GWP are numerically equal. Lower GWP is an important consideration for whether a substitute is safe, so EPA is using GWP instead of EV in the discussion in this section of the rule.

HFCs) by limiting the supply of HFCs on a GWP-weighted basis, while the Technology Transitions Program prohibits the use of certain HFCs in certain sectors and subsectors. There is also precedent for considering not-in-kind technologies under CAA Title VI, such as the ~~Significant New Alternatives Policy (~~SNAP~~)~~ Program and Nonessential Product Bans, and the AIM Act Technology Transitions Program, all of which also evaluate not-in-kind substitutes as possible alternatives to ODS and HFCs, respectively.

EPA is aware that a transition to certain substitutes will require changes to how the HFCs are used in the application (*e.g.*, accommodating a flammable HFC in the manufacturing process). Shifts to not-in-kind technologies will inherently require a change in manufacturing and/or the product, so it would be a consistent approach to also not outright exclude substitute chemicals that would similarly require a change in manufacturing process or the product.

EPA does not want to unnecessarily limit the scope of the substitute analysis at this point in time, and therefore is considering a wide range of possible safe and technically achievable substitutes. The phasedown of HFCs is still nascent, and, at this point, we cannot know the full breadth of technologies that will be developed as replacements for the current HFCs in use.

The Agency is proposing to assess this criterion, specifically that a substitute is safe, technically achievable, and available, on an application-wide basis. For applications that use multiple HFCs, a substitute would need to be able to replace all HFCs used (or multiple substitutes that replace all individual HFCs would need to be available). For applications that have sub-applications (*e.g.*, defense sprays include those intended for humans and those intended for animals), there would need to be a viable substitute for known sub-applications. EPA's interpretation is that it would be unreasonable to consider an application as having met this

criterion and thereby ineligible for renewal unless all known sub-applications can successfully transition away from their currently used HFC(s).

EPA's evaluation of each application is not intended to be a company-specific review; the commercialization[4] of a substitute by one sub-application suggests the substitute is safe or technically achievable for the entire application barring evidence, such as testing data, to the contrary. However, there are additional barriers to commercialization, which are considered when assessing if the identified substitute is available for an entire application. In addition, EPA's interpretation of the statutory language is that applications are intended to be viewed as a whole and not necessarily renewed by sub-application. Specifically, the listing of the applications in subsection (e)(4)(B)(iv)(I) does not break down the application into sub-applications (*e.g.*, "defense sprays" is not listed as multiple separate applications, *e.g.*, "personal defense sprays," "law enforcement defense sprays," and "bear defense sprays"). Similarly, for applications that use multiple HFCs and have specific uses for the individual HFCs, it would not be reasonable to assess this criterion as being met if an application does not have an available safe and technically achievable substitute for each HFC. It is EPA's opinion that Congress did not intend for an application to lose its eligibility for ASAs if it could only transition some, but not all, of the HFCs currently used in the application.

EPA reviewed a range of sources in developing its assessment of the availability of safe, technically achievable substitutes for each application at issue here. Sources include, but are not limited to: manufacturer announcements; information provided by stakeholders under part 84 reporting requirements and other communications; relevant federal and state regulations;

[4] EPA is using the term "commercialization" to mean that the substitute is commercially available and actively being used in an application's equipment or sold on the market (domestically or internationally) for use in the application. "Commercialization" is not intended to be equated with "available," as explained in more detail in the main text.

evaluations carried out under the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) and the SNAP Program; standards from industry, standard-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 MDIs); and peer-reviewed technical reports. The Technical Support Document (TSD) "Draft Review of Applications in the American Innovation and Manufacturing (AIM) Act Section (e)(4)(B)(4)" contains a comprehensive array of sources we looked at for each application, and EPA is taking comment on other relevant sources that should be considered.

As noted, EPA is considering the listings under the SNAP Program as part of its assessment. The SNAP Program has an established history evaluating substitutes for ODS, many of which are also possible substitutes for HFCs. Where relevant, in its assessment of the availability of safe substitutes, EPA considered information from the SNAP Program, including the listings themselves and the information underlying SNAP Program decisions. The SNAP Program does not evaluate substitutes for semiconductor etching and cleaning of CVD chambers. Some military applications are covered under the SNAP Program. In other cases, such as MDIs and SCPPU foams, while these applications are within the scope of the SNAP Program, there may be other sources of information (*e.g.*, the FDA, company information) that may be more appropriate.

In its evaluation of substitutes and related decisions (*e.g.*, to list as acceptable or unacceptable), the SNAP Program carries out a comparative risk evaluation and considers whether a substitute to an ozone-depleting substance presents human health and environmental risks that are lower than or comparable to such risks from other substitutes that are currently or potentially available for the same uses. 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 ozone depletion potential (ODP) and GWP. Information and data relied upon in the SNAP Program are directly relevant to EPA's assessment of substitutes in this rulemaking, and therefore EPA has pulled from and relied upon SNAP Program assessments as appropriate.

Commented [EO 1286621]: Re comment on p. 21, this simple language on agency risk evaluations as basis for acceptable/unacceptable decisions in the SNAP Program would improve understanding and implementation of the safe substitute criterion for ASAs

Commented [EPA22R21]: Comment responded to above.

EPA evaluates substitutes under the SNAP Program on an ongoing basis and over time has listed numerous substances as "acceptable," "acceptable, subject to use conditions," or "acceptable, subject to narrowed use limits." "Acceptable subject to use conditions" indicates that a substitute is acceptable only if used in a certain way. Use conditions can include, but are not limited to, warning labels, compliance with relevant safety standards, and restrictions on where a substitute is used (*e.g.,* HFC-134a is acceptable for FDA-approved MDIs for medical purposes but is not acceptable for a majority of aerosol uses, and some fire suppression substitutes may only be used in typically unoccupied spaces). EPA can also list substitutes as "acceptable subject to narrowed use limits" under SNAP, indicating that a substitute may be used only within certain specialized applications within an end use and may not be used for other applications within that end use (*e.g.,* SNAP has previously listed some substitutes as acceptable for only narrowed use limits for military or space- and aeronautics-related applications). In listing of a chemical as acceptable or acceptable subject to use conditions directly relevant to the application, the SNAP Program makes an assessment that the benefits outweigh the risks relative to other alternatives; these listings are relevant data to support EPA's determination under AIM Act subsection (e)(4)(B) on whether a substitute is "safe" under the interpretation proposed in this rulemaking.

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. EPA has listed substitutes as unacceptable considering the human health criteria described above, as well as the environmental factors considered under SNAP. For example, SNAP has listed certain substitutes as unacceptable due to unusually high ODP, GWP, toxicity and exposure, and flammability (where it is not clear how to mitigate risks sufficiently). Substitutes listed as unacceptable in an end use are prohibited for that use and therefore would not be an available safe or technically achievable substitute for an application under our proposed interpretation of this criterion.

The Agency is also reviewing the evaluations carried out for the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) and relying on information and assessments done in that rulemaking, as appropriate. In establishing restrictions, the Technology Transitions Program factored in the availability of substitutes, considering both safety and technological achievability, among other factors. The Technology Transitions Program relied on information from a wide range of sources when assessing availability, including but not limited to, SNAP, the Montreal Protocol's Technology and Economic Assessment Panel (TEAP), standards bodies, and information provided by industry, states, and environmental non-governmental organizations. Though the Technology Transitions Program looked subsector-wide, not at specific end uses, and did not specifically analyze the applications currently receiving ASAs under subsection (e)(4)(B)(iv), some of these applications (*e.g.*, defense sprays and SCPPU foams for marine and trailer uses) have similarities with the subsectors currently subject to restrictions. As a result, in carrying out the assessments undertaken in this rulemaking, EPA is considering relevant information from the Technology Transition Program's evaluations.

In the assessment undertaken in this rulemaking, EPA is also taking into account other federal standards and regulations, both within EPA and from other U.S. Government agencies. For many applications under review in this rulemaking, there are applicable regulations and standards that outline requirements related to the chemicals or technologies used within an application. In these situations, such standards and regulations may in some instances limit use of possible substitutes. In some instances, it may not be possible for a substitute to ever be used. In other instances, applicable regulations may require entities to go through a regulatory approval process that would affect when an application can transition to a substitute. Some examples of regulations and standards we are considering as part of our proposed evaluations include EPA's regulations covering pesticides such as bear spays and dog sprays (sub-applications of defense sprays) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 U.S.C. 136–136y), the FDA's requirements for MDIs, and the U.S. Federal Aviation Administration's (FAA) requirements for onboard aerospace fire suppression. Additional standards and regulations for each application are discussed further in the relevant chapter of the TSD. EPA invites comment on any other standards or regulations that entities think EPA should consider in determining an application's ability to transition to a substitute.

EPA also considered the work undertaken by the Montreal Protocol's TEAP in the proposed application assessment given the TEAP's analytical work on substitutes and alternative technologies to substances controlled under the Montreal Protocol, including HFCs. TEAP assesses technical and economic information that serves as the basis for parties' assessment of control measures of substances under the purview of the Montreal Protocol. Such information is related to substitutes that may replace the substances controlled under the Montreal Protocol and alternative technologies that may be used without adverse impact on the ozone layer and climate,

production and consumption of controlled substances, emissions of controlled substances, potential alternatives for exempted uses and others, as mandated by the parties. This assessment includes applications listed in AIM subsection (e)(4)(B)(iv). In addition, TEAP develops assessments in response to decisions taken by the parties to the Montreal Protocol, including but not limited to Decision XXVIII/2, which call for an assessment of alternatives to HFCs every five years. EPA particularly looked at the 2022 Assessment Reports by the Medical and Chemical Technical Options Committee, concerning semiconductors, aerosols, and MDIs; the Flexible and Rigid Foams Technical Options Committee (FTOC); and the Fire Suppression Technical Options Committee (FSTOC). TEAP reports have included information on technical achievability and safety. TEAP reports are developed by experts around the world and provide insight into the HFC substitutes currently in use and under development in the United States and globally. As such, EPA is considering relevant information from these reports when carrying out the assessment of available safe or technically achievable substitutes undertaken in this rulemaking.

As described throughout this section, EPA is considering information from a wide range of sources in its assessment of the availability of safe or technically achievable substitutes for the applications receiving ASAs under subsection (e)(4)(B)(iv)(I), and no one source will be determinative for this criterion. Further information about sources consulted for each application can be found in Section V and the TSD. EPA invites comment on its interpretation of "no safe or technically achievable substitute will be available" and the sources it is considering in its assessment of this criterion.

B. How is EPA interpreting the insufficient supply of regulated substances criterion?

Under the second criterion for renewal of an application's eligibility to receive ASAs, EPA must determine that "the supply of the regulated substance that manufacturers or users of the regulated substance for that application are capable of securing from chemical manufacturers…, including any quantities of a regulated substance available from production or import, is insufficient to accommodate the application" (42 U.S.C. 7675(e)(4)(B)(i)(II)). As described here and in the sections of the rule discussing each of the six applications, a determination that there is insufficient supply could be based on a number of different factors, including the available domestic supply of the HFC(s) at issue, demand for said HFC(s), and supply chain constraints particular to a given application (*e.g.,* federally required purity specifications). Priority access to allowances through ASAs has the potential to address insufficient supply of HFCs by allowing entities that use HFCs in an eligible application to more easily procure HFCs from a domestic supplier by conferring allowances to authorize production or import or to import the HFCs themselves.

In this proposed rulemaking, EPA is interpreting this criterion as requiring an assessment related to the supply of the HFC(s) currently used in an application's equipment or to manufacture the application's products for use. Under this proposed interpretation, EPA would not evaluate HFC(s) currently used exclusively for research and development in assessing whether there is insufficient supply. EPA recognizes that the research and development process may find various alternatives to be unsuitable for an application. Therefore, it would be premature to consider supply of potentially unsuitable HFC alternatives until such time as they have been commercialized or are close to commercialization. Further, it could also have the

perverse effect of limiting research into alternatives if an application's initial research could prematurely contribute to removal from eligibility for ASAs.

EPA is proposing to consider regulated substances supplied by chemical manufacturers in its assessment of supply. EPA interprets the reference to regulated substances "from chemical manufacturers" in subsection (e)(4)(B)(i)(II) as direction from Congress to assess supply from chemical manufacturers only, and that this direction could cover both virgin and recovered and reprocessed HFCs. EPA is proposing to include HFCs produced domestically and those that are produced abroad and imported in its assessment of supply under this criterion. Congress directed EPA to consider regulated substances "from chemical manufacturers …, including any quantities of a regulated substance available from production or import" in its assessment under subsection (e)(4)(B)(i)(II). Because of Congress's reference to production and import of regulated substances, and the lack of any language suggesting that chemical manufacturers should be read as limited to only U.S. producers, EPA intends to consider imported material from foreign HFC producers in addition to regulated substances from domestic producers. As a result, EPA is proposing not to consider HFC supply held by and available to entities that do not produce or import HFCs in its assessment of this criterion. This would exclude quantities of HFCs held by entities that do not produce or import HFCs with allowances, potentially including reclaimers, distributors, HFC blenders,[5] and HFC repackagers. EPA considers this proposed interpretation to be most consistent with the statutory language in subsection (e)(4)(B)(i)(II).

The Agency is proposing to consider multiple sources of data in its evaluation of whether supply of a regulated substance is insufficient to accommodate an application. Specifically, in

[5] For a discussion on the difference between producing HFCs consistent with the AIM Act and blending HFCs to make various refrigerant blends, see "Response to Comments", pg 193, Docket ID No. EPA–HQ–OAR–2021–0044, associated with the Allocation Framework Rule (86 FR 55116) and the discussion in the 2024 Allocation Rule (88 FR 46863).

developing the analysis for each application, EPA has drawn information regarding the total expected HFC consumption in the United States, global production of individual HFCs used in the applications, manufacturer announcements regarding production of specific HFCs, past and projected market trends for an application that can inform projected demand for the HFC(s) it uses, and allowance usage by application to date, including conferrals, imports, and open market purchases by ASA holders, as well as expenditures of conferred allowances by suppliers to ASA holders. EPA is intending to consider data from all of these sources collectively in order to gain a more complete picture of projected supply for the relevant individual HFC(s), rather than relying on one data point. EPA is taking comment on these and any other sources the agency should consider when assessing insufficient supply.

EPA is proposing to assess insufficient supply on an application-wide basis. If an application uses multiple HFCs, and the supply of at least one of those HFCs is insufficient to accommodate the application, EPA would consider the criterion met for the application. EPA interprets subsection (e)(4)(B)(i)(II) to require the Agency to review the supply of the regulated substance for each regulated substance an application uses. If there is an insufficient supply for one HFC, EPA would determine that this criterion is met, and the application would continue to be eligible for ASAs, assuming the first criterion regarding substitutes is also met. EPA is proposing that such an approach is the best interpretation of the AIM Act direction in subsection (e)(4)(B)(v)(II) that if both criteria are met, "the Administrator shall authorize the production or consumption, as applicable, of any regulated substance used in the application." A converse approach would result in EPA not renewing the ASA eligibility of an application that has no available substitutes and there is an insufficient supply available of a regulated substance used by that application. EPA is interpreting the AIM Act to provide ASAs to an application where at

least one regulated substance ~~which~~that manufacturers are capable of securing is insufficient to accommodate the application, even if the supply of a different regulated substance is not insufficient.

In addition to looking generally at the supply of HFCs, EPA is also considering relevant restrictions, if any, on the type of HFC or supplier of HFCs that would further limit supply to a particular application. For example, FDA regulations govern use of pharmaceutical-grade HFCs by MDI manufacturers. Facilities manufacturing the regulated substances must comply with FDA regulations, and there are a limited number of purifiers. EPA is considering any applicable relevant federal regulations and standards (examples listed above in Section IV.A.), including required regulatory approvals and purity levels, that could limit the supply of the HFC(s) used within an application.

C. What is EPA's proposed framework for renewing applications?

In outlining the requirement that EPA review the applications eligible for ASAs at least every five years, the AIM Act states that if EPA determines "that the requirements described in subclauses (I) *and* (II) of clause (i) are met" then the EPA will renew the application's eligibility to continue to receive ASAs (42 U.S.C. 7675(e)(4)(B)(v)(II)) (emphasis added). Accordingly, EPA interprets the statutory language to mean that both criterion (I) of clause (i) (that a substitute is not available) and criterion (II) (that supply is insufficient) must be met for an application to be renewed as eligible for ASAs. If either or both criteria are not met as of January 1, 2026, EPA proposes to not renew an application's eligibility to receive ASAs. Put another way, if EPA determines, for example, that supply is not insufficient to accommodate an application as of January 1, 2026, EPA would propose to not renew that application's eligibility for ASAs, regardless of whether a substitute is available.

Commented [Round 323]: How will epa determine that supply is not insufficient? Is this spelled out somewhere?

If both statutory criteria are met as of January 1, 2026, EPA intends to assess whether an application's fulfillment of a criterion may change over the following five-year period. The outcome of this assessment would be determinative of how long EPA will deem an application eligible to receive ASAs. For example, if EPA determines that there is no substitute available as of January 1, 2026, but a substitute will be available by January 1, 2028, EPA would renew the application's eligibility to receive ASAs for only two years (*i.e.,* calendar years 2026 and 2027). Similarly, if supply is deemed insufficient to accommodate the application as of January 1, 2026, but the market will change such that supply will not be insufficient to accommodate the application as of January 1, 2028, EPA would renew the application's eligibility to receive ASAs for only two years (*i.e.,* calendar years 2026 and 2027).

If EPA determines that an application has a safe or technically achievable substitute available that is a regulated substance, EPA proposes to evaluate the supply of the substitute HFC and assess if supply of the substitute HFC is insufficient to accommodate the application. If the Agency did not do this, the application would not be eligible for renewal because it had met the substitute criterion, regardless of the supply of this substitute HFC; EPA sees this as counter to Congress's intent when it established priority access to allowances for these applications. Further, it is EPA's assessment that it would be counterproductive to an application's efforts to transition away from the currently used HFC(s) if EPA did not consider the supply of the HFC substitute when assessing eligibility for renewal for ASAs (*i.e.,* if an application had insufficient supply of the substitute HFC, an entity may be forced to return to using its original HFC). Under the framework proposed in this rule, if EPA determines there is an HFC substitute, but there is insufficient supply of that HFC substitute, EPA would continue to list the application as eligible for ASAs. This approach would allow an entity transitioning to a lower-GWP HFC to remain

eligible to receive allowances until supply of that lower-GWP HFC is no longer insufficient (or a non-HFC substitute is identified).

EPA is also proposing that if an application is eligible to be renewed for ASAs for less than five years, the application will not be reviewed for eligibility for ASAs ahead of the next five-year renewal period. The direction in the statute under subsection (e)(4)(B)(v) is to review each "application receiving an allocation of allowances under clause (i) or (iv)…not less frequently than once every 5 years," and, if the criteria are met, EPA shall renew the application "for renewable periods of not more than 5 years." EPA interprets this language, coupled with the lack of language in the statute directing EPA to do another review of an application that is no longer eligible for allowances at the end of its renewal period, as direction that EPA is not required to re-review this application for eligibility for ASAs ahead of the next five-year period. Congress's direction to undertake a renewal is specific to applications receiving ASAs under subsections (e)(4)(B)(i) and (iv). If an application is renewed for only two of five years at this stage, when the next renewal period arises, it would not be receiving ASAs under subsections (e)(4)(B)(i) or (iv). Therefore, EPA is proposing that the best interpretation of the AIM Act language is that once EPA determines that an application is no longer eligible for ASAs, EPA would not re-review that application at any future time. If an application is determined to no longer be eligible for ASAs and an entity is interested in being considered for eligibility for ASAs again, the ~~application~~ entity would need to petition the Agency to be evaluated for eligibility, and the Agency would then undertake the relevant petition review process; see Section VI for further discussion of the petition process requirements.

Commented [EO 1286624]: Who is this referring to? The manufacturer?

Commented [EPA25R24]: Clarified.

V. Review of the Six Applications Listed in the AIM Act

EPA reviewed the six applications listed in AIM Act subsection (e)(4)(B)(iv)(I)—propellant in MDIs; defense sprays; SCPPU foam for marine use and trailer use; the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector; MCMEU; and onboard aerospace fire suppression—as required under subsection (e)(4)(B)(v)(I). Pursuant to that review, in this rulemaking EPA is proposing and seeking comment on whether the criteria for renewal described in Section IV of this preamble are met for any part, or the entirety, of the 2026–2030 time period. This section begins with an overview of total projected U.S. HFC consumption and then proceeds into EPA's assessment of the criteria for each application and proposed decision regarding whether to renew each application's eligibility to receive ASAs. EPA provides additional information in the TSD available in the docket for this rulemaking.

A. Overview of Total U.S. HFC Consumption

This section contains a summary of total projected U.S. HFC consumption. We assess specific HFC supply considerations on an application-by-application basis below. EPA provides additional information regarding this analysis in the TSD.

The global and domestic HFC markets have been rapidly changing since agreement to the Kigali Amendment to the Montreal Protocol in 2016.[6] The domestic HFC market has been further changing since the passage of the AIM Act in 2020 and the subsequent promulgation of domestic regulations. In 2021, EPA promulgated regulations to implement the required phasedown of HFC production and consumption in the United States. Additional regulations coming into effect, as early as January 1, 2025, will also further alter this overall market and

[6] The United States ratified the Kigali Amendment in October 2022.

Commented [EO 1286626]: My takeaway from reading this section was "EPA has no idea what the total US HFC consumption is during the relevant time period for various reasons." If this is not what EPA is trying to convey, consider leading with a summary or other high-level takeaways.

Commented [EPA27R26]: This section is intended to explain the current available information as it relates to the insufficient supply criterion while also noting where information will continue to evolve between now and when EPA will finalize this rule. While EPA knows what the maximum HFC consumption will be in future years, we cannot know with certainty what actual consumption will be in a given year until that year is over, and data is verified. As the HFC phasedown and the market surrounding it are inherently dynamic, the Agency wants to be transparent about what changes we anticipate ahead of this rule being finalized so that the public is on notice, as much as possible, of what additional information EPA will take into account in finalizing this rule.

Commented [Round 228R26]: Emphasizing that this uncertainty is another reason why EPA should broaden opportunities for public comment consistent with EO 12866

Commented [EPA29R26]: Please see responses to similar comments on page 2 and page 66.

impact demand for certain HFCs. EPA anticipates the market will be dynamic as it responds to these additional regulations and continues adapting to the global phasedown of HFCs.

In the addendum to the HFC Phasedown Regulatory Impact Analysis (RIA) updated for the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023), EPA modeled total HFC consumption to be significantly lower than the limit established by the statutory phasedown cap for all years of the phasedown, assuming compliance with the restrictions. The 2023 Technology Transitions Rule established subsector-level GWP limits and restrictions on the use of certain regulated substances. These requirements take effect as early as January 1, 2025, and as late as January 1, 2028. While some subsectors already use either HFCs that are below the GWP limit or non-HFC substitutes, other subsectors will need to transition away from their currently used HFC to comply with these regulations. In addition, the proposed rulemaking *"Phasedown of Hydrofluorocarbons: Management of Certain Hydrofluorocarbons and ~~Their~~ Substitutes Under Subsection (h) of the American Innovation and Manufacturing Act of 2020"* (88 FR 72216, October 19, 2023) (hereafter "Emissions Reduction and Reclamation Rule") has proposed requirements that reclaimed and recycled HFCs be used for certain equipment in the refrigeration, air-conditioning, and heat pump sector and fire suppression sector (onboard aerospace fire suppression, as an application eligible for ASAs, is currently exempt) as early as early as January 1, 2028. If finalized as proposed, these requirements are also expected to limit use of virgin HFCs for specific activities (*e.g.*, servicing for certain refrigeration and air conditioning subsectors).[7] In general, there is uncertainty associated with these estimates, as they are based on expected industry transitions in response to AIM Act rulemakings and predicted market dynamics. If HFC consumption is lower than the amount allowed under the AIM Act in a

Commented [EO 1286630]: This isn't the title of the rulemaking as it appears in the Federal Register. The correct title is "Phasedown of Hydrofluorocarbons: Management of Certain Hydrofluorocarbons and Substitutes Under Subsection (h) of the American Innovation and Manufacturing Act of 2020". It's pretty confusing for EPA to refer to rulemakings with different terminology, particularly since the rule was published in the FR without a RIN which seems like a problematic oversight.

Commented [EPA31R30]: Edited.

[7] See Emissions Reduction and Reclamation Rule (88 FR 72216, 72292, October 19, 2023).

given year, the result may be that there are more allowances than are needed to meet market demand in that year.[8] If demand for HFCs is lower than the cap, it is possible that general pool consumption and production allowances would be available to allow for the production or import of HFCs for use by entities that historically have relied upon ASAs. It is also possible that all allowances are used, and the HFCs that are not sold in that year are stockpiled in anticipation of future needs.

Commented [Round 332]: Can ASA sectors access HFCs through the general pool? The edited language suggests that without ASAs, these 6 sectors would not have any access to HFCs. Would you clarify?

The Agency cannot fully predict shifts in chemical production, domestically and internationally, that may occur. As the HFC phasedown progresses, EPA anticipates suppliers may focus their business on supplying lower-GWP HFCs, since production and consumption of these lower-GWP HFCs requires the expenditure of fewer allowances for the same volume of substance.[9] At the same time, sectors that are not yet ready to transition and are not covered by the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) may continue to use higher-GWP HFCs and could grow in size.

EPA also does not yet have data on how the market is reacting to the 2024 stepdown in HFC allowances (from 90 percent of the HFC consumption baseline to 60 percent of baseline); at the time of this proposal the market is only a few months into adjusting to the 2024 HFC stepdown, and EPA has received only one set of quarterly reports. Among other things, data on

[8] The actions taken pursuant to subsection (h) and (i) of the AIM Act did not propose to and did not accelerate the HFC phasedown. The RIAs associated with those actions did not analyze an acceleration of the HFC phasedown. Rather, HFCs will continue to be available consistent with the phasedown codified at 40 CFR part 84, subpart A, and this action does not propose to change that phasedown schedule. Even if the requirements finalized pursuant to subsections (h) and (i) in effect reduce the production or consumption of HFCs used in particular sectors or subsectors faster than the scheduled reductions under the AIM Act, that does not make those rules an acceleration under subsection (f).

[9] In the Allocation Framework Rule, EPA established a system whereby allowances are measured on an EV equivalent basis. 86 FR at 55142. To determine the total number of allowances needed, producers and importers multiply the quantity of the HFC they seek to produce or import by its EV. For example, an importer would need to expend 143 consumption allowances to import 100 kilograms (kg) of HFC-134a. Given the variation in EVs, one would need to expend 5.3 allowances to import 100 kg of HFC-152a.

market reactions could inform how the market will react to the next large stepdown in 2029 (from 60 percent of baseline to 30 percent of baseline). For example, the decrease in available consumption allowances could encourage users of HFCs to transition faster than projected. However, given the significant amount of HFCs in inventory at the end of 2022, the transition away from HFCs could also be slower than projected. Though it seems likely that demand could be below the cap for the 2025–2028 period based on existing regulations, it is uncertain if 2029 (the fourth year of the five-year renewal period) will see similar space between consumption and allowed consumption under the cap. EPA also notes the 2024 stepdown in permissible production and consumption is unique given its scale and that it is occurring early in the overall AIM Act implementation. ~~Remaining phasedown steps are much smaller in scale, particularly those that fall within the period that will be reviewed in the next ASA renewal (*i.e.*, 10 percent in 2034 and 5 percent in 2036).~~ There will be significantly more information regarding the state of the HFC market after the January 1, 2024, stepdown at the time EPA is finalizing this proposal, and EPA intends to analyze available data to inform its decisions regarding whether supply of individual HFCs is insufficient to accommodate the individual applications.

Commented [EO 1286633]: Isn't the 2029 step (going from 60% of baseline down to 30% of baseline) the same magnitude change as going from 90% down to 60% in the 2024 step? The examples of "10 percent in 2034 and 5 percent in 2036" is also a bit confusing, suggest changing to "going from 30 percent down to 20 percent of baseline in 2034, and from 20 percent of baseline down to 15 percent of baseline in 2036).

Commented [EPA34R33]: Thank you for this comment. We have deleted the sentence.

In addition, there are also other constraints on supply of specific HFCs used in the six applications that EPA is taking into consideration (*e.g.*, purity specifications required by federal standards and regulations and limited number of producers), as explained in more detail in Sections V.B through V.G. Supply chain dynamics for each of the six applications could affect whether general pool allowances would be able to be used to provide HFCs for each application.

B. Propellants in Metered Dose Inhalers

EPA has been allocating ASAs for regulated substances used for propellants in MDIs in accordance with subsection (e)(4)(B)(iv)(I)(ff) of the AIM Act. In the Allocation Framework

Rule, EPA defined a "metered dose inhaler" 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). Patients using MDIs to treat pulmonary conditions work closely with their healthcare provider to identify the right treatment for their condition. Pharmaceutical grade HFC-227ea and HFC-134a, purified from technical grade HFC-227ea and HFC-134a, respectively, are both used in MDIs as a propellant.

For the reasons discussed in the following sections, EPA is proposing to determine that no safe or technically achievable substitute will be available for propellants in MDIs and that supply of the regulated substance that manufacturers and users are capable of securing from chemical manufacturers is insufficient to accommodate this application through calendar year 2030. Therefore, EPA proposes to renew the eligibility of entities using regulated substances for propellants in MDIs to receive ASAs for the five-year period of calendar years 2026 through 2030.

1. Availability of Safe and Technically Achievable Substitutes

EPA has not identified substitutes that it would propose to deem safe and technically achievable that are available for propellants in the metered-dose inhalers application at this time. In assessing the availability of substitutes for MDIs, EPA reviewed information from sources such as the FDA, the EPA SNAP Program, the TEAP's Medical and Chemicals Technical Options Committee (MCTOC), industry, scientific journal articles, and more, which is described in greater detail in the TSD included in the docket for this proposed action. After reviewing

relevant information and analyses, EPA is aware of two potential replacements for HFC-134a and HFC-227ea as propellants in MDIs, specifically HFO-1234ze(E) and HFC-152a.

~~The FDA considers an~~ MDIs, including those containing an alternative propellant other than HFC-134a or HFC-227ea, are subject to the approval requirements under section 505 of the Federal Food, Drug and Cosmetic Act ~~as a new drug product. Any MDI using HFO-1234ze(E) or HFC-152a as a propellant would need to be approved in accordance with the FDA's requirements for new drug applications~~. ~~This process begins with clinical trials and can anywhere from six and a half to nine years to get to final FDA approval. EPA has consulted with the FDA, and EPA does not expect an FDA approval of an alternative HFC propellant by the end of the renewal period of 2030.~~ The process to develop an MDI with a new propellant is complex and will take time. A sponsor (i.e., MDI manufacturer) will need to reformulate the MDI product to use the new alternative propellant and conduct a development program to obtain data, including clinical data, with the new MDI product. If the development program is successful, ~~then~~ a sponsor will then need to submit an application to the FDA for approval; the review timeline for a new drug application is 10 to 12 months. The overall process to develop an MDI product containing a new alternative propellant is expected to take years.

EPA has consulted with the FDA, and the reformulation of the majority of MDIs with an alternative propellant ~~will~~may extend beyond the end of the renewal period of 2030. EPA is aware that a few MDI manufacturers have begun the development process, some of whom are expecting to soon begin Phase 3 trials~~, which are required prior to drug approval,~~[10] and FDA has stated that it is possible that they may receive new drug applications for ~~and be able to approve~~ a

Commented [Round 235]: We may see a few programs sooner than 2030. Suggest replace this language with the following:

"The process to develop an MDI with a new propellant is complex and will take time. A sponsor will need to develop the new HFA MDI product and conduct a development program to obtain data, including clinical data, with the new MDI product. A sponsor will need to submit an application to the FDA for approval; the review timeline for a new drug application is 10 to 12 months. The overall process is expected to take years. EPA has consulted with the FDA, and reformulation of the majority of MDIs with an alternative HFC propellant will extend beyond the end of the renewal period of 2030."

Commented [EPA36R35]: Edits made per discussion.

Commented [Round 337]: Please rephrase to avoid disclosing deliberative information (e.g., naming EO 12866 interagency reviewers). If this is non-deliberative information, then suggest rephrasing to indicate consultation occurred prior to submission for EO 12866 review.

Commented [Round 338]: This footnote is not appropriate for these programs and should be removed. These are streamlined programs and we are not anticipating P3 studies with several thousand patients. At some point, it also may be possible that some programs come in without P3 studies. I would recommend deletion of "which are required prior to drug approval" and the footnote.

Commented [Round 339]: EPA cannot say that these are going to be approved. Please omit "…and be able to approve…" and see suggested edits below.

~~[10] A Phase 3 trial gathers additional information from several hundred to a few thousand people about safety and effectiveness, studying different populations and different dosages, and comparing the intervention with other drugs or treatment approaches. This is the final phase before potential FDA approval. *See* https://www.nia.nih.gov/health/clinical-trials-and-studies/what-are-clinical-trials-and-studies.~~

small number of MDI products with alternative propellants by 2030. However, these new drug applications will need to undergo FDA review. For new drug applications that receive FDA approval, the commercialization ~~process~~plans for ~~the few products that may receive approval~~new MDIs are unknown but we anticipate commercialization will take additional time. Unlike for some applications of alternative propellants where it may take a few years for commercialization of alternative propellants across the entire application after those products are available on some of the market, for MDIs EPA anticipates that it will take many years before alternatives are available across the application. That is, it will take time for reformulation, approval, and commercialization to occur for each of the individual MDI products used to treat pulmonary disease. For example, manufacturers of generic MDIs may face ~~difficulty~~delay in transitioning to alternative propellants, as generic drug products must be ~~comparable~~shown to be a duplicate of, and bioequivalent to, a previously approved drug product and rely on FDA's finding that the previously approved product is safe and effective. Applicants request approval for generic drug products, including MDIs, in Abbreviated New Drug Applications (ANDAs). 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 committed to review 90% of standard original ANDAs within 10 months from the date of submission, but often multiple review cycles are necessitated by application quality. This review time can be extended if a site/facility is not ready for inspection. The timing of ANDA approval also depends on, among other things, the patent and exclusivity protections for the previously approved product.

Commented [Round 340]: See added language to clarify that the term "application" refers to different uses of propellants, and has a different meaning in the context of new drug application.

Commented [Round 341]: Reviewer has concerns with this language re: patents and exclusivity; in addition, we understand there to be concern about the timing for generics because they may have to wait for the brand drug to first make the switch. As the first part of this paragraph deals with timing of transition of brands, we made edits to clarify that impact on generics. The patent and exclusivities issue is noted in the last sentence.

According to the MCTOC 2022 Assessment Report, the transition from HFC-134a and HFC-227ea to HFC-152a and HFO-1234ze(E) in MDIs is expected to begin in non-Article 5 countries[11] in 2025 and continue through at least 2032, and no other feasible, lower-GWP MDI propellants have been identified in the United States and abroad.[12] HFO-1234ze(E) and HFC-152a, along with other aerosol propellants, are listed as acceptable by EPA's SNAP Program and are commercially available and currently used in commercial and/or technical aerosol products. Furthermore, they also 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 approval before they could replace the current HFCs.

In light of the above analysis, it is EPA's assessment that there is no information before the Agency at the time of this proposal to suggest that there would be a safe and technically achievable substitute available prior to the next five-year review.

2. Supply

As previously mentioned, pharmaceutical-grade HFC-134a and HFC-227ea (also known as HFA-134a and HFA-227ea) are currently used as propellants in MDIs.

As part of the manufacturing process for MDIs, technical grade HFC-134a and HFC-227ea are purified into pharmaceutical-grade HFC-134a and HFC-227ea. Documents the FDA requires as part of the drug approval process must specify the facility manufacturing the HFC propellant. The supply of pharmaceutical-grade HFC-134a comes from technical grade HFC-134a that is produced at a limited number of production facilities in other countries,

[11] Non-Article 5 countries are defined as developed countries under the Montreal Protocol. For a list of Article 5 and non-Article 5 countries see https://ozone.unep.org/classification-parties.
[12] See https://ozone.unep.org/system/files/documents/MCTOC-Assessment-Report-2022.pdf.

including a single plant in the United States, and then purified at a single facility in the United Kingdom and reimported to the United States for consumption in MDIs. In its analysis of other applications, EPA has noted that HFC-134a is the most widely available HFC. However, this fact does not equate to a sizeable supply for the MDI application because MDI manufacturers are not easily able to switch suppliers of pharmaceutical-grade HFCs ~~due to certain FDA requirements~~. Unlike other applications, where EPA has discussed the diverse number of chemical suppliers for HFC-134a globally, in this instance the options are constrained.

As components of drug products, the use of HFCs in MDIs are subject to certain FDA requirements. FDA's Current Good Manufacturing Practice (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. ~~As HFCs are components of drug products,~~ HFC purification occurs in dedicated facilities ~~and~~ that are subject to ~~the~~ FDA~~'s Current Good Manufacturing Practice~~ CGMP requirements ~~(CGMP) (21 CFR 211)~~ 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. ~~The FDA's CGMP requirements for drug components include those related to storage and handling, sampling and testing, and compliance with appropriate purity and quality specifications.~~ If an MDI manufacturer wanted to change their supplier of pharmaceutical grade HFC, this would trigger FDA review. MDI manufacturers who change suppliers of pharmaceutical grade HFCs would

Commented [EO 1286642]: Is this referring to HFC components, purification, or dedicated facilities?

Commented [EPA43R42]: This is referring to the "dedicated facilities." Additional edits have been added to the beginning of the paragraph to provide additional context.

Note that EPA also made edits to the preamble to align with edits and comments made in the TSD so both documents are now consistent.

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, ~~and~~ product quality data of the new propellant source, and 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 the comparability of the HFA sources, additional data may be requested by the FDA (21 CFR 314.70).

There are three suppliers of pharmaceutical-grade HFC-227ea for use in the United States. One of the suppliers is a producer that purifies the technical grade HFC-227ea at one of their facilities in the United States. The second produces and purifies the pharmaceutical-grade HFC-227ea at their facility in Germany, which is then imported by that producer for distribution to domestic MDI manufacturers. The third supplies pharmaceutical-grade HFC-227ea to the United States from their facility in the United Kingdom. At least two of these facilities also supply pharmaceutical-grade HFC-227ea globally for MDI manufacture. Producers of pharmaceutical-grade HFC-227ea must also comply with FDA requirements as described above, which limits their ability to switch to other suppliers of HFC-227ea.

3. What is EPA proposing regarding eligibility for application-specific allowances?

EPA is proposing to renew the eligibility of entities using regulated substances for propellants in MDIs to receive ASAs for the five-year period of calendar years 2026 through 2030. EPA is proposing to determine "that the requirements described in subclauses (I) and (II) of clause (i) are met" in accordance with the requirements of 42 U.S.C. 7675(e)(4)(B)(v)(II). Specifically, for the reasons outlined earlier in this section, EPA is proposing to determine that no safe or technically achievable substitute will be available for propellants in MDIs and that supply of the regulated substance that manufacturers and users are capable of securing from

chemical manufacturers is insufficient to accommodate propellants in MDIs through calendar year 2030. EPA is proposing to determine that the supply of both HFC-134a and HFC-227ea is insufficient to accommodate the propellants in MDIs application.

C. Defense Sprays

Per subsection (e)(4)(B)(iv)(I)(bb) of the AIM Act, EPA has been allocating ASAs for defense sprays since 2021. EPA defined a "defense spray" as "an aerosol-based spray used for self-defense, including pepper spray and animal sprays, and containing the irritant capsaicin and related capsaicinoids (derived from oleoresin capsicum), an emulsifier, and an aerosol propellant," (40 CFR 84.3). Within this application, there are four primary uses: bear sprays, dog sprays, personal defense sprays, and law enforcement sprays. The defense sprays chapter in the TSD contains more details on these product categories. HFC-134a is the primary propellant currently used for the majority of defense sprays and is the only HFC for which EPA has allocated allowances since 2022. After analyzing information relevant to the statutory criteria, as outlined in this section and the TSD, EPA is proposing two options—to not renew the eligibility for entities in this application to receive ASAs or to renew for two years. EPA is also taking comment on the possibility of renewing for a full five-year period.

1. Availability of Safe and Technically Achievable Substitutes

There has already been commercialization of alternatives to HFC-134a as a propellant in some defense spray uses, and transition is underway for other parts of the application. Thus, while many defense sprays currently use HFC-134a as a propellant, EPA is aware of entities that have already successfully commercialized alternative propellants, including non-HFCs, in some of their products. The availability of safe and technically achievable substitutes for this

application will continue to expand, and EPA will take any additional information into account in the final rulemaking.

All dog defense sprays commercialized in the United States and registered with EPA under FIFRA use a non-HFC propellant and have never used an HFC propellant; from company communications, EPA is aware that at least three dog sprays utilize compressed nitrogen gas. In addition, EPA is aware from company communications that two bear sprays using propellants other than HFC-134a are available domestically, one using a non-HFC, HFO-1234ze(E), and one utilizing a lower-GWP HFC, HFC-152a. Both products have been available for multiple years. In addition, there is one bear spray that is manufactured domestically, but sold into the Canadian market, that also utilizes HFO-1234ze(E). EPA is also aware of at least one defense spray used on humans available in other countries, but manufactured in the United States, that uses HFO-1234ze(E).

The commercialization of defense sprays with alternative propellants suggests that there are safe and technically achievable substitutes to HFC-134a available within this application, but it is not clear that they are immediately available for the entire application. In other words, there are multiple different uses within this application, and many of the uses have similar technical requirements (*e.g.*, large spray volume and distance) and safety considerations (*e.g.*, flammability). Thus EPA's assessment is that while there are certain differences amongst the uses, generally a propellant commercialized for one use should be safe and technically achievable for another use as explained in more detail below. It is EPA's understanding that defense sprays have industry-set technical requirements that differentiate them from other

Commented [EO 1286644]: Does EPA have information on the efficacy of bear sprays using alternatives other than HFC-134a relative to those that use HFC-134a?

Commented [EPA45R44]: EPA has information from bear spray manufacturers that is outlined in the TSD, and we also note that there are successful bear sprays on the market already that use propellants other than HFC-134a. EPA expects to receive further information related to this point in comments, and we will take all received information into account before finalizing this rule.

Commented [Round 246R44]: Okay. Reviewer notes that beyond availability, the efficacy (which is a key input for safety) of the substitute is of critical importance for products with safey applications such as bear sprays

Commented [EPA47R44]: EPA notes the reviewer's input. Thank you.

Commented [EO 1286648]: Is this true, since some sprays are intended for animals and others for humans? Presumably the safety of the propellant or other ingredients would differ between bear sprays and defense sprays intended for humans

Commented [EPA49R48]: For purposes of the type of propellant used, flammability is the primary safety consideration between HFCs and substitutes. See the discussion of SNAP evaluation below.

For additional context, the primary difference between bear sprays and sprays used on humans is the concentration of capsaicin. Typically the propellant is the same.

aerosols, but that outside of FIFRA requirements for bear sprays,[13] defense sprays do not need to be certified or comply with federal regulatory standards to be sold in the United States. EPA is aware of some voluntary standards for law enforcement sprays, explained in more detail in the defense sprays chapter of the TSD, that specify performance requirements and test methods for the evaluation of these sprays. EPA's understanding is that defense sprays do not need to be certified under this standard to be sold into the law enforcement market.

While some entities have successfully commercialized alternative propellants, there are steps other entities will need to undertake in order to use these alternatives, such as their own research and development process, approval under FIFRA for bear sprays, and potentially changes to manufacturing facilities. For example, EPA is aware of at least two defense spray manufacturers that had made significant investments to potentially transition to a non-HFC as a propellant that did not pursue the transition due to performance concerns.[14] The multiple defense spray products commercialized using alternative propellants suggests that past challenges can be overcome, though EPA acknowledges that commercialization of alternative propellants across this entire application may take a few years.

Outside of what has already been commercialized by some defense spray companies, EPA is not aware of any other substances under consideration as safe and technically achievable

[13] Defense sprays used to deter bears, dogs, and other animals are considered pesticides under FIFRA, so must comply with related requirements, including approval for the inert ingredients (*e.g.*, the propellant) used in the product. In addition to HFC-134a, both HFC-152a and HFO-1234ze(E) are approved for use as inert ingredients for non-food pesticidal use (*e.g.,* animal sprays). Transitioning a product to another approved propellant is a relatively simple process that only requires submission of product performance data (*i.e.,* no tests related to safety, impacts on human health, etc.), and approval can occur in five to seven months. This action would be a Pesticide Registration Improvement Act B680 or B681. See https://www.epa.gov/pria-fees/pria-fee-category-table-biopesticides-and-pollution-prevention-division-bppd-amendments for more information.

[14] Written testimony submitted for the record from Safariland and Security Equipment Corporation for the U.S. Senate Committee on Environment and Public Works hearing on the AIM Act. https://www.epw.senate.gov/public/index.cfm/2020/3/s-2754-american-innovation-and-manufacturing-act-of-2019-written-testimony-and-questions-for-the-record.

substitutes for this application. Multiple propellants, including HFC-152a, HFO-1234ze(E), and hydrocarbons, have been listed as acceptable under SNAP and identified as technically and economically feasible alternatives for propellants in aerosols by the TEAP's MCTOC. However, there are additional technical demands in the defense spray application that provide unique challenges as compared to other types of aerosol applications. For example, given their use for personal protection and crowd control, defense sprays need to have a larger spray cloud and longer spray distance, and stakeholders have noted that law enforcement's use of defense sprays alongside stun guns (*e.g.*, Tasers) poses specific concerns around flammability. Therefore, alternatives identified as acceptable for aerosols, such as hydrocarbons, may not be available for all defense spray uses. SNAP lists substitutes for aerosols at the end use level, not the application level (*e.g.*, the Agency has listed substitutes for aerosol propellants, which would allow for those substitutes in defense sprays), and TEAP's MCTOC has not specifically discussed or evaluated defense sprays as an individual use. More information about the specialized nature of defense sprays can be found in the defense sprays chapter of the TSD.

To inform determinations in this rulemaking, EPA invites comment on whether the alternatives commercialized for some defense spray uses are not available for the entire application, including any supporting data and information; EPA is particularly interested in data regarding flammability of alternative propellants at the concentrations found in defense sprays and testing results demonstrating safety risks in the situations where defense sprays are typically utilized.

2. Supply

The majority of defense sprays currently use HFC-134a as their propellant. HFC-134a is the most widely produced HFC globally and is produced in substantial quantities in multiple

countries, including the United States. In 2022, domestic production of HFC-134a was 61,377 metric tons (MT), making up 46 percent of U.S. HFC production on a mass basis; this production amount is also nearly double the domestic production amount of the HFC produced in the second highest quantity. EPA is aware that one domestic producer of HFC-134a is transitioning its facility to produce a different chemical.[15] In addition, there are multiple entities that import HFC-134a. In 2022, 7,363.1 MT of HFC-134a were imported into the United States. Overall, HFC-134a made up approximately 32 percent of total U.S. HFC consumption[16] in 2022 on a mass basis. This application has very limited demand for HFC-134a in comparison to U.S. consumption of HFC-134a; allocated ASAs for this application in 2024 are equivalent to 0.1 percent of calculated domestic consumption of HFC-134a in 2022, on a metric tons of exchange value equivalent (MTEVe) basis. In addition, at the end of 2022, suppliers held 51,902.9 MT of HFC-134a in domestic inventory, which is equivalent to about 101 percent of calculated consumption of HFC-134a in 2022, and 1,036.8 MT of HFC-134a was reclaimed; the entities both holding this material in inventory and reclaiming these HFCs are broader than EPA's interpretation of chemical manufacturers (see Section IV.B for more information), so not all of this HFC-134a may be considered available supply.

However, as described in more detail above in Section V.A, the overall market for HFCs and for HFC-134a in particular is likely to continue changing in light of the AIM Act and other restrictions. There is uncertainty regarding how the market is reacting to the stepdown of the level of permissible production and consumption of HFCs that took effect on January 1, 2024, and EPA anticipates further market changes as a result of the stepdown taking effect on January

[15] See https://www.arkema.com/usa/en/media/news/global/corporate/2022/20221006-two-major-steps-develop-supply-forane-1233zd/.
[16] Consumption = (Total Production + Production for Feedstock + Imports [Virgin and Used]) – (Exports [Virgin and Used] + Destruction)

1, 2029. However, global production capacity is expected to remain substantial over the coming years, given production will continue in countries on later HFC phasedown schedules, and EPA expects continued domestic and global demand for HFC-134a. EPA will analyze any available information on market adjustment to the January 1, 2024, stepdown and regulations effective January 1, 2025, in finalizing this rulemaking.

In considering supply of the regulated substance currently used by this application, EPA also notes that the Agency is unaware of any reason why this application cannot use recovered and reprocessed HFCs. For example, EPA is not aware of any specific purity requirements for HFCs used in this application. As a result, the supply of recovered and reprocessed HFCs that can be secured from chemical manufacturers is relevant when assessing whether the supply of HFC-134a is insufficient to accommodate this application. The likeliest source of these reprocessed HFCs for defense sprays would be reclaimed refrigerants, which must meet specific purity requirements.[17] 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. The supply of reclaimed HFC-134a in the United States is substantial and increases the supply of HFC-134a available to this application. However, as is true in many other parts of EPA's supply analysis, there is uncertainty regarding the overall supply and demand for reclaimed HFCs.

[17] In alignment with the definition in 42 U.S.C. 7675 (b)(9), EPA 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.

There is additional uncertainty around the supply and demand for HFC-134a as a result of the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023). GWP restrictions under the 2023 Technology Transitions Rule begin taking effect January 1, 2025, with the latest restriction taking effect on January 1, 2028. Overall demand for HFC-134a could fall since all subsectors subject to Technology Transitions restrictions will not be permitted to use neat HFC-134a, as its GWP of 1,430 is greater than the highest GWP limit (*i.e.*, 700). However, many subsectors subject to Technology Transition restrictions already use chemicals that fall below the GWP restriction levels, and where this is the case EPA does not anticipate any change in demand of HFC-134a. Additionally, some sectors may use blends with HFC-134a as a component where the GWP is below the applicable limit. Moreover, HFC-134a will likely continue to be used in other applications not subject to these restrictions (*e.g.*, heavy-duty trucks), as well as for servicing existing equipment (*e.g.*, light-duty motor vehicle air conditioning). HFC suppliers may also shift their production and import practices, such that supply of HFC-134a changes. EPA intends to review available information on market shifts that occur when the first set of Technology Transition restrictions take effect on January 1, 2025, and where possible will incorporate any relevant information into the analysis underpinning finalization of this rulemaking. Based on this additional information, at finalization of this rule, EPA may be in a position to determine that the supply of HFC-134a is not insufficient to accommodate this application once all of the Technology Transition restrictions take effect as of January 1, 2028, if not earlier (*i.e.,* as early as January 1, 2026).

EPA also intends to finalize a rulemaking under subsection (h) of the AIM Act, the Emissions Reduction and Reclamation Rule (88 FR 72216, October 19, 2023), in the summer of 2024. EPA proposed a number of requirements including those concerning use of reclaimed

HFCs for certain activities. In addition, EPA intends to finalize a rulemaking, "*Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA)"* (88 FR 74712, October 31, 2023), later this year; this rulemaking has proposed to ban the use of TCE due to unreasonable risk of injury to human health. If finalized as proposed, this 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. While this could end the production of HFC-134a in the United States,[18] it is unclear how this change would affect overall supply of HFC-134a, as there is currently still global supply of HFC-134a that could be imported into the United States. EPA anticipates being able to consider the projected effects of these other rules prior to finalizing this rulemaking.

Entities do not need to seek or receive ASAs in order to use HFC-134a in defense sprays. Further, entities do not have to expend an allowance to purchase HFC-134a from another entity that has imported or produced the regulated substance. EPA notes that of the six defense spray entities that have received ASAs at some point for calendar years 2022, 2023, and 2024, three did not receive ASAs in at least one of those years. EPA is also aware of at least two entities selling bear sprays that use HFC-134a that have never applied for, and therefore never received, ASAs. This suggests that at least those two entities were able to acquire HFC-134a on the open market without having ASAs. These facts could suggest that ASAs may not be imperative for entities in this application to access HFC-134a.

In sum, HFC-134a is currently more widely available than other HFCs, and defense sprays' need for HFC-134a is small compared to the overall demand for HFC-134a across a range of sectors. At the same time, there is inherent uncertainty in the HFC market due to future stepdowns and new regulations coming into effect. Further information regarding EPA's

Commented [EO 1286650]: Were there alternative chemicals considered in the proposed rule that could perform the same function as TCE in the manufacture of HFC-134a? This isn't a major point, but asking more to see if such a scenario would mitigate any impact to the overall supply. Regardless, reviewer appreciates EPA's consideration of other rules that are currently proposed, but not yet finalized.

Commented [EPA51R50]: The TCE-TSCA proposed rule discusses the use of PCE which is another feedstock for producing HFC-134a. The PCE-TSCA proposed rule would continue to allow this use of PCE. See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-perchloroethylene-pce

[18] Though there are other pathways to produce HFC-134a, the pathway using TCE is the primary production pathway in the United States, and it is EPA's understanding that it is complex to change production pathways.

assessment of the supply of HFC-134a related to the needs of the defense sprays application can be found in the defense sprays chapter of the TSD.

EPA is also considering the supply of HFC-152a, as it is used in at least one defense spray product, as noted above. HFC-152a is produced in substantial quantities, though the current domestic production of HFC-152a is about half that of HFC-134a, on a mass basis.[19] In 2022, domestic production of HFC-152a was 29,654.9 MT, about 22 percent of U.S. HFC production by mass. There is currently only one U.S. HFC-152a production facility, and that producer has announced plans to increase production by approximately 20 percent by mid-2024.[20] At the time of this proposal, the facility expansion is not yet complete, so EPA cannot say with certainty when it will be available. However, there is also substantial global production of HFC-152a, which also supplies the U.S. market. Multiple entities imported HFC-152a in 2022, importing a total of 5,810.1 MT. Overall, HFC-152a made up approximately 20 percent of total U.S. HFC consumption in 2022 on a mass basis. In addition, at the end of 2022, suppliers held 5,076.3 MT of HFC-152a in domestic inventory, which is equivalent to about 16 percent of calculated consumption of HFC-152a in 2022. The company that has commercialized the bear spray using HFC-152a has never received allowances for HFC-152a, which suggests that at least this entity is able to acquire HFC-152a on the open market without having ASAs.

In addition, HFC-152a has one of the lowest EVs relative to other regulated HFCs, so 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

[19] See https://www.epa.gov/climate-hfcs-reduction/hfc-data-hub/expanded-hfc-data.
[20] See https://www.chemours.com/en/news-media-center/all-news/press-releases/2023/chemours-announces-capacity-increase-of-hfc-152a-providing-reliable-domestic-supply-of-low-global-wa.

HFC-152a—a greater than 90% reduction. This means that, from a strictly allowance-focused view, HFC-152a will be easier to acquire than most other HFCs as the phasedown progresses and the number of HFC allowances is reduced. Allowances allocated to an end user may therefore not be necessary to secure production or import of HFC-152a.

Future projections suggest that there could be increased demand for HFC-152a, although there is inherent uncertainty with how industry will respond to the phasedown of HFCs at this early stage. HFC-152a has a GWP that is below all the GWP limits for sectors and subsectors subject to the 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023). The 2023 Technology Transitions Rule identified HFC-152a as an available or potentially available substitute for all 13 foam subsectors, aerosol propellants, motor vehicle air conditioning, and household refrigerators and freezers.[21] However, there are also multiple other acceptable alternatives, including non-HFCs, and, for subsectors where a transition to another substitute has already occurred (*e.g.,* motor vehicle air conditioning, household refrigerators and freezers), 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 subsectors have begun to move out of HFCs entirely. For example, the MCTOC 2022 Assessment report notes that a significant proportion of aerosols already use non-HFCs as propellants. Similarly, the FTOC 2022 Assessment Report highlights that fluorocarbon use in foams has been falling for decades, and foams are largely expected to continue transitioning to non-HFCs, including hydrocarbons,

[21] 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).

HFOs, and hydrochlorofluoroolefins (HCFOs). Demand for HFC-152a may therefore change in future years as subsectors transition to alternatives from their currently used HFC.

In sum, while there is a reasonably large supply of HFC-152a that is expected to increase over the coming years relative to other HFCs, there is uncertainty around future demand for the reasons described above.

3. What is EPA proposing regarding eligibility for application-specific allowances?

Given the rapidly changing landscape for HFC supply and EPA's assessment of substitute availability application-wide, EPA is proposing two options based on our current analysis and in anticipation of additional available information before this rule is finalized. Specifically, EPA is proposing to finalize one of the following outcomes: (1) no renewal, such that the application will not receive ASAs or (2) renew eligibility for ASAs for two years, such that ASAs are available for calendar years 2026 and 2027.[22] EPA is also seeking comment on renewing eligibility for the full five-year period.

As explained earlier in this proposal, an application must meet both criteria to be eligible to receive ASAs. For the reasons described earlier in this section, EPA is proposing to determine that there is not a safe and technically achievable substitute that is immediately available for the entire application, but a safe or technically achievable substitute will be available for the entirety of the defense spray application by January 1, 2028. In other words, EPA proposes to determine that the criterion in subsection (e)(4)(B)(i)(I) is not met for defense sprays starting January 1, 2028. Under this proposed determination, even if EPA received information to determine that supply of the currently used regulated substance was insufficient, defense sprays would not be

[22] The proposed amendatory text included in this Federal Register notice shows only one of the co-proposed options. This is for illustrative purposes and should not be read as EPA favoring one co-proposal over another.

eligible for renewal as of January 1, 2028, unless they have insufficient supply of a substitute HFC, as discussed in more detail below.

EPA is also proposing to determine that either (1) the supply of HFC-134a is not insufficient to accommodate this application; or (2) the supply of HFC-134a will not be insufficient to accommodate this application as of January 1, 2028. In other words, EPA proposes to determine that the criterion in subsection (e)(4)(B)(i)(I) is either: (1) not met at all for this application for HFC-134a, and therefore the application would not be eligible to receive ASAs starting January 1, 2026; or (2) not met as of January 1, 2028, and therefore the application would not be eligible to receive ASAs starting January 1, 2028. Under the first option, this means that even if the application does not have a safe or technically achievable substitute available, ASAs would not be available for defense spray manufacturers as of January 1, 2026. For the second option, defense sprays would not be an eligible application for ASAs as of January 1, 2028, regardless of the availability of substitutes.

EPA does not have sufficient information to make a definitive determination on whether supply of HFC-152a is insufficient to accommodate this application at the time of this proposal. We are monitoring this issue and will be seeking information on the alternatives that subsectors subject to Technology Transitions restrictions transition into and how much additional domestic production capacity of HFC-152a comes online in the coming year.

EPA is also taking comment on whether defense sprays should be eligible to receive ASAs for the full five-year period from 2026–2030. A full five-year renewal could be without restriction or could be based on and tailored only to the application's need to purchase HFC-152a. As explained earlier, HFC-152a is used commercially in one bear spray product, so this latter scenario could be relevant if HFC-152a is an available safe and technologically

achievable substitute for the entire defense spray application by 2028. Under this scenario, EPA would follow an approach similar to the option proposed for SCPPU foams for marine and trailer uses in Section V.D.3.

EPA intends to review comments and other relevant information received on this proposal to further understand how the market surrounding this application evolves and the availability of substitutes application-wide before EPA finalizes this rule. Specifically, we intend to review additional information on how the HFC market adjusts to the 2024 stepdown, defense sprays' research into alternative propellants and related trials (including relevant data on flammability), what alternatives consumer aerosols transition to (as they are subject to the Technology Transitions restrictions starting in 2025), and research into alternative propellants intended to be used in technical aerosols (which are subject to the Technology Transitions restrictions starting in 2028). EPA invites submission of comment and additional data related to these data gaps. EPA will consider this new information, in addition to public comments, in making a final determination for this application.

4. Proposed Restriction under EPA's Technology Transitions Program

The 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) restricts the manufacture and import of all aerosol products that use HFCs or HFC blends that have a GWP greater than 150. This restriction begins January 1, 2025, for all aerosols except for those specifically listed in the final rule as technical aerosols, which have manufacture and import restrictions starting January 1, 2028. The listed technical aerosols are applications for which EPA received sufficient information through the comment period or through EPA's own analysis indicating that additional time is needed to transition to substitutes due to various technical

requirements, such as non-flammability and/or a specific vapor pressure. The list of technical aerosols does not include defense sprays.

The 2023 Technology Transitions Rule exempts applications that receive ASAs (40 CFR 84.56(a)(2)). However, as finalized in the October 24, 2023, rule, if an application no longer qualifies for ASAs, the Technology Transitions restrictions then apply.

While most aerosols are required under the Technology Transitions Program to meet a 150 GWP limit starting on January 1, 2025, the EPA provided additional time to comply with this limit for some technical aerosol uses. Most of the U.S. aerosol industry subject to the January 1, 2025, compliance date has already transitioned to using propellants that meet the 150 GWP limit,[23] and therefore has available substitutes for use based on EPA's consideration of the factors listed in subsection (i)(4)(B) (*e.g.*, technological achievability, commercial demands, safety, consumer costs, etc.). By contrast, the uses that received an extension for compliance with the 150 GWP limit until January 1, 2028, 40 CFR 84.54(a)(16)(i)(A)-(O), currently use HFC-134a (most often as a propellant) and have limitations that require additional time "to reformulate, test, and transition" to ensure availability of substitutes under subsection (i)(4)(B) for these technical uses.

EPA is proposing that defense sprays would be considered under the Technology Transitions Program consistent with technical aerosols, with the corresponding compliance deadlines on the manufacture and import of defense sprays using HFCs and blends containing HFCs with a GWP of 150 or greater beginning January 1, 2028, with a three-year sell-through of those products. As discussed in Section V.C.1 of this preamble, while some defense spray uses

[23] See Household and Commercial Products Association (HCPA) and National Aerosols Association (NAA) Technology Transitions Petition to EPA dated July 6, 2021. Available in the public docket at EPA-HQ-OAR-2021-0289-0037.

Commented [EO 1286652]: As we've discussed in previous rulemakings, manufacturing compliance dates are preferable to sell-through dates, which can lead to stranded inventory. EPA is already seeing this happen in other markets as a result of HFC allocation rulemakings. EPA should consider removing the sell-through period and relying on a single date of prohibition, i.e., the manufacture date

Commented [EPA53R52]: The stranded inventory concerns raised under the Technology Transition Rule are for Variable refrigerant flow air conditioning systems used in large buildings, and residential unitary split air conditioning units in the residential air conditioning subsector. Both of these types of equipment are not subject to a manufacturing or import restriction and sell through date, but instead are subject to an installation restriction. Under the TT rule products that are fully complete when they leave the factory such as aerosols are products and subject to a manufacturing and import restriction with a three year sell through. We have not received any letters or concerns from the aerosol industry concerned about stranded inventory since the final rulemaking.

In this rule, EPA is proposing that defense sprays would be subject to the existing aerosol subsector restrictions, which also has the effect that defense sprays would be subject to the framework of restrictions under the Technology Transitions program, which includes the sell through provision that was established in the 2023 Technology Transitions Rulemaking. Given how the two aerosol subsectors are laid out in the regulatory text, we are clarifying in the regulatory text ... [1]

Commented [Round 254R52]: This is a subject on which EPA should seek further comment in this NPRM, providing aerosol manufacturers an opportunity to voice concerns (if any) about this approach. EPA's characterization of previous comments on the TT rule sell through as "not a point that was widely raised" suggests that the point was still raised and concerns could be lingering, which would be best to resolve before EPA is in a final rule stance.

Commented [EPA55R52]: EPA is not supportive of adding a request for comment on the timing of the sell-through period. EPA finalized a 3 year sell through for all aerosol products in the Technology Transitions (TT) rule. EPA understands the point the commenter is making, which EPA understands could be relevant for other applications that are not considered in this rulemaking. This section solely concerns an application within the aerosols sector. Since the issuance of the final TT rule, EPA has not heard any concerns from the relevant trade associations or ... [2]

Commented [Round 356R52]: This is already open for public comment as a component of the proposed rule regardless of EPA's willingness to add a specific request for comment, so EPA's response here doesn't make much sense. Surely EPA does not view the proposals in this NPRM, of which this is one, as pre-determined for a final rule? EPA would do better to invite comments on a broad array of topics, for a full comment period, and EPA's responses throughout are both disappointing and not consistent with agency best practice.

may have substitutes available in the near term that are technically achievable and safe, EPA's proposed assessment under subsection (e)(4)(B) is that such substitutes are not immediately available across all defense spray uses. In particular, the flammability or specific vapor pressure of potential substitute propellants present availability concerns for some uses in the near term. Consideration of technological achievability and safety, as well as other subsection (i)(4)(B) factors, indicates that a compliance date of January 1, 2025, for transition of all defense spray uses is not appropriate, but the approval of substitute propellants as safe under SNAP and TEAP analyses (see Section V.C.1), as well as EPA's assessment that many propellant uses in this subsector have been able to successfully transition to substitutes, provides support for EPA's proposed finding that all defense sprays will have available substitutes by January 1, 2028. We invite comment on whether availability of substitutes for use in defense sprays, particularly considering those factors enumerated under subsection (i)(4)(B), indicates that defense sprays could in fact meet the existing 150 GWP limit restriction if the application ceased being eligible for ASAs on January 1, 2026. We note that given the January 1, 2028, compliance date for the transition of the remaining aerosol sector, comments urging the Agency to provide additional time for compliance beyond that date will need to provide very specific and detailed information in support of that request, speaking to the statute's factors under subsection (i)(4) and in particular the subsection (i)(4)(B) factors.

Under the 2023 Technology Transitions Rule, the labeling requirements are effective at the same time as the manufacture and import restrictions, which, if EPA finalizes this action as proposed, would be January 1, 2028. Recordkeeping and reporting provisions are effective for all sectors and subsectors under the 2023 Technology Transitions Rule starting January 1, 2025. EPA proposes that the recordkeeping requirements would apply to defense spray manufacturers

and importers beginning January 1 of the year that use no longer qualifies for ASAs, and the first report would be due March 31 of the following year. For example, if defense sprays are no longer eligible for ASAs in 2026, manufacturers and importers would need to keep records as required by the 2023 Technology Transitions Rule starting January 1, 2026, and submit their first Technology Transitions report to EPA by March 31, 2027, even if EPA finalizes its proposal that the 150 GWP limit for the manufacture and import of defense sprays using HFCs would not apply until January 1, 2028.

EPA requests comment on the proposal to consider defense sprays consistent with technical aerosols for purposes of the Technology Transitions Program and the restrictions that result from such a classification, such as the GWP limit, use restrictions, and labeling and reporting requirements.

EPA has previously determined that available substitutes for use as aerosol propellants include HFC-152a (GWP 124) and HFO-1234ze(E) (GWP <1) (88 FR 73098, October 24, 2023). EPA is also interested in any supporting data and information related to the availability of substitutes and whether a different timeline is more appropriate for transitioning in this application or for a subset of products in this application.

D. Structural Composite Preformed Polyurethane Foam for Marine Use and Trailer Use

The third application to which EPA has been allocating ASAs to since 2022 is SCPPU foam for marine and trailer uses, in accordance with subsection (e)(4)(B)(iv)(I)(cc) of the AIM Act. In the Allocation Framework Rule (86 FR 55116, October 5, 2021), EPA defined this application 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

Commented [EO 1286657]: Interagency reviewer recommends extending the exemption eligibility to use hfc-134a to 2030, the full five-year period for the next exemption. The boating industry uses this hydrofluorocarbon to build boats, making structural components (i.e., stringers) that are stronger than wood and not susceptible to rot. The reviewing agency understands the need for phaseout of this product, and the industry estimates they are 85% of the way there. However, the industry may not have an acceptable alternative by the time the current exemption expires in 2025. Given boats built from this product are safer, the reviewing agency supports extending this exemption up to five years (i.e., 2030) to allow for the development and implementation of an alternative.

Commented [EPA58R57]: Thank you for this input. Companies in this application have told EPA that they expect to transition out of HFC-134a by 2025, and it is EPA's assessment that there is sufficient information to support that this application's transition is feasible.

We have noted in the Technology Transitions proposal that we are requesting data and information related to the availability of substitutes and the proposed timeline for transitioning in this application. Companies may similarly comment if they do not believe the proposed restriction is appropriate, and EPA will take all comments into account when finalizing this rulemaking.

CFR 84.3). SCPPU foam is different from other types of polyurethane (PU) foams due to its specialized structural properties, and it is preformed into required shapes (*e.g.*, specific boat or trailer design). HFC-134a is the current HFC used in the blowing process for SCPPU foam. After analyzing information relevant to the statutory criteria, as outlined in this section and the TSD, EPA is proposing a range of options—to not renew the eligibility for entities in this application to receive ASAs, to renew for two years, or to renew access to ASAs for five years with allowances determined based on the use of a lower-GWP HFC substitute for HFC-134a. EPA is also taking comment on the possibility of renewing for a full five-year period consistent with the current allowance allocation approach.

1. Availability of Safe and Technically Achievable Substitutes

EPA anticipates that SCPPU foam for marine and trailer uses' commercialization of formulations using alternatives to HFC-134a as blowing agents is well underway and will evolve significantly between issuance of this proposed rulemaking and its finalization. The Agency will consider information collected from regulated entities and other relevant sources through the public comment period and the current reporting requirements to inform a final determination.

EPA is aware, from manufacturer communications and reporting, of two substitutes currently under development for this application—an HFC-152a/cyclopentane blend and an HFO. EPA notes that SNAP has listed both HFC-152a and cyclopentane as acceptable for all PU foams, including rigid PU uses in both marine flotation and commercial refrigeration (the two respective end uses for this application). Based on information from the manufacturers of SCPPU foam for marine and trailer uses, EPA understands that the research and development phase for both potential substitutes is nearing completion and that companies are nearing a phase where they will be able to commercialize use of substitutes. If commercialization occurs as

companies anticipate and as shared with EPA, the entire application would be able to use a substitute different from HFC-134a before January 1, 2026. According to the information shared with EPA, one substitute seems close to being commercialized for SCPPU foam for marine use, and the other substitute seems close to being commercialized for SCPPU foam for trailer use. The company that is close to commercializing use of the HFC-152a/cyclopentane blend performed multiple early trial runs with HFOs, all of which failed to meet their needs, so the company decided to pursue the HFC-152a blend. On this basis, we are proposing to determine that the HFO is not an available substitute application-wide for the five-year period from 2026–2030, given additional research and development trials are needed, as well as the subsequent ramp up to commercialization. EPA understands that often different companies use different blowing agents to produce the same foam. At this time, it is unclear why an HFC-152a/cyclopentane blend cannot be used across the entirety of the application and similarly whether at some future date another blowing agent (*e.g.*, an HFO) might be used application-wide. To inform determinations in this rulemaking, EPA invites comment on any potential reasons why an HFC-152a/cyclopentane blend might not be safe and technically achievable for the entire application, including any supporting data and information, such as trial data. While there are two different end uses in this application, the foam used in both sub-applications is the same (*i.e.,* it is an SCPPU foam).

Other than an HFO and an HFC-152a/cyclopentane blend, EPA is not aware of other safe and available alternatives at this time. There are currently a range of alternatives identified as acceptable by SNAP and as technically proven by the TEAP's FTOC for other PU foams, including rigid PU uses in both marine flotation and commercial refrigeration. Alternatives include a lower-GWP HFC (*i.e.,* HFC-152a), hydrocarbons, and HFOs. However, alternatives

identified as acceptable for PU foams are not necessarily available for SCPPU foam, given the unique technical requirements for this foam (*e.g.,* specialized structural properties). SNAP generally lists substitutes at the sector and end use level, not the application level (*e.g.,* the Agency has listed substitutes for rigid PU foam, which would allow for those substitutes in SCPPU foam, but it has not evaluated the use of these substitutes for SCPPU foam in particular), and TEAP's FTOC did not specifically discuss or evaluate SCPPU foam as an individual use in its 2022 assessment report. More information about the specialized nature of SCPPU foam can be found in the SCPPU foam chapter of the TSD.

Aside from the limitations noted above, EPA is not aware of significant federal regulatory restrictions on the type of substitutes that could be considered for this application. EPA is also not aware of any required standards that SCPPU foam needs to meet to be manufactured and sold in the United States. The SCPPU foam chapter of the TSD contains further information on sources consulted, and EPA invites comment on any additional information the Agency should consider in analyzing substitutes for this application.

After reviewing the available information, including reports on progress made by manufacturers of SCPPU foam for marine and trailer use, EPA has not identified a safe and technically achievable substitute that is available at the time of this proposal, but anticipates that substitutes will likely be available soon. We are monitoring this issue and are seeking information from the entities that use HFCs in this application on whether progress continues as anticipated to inform our final determination.

2. Supply

Entities manufacturing SCPPU for marine and trailer uses currently use an HFC-134a formulation. As described in more detail in Section V.C.2, HFC-134a is the most widely

produced of all HFCs. There is substantial domestic and global production of HFC-134a. This application's demand for HFC-134a is very small compared to domestic consumption; allocated ASAs for this application in 2024 are equivalent to 0.1 percent of calculated domestic consumption of HFC-134a in 2022, on an MTEVe basis. However, as noted earlier, the global and domestic HFC markets are continuing to adapt to regulations promulgated pursuant to the AIM Act, including the implementation of the phasedown of production and consumption of HFCs, and other authorities. EPA anticipates this market will continue to change, and EPA will analyze additional information as it becomes available ahead of finalizing this rulemaking. Such additional information will include whether there were immediate market shifts as a result of both the stepdown of the level of permissible production and consumption of HFCs that took effect on January 1, 2024, and regulations effective January 1, 2025.

In addition to changes in the HFC market due to the overall phasedown of production and consumption, other AIM Act regulatory programs are expected to take effect both between proposal and finalization of this rulemaking and during the applicable period under review in this rulemaking, as described in more detail in Section V.C.2. These requirements may reduce demand for HFC-134a domestically for certain other uses, though EPA expects continuing demand for HFC-134a in applications not subject to restrictions will continue. There may also be new or expanded use of blends with HFC-134a as a component designed to meet new restrictions. In addition, other EPA regulations may impact domestic supply of HFC-134a, but global supply should remain substantial in comparison to this application's demand for HFC-134a.

EPA is currently not aware of any applicable restrictions on where this application could purchase HFCs, including any purity requirements or regulatory restrictions on supply. As such,

it is EPA's assessment that this application may be able to use recovered and reprocessed HFCs supplied by chemical manufacturers. This is relevant in assessing what supply of regulated substance may be available to an application, since in such a case EPA does not need to limit its analysis to only virgin chemicals. The likeliest source of reprocessed HFCs for this application would be reclaimed refrigerants, which are held to AHRI 700 standards (see footnote 17 in Section V.C.2). Since there are no federal purity requirements for HFCs used in foams or any industry requirements, the purity of reclaimed HFCs is likely the same or higher than the virgin HFCs used in this application. While EPA is not aware of specific purity requirements for this application, EPA notes that efficacy of blowing agents can be influenced by their composition and purity. As described in more detail in Section V.C.2, the supply of reclaimed HFC-134a in the United States is significant, though there is uncertainty regarding the future demand for this material.

As part of this proposed analysis, EPA is also considering the supply of HFC-152a. As further explained in Section IV.C, as part of the framework for its analysis EPA is proposing to evaluate the supply of a substitute HFC if that HFC is a safe or technically achievable substitute for an application. As outlined in the prior section (Section V.D.1), EPA's analysis suggests that HFC-152a blended with cyclopentane appears to be a safe and technically achievable substitute for this application. EPA is therefore evaluating the supply of HFC-152a to determine whether it would be insufficient to accommodate this application. As described in more detail in Section V.C.2, other AIM Act regulations may increase demand for HFC-152a domestically for certain uses, though EPA notes that many sectors where HFC-152a is a technically achievable substitute have already transitioned to other alternatives. Domestic production capacity is also expected to

increase, but EPA cannot say with certainty when it will be available. Global supply should also remain substantial in comparison to this application's demand for HFC-152a.

3. What is EPA proposing regarding eligibility for application-specific allowances?

In light of the rapid evolution of information regarding both the availability of substitutes for this sector (including all companies in this application's stated plans to transition away from HFC-134a before 2026) and HFC supply, EPA is proposing a range of options based on the current Agency analysis and in anticipation of increased available information before this rule is finalized. Specifically, EPA is proposing to finalize any of the following outcomes: (1) no renewal, such that the application will not receive ASAs, (2) renew eligibility for ASAs for two years, such that ASAs are available for calendar years 2026 and 2027, or (3) renew eligibility to continue receiving ASAs for the full five-year period with allowance amounts determined based on the EV of HFC-152a.[24]

Before finalization of this rule, we anticipate new information to become available on the supply of HFCs and availability of substitutes for the application, as outlined in detail in this section. EPA will consider this new information, in addition to public comments, in making a final determination for this application.

As explained earlier in this section, the development of safe or technically achievable substitutes for this application is a rapidly evolving space, such that multiple possible outcomes can reasonably be expected to occur through 2030. All entities that have received ASAs for SCPPU foam for marine and trailer uses to date have told EPA that they plan to transition to substitutes before January 1, 2026. One potential outcome at rule finalization is that EPA depends on these statements to determine that a "safe or technically achievable substitute is

[24] The proposed amendatory text included in this Federal Register notice shows only one of the co-proposed options. This is for illustrative purposes and should not be read as EPA favoring one co-proposal over another.

Commented [EO 1286659]: Could EPA provide proposed amendatory text for all considered proposals? This would benefit public commenters and prevent EPA from proceeding at final rule with regulatory text that was not actually included in the proposal.

Commented [EPA60R59]: In the proposed regulatory text, we have provided regulatory text that would apply to the most complex regulatory scenario (co-proposal #3). For other options, there are only minor regulatory deviations around the year provided, so we do not believe providing additional alternative regulatory text is necessary for the public to have complete notice of EPA's co-proposals.

Commented [EO 1286661]: It seems like in many ways EPA is putting the cart before the horse by proposing this rule before the needed information is available. Why is EPA proceeding with this sequencing? It would help if EPA could clearly describe in the preamble what its actual timing constraints are, otherwise this approach seems illogical

Commented [EPA62R61]: The AIM Act only authorizes these applications to receive allowances through calendar year 2025. If this rule is not finalized in time for the allocation of 2026 allowances (Oct 1, 2025), none of these applications will be eligible to receive allowances for 2026. In addition, there is a statutory requirement to review these applications at least once every 5 years. The rulemaking schedule, including building in time for public comment and EO12866 reviews of both proposed and final rules, necessitates that we begin development of this rule now. An additional sentence has been added in I.A and II.B to further clarify the timing and statutory requirements.

In addition, the primary purpose of the proposal process is for the public to assess and react to the Agency's current position. We will of course take into account any comments we receive, particularly around the points of uncertainty, before making any final decisions.

For this application in particular, as described in this section, the information currently available supports that this application has already made significant progress towards transitioning in the past two years.

Commented [Round 263R61]: For the reviewers benefit, is the primary time constraint due to the allocation deadline for 2026 allowances, or the statutory requirement to review applications once every 5 years? We see the allocation deadline as being more "forcing" than the 5-year review timeframe

Commented [EPA64R61]: The ultimate timing driver for this rule is that if we do not get this rule done, the result will be that these applications do not receive ASAs, which are necessary for the priority access that Congress intended. ASAs are available to entities for calendar years 2022, 2023, 2024, and 2025. *See* 40 CFR 84.13(a). Under EPA's regulation, EPA cannot allocate ASAs to any entity for calendar year 2026 until this rule is finalized. EPA wants to ensure that this rulemaking is completed on time to ensure that ASAs meeting the statutory criteria for renewal will receive priority access to allowances in calendar year 2 ... [3]

available for the applicable period" for this application. Statements from all of the companies that use regulated substances to manufacture SCPPU foam that they will transition to substitutes before the next ASA period could serve as a reasonable basis to determine that safe and technically achievable substitutes are available. There are also specific milestones that these entities have reached, such as one company receiving a final air permit for an expansion of the manufacturing facility that will use the HFC-152a/cyclopentane blend, indicating the company is able to move forward with full-scale testing and commercialization. If the entities' plans shared with EPA remain the same at the time when EPA is finalizing this rule, particularly if they have already commercialized use of the substitutes, it is likely that EPA would determine that a safe or technically achievable substitute is available for this application. If EPA makes this determination, SCPPU foam for marine and trailer uses will not be eligible for ASAs as of January 1, 2026, even if EPA receives information to determine that supply of the currently used regulated substance is insufficient, unless the application has insufficient supply of a substitute HFC, as discussed in more detail below in this section. However, EPA recognizes there is uncertainty as to whether plans to commercialize will remain the same, be delayed, or be subject to unanticipated hurdles that could require additional evaluation of this alternative. EPA also has less information regarding the deployment of the HFO alternative outside of statements from the entity working toward its development and commercialization. Before finalization of this rule, EPA intends to review and consider, as appropriate, all available information, specifically regarding expected timelines and testing data. EPA invites comment regarding the availability of safe or technically achievable substitutes for this application. The Agency will continue to collect information from regulated entities and other relevant sources through the public comment

period and the current reporting requirements to inform a final determination of whether the criterion in subsection (e)(4)(B)(i)(I) is met.

EPA is also proposing to determine either: (1) the supply of HFC-134a is not insufficient to accommodate this application; or (2) the supply of HFC-134a is not insufficient to accommodate this application as of January 1, 2028. In other words, EPA proposes to determine that the criterion in subsection (e)(4)(B)(i)(I) is either: (1) not met at all for this application for HFC-134a, and therefore the application would not be eligible to receive ASAs with allowances calculated based on HFC-134a use starting January 1, 2026; or (2) not met as of January 1, 2028, and therefore the application would not be eligible to receive ASAs with allowances calculated based on HFC-134a use starting January 1, 2028. Under the first option, this means that even if the application did not have a safe or technically achievable substitute available, ASAs would not be available for manufacturers of SCPPU foam for marine and trailer uses as of January 1, 2026. For the second option, SCPPU foam for marine and trailer uses would not be an eligible application for ASAs as of January 1, 2028, regardless of the availability of substitutes. However, if the available substitute is an HFC with insufficient supply, EPA may determine SCPPU foam for marine and trailer uses are eligible for renewal for that substitute HFC.

Given the current uncertainty over which EPA anticipates having more clarity ahead of finalization of this rule, at this time EPA contends that it could determine that the criterion in subsection (e)(4)(B)(i)(I) is met now, met as of January 1, 2028, or is not met at all through the entire renewal period with respect to HFC-152a. Under the first possible determination (supply of HFC-152a is not insufficient now), even if the application did not have a safe or technically achievable non-HFC substitute available as of January 1, 2026, the application would not be eligible for renewal as of that date. Under the second possible determination (supply of

Commented [EO 1286665]: The degree of uncertainty associated with this NPRM raises questions as to whether EPA should be proceeding with a rulemaking at this time

Commented [EPA66R65]: Please see response to comment on p. 66 that explains the statutory requirements regarding the timing of this rulemaking.

HFC-152a is not insufficient as of January 1, 2028), the application would not be eligible for ASAs as of January 1, 2028, even if the application did not have a safe or technically achievable non-HFC substitute. Under the third possible determination (supply of HFC-152a is insufficient), the application would be eligible for ASAs if there was no safe or technically achievable non-HFC substitute for the entire application. EPA will monitor reported data over the next year on the noted areas of uncertainty and invites comment on this issue.

In light of the range of outcomes EPA has proposed regarding its determinations on whether the criteria in subsection (e)(4)(B)(i)(I) and (II) are met, EPA is proposing three potential outcomes on whether and how SCPPU foam for marine and trailer uses may be eligible for future ASAs: (1) not eligible to receive ASAs; (2) eligible to receive calendar year 2026 and 2027 ASAs; and (3) eligible to receive ASAs for the five-year period of calendar years 2026-2030 with allowance amounts determined based on the EV of HFC-152a. EPA is also taking comment on SCPPU foam for marine and trailer uses eligibility to receive ASAs consistent with the current approach through calendar year 2030 ASAs. EPA also could finalize different outcomes based on how the transition to substitutes progresses between this proposal and rule finalization.

Under outcome (3), EPA is proposing to allocate allowances based on an expectation that the application can use HFC-152a. To achieve this, EPA is proposing to base the calculation of allowance allocations on the estimated total mass of HFCs needed by the application and allocate at the level necessary to purchase HFC-152a on an EV-weighted basis. For example, if a company used 1,000 kg of HFC-134a and 500 kg of HFC-152a in Year 3 (as defined by the regulatory formula; see Section VII for further discussion of regulatory formula and proposed revisions), and HFC-152a substituted for HFC-134a one-for-one on a gram basis for this

application, EPA would multiply 1,500 kg by the applicable average annual growth rate (AAGR) and then by the EV of HFC-152a to calculate the company's allowance allocation for the following year. EPA would not limit which HFCs could be purchased for use in the application once the allowances are issued. EPA is taking comment on whether the Agency should apply any relevant mass conversions in this calculation (*i.e.,* if an application needed more or less HFC-152a on a gram-by-gram basis when substituting for HFC-134a) where the total mass of HFCs used would be multiplied by a mass ratio, as appropriate, then multiplied by the AAGR.

As outlined in detail elsewhere in this section, before EPA finalizes this rule, the Agency intends to review available information and comments received on this proposal to get further clarity on progress toward commercialization of substitutes, how the overall HFC market has adjusted to the 2024 stepdown, what alternatives are adopted by subsectors subject to 2025 Technology Transitions Program restrictions, and how much additional domestic HFC-152a production capacity comes online.

4. Proposed Restriction under EPA's Technology Transitions Program

The 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) restricts the manufacture and import of foam products that use as a blowing agent HFCs or HFC blends that have a GWP of 150 or greater (hereafter, "foam products"). This restriction begins January 1, 2025. Examples of items subject to this restriction include products that are foams, such as extruded polystyrene boardstock; products for blowing foam, such as two-part foam systems for blowing PU foam; and products that are manufactured using foam, such as boats or refrigerated trailers.

The 2023 Technology Transitions Rule exempts applications which receive ASAs (40 CFR 84.56(a)(2)). However, as finalized in the October 24, 2023, rule, if an application no longer qualifies for ASAs, the Technology Transitions restrictions would apply.

As discussed in the preamble to the 2023 Technology Transitions Rule, the transition to non-HFC and lower-GWP substitutes is already well underway or completed for much of the foams sector (*see* 88 FR 73184). EPA therefore established a uniform GWP limit of 150 for the entire foams sector starting January 1, 2025. The sole exception to this restriction for the foams sector was SCPPU foam for marine and trailer uses, per their receipt of ASAs. As discussed above in Section V.D.1, EPA proposes that while there are no safe and technically achievable alternatives available at this time under subsection (e)(4)(B) specifically for use in SCPPU foams for marine and trailer uses, we anticipate, based on currently available information, that the development of substitutes for these uses is progressing rapidly, such that by the time EPA finalizes this action, substitutes meeting the (e)(4)(B)(i)(I) criterion may be available. While the list of considerations under subsection (i)(4)(B) that EPA is to factor in, to the extent practicable, when considering availability of substitutes for issuing restrictions under subsection (i) includes factors beyond those characteristics listed in subsection (e)(4)(B)(i)(I), in this instance EPA's view is that technological achievability of lower-GWP substitutes in marine and trailer uses is the primary barrier to transitioning away from the use of HFC-134a in these two uses. Many of the factors listed in subsection (i)(4)(B) are not relevant to EPA's assessment of availability of substitutes for these two uses, such as building codes, appliance efficiency standards, and contractor training costs. As noted in Section V.D.1, EPA's SNAP Program has already listed as acceptable the potential substitutes under consideration and the entities actively developing the

substitutes and working to bring those substitutes to market are almost certainly considering costs to consumers and affordability for small business consumers as part of their efforts.

We propose that the applicability of the restriction on HFC foam blowing agents in the 2023 Technology Transitions Rule to SCPPU foam for marine and trailer uses will depend entirely on which of the three co-proposals EPA ultimately finalizes. That is, under co-proposal (1), where EPA would not renew ASAs for SCPPU for marine and trailer uses as of the effective date of a final rule based on this proposal, requirements of the Technology Transitions Program, which include labeling, reporting, recordkeeping, and restrictions on HFCs, would apply beginning January 1, 2026. Under co-proposal (2), where EPA would renew ASAs for SCPPU for marine and trailer uses for 2026 and 2027, requirements of the Technology Transitions Program would apply beginning January 1, 2028. For both co-proposals (1) and (2), EPA proposes that the recordkeeping requirements would apply to manufacturers of SCPPU foams for marine and trailer uses beginning January 1 of the year those uses no longer qualify for ASAs, and the first report would be due March 31 of the following year, as discussed above in Section V.C.4. For example, under co-proposal (1), manufacturers would need to keep records as required by the 2023 Technology Transitions Rule starting January 1, 2026, and submit their first Technology Transitions report to EPA by March 31, 2027; under co-proposal (2), manufacturers would need to keep such records starting January 1, 2028 and would submit their first Technology Transitions report by March 31, 2029. Under co-proposal (3), where EPA would renew ASAs for SCPPU for marine and trailer uses based upon the use of HFC-152a instead of HFC-134a, SCPPU for marine and trailer uses would continue to be exempt from the 2023 Technology Transitions Rule. The requirements under each co-proposal for SCPPU for marine and trailer uses are summarized in Table 2 below. EPA is ~~also~~ interested in ~~any supporting~~ data and

information related to the availability of substitutes and the proposed timeline for transitioning in this application.

Commented [EO 1286667]: For better readability, please add a table to show the different requirements of options 1, 2, and 3, along with the various interactions with the labeling, reporting, etc. requirements of the TT rule

Commented [EPA68R67]: Table added below

Table 2. Applicability of Technology Transitions Requirements under Co-proposals for SCPPU for Marine and Trailer Uses

Co-proposal	Technology Transitions GWP Limit and Compliance Date		Date Technology Transitions Labeling Requirements Begin	Date Technology Transitions Reporting Requirements Begin
(1) No renewal of ASAs	GWP limit of 150 beginning January 1, 2026		January 1, 2026	First report due March 31, 2027, including data from January 1, 2026 through December 31, 2026
(2) Renew eligibility for ASAs for 2026 and 2027	GWP limit of 150 beginning January 1, 2028	January 1, 2028	First report due March 31, 2029, including data from January 1, 2028 through December 31, 2028	
(3) Renew eligibility for 2026–2030 with allowance amounts determined based on the EV of HFC-152a	Because application continues to be eligible for ASAs, it is exempt from Technology Transitions requirements			

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

EPA has been allocating ASAs for regulated substances used for the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector in accordance with subsection (e)(4)(B)(iv)(I)(dd) of the AIM Act. 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." (40 CFR 84.3). EPA defined "chemical vapor deposition chamber cleaning" (hereafter referred to as "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). At the time of this proposal, EPA is aware of three HFCs that are used for this application in manufacturing. 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-ratio hole etching. HFC-23, HFC-32, and HFC-41 may also be minimally used in chamber cleaning processes.

EPA is proposing to determine that no safe or technically achievable substitute will be available for the semiconductor application and that supply of the regulated substance that manufacturers and users are capable of securing from chemical manufacturers is insufficient to accommodate the semiconductor application through calendar year 2030. Therefore, EPA proposes to renew the eligibility of entities using regulated substances for the defined semiconductor application to receive ASAs for the five-year period of calendar years 2026 through 2030.

1. Availability of Safe and Technically Achievable Substitutes

EPA has not identified any substitutes that it would propose to deem safe and technically achievable that are available for the entirety of the defined semiconductor application.

In developing this assessment, EPA reviewed information from industry trade groups, the TEAP's MCTOC, the Intergovernmental Panel on Climate Change (IPCC), scientific journal articles, and more. The sources examined by EPA are outlined in greater detail in the TSD included in the docket for this proposed action.

The MCTOC 2022 Assessment report reviewed HFC gases commonly used in semiconductor manufacturing, along with their alternatives, using the following criteria: commercially available, technically proven, environmentally sound, economically viable and cost effective, safe to use in industrial applications considering flammability and toxicity issues, and easy to use and maintain.[25] Based on this report and other sources, EPA is aware that ~~the~~ semiconductor manufacturers currently utilize other fluorinated gases, such as sulfur hexafluoride (SF_6), nitrogen trifluoride (NF_3), some saturated PFCs (*i.e.*, CF_4, C_2F_6, c-C_4F_8), and some unsaturated PFCs (*i.e.,* C_4F_6, C_5F_8) for the processes of etching and chamber cleaning. The MCTOC 2022 Assessment report lists these chemicals as both commercially available and technically proven and can be used as substitutes for etching and chamber cleaning. In developing its proposed determination regarding substitutes, however, EPA did not consider many of these chemicals in its proposed consideration of the availability of safe and technically achievable substitutes~~. Many of these substances have~~because of their higher GWPs, ~~have~~ lower utilization rates (*i.e.,* higher emission rates), or ~~are more~~higher toxicity than HFCs. Sulfur hexafluoride (SF_6), which is used in the etching of silicon, silicon dioxide (SiO_2), and silicon nitride (SiN), as well as chamber cleaning, has a 100-year GWP of 22,800. Nitrogen trifluoride (NF_3), which is used in the etching of silicon and silicon nitride (SiN), as well as for chamber cleaning, has a 100-year GWP of 17,200. Saturated PFCs, used in the etching of silicon, silicon

[25] See https://ozone.unep.org/system/files/documents/MCTOC-Assessment-Report-2022.pdf.

dioxide (SiO_2), and other materials, have a 100-year GWP ranging between 7,390 to 12,200. Saturated PFCs are also difficult to abate and have relatively low utilization rates.

Unsaturated PFCs are used in high-aspect-hole-ratio etching. They have GWPs of less than two; however-, these compounds have not been widely adopted at least in part since these chemicals can only be used in certain processes and are not necessarily viable for all types of etching, etching all materials, or chamber cleaning.. For example, unsaturated PFCs are not known to be used in chamber cleaning, so the Agency does not consider unsaturated PFCs as available for the entire application.

The MCTOC 2022 Assessment report also lists other compounds that are currently being studied for use but are not yet technically proven, are not considered safe or easy to use, and may have additional toxicity concerns. These chemicals include carbonyl sulfide, HFO-1336mzz(E), PFC-1216, chlorine trifluoride (ClF_3), hexafluoroisobutylene (HFIB), and trifluoroiodomethane (CF_3I). Carbonyl sulfide, used in certain etching applications, is also highly flammable and toxic. HFO-133mzz(E) is being considered as a replacement for certain etching chemicals. PFC-1216 is being studied for use in etching silicon dioxide (SiO_2). Chlorine trifluoride (ClF_3) may be used for chamber cleaning for Low Pressure CVD chambers but is extremely flammable and is not considered safe or easy to use. Although not known to currently be used, hexafluoroisobutylene (HFIB) could be used in certain etching applications for silicon containing material. Trifluoroiodomethane (CF_3I) is used for etching of silicon dioxide (SiO_2) and silicon nitride (SiN), but the MCTOC 2022 Assessment report does not list it as safe or easy to use.

EPA is aware of certain HFCs that may be in the early stages of research for high-aspect-ratio hole etching, such as HFC-134a and HFC-125. ASA holders have stated that research on lower-GWP alternatives is ongoing and there are currently no known alternatives to HFCs,

Commented [EO 1286669]: Are these alternatives to the currently-used products, or are these the primary substances used for these purposes? Not clear based on the writeup, and that context would help to situate these very high 100-year GWPs

Commented [EPA70R69]: The chemicals are currently used by industry for these applications and could be used as substitutes to HFCs. We modified the text for clarity.

PFCs, and nitrogen trifluoride (NF_3), and any alternatives would not be commercially available until at least 2030.

In light of the above analysis, EPA has not identified a safe and technically achievable substitute that is available at the time of this proposal. When a substitute or substitutes are identified for the entirety of the application, it would still take significant time to replace the current HFC(s) with the substitute(s). One industry trade group has stated that semiconductor technologies require at least 10 years from fundamental research to high volume manufacturing to innovate and implement new technologies and their associated raw materials. Given that no promising substitutes have been identified, there is no information before the Agency at the time of this proposal to suggest that there would be a safe and technically achievable substitute available prior to the next five-year review.

2. Supply

HFC-23, HFC-32, and HFC-41 are all currently used in the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector. As described earlier in Section IV.B of the preamble, EPA is proposing to determine that an application meets this criterion if EPA determines that any of the HFCs currently used in an application's equipment or to manufacture the application's products for use have insufficient supply.

As described above in section Section E of the preamble, HFC-23 is used in the etching of silicon dioxide (SiO_2) and silicon nitride (SiN) and is also used minimally in chamber cleaning. In 2022, domestic producers produced approximately [890.5 MT] of HFC-23. [719.2 MT] were subsequently destroyed, and one producer sold 5.2 MT of this HFC-23 for consumptive uses, which could be used for semiconductors as well as other uses. In addition,

Commented [EO 1286671]: Are these placeholders?

Commented [EPA72R71]: Yes. EPA is currently in the final stages of completing its QA/QC process with respect to HFC-23 data for 2022 and will update these figures, if needed, before signing this proposed action.

there were about a half dozen entities that imported HFC-23 with total amount of imports equaling 125.6 MT. Overall, HFC-23 made up only 0.07 percent of total U.S. HFC consumption in 2022 on a mass basis. Moreover, as HFC-23 has the highest EV, it may be possible that this supply is further constricted in the future as the phasedown progresses and the number of available allowances is reduced. As stated elsewhere in this proposed rule, EPA recognizes that there is inherent uncertainty regarding HFC production, and in particular for HFCs with a more limited number of production facilities and/or higher GWPs than other regulated HFCs, this uncertainty may be greater. Therefore, EPA understands there will be changes to the market conditions resulting from the domestic and global phasedown of HFC production and consumption.

In addition, the use of HFC-23 in the semiconductor manufacturing application is large compared to the annual consumption of HFC-23. In 2022, semiconductor ASA holder purchases[26] of HFC-23 accounted for about 81 percent of calculated consumption of HFC-23. Furthermore, at the end of 2022, suppliers held 304.0 MT of HFC-23 in domestic inventory, which is equivalent to about 293 percent of calculated consumption of HFC-23 in 2022; not all of this HFC-23 may be considered available supply, as the entities both holding this material in inventory and reclaiming these HFCs are broader than EPA's interpretation of chemical manufacturers (see Section IV.B for more information).

EPA also analyzed the supply of HFC-32. In 2022, the one domestic producer of HFC-32 produced 17,744.3 MT of HFC-32. There were also over a dozen entities that imported HFC-32, with total import quantities equaling 9,885.3 MT. Overall, HFC-32 made up approximately 17 percent of total U.S. HFC consumption in 2022 on a mass basis. The use of HFC-32 in the

[26] For this calculation, EPA is using purchases in 2022 instead of allowances allocated so that percent of consumption can be calculated for each HFC.

semiconductor manufacturing application is small compared to the annual consumption of HFC-32. In 2022, semiconductor ASA holder purchases of HFC-32 accounted for less than 0.035 percent of calculated consumption of HFC-32. At the end of 2022, suppliers held 21,435 MT of HFC-32 in domestic inventory, which is equivalent to about 80 percent of calculated consumption of HFC-32 in 2022; similar to considerations for supply of HFC-23 and for other applications, not all of this inventory may be considered available.

Another factor EPA is considering is the impact that other regulatory actions may have for the available supply of HFC-32. As described in more detail above in Section V.A, the overall market for HFCs is likely to continue changing in light of AIM Act and potentially other restrictions. There is particular uncertainty regarding demand for HFC-32. The 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) set a GWP threshold of 700 for certain sectors and subsectors where previously higher-GWP HFCs or HFC blends have been used. HFC-32 has a GWP of 675 and may be a suitable alternative in those sectors and subsectors. In other cases, the 2023 Technology Transitions Rule set a GWP threshold of 150 and thus HFC-32 could not be used unless as a component of blends. The first set of restrictions under the 2023 Technology Transitions Rule have compliance dates of January 1, 2025, with the latest compliance dates taking effect on January 1, 2028. Additionally, the proposed Emissions Reduction and Reclamation Rule (88 FR 72216, October 19, 2023) proposes requirements for the use of recycled or reclaimed HFCs for certain uses, as discussed elsewhere in this preamble. When finalized, that rule may affect the use of reclaimed HFC-32.

EPA also analyzed the supply of HFC-41. There is one domestic supplier of HFC-41 that produced 22.2 MT of HFC-41 in 2022. In addition, there were multiple entities that imported HFC-41, with total import quantities equaling 38.3 MT. Overall, HFC-41 made up only 0.03

percent of total U.S. HFC consumption in 2022 on a mass basis. The use of HFC-41 in the semiconductor manufacturing application is moderately large compared to the annual consumption of HFC-41. In 2022, semiconductor ASA holder purchases of HFC-41 accounted for 21.5 percent of calculated consumption of HFC-41. At the end of 2022, suppliers held 26.7 MT of HFC-41 in domestic inventory, which is equivalent to about 60 percent of calculated consumption of HFC-41 in 2022; as noted for the supply of HFC-23 and HFC-32 and for other applications, not all of this inventory may be considered available.

One factor that plays into the sufficiency of supply of these HFCs is the purity specifications used by individual companies in the semiconductor manufacturing sector. While there is no federal standard or regulation governing the purity of HFCs used in semiconductor manufacturing, EPA is aware that individual companies in this sector set their own requirements. HFCs purchased for use in semiconductor manufacturing is produced at around 95–97 percent purity and then typically is purified to 99.999–99.9999 percent purity before it is used by semiconductor manufacturers. Supplying refined HFCs to end users can take up to one year, as purifiers require long lead times.

These purity requirements are also relevant when considering if reclaimed HFCs can be used in this application. EPA notes that virgin HFCs produced for semiconductor use are typically only at 95–97 percent purity, so EPA is not aware of why reclaimed HFCs cannot also be purified to industry specifications; EPA invites comments on this. Of the three HFCs utilized by the semiconductor industry, only HFC-23 and HFC-32 were reclaimed in 2022 and thereby could be a source of supply for this application, though the amount of reclaimed material is small. In addition, it is possible to capture the unreacted process gases used in semiconductor

manufacturing, but the reclamation of fluorinated gases from the semiconductor manufacturing process is not currently economically viable.

There are other factors that may further impact the supply of HFCs for this application. The Creating Helpful Incentives to Produce Semiconductors Act of 2022 (CHIPS Act) has allocated over 50 billion dollars to semiconductor research, development, manufacturing, and workforce development in the United States, which has led to additional investment by semiconductor manufacturers. The U.S. market share of memory chip production is projected to grow from less than 2 percent to up to 10 percent over the next decade.[27,28]

3. What is EPA proposing regarding eligibility for application-specific allowances?

EPA is proposing to renew the eligibility of entities using regulated substances for the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector to receive ASAs for the five-year period of calendar years 2026 through 2030. EPA is proposing to determine "that the requirements described in subclauses (I) and (II) of clause (i) are met" in accordance with the requirements of 42 U.S.C. 7675(e)(4)(B)(v)(II). Specifically, for the reasons outlined earlier in this section, EPA is proposing to determine that no safe or technically achievable substitute will be available for the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector for the entire five-year period. EPA is also proposing to determine that supply of the regulated substance that manufacturers and users are capable of securing from chemical manufacturers is insufficient to accommodate this application through calendar year 2030. As explained earlier, EPA is proposing to determine the supply criterion is

[27] See https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/21/fact-sheet-biden-harris-administration-bringing-semiconductor-manufacturing-back-to-america-2/.
[28] See https://www.mckinsey.com/industries/industrials-and-electronics/our-insights/semiconductor-fabs-construction-challenges-in-the-united-states.

met if supply of one HFC used by the application is insufficient to accommodate the application. EPA proposes to determine that the supply of HFC-23 and HFC-41 are insufficient to accommodate the application for the reasons outlined in the prior section.

F. Mission-critical Military End Uses

EPA has been allocating ASAs for regulated substances used for MCMEU in accordance with subsection (e)(4)(B)(iv)(I)(ee) of the AIM Act. In the Allocation Framework Rule, EPA defined "mission-critical military end uses" as "those uses of regulated substances by an agency of the Federal Government responsible for national defense which have a direct impact on mission capability, as determined by the U.S. Department of Defense (DOD), including, but not limited to uses necessary for development, testing, production, training, operation, and maintenance of Armed Forces vessels, aircraft, space systems, ground vehicles, amphibious vehicles, deployable/expeditionary support equipment, munitions, and command and control systems" (40 CFR 84.3). In the Allocation Framework Rule, EPA finalized an approach that treats the allocation of MCMEU allowances differently than the other applications given the "complex nature of the way DOD sources and uses HFCs for mission-critical applications," (*e.g.*, significantly larger networks of sites and users, including contractors, of HFCs than others covered by ASAs) (86 FR 55116, 55153, October 5, 2021). EPA set up a system whereby DOD must provide the amount of HFCs needed for mission-critical military use and that the two agencies would "work together to ensure the amount necessary is available for mission-critical military applications" (86 FR 55116, 55153, October 5, 2021).

As the definition states, DOD has discretion to identify which uses of HFCs have a direct impact on mission capability. DOD is required to report to EPA "the broad sectors of use covered by current mission-critical military end uses in the next calendar year," per 40 CFR

84.31(h)(3)(iv). Given the complex nature of the way DOD sources and uses HFCs for mission-critical applications, EPA has always maintained that DOD should have discretion to request the amount of allowances necessary to meet its mission-critical end uses and the Agency is not altering that approach through this rulemaking.

Recognizing the sensitive nature of the application, as well as the expert judgement that DOD has in identifying which uses of HFCs have a direct impact on mission capability, EPA consulted~~mmunicated~~ with DOD throughout development of this proposed rule, including in advance of interagency review, and received input to support EPA's evaluation of the statutory criteria described in Section IV.

Commented [EO 1286673]: Can EPA rework this slightly so that it doesn't sound like deliberative information? For example, we presume the referenced coordination occurred prior to EPA's submission of NPRM for review and it would be good to say so

Commented [EPA74R73]: See revisions. EPA did consult with DoD prior to submission of the NPRM to OMB for interagency review.

After analyzing information relevant to the statutory criteria, as outlined in this section and based on input from DOD, EPA is proposing to determine that no safe or technically achievable substitute will be available for the MCMEU application and that the supply of the regulated substances that the application is capable of securing from chemical manufacturers is insufficient to accommodate the MCMEU application through calendar year 2030. Therefore, EPA proposes to renew the eligibility of the MCMEU application to receive ASAs for the five-year period of calendar years 2026 through 2030.

1. Availability of Safe and Technically Achievable Substitutes

As discussed earlier in the preamble, in situations where there are not safe and technically achievable substitutes available for the entirety of the application, EPA would consider the statutory criterion regarding substitutes as being met. In public technical reports DOD (included in the rulemaking docket), DOD identified mission-critical end uses that do not have safe and technically achievable substitutes available. For example, DOD uses a mixture of HFC-227ea and sodium bicarbonate dry chemical in automatic fire extinguishing systems that protect the

crew compartments of ground vehicles. DOD has tested potential replacements but has not identified a viable alternative to date. There are distinct technical specifications for some mission-critical end uses that are distinct from civil standards for the same category of use (*e.g.*, refrigerants and fire suppression agents). For example, automatic fire suppression systems in ground vehicles must meet unique military requirements for inhalation toxicity that allow personnel to stay within the protected space for at least five minutes after fire suppression.

Furthermore, because Congress defined this application as what is "mission-critical," EPA has always acknowledged that this application is more fluid in terms of what particular HFC uses fall within the application. DOD may change which end uses it determines to be mission-critical over time. This further feeds into EPA's proposed assessment that the Agency cannot determine at this time that there will be safe and technically achievable substitutes available for the entirety of the application.

2. Supply

In 2021, DOD sent a letter to EPA with information regarding mission-critical end uses at the time, including a list of six HFCs used in the application (HFC-125, -134a, -143a, -227ea, -236fa, and -32). EPA has determined through communications with DOD that at least some of these HFCs continue to be utilized in mission-critical end uses. As described in section IV.B of the preamble, EPA is proposing to determine that an application meets this criterion if EPA determines that any of the HFCs currently used to manufacture products or systems for use in the application have insufficient supply.

In the analysis of other applications in this proposal, EPA has evaluated the supply of five out of six HFCs that DOD identified as using in 2021 (*i.e.,* all but HFC-143a). EPA is proposing to determine that supply of some of these HFCs is insufficient to accommodate the

application. For example, in the evaluation of supply for the onboard aerospace fire suppression application, EPA is proposing to determine that the supply of HFC-227ea and HFC-236fa is insufficient to accommodate the application. This is in addition to the unique restrictions that apply to the Defense Logistics Agency and DOD purchasing requirements that impact the available supply of HFCs to DOD for MCMEUs. For example, there are Buy America requirements in Federal Acquisition Regulation (FAR) 25.1 and Defense Federal Acquisition Regulation Supplement (DFARS) 225.1 which may restrict how DOD can procure goods, which may include HFCs. Furthermore, as noted in the substitutes discussion for the MCMEU application, EPA has always acknowledged that this application is more fluid in terms of what HFC uses fall within the application. DOD may change which end uses it determines to be mission-critical over time. The fact that DOD may determine that different HFCs and different annual quantities of those HFCs are necessary for mission-critical end uses further feeds into EPA's proposed assessment that the supply of HFCs will be insufficient to accommodate the application.

3. What is EPA proposing regarding eligibility for application-specific allowances?

EPA proposes to renew eligibility for DOD to receive MCMEU ASAs for the five-year period of calendar years 2026 through 2030. EPA is proposing to determine "that the requirements described in subclauses (I) and (II) of clause (i) are met" in accordance with the requirements of 42 U.S.C. 7675(e)(4)(B)(v)(II). Specifically, for the reasons outlined earlier in this section, EPA is proposing to determine that no safe or technically achievable substitute will be available for the entirety of the application and that the supply of the regulated substance that manufacturers and users are capable of securing from chemical manufacturers is insufficient to accommodate the application through calendar year 2030.

G. Onboard Aerospace Fire Suppression

EPA has been allocating ASAs for regulated substances used for onboard aerospace fire suppression in accordance with subsection (e)(4)(B)(iv)(I)(ff) of the AIM Act. In the Allocation Framework Rule, EPA defined "onboard aerospace fire suppression" as the "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). At the time of this proposal, EPA is aware of only one area, lavatory trash receptacles, in which HFCs (specifically HFC-227ea and HFC-236fa) are used in commercial aviation. For military uses, HFC-125 has been used in engine nacelles and APUs, and HFC-236fa has been used in a streaming application (*i.e.,* a portable extinguisher).[29] In addition to HFC uses in commercial and military aviation, EPA is aware that HFCs have limited usage in general aviation, which consists of private and/or business aircraft. The Agency seeks additional information on how HFCs are used for general aviation and how widespread the use is.

After analyzing information relevant to the statutory criteria, as outlined in this section and the TSD, EPA is proposing to determine that no safe or technically achievable substitute will be available for the entirety of onboard aerospace fire suppression and that supply of the regulated substance that manufacturers and users are capable of securing from chemical manufacturers is insufficient to accommodate the onboard aerospace fire suppression application through calendar year 2030. Therefore, EPA proposes to renew the eligibility of entities using

[29] See https://www.epw.senate.gov/public/_cache/files/d/1/d152a591-878f-4a4d-b9c1-dc7121c06eca/9D366FF1E61F7EFFD6A71C37C92924A5.04.03.2020-boeing.pdf.

regulated substances for onboard aerospace fire suppression to receive ASAs for the five-year period of calendar years 2026 through 2030.

1. Availability of Safe and Technically Achievable Substitutes

Identification of available safe and technically achievable substitutes in this application requires considering a range of factors, including fire suppression effectiveness, toxicity, and space and weight considerations. EPA has not identified available substitutes that it would propose to deem safe and technically achievable for the entirety of the onboard aerospace fire suppression application. As discussed earlier in the preamble, in situations where there are not safe and technically achievable substitutes available for the entirety of the application, EPA would not consider this statutory criterion met.

HFCs are used in onboard aerospace fire suppression in fixed systems for total flooding applications and in portable equipment for streaming uses (*e.g.*, handheld fire extinguishers). Fire suppression agents must satisfy environmental and safety criteria, including but not limited to acceptable ODPs and GWPs, be effective extinguishants, and, for spaces where people would be present, have sufficiently low toxicity such that under normal use the discharge of agent in occupied spaces would not harm people. Other important features that are sometimes relevant for onboard aerospace fire suppression include being electrically non-conductive, and "clean" in certain applications such as for high-value electronics, controls, or other critical systems in the protected spaces where it is important to leave no non-volatile residue that could damage the equipment.

As noted at the start of this section, HFCs are used in limited areas within the application. Because there are potentially overlapping ASAs available for a military use of HFCs, EPA has focused its analysis of substitute availability primarily on commercial aviation. EPA is aware of

only one application where HFCs are used in commercial aviation: lavatory trash receptacle fire extinguishing systems. Lavatory trash receptacle systems are total flooding systems; total flooding systems are designed to automatically discharge a fire extinguishing agent throughout a confined space. EPA has not identified any safe and technically achievable substitutes for lavatory trash receptacle systems. In coming to this proposed determination, EPA reviewed information from multiple sources including FAA, the EPA SNAP Program, FSTOC, and the International Civil Aviation Organization (ICAO) which is outlined in greater detail in the TSD included in the docket for this proposed action. The FSTOC 2022 Assessment Report noted that it is not aware of any research to develop an HFC substitute in lavatory trash receptacle fire extinguishing systems. Furthermore, FSTOC noted that identifying substitutes for lavatory trash receptacles is a low priority for industry given that it makes up less than one percent of the installed fire suppression base on board aircraft.

Commented [EO 1286675]: Please define what is meant by this, in layman's terms

Commented [EPA76R75]: Explanation added.

In developing its proposed determination, given the global effort to find viable halon alternatives, EPA did not consider halons in its proposed consideration of the availability of safe and technically achievable substitutes. However, both Halon 1301 and Halon 1211 are technically achievable and continue to be used in onboard aerospace fire suppression. Although the onboard aerospace fire suppression industry has relied on halons for fire suppression for decades, 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 nearly 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.

In assessing whether there was a safe and technically achievable substitute available, EPA also considered what alternatives are listed for use under SNAP for fire suppression that would be relevant for these applications. EPA notes that 2-bromo-3,3,3-trifluoropropene (2-BTP) is listed as an acceptable substitute subject to use conditions for use as a streaming agent in handheld extinguishers and for certain total flooding applications (*e.g.*, engine nacelles and APUs). FAA has approved the use of 2-BTP in handheld extinguishers, and commercial aircraft manufacturers have begun replacing Halon 1211 with 2-BTP extinguishers on newly designed aircraft. As noted above, the SNAP Program listed 2-BTP as acceptable as a total flooding agent in engine nacelles and APUs; however, 2-BTP has not been listed as acceptable in lavatory trash receptacles and the factors for consideration are different from other acceptable SNAP-listed uses. For examples, use in lavatory trash receptacles would be in a space occupied by people, whereas use in engine nacelles and APUs are in unoccupied spaces. Furthermore, FAA has not approved 2-BTP for any total flooding systems to date.

As noted in the introduction to this section, in addition to the use of HFCs for lavatory trash receptacles in commercial aviation, HFC-125 has been used in engine nacelles and APUs on commercial-derivative aircraft for military use. Industry has explored several other fire suppression agents in engine nacelles and APUs, but none have proven to be a viable solution. For example, the industry previously explored FK-5-1-12 for use as a fire suppression agent in engine nacelles, but it failed an FAA-required live fire test. As a result, for the purposes of its evaluation under the AIM Act subsection (e), EPA has not identified safe and technically achievable substitutes that are available for use in engine nacelles or APUs.

In addition to the areas in which HFCs are used in total flooding systems, HFC-236fa is used as a streaming agent in commercial-derivative aircraft for military use. As previously noted

in this section, 2-BTP has been listed as acceptable by SNAP, is FAA-approved, and commercial aircraft manufacturers have begun transitioning to 2-BTP extinguishers on newly produced aircraft. While EPA analysis suggests that 2-BTP is available as a safe and technically achievable substitute, as explained elsewhere in this proposal, EPA would only determine the statutory criterion in subsection (e)(4)(B)(i)(I) is not met if the Agency determines substitutes are available for the entirety of the application.

If a substitute were identified for the entirety of the application, it would still take significant time for transition to the substitute to occur for this application. FAA has testing requirements and minimum performance standards that a new fire suppression agent must meet before it can be used commercially. While there is no prescribed amount of time it takes to meet these requirements, a stakeholder indicated to EPA in a November 2023 public stakeholder meeting that the certification process can take three to five years. Another stakeholder described the FAA process as arduous and noted that it could take many years to receive certification for a new fire suppression agent. There is no information before the Agency at the time of this proposal to suggest that there would be a safe and technically achievable substitute available prior to the next five-year review.

2. Supply

As previously discussed, HFC-227ea, HFC-236fa, and HFC-125 are all currently used in onboard aerospace fire suppression. As described in Section IV.B of the preamble, EPA is proposing to determine that the requirements of 42 U.S.C. 7675(e)(4)(B)(i)(II) are met for this application if EPA determines that any of the HFCs currently used in a commercial product or to manufacture products for use in the application have insufficient supply.

HFC-227ea is the only regulated substance for which onboard aerospace fire suppression allowances have been expended to date. As previously stated, HFC-227ea is used in commercial aviation whereas HFC-236fa and HFC-125 are used in commercial-derivative aircraft for military use. As intended in the Allocation Framework Rule, there is overlap between the onboard aerospace fire suppression application and the MCMEU application. EPA is not reopening this approach through this rulemaking, so as long as DOD continues to classify the operation of Armed Forces aircraft as mission-critical, then DOD may use MCMEU allowances for fire suppression equipment installed on commercial-derivative aircraft. Therefore, in addition to HFC-227ea being the only regulated substance for which onboard aerospace fire suppression allowances have been expended, the uses of HFC-227ea are the only uses for which the onboard aerospace fire suppression application is the sole pathway to receive allowances. In 2022, the sole domestic producer of HFC-227ea produced 1,324.7 MT of HFC-227ea, comprising one percent of U.S. HFC production on a mass basis. In addition, there were nine entities that imported HFC-227ea with the total amount of imports equaling 454.2 MT. Overall, HFC-227ea made up only 0.2 percent of all U.S. HFC consumption in 2022 on a mass basis. At the end of 2022, suppliers held 1,008.3 MT of HFC-227ea in domestic inventory, which is equivalent to about 323 percent of calculated consumption of HFC-227ea in 2022; as noted in the supply discussions for the other applications above (Sections B–E), not all of this HFC-227ea may be considered available supply, as the entities holding this material are broader than EPA's interpretation of chemical manufacturers. As stated elsewhere in this proposed rule, EPA recognizes that there is inherent uncertainty regarding HFC production, and in particular for HFCs with a more limited number of production facilities and/or higher GWPs than other regulated HFCs, this uncertainty may be greater; HFC-227ea has one of the highest GWPs of the

regulated HFCs. Additionally, EPA understands there will be changes to market conditions resulting from the domestic and global phasedown of HFC production and consumption that could affect future supply of HFC-227ea. Given the relative size of the market for HFC-227ea and the limited number of producers in the United States and abroad, the supply chain for HFC-227ea is potentially more fragile than other supply chains (*e.g.*, HFC-134a). This makes it more likely that the supply of HFC-227ea available from chemical manufacturers will be insufficient during 2026–2030 for this application.

The use of HFC-227ea in onboard aerospace fire suppression is small compared to the annual consumption of HFC-227ea. Allocated ASAs for this application in 2024 are equivalent to 0.8 percent of calculated consumption of HFC-227ea in 2022. While this small usage could make it easier for suppliers to divert a fraction of their available supply to this application, the supply chain for HFC-227ea remains fragile for reasons mentioned earlier in this section, including low production and a limited number of suppliers.

Another factor EPA is considering is the impact that other regulatory actions may have for the available supply of HFC-227ea. Specifically, the proposed Emissions Reduction and Reclamation Rule proposes requirements for the use of recycled HFCs for the initial charge (*i.e.,* installation) and/or servicing in fire suppression systems generally, but not onboard aerospace fire suppression systems as long as the application continues to be eligible for ASAs. If this requirement is finalized as proposed, this could decrease the demand for virgin HFC-227ea.

EPA also analyzed the supply of the other HFCs currently used in this application to determine whether supply of those HFCs was also insufficient to accommodate the application. HFC-236fa is used in portable extinguishers in commercial-derivative aircraft. There is currently one producer in the United States of HFC-236fa, however, there was no domestic production

reported in 2022. Globally, HFC-236fa is produced in even smaller quantities than HFC-227ea. In 2022, there were seven entities that imported HFC-236fa with the total amount of imports equaling 301.4 MT. Overall, HFC-236fa made up less than 0.2 percent of all U.S. HFC consumption in 2022 on a mass basis. At the end of 2022, suppliers held 127.5 MT of HFC-236fa in domestic inventory, which is equivalent to about 47 percent of calculated consumption of HFC-236fa in 2022; as noted for HFC-227ea and other HFCs discussed in this preamble, not all of this inventory may be considered available supply (see Section IV.B for more information). While onboard aerospace fire suppression allowance holders have not used allowances for HFC-236fa to date, allocated ASAs for this application in 2024 are equivalent to 0.3 percent of calculated consumption of HFC-236fa in 2022. However, similar to the analysis for HFC-227ea, given the relative size of the market for HFC-236fa and the limited number of producers in the United States and abroad, the supply chain for HFC-236fa is potentially more fragile than other supply chains (*e.g.*, HFC-134a). This makes it more likely that the supply of HFC-236fa available from chemical manufacturers will be insufficient during 2026-2030 for this application. Also, if finalized as proposed, the Emissions Reduction and Reclamation Rule (88 FR 72216, October 19, 2023) could result in similar changes for HFC-236fa as previously discussed with HFC-227ea.

HFC-125 is used in engine nacelles and APUs in military use. HFC-125 is one of the most widely produced HFCs in the world with multiple producers in the United States and globally. In 2022, U.S. production of HFC-125 totaled 19,175.7 MT, comprising 14 percent of U.S. HFC production on a mass basis. In addition, there were 19 entities that imported HFC-125 with the total amount of imports equaling 23,849 MT. Overall, HFC-125 made up approximately 25 percent of total U.S. HFC consumption in 2022 on a mass basis. At the end of 2022, suppliers

held 56,208.2 MT of HFC-125 in domestic inventory, which is equivalent to about 141 percent of calculated consumption of HFC-125 in 2022; for reasons explained elsewhere in this preamble, not all of this inventory may be considered available supply. Allocated ASAs for this application in 2024 are equivalent to 0.0059 percent of calculated consumption of HFC-125 in 2022. The 2023 Technology Transitions Rule (88 FR 73098, October 24, 2023) is restricting the use of HFCs and HFC blends above certain GWP limits in a number of sectors and subsectors as early as 2025. In all likelihood, demand for certain blends containing HFC-125 will decrease. However, given HFC-125 could be used in lower-GWP blends, including blends with GWPs that are less than the relevant GWP limits, there is uncertainty regarding how HFC-125 demand will be impacted. A reduction in demand for HFC-125 in the refrigeration and air conditioning sectors could result in an increase in available supply for use in fire suppression equipment.

3. What is EPA proposing regarding eligibility for application-specific allowances?

EPA is proposing to renew the eligibility of entities using regulated substances for onboard aerospace fire suppression to receive ASAs for the five-year period of calendar years 2026 through 2030. EPA is proposing to determine "that the requirements described in subclauses (I) and (II) of clause (i) are met" in accordance with the requirements of 42 U.S.C. 7675(e)(4)(B)(v)(II). Specifically, for the reasons outlined earlier in this section, EPA is proposing to determine that no safe or technically achievable substitute will be available for onboard aerospace fire suppression and that the supply of the regulated substance that manufacturers and users are capable of securing from chemical manufacturers is insufficient to accommodate onboard aerospace fire suppression through calendar year 2030. As explained earlier, EPA is proposing to determine the supply criterion is met if supply of one HFC used by the application is insufficient to accommodate the application. EPA proposes to determine that

the supply of HFC-227ea and the supply of HFC-236fa are insufficient to accommodate the application for the reasons outlined in the prior section.

VI. What are the proposed requirements associated with a petition to be listed as an application that will receive application-specific allowances?

The Agency is proposing a procedural framework for a petition filed pursuant to 42 U.S.C. 7675(e)(4)(B)(ii) requesting the designation of an application as eligible for ASAs. Subsection (e)(4)(B)(ii) outlines requirements that apply if the Administrator receives a petition requesting consideration of eligibility for ASAs. In the event a complete petition is received, the Agency would make a determination on whether to designate the application as eligible for ASAs after considering the criteria listed in subsection (e)(4)(B)(i). The AIM Act specifies a timeline by which the Agency must consider these petitions. Within 180 days, the Agency must make the complete petition available to the public and propose and seek comment on whether to designate the application as eligible for ASAs and if so, the requisite number of allowances. Within 270 days of receiving the petition, the Agency must take final action on the petition.

In order to have sufficient information to evaluate a petition based on the criteria in subsection (e)(4)(B)(i), EPA is proposing to require that certain information must be included in order for a petition to be considered complete. The information listed as required is not meant to be a comprehensive list of what a petition may include, but rather a minimum threshold after which the Agency would consider a petition complete. EPA would only consider the statutory timeline triggered upon the filing of a complete petition. If the Agency were to receive a petition that did not include all required elements listed in this section, EPA proposes that it would consider that petition incomplete. In the event that an entity filed an incomplete petition, EPA would notify that entity that their petition was incomplete, but not process the petition any

Commented [EO 1286677]: Why is EPA not using the "essential uses" term from the AIM Act?

Commented [EPA78R77]: In the HFC Allocation Framework rule we implemented the essential use provision as "application-specific allowances." Since EPA is proposing to treat current applications and new applications that come in through the petition process the same and rely on the same regulatory provisions for allocating allowances, we are continuing to use the same framing here.

further. After a petition is submitted, if the petitioner supplements the petition, EPA would consider the petition to be re-submitted, and the statutory timelines for action would restart. New information may fundamentally alter the merits of a petition and therefore EPA would have to restart its review in order to account for new information holistically. Comments on EPA's proposed determination would not restart the statutory timelines unless the petitioner formally requested to supplement or revise their petition.

EPA proposes that a complete petition must include, at a minimum:

- A description of the application, including an explanation of what the application is, what purpose or function it achieves, and what populations or commercial products benefit from the application;
- A list of regulated substances and description of their use in the application and an explanation as to why HFCs are required in the application;
- Evidence that no safe or technically achievable substitute, including not-in-kind technologies, is or is expected to be available, and that the petitioner has conducted research to evaluate substitutes for the HFC(s). Examples of evidence that may be accepted include, but are not limited to, third-party analyses and technical reports by recognized experts in the field, test results evaluating ~~of~~ potential substitutes on safety and technical achievability, decisions by EPA to list alternatives under the SNAP Program, or federal regulatory standards that inhibit the ability of the application to transition to a substitute;
- Evidence that supply of the regulated substance(s) used in the application is insufficient to accommodate the application. Examples of evidence that may be accepted include, but are not limited to, signed and notarized communication from responsible corporate

Commented [EO 1286679]: consider updating to "and" for consistency with Section IV.A above.

Commented [EPA80R79]: For this specific element, EPA is aligning the requirement with the statutory language, our interpretation of which is explained in Section IV.A.

Commented [EO 1286681]: Consider a requirement that such reports include the HFCs themselves for comparison and that they include elements necessary for safety determinations similar to a SNAP program review, such as human health risks, ODP, and GWP.

Commented [EPA82R81]: EPA anticipates that information submitted under the prior bullet point would provide sufficient information regarding the currently used HFC(s) in the application. On the latter point, added additional clarifying text.

officers at ~~10 or more~~multiple representative suppliers and potential suppliers for the sector or related sectors that the application falls in stating that the currently used HFCs cannot be sourced; signed and notarized communication from responsible corporate officers at 10 or more allowance holders, including at least three of the 10 largest consumption allowances holders, stating that the currently used HFCs cannot be sourced;

- A signed certification from a responsible corporate officer at the requesting entity that the application cannot use recovered and reprocessed HFCs in conjunction with or in place of virgin HFCs, either due to demonstrated lack of technical achievability or insufficient supply, and an explanation and evidence documenting why recovered and reprocessed HFCs cannot be used for the application;
- Total quantity (in kg) of all regulated substances acquired for the application specified in the petition in each of the previous three years, including a copy of the sales records, invoices, or other records documenting that quantity; if multiple entities are submitting the petition, they must each provide this information individually to EPA;
- The name of the entity or entities supplying regulated substances for and contact information for those suppliers over the past three years; if multiple entities are submitting the petition, they must each provide this information individually to EPA;
- Total quantities (in kg) of regulated substances held in inventory as of the date the petition is submitted; if multiple entities are submitting the petition, they must each provide this information individually to EPA;
- An estimate of the total quantity of HFCs the petitioner expects to purchase in the first year it would be eligible for ASAs;

Commented [EO 1286683]: Why 10 or more suppliers? Is this intended to be a small portion or significant portion of the affected sector? Is it possible that for some sectors, there are not 10 or more suppliers?

Commented [EPA84R83]: This is only an example of what a petition could include as evidence that supply is insufficient to accommodate the application; EPA would consider the contents of a petition on a case by case basis. The intent of these examples is to ensure that a petitioner has done sufficient due diligence to seek out multiple suppliers to confirm a lack of supply of the HFC(s) in question. Suppliers can be entities currently serving that user or market, or could potentially serve that user or market. While some uses may not have as large a network, 10 seems reasonable, as supplier could be read to include any entity in the supply chain, including allowance holders.

Commented [Round 285R83]: Since this is just an example would it be reasonable to make this more general? E.g., "Examples of evidence that may be accepted include, but are not limited to, signed and notarized communication from responsible corporate officers at ~~10 or more~~ representative suppliers for the sector or related sectors…"

Commented [EPA86R83]: Please see the revised text. EPA can remove the example of 10 suppliers, but will still indicate that petitioners seek out communications from multiple entities to provide evidence that they have done due diligence to secure a supply of HFCs and that there may in fact be an insufficient supply for their particular use.

Commented [Round 387]: Please seek comment on how burdensome this notary requirement may be

Commented [Round 388]: Would you seek comment on whether multiple parties can submit a joint petition?

- Data on the proportion of the overall cost of the product or system that reflects the cost of regulated substances; if multiple entities are submitting the petition, they must each provide this information individually to EPA;
- Historic and projected sales of the product or system; if multiple entities are submitting the petition, they must each provide this information individually to EPA;
- Evidence of research into design changes to decrease the amount of HFCs used in the product or system;
- An explanation regarding whether the use of the regulated substance is necessary for the health, safety, or is critical for the functioning of society (encompassing cultural, ~~and~~ intellectual, and economic aspects);
- An explanation regarding steps taken to minimize the use of the regulated substance and any associated emission of the HFC(s); and
- Information on regulatory restrictions related to possible alternatives and substitutes.

Requiring minimum information be included in order for the Agency to deem a petition complete and process that petition would help provide clarity for the Agency and ensure timeliness and transparency for the petitioner. If EPA does not take this approach, it could prevent EPA from having sufficient data to determine whether the application warrants receiving ASAs and would unnecessarily delay a response from the Agency. This would mean that a petitioner would have to wait longer to re-submit a petition if a necessary element were omitted from the original submission.

In addition to proposing to establish required elements of a complete petition, EPA is providing a non-exhaustive list of other elements that are optional, but the Agency may find compelling or helpful in making a determination on a petition:

Commented [EO 1286689]: What does EPA envision here?

Commented [EPA90R89]: "Critical for the functioning of society" may encompass critical HFC uses that are not directly tied to health and/or safety, such as uses that are critical to the economy. EPA's intent is to solicit information regarding the petitioner's use of regulated substances and its eligibility for application-specific allowances.

Commented [Round 291R89]: In that case would recommend including the word "economic"; see edit

Commented [EPA92R89]: Edit accepted.

- Market research on the application, which could includ~~ing~~: an estimate of the number of domestic entities within the application; an estimate of the amount of bulk HFCs used domestically within the application; an estimate of the projected annual growth rate for the duration of the period for which the application is seeking eligibility to receive ASAs, with supporting evidence by third-party sources
- Economic research on the ~~elasticity of~~ demand for products or systems within the application, with supporting evidence by third-party sources
- Research on whether products or systems in the application outside of the United States have had success in transitioning to substitutes or otherwise reducing use of HFCs
- Other information that may be relevant as the Agency evaluates the petition, based on the factors listed in subsection (e)(4)(B)(i)

Commented [EO 1286693]: It seems unlikely that petitioners can provide this information, considering how sparse EPA's own projections have been in this preamble

Commented [EPA94R93]: EPA acknowledges that some entities may not be able to provide this information, which is why it has been included as an optional element. Text edits accepted.

Commented [Round 395]: This seems really odd for entities to provide this information. We suggest generalizing this information request to "demand" rather than something specific like "elasticity of demand."

Commented [EO 1286696]: While this could be interesting, it is unlikely that petitioners will be able to furnish this information

Commented [EPA97R96]: EPA acknowledges that some entities may not be able to provide this information, which is why it has been included as an optional element.

EPA notes that for an entity to be eligible to receive ASAs in a given calendar year, a complete petition should be submitted no later than January 31 two calendar years prior to provide the Agency sufficient time to review a petition and be able to issue allowances in advance of the statutory deadline of October 1 each year. For example, if an entity would like to receive allowances in calendar year 2027, the entity should submit a complete petition no later than January 31, 2025. EPA is setting this clear expectation so entities can factor this into their planning when deciding to petition EPA to be added to the list of eligible applications. This proposed timeline would allow the Agency the requisite time to review and take final action on the petition, consistent with the statutory timeline in subsection (e)(4)(B)(ii), and also issue a final rule to effectuate that decision in 40 CFR 84.13.

EPA proposes to allocate allowances to entities in a new application through the same manner as other entities receiving ASAs, per 40 CFR 84.13 and 40 CFR 84.31(h). EPA contends

that allocating allowances based on the established regulatory approach would be the fairest and most transparent method of determining allowance allocations for entities in a new application. While EPA is proposing that a petition be required to include some of the information that would be necessary to determine an allowance allocation, it is possible that not all entities within an application would be involved in the submission of the petition. In other words, having entities within a new application request ASAs by July 31 like all other applications (per 40 CFR 84.13(b)) would ensure that all entities in a new application have equal opportunity to request allowances. This may mean that in cases where there is a final rule pending to add an application to the list of entities eligible for ASAs at 40 CFR 84.13, any entity wishing to be eligible for ASAs in the next calendar year would need to provide the information required at 40 CFR 84.13(h)(2) by July 31.

EPA proposes that if a petition is granted and a new application is listed as eligible to receive ASAs, that eligibility would apply until the end of the five-year review cycle during which its petition was granted. Per subsection (e)(4)(B)(v), EPA must review each ~~essential~~ ASA use application receiving an allocation of allowances not less frequently than once every five years. EPA proposes that, at the end of each five-year review cycle, it will review any applications listed in 40 CFR 84.13(a) at the time of review, regardless of how they were initially included on the list. For example, the five-year review period covered in this rule includes calendar years 2026 through 2030. If a petition were granted to receive ASAs starting for calendar year 2028, that application would be eligible for calendar year 2028, 2029, and 2030 allowances, and then EPA would review the eligibility for that application to continue receiving ASAs starting with calendar year 2031 allowances.

Commented [Round 398]: Suggest "ASA" rather than "essential" as they both have very distinct meanings

Consistent with the reporting requirements under 40 CFR 84.31(a), EPA is proposing that all reports, petitions, and any related supporting documents must be submitted electronically in a format specified by EPA;[30] records and copies of reports required by this section must be retained for five years; and quantities of regulated substances must be stated in terms of kilograms unless otherwise specified.

VII. Proposed Revisions to Existing Regulations

EPA finalized an approach under the Allocation Framework Rule for issuing ASAs for the initial years after enactment of the AIM Act. EPA set up a framework to determine ASA allocations for calendar years 2022 through 2025 for five of the six applications identified in the AIM Act: propellants in MDIs; defense sprays; SCPPU foam for marine use and trailer use; etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector; and onboard aerospace fire suppression. As explained in more detail in the Allocation Framework Rule, EPA allocates ASAs differently for MCMEU, given the complex nature of the way DOD sources and uses HFCs in the mission-critical context (86 FR 55116, 55153, October 5, 2021).

The 2024 HFC Allocation Rule did not reopen the methodology for issuing ASAs but noted that the Agency had begun development of this rule to review and consider whether to renew eligibility for each of the six applications for ASAs and would herein consider revisions to existing regulatory requirements (88 FR 46836, 46840, July 20, 2023). As EPA foreshadowed in the 2024 HFC Allocation Rule, the Agency is proposing targeted regulatory changes after considering whether any changes should be made to the existing regulatory requirements governing ASAs based on implementation over the past several years. EPA is also proposing one

[30] Currently, most HFC reports under the AIM Act are submitted through the HAWK module in the electronic Greenhouse Gas Reporting Tool (eGGRT).

Commented [EO 1286699]: What does this mean? Can the agency provide more detail?

Commented [EPA100R99]: This language is consistent with other EPA programs and is designed to allow flexibility when electronic reporting systems change. For example, EPA currently receives HFC reports through the HAWK module in the electronic Greenhouse Gas Reporting Tool (eGGRT). Rather than state in the regs that submissions should be through HAWK and eGGRT forever, EPA uses this phrasing to provide future flexibility to use a potential replacement system. A footnote was added for clarity.

Commented [EO 12866101]: Consistent with 5 CFR 1320.5, OMB cannot approve an information collection that includes a records retention of >3 years unless the agency can demonstrate that such a long records retention is necessary. Please provide such a demonstration or remove the requirement from this proposal

Commented [EPA102R101]: A five year retention schedule aligns with the AIM Act mandate to review eligibility of these applications every five years. It's appropriate to require the petitioner to keep these records for that full duration in case the information is needed for the 5-year statutory review. In addition, the Allocation Framework Rule and the subsequent rules have required all records under 40 CFR part 84, subpart A, to be maintained for 5 years. This proposal is consistent with that prior determination and ensures consistency across all records under these provisions. A piecemeal approach seems unnecessarily confusing for the regulated community without a demonstrated rationale for why this should be maintained for less time.

Commented [Round 2103R101]: EPA has described why a 5-year reporting requirement would be appropriate and consistent but not why it is necessary. Please revise the justification and if EPA is unable to support the necessity of this requirement it should be struck.

Commented [EPA104R101]: We understand your comment and the requirement of 5 CFR 1320.5 to relate to when OMB can approve an information collection. We also understand that a similar comment has been made on the ICR related to this rule. We welcome conversations about the record retention and the requirement of 5 CFR 1320.5 during the process related to EPA's proposed ICR and OMB's ability to approve that ICR. We believe that is the appropriate forum for that discussion. We note that this package is a proposed rule, so there is flexibility to change things during rule finalization dependent on how the ICR discussions resolve.

Commented [Round 3105R101]: Our stance is that EPA should not be proposing this requirement unless it can satisfy the criteria in 5 CFR 1320.5, which it currently appears unable to do. EPA should not be proposing a requirement that is not consistent with 5 CFR 1320. If EPA can provide a demonstration, it should be in the proposed rule so that the public can comment on whether such retention is necessary consistent with 5 CFR 1320.

specific regulatory change to clarify how EPA's regulations would apply to any illegally imported HFCs that are seized and auctioned by enforcement officials, proposing to require exporting companies to report ITNs quarterly, and proposing to simplify the "date of purchase" requirement for a RACA.

Under the current regulations established in the Allocation Framework Rule, EPA issues ASAs based on multiplying the company's HFC use in the prior year by the higher of:

- the AAGR of use for the company over the past three years; or
- the AAGR of use by all entities requesting that type of ASA (*e.g.,* for MDIs) over the past three years.

For the calculation of AAGR, EPA calculates the growth rate between the first and second year plus the growth rate between the second and third year, divided by two. The formula is as follows:

$$\frac{\left(\left(\frac{\text{Application or Entity HFC Purchases in Year 2}}{\text{Application or Entity HFC Purchases in Year 1}}-1\right)+\left(\frac{\text{Application or Entity HFC Purchases in Year 3}}{\text{Application or Entity HFC Purchases in Year 2}}-1\right)\right)}{2}$$

EPA relies on activity from July 1 to June 30 for each of the three preceding years prior to the annual allocation because of the biannual reporting deadlines and to include the most recent year of data prior to the October 1 allocation deadline in the allowance allocation determinations. EPA established the information an entity requesting ASAs must provide in 40 CFR 84.31(h)(2). EPA is proposing to codify the existing practice such that entities reporting on or applying for ASAs provide supporting documentation to verify reported data on total quantities of HFCs acquired through conferring allowances, expending allowances for direct import, purchases without expending allowances, and quantity held in inventory.

EPA also established that the Agency would consider unique circumstances that are not reflected by the rates of growth calculated in the methodology outlined above that are also factually documented when determining allowance allocations. EPA finalized the following circumstances as potentially meriting an increased allocation to an individual company beyond historical growth rates: (1) additional capacity will come on line in the next year, such as a new manufacturing plant or expanded manufacturing line, (2) a domestic manufacturer or some of its manufacturing facilities has been acquired, and (3) a global pandemic or other public health emergency increases demand for use of HFCs in an application, such as an increase in patients diagnosed with medical conditions treated by MDIs. These scenarios could provide reasons to increase allowance allocations to affected companies in the affected years. Furthermore, if a company wanted to make a claim that it qualifies for individualized treatment due to one of these unique circumstances, the company must sufficiently document in a verifiable way why it qualifies. Specific documentation includes, but is not limited to, recent invoices for new tools; permit documentation for new facilities, facility expansion, or installation of equipment related to retooling; agency or company press releases for the launch of new products; or Securities and Exchange Commission filings documenting facility acquisitions or expansions. Ultimately, accommodating unique circumstances that are fully documented and proven help the Agency fulfill Congress's mandate that EPA “allocate the full quantity of allowances necessary” (86 FR 55116, 55151, October 5, 2021). As a result of the multiple allocations between 2021 and 2023 and the lessons learned through this process, EPA is now proposing limited changes to these existing regulations.

Specifically, EPA is proposing: to require companies provide the total expected amount of HFCs they intend to purchase in the calendar year, to expand permissible scenarios that could

qualify as unique circumstances, a different allocation methodology for certain very small users of HFCs and entities with irregular purchasing history, how to account for inventory in allocation decisions, new requirements for conferrals of MCMEU allowances, to establish a pool of set-aside allowances for situations that meet the criteria for unique circumstances related to medical conditions treated by MDIs, and to allow ASA holders to return a portion of their allowances voluntarily if they do not intend to use them. EPA is proposing other specific regulatory changes to: clarify how EPA's regulations would apply to any illegally imported HFCs that are seized and auctioned by enforcement officials, require exporting companies to report ITNs quarterly, and simplify the "date of purchase" requirement for a RACA.

A. Expected Total HFC Purchases

Under EPA's current program, entities may voluntarily state the total amount of HFCs they expect to purchase for the next year. EPA has encouraged entities to provide this data on a voluntary basis to provide an additional data element for the Agency to consider in making allocation decisions.

EPA proposes to amend the regulations to require all entities to provide their total expected HFC purchases for the next calendar year as a component of overall applications due July 31 for ASAs for the following calendar year. Under this proposed requirement, entities would be required to provide an estimate of the total quantity of HFCs they expect to purchase next year based on their expected eligibility for allowances. EPA will allocate at that level if it is lower than what that entity is eligible for based on the regulatory formula.

EPA is proposing this approach to better understand each entity's HFC needs in the next year. The regulatory allocation methodology established in the Allocation Framework Rule, and outlined at the start of this section, is designed to determine an allocation based on "projected,

Commented [Round 3106]: while we understand EPA's reason for this information request, wouldn't this potentially lead to companies overstating their need?

current, and historical trends." However, this formula may not fully take into account other considerations that could impact an entity's HFC needs in the next year. This proposed approach may also avoid overallocation at the expense of general pool allowance holders.

B. Unique Circumstances

Under EPA's current regulations, entities may request that EPA consider unique circumstances that are not reflected by the rates of growth calculated. Entities "must provide additional information if requesting that EPA consider unique circumstances" under 40 CFR 84.13(b)(1). EPA is proposing to codify into the regulations the Agency's existing practice of requiring entities to provide supporting documentation to verify any claimed need. EPA previously codified three situations that would be considered as unique circumstances (40 CFR 84.13(b)(1)). After multiple allocations and many conversations with stakeholders, EPA is proposing to add to the list of unique circumstances under which EPA may allocate additional allowances beyond what is calculated from the regulatory allocation formula. EPA is also proposing to broaden the third unique circumstance related to MDIs.

First, EPA is proposing to create a unique circumstance for economic disruption outside the immediate control of the entity applying for ASAs, such as an economy-wide recession or other documented short- to medium-term market events that negatively impact a company's operations, such as a strike that affects product demand or supply chain disruption. EPA proposes to consider this situation as a unique circumstance as such an event could lead to an increased need to purchase HFCs beyond what is reflected in the regulatory formula, but likely would not be captured under an existing scenario that EPA would consider as an acceptable unique circumstance. If finalized, entities would still have to submit documentation that verifies that this situation has taken place, the current status of the market event (*e.g.*, whether it has

concluded and demand for the HFCs has returned), and that this situation has materially impacted an entity's HFC needs. The entity would also have to provide supporting documentation to justify the projected amount of HFCs needed, including explaining how projections compare to pre-market event use.

EPA is also proposing to add building a stockpile of a specific HFC as a scenario which EPA would consider a unique circumstance in the event a major producer for an application announces they will be ceasing production of the HFC used by the application-specific entity in the near future. An entity could request additional allowances for the purpose of building inventory ahead of the cease in production. For an entity to be eligible for additional allowances under this unique circumstance, EPA proposes that the entity must provide EPA with a letter from their supplier signed by a responsible corporate officer[31] stating that the supplier is ceasing all production of the HFC at issue within three years. Further, EPA proposes that an eligible entity must certify that they have regulatory requirements beyond the 40 CFR part 84 requirements that limit its ability to switch suppliers or there are no other suppliers that could meet their needs (*e.g.*, because there no other chemical manufacturers that can supply the needed HFC). EPA proposes to also require evidence that the entity has a restricted HFC supply chain, such as required purity requirements. If additional allowances were granted because of this requested unique circumstance, EPA proposes to require reporting specific to the building of inventory by the entity that would be allocated ASAs in advance of their supplier's production facility ceasing production. Such inventory buildup must be held by the entity that is allocated

[31] EPA is also proposing to define this term, which is used elsewhere under the HFC Allocation Program. For purposes of 40 CFR part 84, subpart A, EPA is proposing that *responsible corporate officer* and *responsible official* mean a person who is authorized by the regulated entity to make representations on behalf of, or obligate the company as ultimately responsible for, any activity regulated under 40 CFR part 84, subpart A.

allowances, and EPA would subtract those quantities from the entity's purchase history such that it is not included in the regulatory formula to determine the entity's allocation the following year.

EPA is also proposing to expand the scope of the unique circumstance for a global pandemic or other public health emergency that increases patients diagnosed with medical conditions treated by MDIs to include "healthcare system needs." EPA notes that the reference in the regulations to an "other public healthy emergency" is not limited to situations where the Department of Health and Human Services (HHS) has officially declared a public health emergency. The~~is~~ propos~~al~~ed expansion of the unique circumstance is a direct outgrowth of experience over the past three years of implementing the phasedown and is designed to ensure a sufficient volume of HFCs is available to manufacture MDIs to treat asthma, chronic obstructive pulmonary disease, and other respiratory diseases when unexpected market events occur.

EPA proposes to define a healthcare system need as circumstances where an increase in demand for MDIs used to treat asthma, chronic obstructive pulmonary disease, and other respiratory diseases may occur because of a change in market conditions that otherwise would not be included in calculated rates of growth. If finalized, EPA intends to consult closely with the FDA and potentially ~~the Department of Health and Human Services~~HHS more broadly before allocating allowances for "healthcare system needs."

Examples of the types of events that could fall into a healthcare system need include, but are not limited to:

- A manufacturer that makes MDIs outside of the United States stops selling approved MDI products in the United States;
- Major recall or suspension of production of alternative (non-MDI) emergency asthma treatments prompting increase in MDI demand;

Commented [EO 12866107]: Has EPA already discussed w/ FDA and HHS? Want to make sure their Front Offices are tracking.

Would also be curious to hear more about the stakeholder engagement with/from the health care community.

Commented [EPA108R107]: EPA did not consult with FDA/HHS on this specific proposal, but regularly consults with FDA on MDIs, including in our annual allocation of allowances and as issues arise. EPA seeks to confirm that FDA/HHS has seen this proposed change and welcomes a call if helpful to confirm this need for this type of provision.

Additionally, EPA has engaged with various stakeholders in the MDI industry, including through stakeholder meetings for the app-specific rule as well as consultations with MDI manufacturers prior to developing the app-specific proposal. EPA expects to receive comments related to this topic as well, which we will take into account before finalizing the rule.

Commented [EO 12866109]: But not limited to?

Commented [EPA110R109]: Accepted.

- Change in preferred products from pharmacy benefit managers or state Medicare programs to patients;
- FDA compliance or enforcement actions that impact MDI market dynamics by reducinge availability of generic drug products that ~~impacts MDI market dynamics~~;
- Significant increase in respiratory infections in general population (*e.g.*, respiratory syncytial virus (RSV), coronavirus disease (COVID)); and
- Decrease in availability of active pharmaceutical ingredient or device component for one or more MDI manufacturers causing a supply shortage.

Commented [Round 2111]: Consider deleting s for subject-verb agreement if the subject is FDA's actions; or, if it's the availability that affects market dynamics, consider replacing "that impacts" with ", which impacts"

Commented [EPA112R111]: We have reorganized the sentence to make it clearer.

C. Methodology for Entities with Irregular Purchasing History and Very Small Users

EPA has observed that there are certain entities with purchase patterns for which the regulatory formula either is not able to calculate an allocation or applying the terms of the regulatory formula would produce absurd results. For these entities, EPA is proposing an alternative approach for calculating the quantity of allowances each entity is eligible to receive. Specifically, EPA is proposing to create an alternative method of allocating to entities that are either of the following: (1) entity has small purchases of HFCs (<100 kg) at least one of the last three years where their purchase history would result in 200 percent or higher AAGR of use for the company over the past three years, or (2) entity's growth rate cannot be calculated because it had zero purchases in one of the last three years for reasons other than newly using HFCs. For entities that fall into either category, the Agency is proposing to allocate the highest, as measured in exchange value equivalent (EVe), verified purchase amount in the last three years.

With respect to the first category, EPA is proposing these cutoff numbers to allow for some narrow flexibility in an entity's purchasing patterns and to recognize the variability for entities that purchase relatively small quantities of HFCs. EPA is proposing to move away from

applying the existing regulatory formula for entities where a relatively small fluctuation in purchasing measured on a mass basis would result in an extraordinarily large and nonsensical growth rate. EPA reviewed data from the past three October 1 allocation cycles and found that the top three highest entity-specific AAGRs from each of the allocation cycles ranged from about 125 percent or higher, with the lowest "small use" of HFCs in a particular year of less than 5 kg. Thus, the Agency is proposing 200 percent as the AAGR cutoff and less than 100 kg as the "small use" cutoff.

For the second category, it is mathematically impossible to calculate a growth rate based on zero purchases in a year under EPA's existing regulatory formula. Entities that had zero purchases in one of the three years under consideration would also have to be determined to be an active purchaser prior to a year with zero purchases. It is not EPA's intent to capture entities that are new in an application under this alternative pathway.

EPA is separately proposing a different allocation approach for all very small purchasers of HFCs. EPA is proposing to define entities in this category as anyone whose HFC purchases add up to less than 100 kg in each of the previous three years. The Agency recognizes there are certain entities that purchase the same small quantities of regulated substances every year who may not follow a growth-oriented use similar to that of entities that use HFCs in wide-scale, commercial operations. Examples of these uses could include those meant for small batch use in one of the eligible applications for research and development and/or entities that may not yet be manufacturing commercially if, for example in the case of MDIs, the entity is still in the product development phase, is only manufacturing small numbers of MDIs (*e.g.*, for clinical trials), and is waiting for final FDA approval. For these entities, EPA proposes to allocate the highest, determined on an EVe basis, of an entity's past three years' worth of purchases, since their use

stays relatively consistent over time. EPA is taking comment on whether the Agency should look back further at up to five years' worth of purchase history. EPA based this number on the past three October 1 allocation cycles, and reviewed purchasing patterns for the smallest purchasers who are not new to the HFC market and would not be considered entities with irregular purchase histories. EPA is taking comment on the cutoff threshold on what size purchases would allow for an entity to be considered a "small user." EPA is also soliciting comment on whether, combined with this approach or as an alternative to this approach, EPA should round allowance allocations for very small purchasers to account for purchase of a specific cylinder volume. In order to take this approach, EPA requests comment on the typical cylinder volume sizes used in these small purchases. EPA would also require eligible applicants to provide information on the cylinders being purchased in their biannual reporting.

D. Average Annual Growth Rate Calculations

EPA currently calculates AAGR on an MTEVe basis. This process involves converting the mass (*e.g.,* kilogram) of each HFC into MTEVe and summing those MTEVe quantities across each year, before applying the AAGR formula described earlier in this section. The Agency is providing courtesy notice of a change going forward to calculate AAGR on a mass basis. This new process would be based on summing all HFCs together for each year to get a total quantity based on mass and using this mass quantity in the AAGR formula. AAGR calculations are not codified in the regulations, so this is not a regulatory revision, but EPA is providing this notice given broader methodology changes proposed in this rulemaking.

EPA is modifying this calculation because we are concerned that as entities transition to lower-GWP HFCs, an AAGR calculated on an MTEVe basis will not appropriately reflect their projected demand for HFCs in the upcoming calendar year. For example, under an MTEVe-

based AAGR calculation, an entity transitioning to a lower-GWP HFC, which has an associated lower EV, could have a negative AAGR while simultaneously experiencing a growth in actual HFC usage. In this situation, the entity would be allocated an amount of allowances lower than its current year's HFC use. While entities will require fewer allowances to purchase these lower-GWP HFCs, until a company has a full three years of purchase data with this lower-GWP HFC, the calculated allowances may be substantially less than projected demand, either increasing by too small an amount or in some cases declining despite an actual increase in demand. It would be a perverse outcome for entities to receive an insufficient HFC allocation because they are transitioning to a lower-GWP alternative.

In addition, growth calculated on a mass basis is more reflective of demand than MTEVe and is not impacted by any potential swings resulting from purchasing differing levels of HFCs with different EV values each year. For example, a company purchasing 20 kg of HFC-41 in one year and 40 kg of HFC-23, which has an EV approximately 160 times that of HFC-41, the following year would have the same growth rate as a company purchasing 20 kg of HFC-41 in one year and 40 kg of HFC-41 the next year (*i.e.,* the growth rate for that year is 100 percent for both companies versus 32,000 percent for the first company and 100 percent for the second company).

E. Inventory

EPA's current regulations require entities receiving ASAs to provide, as part of their biannual reporting requirements, information on the quantities of HFCs left in their inventory at the end of the previous six-month reporting period (40 CFR 84.31(h)(1)(iv)). Upon finalization of this rulemaking and heading into the allocation of calendar year 2026 allowances, EPA will have several years of data on inventory, including how inventory levels have changed over time.

In the Allocation Framework Rule, EPA noted its intent to account for changes in inventory in the allocation of ASAs (86 FR 55116, 55152, October 5, 2021).

EPA is proposing to include verified changes in inventory into the calculation of the quantity of HFCs an entity used over the 12-month period for all allocations except MCMEU. Changes in inventory are documented information as to how an entity used HFCs in a particular year. For example, if an entity purchased 100 kg of HFCs, and their inventory grew by 50 kg, this would suggest that the entity used 50 kg in the manufacturing process under the applicable application. In this instance, consideration of purchases minus inventory buildup is a more accurate reflection of HFC use by the entity than HFC purchases would be alone. EPA proposes to factor in both drawdown and growth in inventory; a drawdown of inventory would be added to HFC purchases and a buildup of inventory would be subtracted from HFC purchases.

EPA is proposing that this approach would not apply to calculation of MCMEU allowance allocations because DOD has a history of building up inventory and may need to do so for mission-critical or national security purposes. The Agency acknowledges that building inventories can be an important strategy for other entities to navigate changing market conditions, especially in advance of the 2029 reduction step. Therefore, as part of this proposal, EPA is also including that entities may provide a rationale as to why a buildup in inventory should not be subtracted from the quantities of HFCs they annually acquire. An example of what the Agency would consider to be acceptable rationale would be if a producer announced that they would be ceasing production of an HFC that is used in a particular application, and the entity wanted to build up inventory of that HFC to continue manufacturing of their product while they figured out their transition timeline. Another example could include a situation where an

entity had to purchase a minimum volume (*e.g.*, a full ISO tank) and that last purchase resulted in an increase in inventory.

In the alternative, EPA is proposing to not incorporate small amounts of growth in inventory in allocation decisions. EPA would propose to define a small amount of growth as below 20 percent or, alternatively, growth in inventory for only a single year. EPA invites comment on this alternative pathway and also what the Agency should consider to be a small amount of inventory growth.

F. Department of Defense Conferrals

In the Allocation Framework Rule, EPA finalized that anyone conferring an ASA, except for the conferral of allowances for MCMEU, would be required to submit information about each conferral prior to conferring allowances (40 CFR 84.31(h)(4)). While DOD was not required to submit conferral information to EPA, DOD was required to maintain records documenting the conferral(s) of ASAs to other entities up to and including the producer or importer of the chemical (40 CFR 84.31(h)(7)(iv)).

In order to ensure that certain imports are not delayed or denied, EPA is proposing to modify the Part 84, subpart A regulations to require that DOD report information consistent with the required reporting of conferral data from all other ASA holders. This would include the identity of each conferrer and conferee and the quantity in MTEVe of ASAs being conferred. This proposed regulatory change would not be a significant burden for DOD because DOD is already required to track this data internally (40 CFR 84.31(h)(7)).

If finalized, this regulatory revision would bring the process for conferring MCMEU allowances in line with other entities receiving ASAs. The Allocation Framework Rule noted that one of the goals of this requirement was "to ensure EPA has the requisite information to

track application-specific allowances" (86 FR 55116, 55189, October 5, 2021). When an HFC supplier reports to EPA that they have expended ASAs other than MCMEU allowances, conferral reports have allowed EPA to confirm whether that supplier was in possession of ASAs. With MCMEU allowances, given that DOD is not required to share information about the conferral of MCMEU allowances with EPA, the Agency has encountered difficulty verifying whether suppliers are in possession of MCMEU allowances. EPA is particularly concerned that without conferral information for MCMEU allowances, the Agency would recommend that U.S. Customs and Border Protection (CBP) deny entry of an import of HFCs bound for MCMEU. This could cause unnecessary delays for DOD and extra costs for importers. Different reporting requirements for MCMEU allowances has resulted in unexpected confusion and delays in the approval of some producer and/or importer quarterly reports, increasing administrative burden for DOD, entities who are producing and importing on behalf of DOD, and EPA. If finalized, this regulatory change would help address these issues.

In addition to bringing the process for conferring MCMEU allowances in line with other entities receiving ASAs, EPA is proposing one additional requirement for the conferral of MCMEU allowances, per a request from DOD. To enable clearer tracking of MCMEU allowances from initial conferral to expenditure, EPA is proposing to require that a certificate number, generated by DOD, be reported to EPA for each conferral and expenditure of MCMEU allowances. For example, if an intermediary receives a conferral of MCMEU allowances from DOD and then confers the allowances further to a supplier, both DOD and the intermediary must report the same certificate number as part of the conferral. Finally, when the supplier expends the conferred MCMEU allowances for production or import of HFCs, the supplier must report the certificate number in the same report in which the expenditure of MCMEU allowances is

reported. This additional layer of tracking conferrals could further relieve any unexpected confusion.

G. Limited Set-aside for Unique Circumstances Related to MDIs

Some stakeholders have expressed concern that an annual allocation decision is not always sufficient to meet the needs of the entities eligible for ASAs. Entities have noted that unanticipated events may arise after July 31, when requests for ASAs are due, that legitimately necessitate an increased need to purchase more HFCs than expected. EPA received a comment to the Allocation Framework Rule (86 FR 55116, October 5, 2021) requesting that EPA create a separate additional pool of allowances to accommodate growth, new mid-year entrants, and "under-allocation." At the time of that rulemaking, EPA determined that establishing such a pool of allowances was unnecessary because the Agency had set up an allocation formula to allocate the full quantity of allowances necessary, and setting allowances aside just in case they were needed would reduce the allowances available to general pool allowance holders thereby reducing how many HFCs can be imported or produced if the set-aside allowances went unexpended. EPA also noted that a company can access HFCs from the open market; if a company used more HFCs in a given year, that increased use would be reflected in the next year's allocation. However, EPA also noted that the Agency would learn from implementation of the program and consider adjusting the methodology (86 FR 55116, 55151, October 5, 2021).

Based on the Agency's observations in implementing the ASA allocations over the past three years, EPA is proposing to create a set-aside of allowances specifically for situations that meet the criteria for the unique circumstance established in 40 CFR 84.13(b)(1)(iii), including the proposed changes described in Section VII.B. In other words, this would be a set aside to accommodate unforeseen need for regulated substances related to a global pandemic, other

public health emergency, or other healthcare system needs related to increased patients diagnosed with medical conditions treated by MDIs. EPA still sees significant downsides to creating a set-aside of allowances for unforeseen demands in the eligible applications as outlined in the Allocation Framework Rule, but does see benefit in creating a set-aside for the singular narrow possibility of a public health emergency or other unforeseen event that would specifically affect availability of MDIs. As a result, EPA is proposing to set aside allowances that would be available for the use of HFCs as a propellant in MDIs if the requester meets the criteria for the unique circumstance as defined in in 40 CFR 84.13(b)(1)(iii). Application-specific entities could apply to EPA for these allowances based on a demonstrated need to purchase more HFCs in the present calendar year in light of events that were unforeseen at the time of the entity's application for ASAs for the calendar year at issue. For example, during the beginnings of the COVID-19 pandemic in 2020, MDI manufacturers purchased nearly 40% more HFC-134a than they did in 2019, which is substantially more than they would have been allocated based on Year 3 purchases and the application's AAGR; this extra demand also could not have been predicted in July 2019, when manufacturers would have applied for calendar year 2020 allowances. EPA would consult with the FDA in determining whether the presented situation meets the criteria as defined, but scenarios could include a global pandemic. Other examples of situations that could qualify are described in Section VII.B. EPA is also taking comment on whether there are other analogous situations where an unexpected increased need for HFCs resulting from the other established and proposed unique circumstances could arise in which the facts would justify the potential use of another set-aside for ASA holders. If a commenter identifies such a situation, EPA requests that the commenter also provide information on how EPA would appropriately cabin requests to demand that was truly unexpected and unforeseeable and also information on

what entities should have to provide as evidence when applying for set-aside ASAs. At a minimum, it seems appropriate to require a requesting entity to present EPA with information on how facts have changed that were unknowable at the time the entity applied for that year's ASAs and also evidence that the entity has been unable to acquire needed HFCs from the open market or through allowance transfer. EPA seeks comment on the appropriate records that would need to be provided to EPA to document the entity's unsuccessful efforts to acquire HFCs without additional allowances from EPA. EPA would likely require at least some of the records described in Section VI.

EPA is presenting a series of options for comment on how such a set-aside pool would be created. Under Option 1, which is EPA's preferred option, EPA would form this pool by setting aside 10 percent of the allocation of ~~any~~ certain entities~~y~~ ~~—~~ those that produced or imported HFCs during 2011–2019 ~~on behalf of~~to serve ~~entities comprising~~ the applications eligible for ASAs, except MCMEU. An entity that produced or imported HFCs in the time range of 2011–2019 for a separate entity now receiving ASAs is getting a current HFC allowance allocation based on those past purchases. At the same time, ASAs are being issued to entities for conferral to a producer or importer. This can be viewed as a double allocation. For example, if Entity A imported for an MDI manufacturer in 2011–2019, those historic imports are included in calculating Entity A's allowance allocation. In other words, Entity A is getting a higher allowance allocation because of their imports for an MDI manufacturer. At the same time, the MDI manufacturer is being allocated ASAs, which can be conferred to Entity A to import HFCs for the MDI manufacturer. Therefore, Entity A has two sets of allowances available to them as a result of being an importer for MDI manufacturers. Because of this aspect of the design of EPA's allocation system, if EPA were to create a set-aside of allowances for application-specific

Commented [EO 12866113]: This is better explained down below, but on first read this sentence can sound like EPA is setting aside 10% of all the allowances, and then holding those for entities with ASA eligibility. Suggest re-wording to, "EPA would form this pool by setting aside 10 percent of the allocation of certain entities: those that produced or imported HFCs to serve applications eligible for ASAs, except MCMEU given that…"

Commented [EPA114R113]: Thank you for this suggestion. Edits have been incorporated.

Commented [EO 12866115]: Why not MCMEU? Is it for the same reason given above: "EPA is proposing that this approach would not apply to calculation of MCMEU allowance allocations because DOD has a history of building up inventory and may need to do so for mission-critical or national security purposes."

Commented [EPA116R115]: If the commenter would like to discuss further, we are happy to have a call.

entities, EPA proposes to hold back 10 percent of the allocation of entities that produced and imported for application-specific uses during 2011–2019. This appears more equitable than holding back a set amount of allowances from ~~for~~ all general pool allowance holders, since only those that historically imported and produced for application-specific uses may have two sets of allowances now available to them. Of course, because a company that historically produced or imported for application-specific uses has two sets of allowances available to them, it seems that they should have sufficient production and/or consumption allowances available to purchase additional HFCs for an application-specific entity if an unexpected need arises. EPA is soliciting comment on whether, because of this fact, a set-aside is not truly needed, or if a set-aside is necessary because historic importers and producers are requiring conferral of ASAs to meet the needs of application-specific entities.

Commented [EO 12866117]: This wording is confusing – assuming it's supposed to constrast, should it say "whether, because of this fact, a set-aside is not truly needed, or if a set-aside is necessary"?

Commented [EPA118R117]: Edit accepted

Under this proposed Option 1 approach, EPA would withhold 10 percent of the identified entities' allowances until April 30. If no application-specific entity applied for the allowances by April 30, then the withheld allowances would be issued to the entities from which they were withheld. If a request is pending, EPA would withhold allowances until that request was evaluated and allowances were issued. Such issuance would be done in a proportionate fashion if some, but not all, of the set-aside allowances were allocated to application-specific entities. EPA seeks comment on whether April 30 is late enough in the year to provide the appropriate safety value for unforeseen public health emergencies and other healthcare system needs.

Alternatively, Option 2 would be that EPA would create a set-aside pool for application-specific entities in the event of a public health emergency or other healthcare system need from any revoked allowances, including from administrative consequences already finalized. In the Allocation Framework Rule, EPA created administrative consequences whereby EPA can adjust

allowance allocations if EPA determines that a person failed to comply with certain requirements relating to the HFC allowance allocation and trading program. Under the administrative consequence tool, a revoked allowance is one that EPA takes back from an allowance holder and redistributes to all other allowance holders (86 FR 55116, 55169, October 5, 2021). Under this second option, instead of redistributing revoked allowances to all other allowance holders, EPA would put the revoked allowances into a set-aside pool in case additional ASAs were needed as a result of a public health emergency. One potential flaw with this proposed approach is that to date, entities could expend ASAs to either produce or import HFCs. EPA created ASAs to function this way because end users in the identified applications may not know in advance how they will procure HFCs, and this method provides flexibility to ensure that end users receive the "full quantity of allowances necessary," (86 FR 55148). To ensure that these ASAs are provided within the overall annual production and consumption caps, EPA subtracts the amount of ASAs allocated from both the production and consumption general allowance pools (40 CFR 84.9(a)(3); 84.11(a)(3)). However, to date, EPA has only revoked consumption allowances.[32] EPA would likely need to hold back some amount of production allowances under this option, up to 1,000,000 MTEVe, to ensure sufficient allowances were available.

A third, less preferred option, would be to hold back a set amount of allowances. This set-aside would be created from all general pool allowance holders. EPA proposes that the Agency could hold back allowances in the range of 500,000 to 1,000,000 MTEVe production and consumption allowances. If no application-specific entity applied for the allowances by April 30, then the withheld allowances would be issued to the entities from which they were withheld. If a request is pending, EPA would withhold allowances until that request was

[32] See https://www.epa.gov/climate-hfcs-reduction/administrative-consequences-under-hfc-allocation-rule.

evaluated and allowances were issued. As explained previously, this approach seems less equitable than Option 1. This approach also does not allay the concerns identified by EPA in the Allocation Framework Rule for establishing a set-aside for ASAs. However, EPA is interested in stakeholder input regarding this option.

Finally, as an alternative to creating a set-aside at all, EPA is taking comment on the possibility of allowing conferral of ASAs from other applications in the event an unforeseen event that meets the unique circumstance outlined in 40 CFR 84.13(b)(1)(iii). Under EPA's current regulations, conferred ASAs may only be used to produce or import HFCs for the application-specific use associated with the allowance(s) (40 CFR 84.13(h)). Under this alternative, EPA would amend the regulations such that if an unforeseen event meeting 40 CFR 84.13(b)(1)(iii), ASAs could be conferred and expended to produce or import HFCs for application-specific use different from the application associated with the allowance. For example, if EPA agreed that there was a public health emergency that created an unexpected need to purchase more HFCs for MDI manufacturing, under this approach ASAs allocated for aerospace fire suppression could be conferred to import or produce HFCs for use in MDI manufacturing.

EPA seeks comment on these proposals, in particular on the scope of the need, the number of allowances that are expected to need to be set aside, the date by which requests must be received to be considered, and all other aspects of the proposal.

H. Return of Unneeded Allowances

EPA is aware that some application-specific entities are allocated more allowances than are necessary to accommodate their needs for a given calendar year. This may be because for that specific year, the regulatory formula overestimated that individual entity's need. It is also

possible that the entity's expectations for the year did not match reality because of unexpected intervening events, such as a drop in demand for the entity's products or supply chain difficulties. In light of these considerations, EPA is proposing to allow ASA holders to return their allowances voluntarily if they do not intend to use them. ASA holders could return allowances up to and including June 30 of the year for which the allowances can be expended (*e.g.*, calendar year 2025 allowances would have to be returned by June 30, 2025). This would be completely optional and intended to be used at the discretion of the ASA holder. EPA proposes to use any returned allowances to either: (1) fulfill unexpected higher demand of another ASA holder (see proposal in Section VII.G) or (2) return the allowances to the general pool of allowance holders proportionate to respective market shares. EPA sees benefit of redeploying allowances that would go unused into the overall HFC market for smoother transition and to ease the overall HFC phasedown.

EPA is soliciting comment on this proposal, including whether it is needed if EPA finalizes other proposals outlined in this notice. EPA is particularly interested in whether this proposed approach is needed if EPA finalizes the requirement for entities to include in their application for allowances their anticipated need for the following calendar year. EPA is also interested in stakeholder input on whether codifying an ability for entities to return unneeded allowances would have unintended negative effects, including limiting the availability of allowances for transfer to another application-specific entity that has an unanticipated need for more allowances during the calendar year.

I. Enabling Auctions of Illegally Imported HFCs

In addition to the proposed changes to EPA's application-specific regulations outlined in this section, EPA is also proposing a targeted change to the regulations related to the

enforcement and compliance provisions EPA finalized in the Allocation Framework Rule. As explained in the Allocation Framework Rule, EPA established a comprehensive system of mechanisms that together and by themselves discourage and prevent illegal production, import, and subsequent sales of illegally produced or imported HFCs. Since the requirement came into effect that entities must expend allowances to produce or import HFCs, EPA has been working with partner agencies across the federal government to implement a comprehensive enforcement and compliance program.

One issue that EPA has been grappling with is what to do with HFCs that an entity imports or attempts to import without expending the requisite number of allowances. Among other things, the federal government has been considering reexport, destruction, and auctions as potential available pathways for such HFCs. EPA is in the process of working with partner federal agencies, particularly CBP, to consider the feasibility of an auction of HFCs that have been stopped or seized by CBP as was done in the past with illegally imported ODS. As part of this process, EPA has identified a provision in the existing 40 CFR part 84 regulations that could be read to inhibit some auctions of HFCs, although there is nothing in 40 CFR part 84 that prohibits auctions. In order to ensure auctions are an option, if the federal government otherwise chooses to pursue them, EPA in this rulemaking is proposing to amend the prohibition relating to the sale and prohibition of illegally imported HFCs in 40 CFR 84.5 to clarify that a person may sell or distribute, or offer for sale or distribution, a regulated substance purchased at an auction authorized by CBP if the buyer expended consumption allowances or ASAs in a quantity equal to the EV-weighted equivalent of the illegally imported regulated substances. This proposed

Commented [EO 12866119]: Can EPA say more to explain that 40 CFR part 84 does not say anything to prohibit auctions, it's just that EPA wants to clarify to potential future re-sellers or distributors of auctioned HFCs that they can proceed with sale/distribution since those HFCs would no longer be considered subject to the scope of 40 CFR 84.5 prohibition on sale/distribution of illegally imported HFCs?

Commented [EPA120R119]: Clarification added.

Commented [EO 12866121]: Consumption allowances?

Commented [EPA122R121]: Corrected.

change would provide explicit clarity to an entity that purchases HFCs at such an auction that the HFCs they purchase can be sold as if they were initially imported with allowances.[33]

EPA is also proposing targeted changes to the reporting requirements to provide clarity in the regulations for how such purchases would be reported. EPA proposes that entities purchasing HFCs at auction would need to report the import of those HFCs (that was done by another entity prior to the auction purchase) under 40 CFR 84.31(c)(1) and maintain records consistent with 40 CFR 84.31(c)(2). EPA proposes that entities would use the date that entry was filed for the HFCs purchased at auction for purposes of 40 CFR 84.31(c)(1) reporting and maintain records of that purchase under 40 CFR 84.31(c)(2). This would provide a date that can be easily verified and would align with when the entity formally expressed intent to CBP to enter the HFCs into U.S. commerce.

Additionally, EPA is proposing that entities who purchase HFCs at auction would not be subject to the advance notification requirement in 40 CFR 84.31(c)(7) for HFCs purchased via an auction authorized by CBP, as the window for the notification would have already passed and EPA would be verifying whether a prospective purchaser has sufficient allowances as part of any auction. However, EPA proposes that entities would still have to provide notification to EPA via a CBP-authorized electronic data interchange system, such as the Automated Broker Interface, prior to the HFCs entering U.S. commerce and provide the same data elements as in 40 CFR 84.31(c)(7). If a certificate of analysis (see 40 CFR 84.31(c)(7)(xvi)) is not available at the time of filing entry, EPA is proposing that the entity would need to do any required sampling and testing prior to sale in U.S. commerce.

[33] The sales provision in 40 CFR 84.5 does not apply to other government personnel or contractors that need to move the HFCs for eventual disposition consistent with the regulatory requirements, such as through an auction with verification by EPA prior to sale.

J. Quarterly Exporter Reporting of Internal Transaction Numbers

ITNs uniquely identify shipments being exported from the U.S. to another country. EPA currently requires companies to report ITNs when they request additional consumption allowances after exporting bulk HFCs. EPA is proposing to require companies to additionally report ITNs quarterly for all HFC exports. It is EPA's understanding that reporters can obtain ITNs from either CBP or their broker with relative ease, once they have a process to do so in place. Many reporters already gather ITNs on a regular basis for the purpose of submitting RACA reports.

Under CBP regulations, there are some instances in which exporters may acquire ITNs, but are not required to do so. These instances may include exports to Canada and lower-value exports, for example. EPA proposes that exporters would not be required to report ITNs for shipments that are exempt from needing ITNs under CBP regulations. EPA is not proposing any changes to the existing regulations related to RACAs, so reporters would still need to obtain ITNs for any exports listed in RACA submissions (*e.g.,* exports to Canada).

EPA is proposing to require exporters to report ITNs quarterly to better enable EPA to perform quality assurance and integrity checks between exports reported to the Agency under the reporting requirements in 40 CFR 84.31 with Customs records. This, in turn, will enable EPA to better ensure the accuracy of the overall volume of HFCs that are exported, which is a critical component of the overall calculation of the HFC phasedown, in addition to being communicated for transparency to stakeholders and being a key part of the Agency's international reporting obligations under the Montreal Protocol.

K. Date of Purchase for Requests for Additional Consumption Allowances (RACAs)

EPA is proposing to change the existing requirement in 40 CFR 84.17(a)(5) to report the date HFCs were purchased as part of a RACA. Instead, EPA would require an entity to only report whether the HFCs exported were purchased before January 1, 2022, or after that date.

EPA has received feedback from entities requesting RACAs that it is difficult to report the date HFCs were purchased because the information can be difficult to obtain. For example, a company may purchase several batches of HFCs over the course of several months and combine these batches into a homogenous mixture in an on-site holding tank. These batches of HFCs could come from multiple suppliers. The contents of the holding tank are then siphoned off into smaller containers and exported to a foreign country, at which point the company seeks a RACA for those exported HFCs. In this scenario, it is difficult to determine what the "date of purchase" was for any given container of HFCs that was exported.

When EPA initially codified the requirement to provide the date purchased as part of a RACA, the primary purpose of this data element was to track how much material is being exported out of pre-2022 inventory, before the phasedown program was in effect. This, in turn, helps the Agency understand certain market trends (*e.g.,* how many containers are being sold out of older inventory as opposed to more recently purchased inventory). However, EPA can track this trend with a simpler data element. Accordingly, EPA proposes to change the existing requirement to provide the date HFCs were purchased to whether the HFCs were purchased before or after January 1, 2022.

Commented [EO 12866123]: Reviewer supports simplifying reporting requirements in this fashion, here and wherever else EPA is able to do so, to reduce burdens on the regulated public.

VIII. Authorization to Produce for Export

In previous rulemakings, *i.e.,* the Allocation Framework Rule and the 2024 Allocation Rule, some commenters expressed concern that under EPA's methodology for issuing production

and consumption allowances, certain producers were not allocated sufficient allowances to meet the demands of their international customers working in applications for which ASAs were allocated to the domestic manufacturers. Commenters said that foreign semiconductor manufacturing remains important even while domestic semiconductor manufacturing increases under the CHIPS Act.

This issue was generally beyond the scope of prior rulemakings, but EPA recognizes that under the methodology for issuing general pool production and consumption HFC allowances[34] in tandem with how ASAs have historically been issued, domestic HFC producers that manufacture low EV HFCs with proportionally smaller market shares may face challenges due to a combination of the phasedown itself, EPA's allocation methodology, and that EPA does not allocate ASAs for entities' operations outside the United States.

Subsection (e)(5) of the AIM Act provides that the Administrator may authorize an entity to produce a regulated substance in excess of the number of production allowances otherwise allocated to that entity, subject to several conditions including:

- the authorization is valid for a renewable period of not more than five years;
- authorization must be established via notice and opportunity for public comment; and
- the production is solely for export to, and use in, a foreign country that is not subject to the prohibition in subsection (j)(1);[35] and
- the production so authorized would not violate the production or consumption limits.

[34] EPA is not reopening nor proposing to revisit the methodology for issuing general pool production and consumption HFC allowances in this rulemaking.

[35] Given that the prohibition of (j)(1) does not take effect until 2033, and EPA is proposing to make allowances available to Iofina through 2030, EPA does not consider this restriction related to subsection (j)(1) as relevant to this rulemaking.

EPA has received a request from Iofina Chemical (Iofina) to authorize additional production of HFCs under subsection (e)(5) that can be exported to supply semiconductor manufacturers outside of the United States. Iofina has informed EPA that it has experienced challenges acquiring HFC allowances via a transfer from another allowance holder so it can produce low-EV, HFC-41, to sell to semiconductors manufacturers abroad. Iofina has flagged this challenge for EPA for several years. The company has also noted that even if it were able to secure a transfer for a single year, Iofina could not plan over multiple years.

EPA has considered Iofina's specific situation, the limited number of allowances that would be needed to accomodate its request, and its stated intent to export HFCs for use in an application that Congress specified in subsection (e)(4)(B) of the AIM Act, and is proposing to authorize Iofina to undertake additional production for export as contemplated by AIM Act subsection (e)(5). To operationalize this subsection of the AIM Act, EPA is proposing to establish a production for export category of allowances and associated recordkeeping and reporting requirements. EPA is proposing that this new category of allowances would be nontransferable. Consistent with language in subsection (e)(5) of the AIM Act that EPA may "authorize *an entity*" (emphasis added), the Agency is proposing that these production for export allowances would be available only to Iofina to supply regulated HFCs to application-specific end users located abroad, specifically and only for the etching of semiconductor material or wafers and cleaning of CVD chambers within the semiconductor manufacturing sector. EPA is proposing to issue 3,000.0 MTEVe of allowances annually to Iofina for the stated purpose for each of the calendar years 2026 through 2030.

EPA proposes to determine that authorization of production for export to Iofina in this instance is appropriate and consistent with subsection (e)(5) of the AIM Act. EPA proposes that

this is particularly true where the ASA requirements of subsection (e)(4)(B)(iv) provide priority access to HFCs for defined applications. This proposal is intended to address a need that has been voiced consistently and exclusively by Iofina, for which Iofina has provided supporting information to substantiate the request.

EPA is proposing to allocate 3,000.0 MTEVe non-transferrable production for export allowances exclusively to Iofina on an annual basis for each of the calendar years 2026 through 2030. A detailed discussion of the rationale for the Agency's proposal follows.

Commented [Round 3124]: Given that Kigali has been ratified, how does export of HFCs work since that it's in the framework of Montreal Protocol? Shouldn't the foreign firm needing HFCs from Iofina expend their production/consumption allowances instead of the USG having to put a non-transferrable production allowance? Should there be a general export framework that EPA should consider?

A. To what entities is EPA proposing to allocate production for export allowances?

As described above, EPA is proposing to only allocate production for export allowances to Iofina. The Agency has determined that the company has demonstrated their need for production for export allowances. Iofina has made good faith efforts to acquire allowances via an inter-company transfer and has had difficulty finding another allowance holder willing to transfer production and consumption allowances to them in order to produce regulated HFCs for export. Iofina has documented foreign customer demand in an application-specific end use for the HFC they produce. Iofina has committed to conduct extensive due diligence to verify and ensure that the HFCs they sell abroad are only sold to an entity that will use the HFC for the etching of semiconductor material or wafers and cleaning of CVD chambers within the semiconductor manufacturing sector and are not going to be diverted for some other use (*e.g.*, destroyed for carbon credits, sold to another entity that will use the HFCs for another end use).

EPA has also considered how this authorization supports the HFC phasedown overall. Iofina produces only one HFC, HFC-41, one of the lowest EV HFCs controlled by the AIM Act with an EV of 92, at its facility in Covington, Kentucky. Iofina produced HFCs during the 2011–2019 timeline and in subsequent years, and accordingly have been allocated allowances for

calendar years 2022, 2023, and 2024. Because Iofina has always produced a low EV HFC, their allocation is smaller than companies that have historically produced higher EV HFCs, which now have flexibility to transition into a lower EV HFC at higher volumes. HFC-41 comprises a small portion of overall U.S. HFC calculated production[36] (0.02 percent in 2022 on a mass basis and approximately 0.001 percent on an EVe basis), and Iofina is the only U.S. producer of HFC-41 for consumptive use. Further, HFC-41 has a lower EV than all other regulated substances used in the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector. Coupled with the extremely small volume of allowances that this production would require, EPA sees authorizing this additional flexibility as appropriate to support continued U.S. production of HFC-41.

EPA recognizes that upon reviewing this proposed rulemaking, there may be other HFC producers who would be interested in receiving production for export allowances for application-specific uses abroad. At this time, EPA has only assessed the appropriateness of proposing an allocation for Iofina in light of the specific circumstances presented by that entity. The Agency is not proposing, nor creating a mechanism to finalize, production for export allowances for any other entity through this rulemaking. If other producers were to express a similar interest, EPA would consider whether to act in a separate rulemaking under subsection (e)(5), but we emphasize that this action is dependent on facts specific to Iofina, including the relatively small size of Iofina's production and the modest impacts on the overall market for HFCs that will result.

[36] See EPA HFC Data Hub at https://www.epa.gov/climate-hfcs-reduction/hfc-data-hub.

B. How many production for export allowances is EPA proposing to issue to Iofina on an annual basis, and for how many years is EPA proposing to issue these allowances?

EPA is proposing to issue Iofina non-transferrable production for export allowances in the amount of 3,000.0 MTEVe on an annual basis. The Agency arrived at this proposed amount based on an evaluation of a combination of factors including: Iofina's request; supporting information from the company explaining and demonstrating the need for production for export allowances; Iofina's relative market share of production allowances and recent yearly allocations from EPA; recent conferral activity where Iofina is the recipient; and, the general effect to other producers of issuing Iofina production for export allowances in the proposed amount.

The production cap for calendar year 2024 through 2028 (the current phasedown step) is 229,521,263 MTEVe and the production cap for calendar year 2029 through 2033 (the next phasedown step) is 114,760,632 MTEVe. The proposed number of production for export allowances the Agency would issue Iofina would be approximately 0.001 percent of the overall production cap for 2026 through 2028 and 0.003 percent for 2029 and 2030.[37] Accordingly, the Agency does not envision any shortage of production allowances for these years as a result of the proposal to issue Iofina 3,000.0 MTEVe of production for export allowances. In essence, the proposed 3,000.0 MTEVe of production for export allowances issued to Iofina would not materially affect any other domestic producer even in light of the next phasedown step.

Consistent with the provisions in subsection (e)(5)(A)(i), EPA is proposing that if finalized, Iofina would be issued production for export allowances on an annual basis for a five-year period between 2026 through 2030.

[37] Percent = (Number of Production of Allowances Issued)/(Production Cap)*100

C. Would Iofina need to expend consumption allowances for materials produced with production for export allowances and subsequently exported?

Subsection (e)(5) of the AIM Act allows EPA to "authorize a person to produce" for export if such production would not violate the yearly cap described in subsection (e)(2)(B). To operationalize this statutory requirement, EPA proposes to require that any material produced with production for export allowances must be exported in the same year it was produced. The AIM Act defines "consumption" as the amount of HFCs produced and imported minus the quantity of HFCs exported. Therefore, production of an HFC in a given year would be "netted out" when calculating consumption if that HFC is exported in that same year. Because HFCs produced with production for export allowances would be exported in the same year and therefore would be "netted out" when evaluating the United States' calculated yearly consumption, EPA is proposing that when Iofina produces for export using this specific category of allowances, it is not required to expend consumption allowances in an equivalent amount. Relatedly, EPA is also proposing that Iofina's materials produced with production for export allowances are not eligible for additional consumption allowances through the RACA provisions in 40 CFR 84.17.

D. How will this process affect the issuance of other types of allowances?

Under 40 CFR part 84, subpart A, EPA first issues ASAs. Because the Agency is proposing an annual finite number of production for export allowances for Iofina, EPA proposes to issue these non-transferrable allowances immediately after ASAs are issued. As a result, EPA is proposing small modifications to 40 CFR 84.9 to reflect that the number of available general pool production allowances is the difference between the yearly production cap and the sum of ASAs issued and the number of production for export allowances. It should be noted that

because production for export allowances is a separate category from general pool production allowances, Iofina would be eligible for both of these types of allowances beginning in 2026 through 2030 if the production for export allowance provisions are finalized. EPA is not proposing any changes to how general pool consumption allowances are issued on an annual basis and is neither revising nor reopening the methodology codified in 40 CFR 84.11.

E. What are the proposed recordkeeping and reporting requirements for production for export allowances?

In order to maintain overall stringency while allowing for the flexibilities in the AIM Act described in this general information section of the preamble, EPA is proposing that Iofina comply with recordkeeping and reporting requirements in addition to what is already required of the entity as a domestic producer under 40 CFR 84.31(a) and (b) and as an exporter under 40 CFR 84.31(d).

1. Annual Certifications

EPA is proposing that Iofina secure signed certifications by a responsible corporate officer from their overseas application-specific customers attesting that any regulated HFCs produced using production for export allowances will only be used in application-specific uses (*i.e.,* only for the etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector). EPA is proposing that Iofina must provide such written and signed certification for each of their overseas customers, accompanied by a description of how the foreign use aligns with the definitions in 40 CFR 84.13(a) and 40 CFR 84.3. If the regulated HFCs produced by Iofina using product for export allowances are to be held at an intermediary prior to receipt by the semiconductor manufacturer, the intermediary must also submit the same certification. As part of the yearly written certification, EPA is

proposing that the name and address of the foreign entity, and the contact person's name, email address, and phone number are included. Further, EPA is proposing that Iofina must provide copies of these signed certifications with its end of year fourth quarter report due February 14 (*i.e.,* certifications for calendar year 1 are due on February 14 of year 2).

2. Quarterly Export and Inventory Reporting

In addition to submitting the quarterly exporter reports currently required under 40 CFR 84.31(a) and (b), the Agency is proposing that Iofina must, as part of these quarterly exporter reports, document the amounts exported that were produced using production for export allowances. Iofina would also be required to document the country to which HFCs were exported. As part of this documentation and to help ensure that EPA can quickly locate exports of regulated HFCs produced by Iofina, the Agency is proposing that an ITN be provided for each shipment regardless of monetary value, destination country, or other characteristics that could otherwise exempt or preclude an exporting entity from obtaining an ITN. Additionally, EPA is proposing that Iofina report quarterly no later than 45 days after the applicable quarterly control period on inventory of regulated HFCs produced with production for export allowances so EPA can effectively track their use. Inventory of regulated HFCs produced with production for export allowances must be zero as of December 31 for that calendar year; otherwise, EPA may pursue actions including but not limited to allowance adjustments, *i.e.,* administrative consequences, or enforcement action. All reports described in this section would be subject to EPA's auditing provisions under 40 CFR 84.33 if finalized as proposed.

3. Recordkeeping

EPA is proposing that Iofina maintains for a period of five years the certifications from all of its customers and any intermediaries attesting that the regulated HFCs they are receiving

are only to be used for the etching of semiconductor material or wafers and cleaning of CVD chambers within the semiconductor manufacturing sector. The Agency is also proposing that Iofina maintain for a period of five years records demonstrating that Iofina has conducted extensive due diligence to verify and ensure that the HFCs they sell abroad are only sold to an entity that will use the HFC for an application-specific use and are not going to be diverted for some other use (*e.g.*, destroyed for carbon credits, sold to another entity that will use the HFCs for another end use).

IX. How will EPA handle confidentiality for newly reported information?

Consistent with EPA's commitment to transparency in program implementation, as well as to proactively encourage compliance, support enforcement of program requirements, and enable third-party engagement to complement EPA's enforcement efforts, EPA is proposing several ways it intends to release data that would be collected if this rule were finalized as proposed.

EPA has reviewed the data elements that are proposed to be reported under this rule. Based on that review, EPA is proposing certain confidentiality determinations in advance through this notice and comment rulemaking for individual reported data elements that EPA would be collecting through this rulemaking. This proposal identifies certain information that must be submitted to EPA that may be subject to disclosure to the public without further notice because the Agency proposes to find that the information does not meet the standard for confidential treatment under Exemption 4 of the Freedom of Information Act (FOIA). EPA is also proposing to identify certain other categories of information that would be entitled to confidential treatment. For data elements for which EPA is not making a confidentiality determination in this action, EPA will apply the 40 CFR part 2 process for establishing case-by-

case confidentiality determinations. The confidentiality determinations in this proposed action are intended to increase the efficiency with which the Agency responds to FOIA requests and to provide consistency in the treatment of the same or similar information. Establishing these determinations through this rulemaking will provide predictability for both information requesters and entities submitting information to EPA. The confidentiality determinations are also proposed to increase transparency around this program's implementation.

F. Background on Determinations of Whether Information is Entitled to Treatment as Confidential Information

Exemption 4 of the FOIA exempts from disclosure "trade secrets and commercial or financial information obtained from a person [that is] privilieged or confidential" (5 U.S.C. 552(b)(4)). In order for information to meet the requirements of Exemption 4, EPA must find that the information is either: (1) a trade secret, or (2) commercial or financial information that is: (a) obtained from a person, and (b) privileged or confidential.

Generally, when we have information that we intend to disclose publicly that is covered by a claim of confidentiality under FOIA Exemption 4, EPA has a process to make case-by-case or class determinations under 40 CFR part 2 to evaluate whether such information qualifies for confidential treatment under the exemption. 40 CFR 2.205.[38] In this action, EPA is proposing to make categorical confidentiality determinations in advance through this notice and comment rulemaking for some information that must be submitted to EPA under the proposed

[38] This approach of making categorical determinations for a class of information is a well-established Agency practice. Prior examples of rules where EPA has made such categorical determinations include *Confidentiality Determinations for Data Required Under the Mandatory Greenhouse Gas Reporting Rule and Amendments to Special Rules Governing Certain Information Obtained Under the Clean Air Act* (76 FR 30817) (May 26, 2011); *Control of Air Pollution From New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards* (88 FR 4296) (January 24, 2023); and *Renewable Fuel Standard (RFS) Program: RFS Annual Rules* (87 FR 39600) (July 1, 2002).

requirements. If EPA finalizes these determinations, that information could be disclosed to the public without further notice.

The U.S. Supreme Court decision in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019) (*Argus Leader*) addresses the meaning of "confidential" within the context of FOIA Exemption 4. The Court held that "[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Argus Leader*, 139 S. Ct. at 2366. The Court identified two conditions "that might be required for information communicated to another to be considered confidential." *Id*. at 2363. Under the first condition, "information communicated to another remains confidential whenever it is customarily kept private, or at least closely held, by the person imparting it." *Id*. (internal citations omitted). The second condition provides that "information might be considered confidential only if the party receiving it provides some assurance that it will remain secret." *Id*. (internal citations omitted). The Court found that the first condition necessary for information to be considered confidential within the meaning of Exemption 4, but did not address whether the second condition must also be met.

Following the issuance of the Court's opinion in *Argus Leader*, the U.S. Department of Justice (DOJ) issued guidance concerning the confidentiality prong of Exemption 4, articulating "the newly defined contours of Exemption 4" post-*Argus Leader*.[39] Where the Government provides an express or implied indication to the submitter prior to or at the time the information is submitted to the Government that the Government would publicly disclose the information,

[39] "Exemption 4 After the Supreme Court's Ruling in Food Marketing Institute v. Argus Leader Media and Accompanying Step-by-Step Guide," Office of Information Policy, U.S. DOJ, (October 4, 2019), available at *https://www.justice.gov/oip/exemption-4-after-supreme-courts-ruling-food-marketing-institute-v-argus-leader-media.*

then the submitter generally cannot reasonably expect confidentiality of the information upon submission, and the information is not entitled to confidential treatment under Exemption 4.[40] In this proposed rule, EPA intends to clearly assert that certain information would not be kept confidential and may be disclosed publicly, if it is determined to not be entitled to confidential treatment in the final version of this rule. This assertion aligns with the Supreme Court's decision, and the subsequent DOJ guidance that the government's assurances that a submission will be treated as *not* confidential should dictate the expectations of submitters. If EPA were to finalize these determinations, submitters would be on notice before they submit any information that EPA has determined that the identified information outlined in the memorandum provided in the docket for this action titled *Proposed Confidentiality Determinations for Data Elements in the Proposed Rule,* will not be entitled to confidential treatment upon submission and may be released by the Agency without further notice. As a result, submitters will not have a reasonable expectation that the information will be treated as confidential; rather, they should have the expectation that the information will be disclosed.

As described further below, EPA is proposing to make categorical confidentiality determinations as some of the proposed data elements that would be submitted to EPA contain information that is not entitled to confidential treatment. For data elements not explicitly listed in the document in the docket, EPA will apply the 40 CFR part 2 process for establishing case-by-case confidentiality determinations.

There may be additional reasons not to release information determined to not be entitled to confidential treatment, for example if it is personally identifiable information (PII). The

[40] *See id.;* see also "Step-by-Step Guide for Determining if Commercial or Financial Information Obtained from a Person is Confidential under Exemption 4 of the FOIA," Office of Information Policy, U.S. DOJ, (updated October 7, 2019), available at *https://www.justice.gov/oip/step-step-guide-determining-if-commercial-or-financial-information-obtained-person-confidential.*

Agency will separately determine whether any data should be withheld from release for reasons other than business confidentiality before data is released. EPA requests comment on the proposed confidentiality determinations.

G. Data Elements Associated with a Petition to be Listed as an Application that will Receive Application-specific Allowances

In light of the statutory requirement in subsection (e)(4)(B)(ii) to make a complete petition available to the public, and consistent with EPA's commitment to transparency in program implementation, EPA has reviewed the data elements EPA has proposed would be required for a petition to be listed as an application that will receive ASAs. Specifically, EPA proposes to not provide confidential treatment to, and may release without further process, all required elements of the petition, except for a subset of the elements for which EPA has proposed that multiple entities could submit information individually to EPA;[41] and all information submitted to EPA that does not correspond to a required element. The memorandum to the docket lists each individual element of a complete petition, as proposed by EPA, with an accompanying proposed determination on whether that element would be entitled or not to confidential treatment. EPA is proposing that through this rulemaking notice, entities are put on notice of data release in line with the *Argus Leader* decision. EPA is providing an express indication to all potential petitioners prior to the time information is submitted to EPA that EPA will publicly disclose the information without further process. Therefore, potential future submitters cannot reasonably expect confidentiality of the information upon submission, and the

[41] For example, EPA is proposing that (1) data on the proportion of the overall cost of the product or system that reflects the cost of regulated substance(s) and (2) historic and projected sales for the product or system would not be treated as confidential business information, as these are important elements for the public to consider when EPA is taking action on a petition for application-specific allowances.

information is not entitled to confidential treatment under Exemption 4. EPA invites comment on this proposed determination.

H. Data Elements Related to Proposed Revisions to Existing Regulations

To maximize program transparency, EPA is proposing to release several data elements associated with the proposed limited changes to existing regulations, including specific data elements associated with the following proposed regulatory revisions: (1) a pool of set-aside allowances for situations that meet the criteria for unique circumstances related to the propellants in MDIs application; (2) allowing ASA holders to return their allowances voluntarily if they do not intend to use them; and (3) the "date of purchase" requirement for a RACA. The memorandum to the docket lists each individual element EPA has proposed related to these regulatory revisions with an accompanying proposed determination on whether that element would be entitled or not to confidential treatment. EPA is proposing that through this rulemaking notice, entities are put on notice of data release in line with the *Argus Leader* decision. EPA is providing an express indication to all entities prior to the time information is submitted to EPA that EPA will publicly disclose the information without further process. Therefore, potential future submitters cannot reasonably expect confidentiality of the information upon submission, and the information is not entitled to confidential treatment under Exemption 4. EPA invites comment on this proposed determination.

EPA is proposing to regulatorily determine that certain other information would be entitled to confidential treatment. EPA is proposing that supporting documentation verifying a need to purchase regulated substances in the present calendar year for purposes of the proposed set aside because it is likely to include the type of information that submitters customarily keep private or closely held. EPA is also proposing that data elements associated with the following

proposed regulatory revisions would be entitled to confidential treatment: (1) requiring companies provide the total expected amount of HFCs they intend to purchase in the calendar year; (2) new requirements for the conferral of MCMEU allowances; and (3) requiring exporters to report ITNs quarterly. These data elements constitute the type of information that submitters customarily keep private or closely held. Furthermore, in the case of ITNs reported by exporters, it is EPA's understanding that the ITN, as part of the Electronic Export Information (EEI) contained in the Automated Export System (AES), is considered confidential by the Department of Commerce. Additional information on the proposed determinations for specific data elements associated with the proposed regulatory revisions is provided in the memorandum in the docket for this action. EPA invites comments on these proposed confidentiality determinations, including information on whether the listed elements are the type of information customarily kept private or closely held.

I. Data Elements Reported to EPA related to Production for Export

EPA is proposing to establish a production for export category of allowances as described in Section VIII. If EPA were to finalize the proposal for production for export allowances, EPA is proposing to release several data elements that a production for export allowance holder would be required to submit, including: (1) quantity of allowances expended for each regulated substance; (2) quantity of each regulated substance produced for export; (3) quantity of each regulated substance, produced using production for export allowances, that was exported; (4) quantity of each regulated substance held in inventory at the end of the quarter; and (5) the country to which regulated substances, produced using production for export allowances, were exported. The memorandum to the docket lists each individual element EPA has proposed related to the production for export allowances with an accompanying proposed determination on

whether that element would be entitled or not to confidential treatment. EPA is proposing that through this rulemaking notice, entities are put on notice of data release in line with the *Argus Leader* decision. EPA is providing an express indication to all entities prior to the time information is submitted to EPA that EPA will publicly disclose the information without further process. Therefore, potential future submitters cannot reasonably expect confidentiality of the information upon submission, and the information is not entitled to confidential treatment under Exemption 4. EPA invites comment on this proposed determination.

EPA is proposing that the ITNs submitted for all exports of regulated substances produced using production for export allowances would be entitled to confidential treatment for the same rationale described earlier in this section for the proposed requirement that exporters report ITNs on a quarterly basis. EPA requests comment on this proposed determination, including comments on why this information may not be entitled to confidential treatment.

EPA is proposing that the signed certifications would be entitled to confidential treatment because it is EPA's understanding that these certifications could have the potential to reveal confidential business relationships (*i.e.,* the relationship between the allowance holder, overseas customer, and any intermediaries). EPA requests comment on this proposed determination, including comments on why this information may not be entitled to confidential treatment. Specifically, EPA requests comment on whether the existence of a business relationship between an HFC producer and customer is information that is customarily closely held.

X. What are the costs and benefits of this action?

The changes~~is~~ proposed in this rule would~~ill~~ not result in any significant changes to the phasedown program as a whole, and thus do~~es~~ not fundamentally change the assumptions made in the Allocation Framework Rule RIA and subsequent RIA addenda. The Allocation

Framework Rule RIA estimated benefits and costs for the HFC phasedown between 2022 and 2050, including assuming for analytical purposes that the allocation system would continue unchanged for years past the initial period (*i.e.,* for 2024 and beyond). This action would not change the total number of allowances issued each year or the associated environmental impacts. Further, the 2023 Technology Transitions Rule RIA Addendum quantified the costs and benefits associated with the transitions necessary for compliance based on the sector- and subsector-specific restrictions finalized in that rule. Given that the 2023 Technology Transitions Rule promulgated restrictions for sectors that encompass both defense sprays and SCPPU foams (aerosols and foam blowing sectors, respectively), the compliance costs associated with the proposals described in Section V of this proposed rule to restrict the use of certain HFCs in defense sprays and SCPPU foams have already been accounted for in the 2023 Technology Transitions Rule RIA Addendum. Therefore, EPA is not developing an update to the RIA for this proposed rule; however, given that some elements proposed in this rule could result in incremental impacts for a subset of entities, the Agency did analyze potentially salient costs and benefits considerations associated with this proposed rulemaking. A summary of this analysis is included below and ~~D~~additional details ~~of this analysis~~ are presented in *Discussion of Costs and Benefits for Phasedown of Hydrofluorocarbons: Review and Renewal of Eligibility for Application-specific Allowances*, which is available in the docket for this action (EPA–HQ–OAR–2024–0196).

This analysis is intended to provide the public with information on the relevant costs and benefits of this action and to comply with Executive Orders. ~~The analysis does not form a basis or rationale for any of the actions EPA is proposing in this rulemaking.~~

Commented [EO 12866125]: EPA should expand the discussion of why there are no (or limited) incremental effects relative to the cited RIAs, including the assumptions made in those RIAs re: whether allowances would continue to be granted and accompanying transitions. Please also specify how this relates to the sectors for which EPA is considering potentially not extending eligibility for ASAs

Commented [EPA126R125]: Additional details regarding RIA added. Details on how this rule impacts applications for which EPA is co-proposing an option to not renew has been added later in this section.

Commented [Round 3127]: We are not comfortable with this sentence and are striking

For entities in applications for which EPA is co-proposing an option to not renew eligibility for ASAs, the biggest drivers for any costs would be no longer being exempted from the restrictions promulgated under the Technology Transitions Program. However, entities within those applications that currently receive ASAs would also avoid recordkeeping and reporting costs associated with being an ASA holder because they would no longer receive ASAs and thereby no longer need to comply with related recordkeeping and reporting provisions, resulting in burden relief.

General pool allowance holders may receive benefits in the form of additional allowances if EPA finalized one or more applications no longer being eligible~~ility~~ for ASAs. However, EPA anticipates that the number of additional allowances would be insignificant, totaling well under one percent of consumption allowances in a given year. For example, the number of allowances allocated in calendar year 2024 to the two applications for which EPA is co-proposing an option to not renew is equivalent to 0.1 percent of calendar year 2024 consumption allowances. In addition, as these marginal benefits constitute a transfer from one group to another and do not change the total number of allowances issued, there is no net societal impact.

EPA estimates that there may be costs related to the proposed requirements for ASA petitions and revisions to existing regulations. For example, in a scenario in which EPA does not renew the defense sprays and SCPPU foam for marine and trailer uses applications, the estimated costs of this rule would be $19,052 in one-time costs and $54,310 in annual costs. More discussion of this scenario is included in the costs and benefits memo available in the docket that is referenced above. Other than these costs, EPA has not identified additional costs or benefits beyond those estimated in the Allocation Framework Rule RIA and subsequent RIA addenda.

Commented [EO 12866128]: Wouldn't these be transfers rather than benefits?

Commented [EPA129R128]: Added clarifying text at the end of the paragraph.

Commented [EO 12866130]: Please provide a summary of these costs here and provide a table of estimated costs and relevant benefits in the following section

Commented [EPA131R130]: EPA added a summary of the costs and highlighted the costs associated with the proposal not to renew eligibility for two applications to show the scale of potential costs.

Commented [Round 2132R130]: Please provide a table of total estimated costs and benefit benefits in the following sction XI.A

Commented [EPA133R130]: EPA has added a sentence reiterating the high end cost estimate in section XI.A. This should provide sufficient clarity to the reader of the potential aggregate costs associated with this rule, while reducing the cost, complexity, and time needed to publish the proposed rule in the Federal Register.

Commented [Round 3134R130]: Please add a table to section XI.A of total and annual costs and benefits. This is a standard request across EPA and other agency rules for the EO 12866 section of the rule.

XI. Statutory and Executive Order Review

A. *Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review*

This action is a "significant regulatory action" as defined in Executive Order 12866, as amended by Executive Order 14094. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an economic analysis of the potential impacts associated with this action. This analysis, "*Discussion of Costs and Benefits for Phasedown of Hydrofluorocarbons: Review and Renewal of Eligibility for Application-specific Allowances,"* is available in the docket for this action (EPA–HQ–OAR–2024–0196) and is briefly summarized in Section X of this preamble, titled, "What are the costs and benefits of this action?". The high end estimated costs of this rule would be $19,052 in one-time costs and $54,310 in annual costs.

B. *Paperwork Reduction Act (PRA)*

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number **[XXXX.XX]**. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

Subsection (d)(1)(A) of the AIM Act specifies that on a periodic basis, but not less than annually, each person that, within the applicable reporting period, produces, imports, exports, destroys, transforms, uses as a process agent, or reclaims a regulated substance shall submit to EPA a report that describes, as applicable, the quantity of the regulated substance that the person: produced, imported, and exported; reclaimed; destroyed by a technology approved by the

Administrator; used and entirely consumed (except for trace quantities) in the manufacture of another chemical; or, used as a process agent. EPA collects such data regularly to support implementation of the AIM Act's HFC phasedown provisions. EPA requires quarterly reporting to ensure that annual production and consumption limits are not exceeded. It is also needed for EPA to be able to review allowance transfer requests, of which remaining allowances is a major component of EPA's review. In addition, EPA collects information to calculate allowances, to track the movement of HFCs through commerce, and to require auditing. Collecting these data elements allows EPA to confirm that the entity has not exceeded its allowed level of production and consumption and that the aggregated annual quantity of production and consumption in the United States does not exceed the cap established in the AIM Act. As described above in this preamble, EPA is proposing a procedural process for submitting a petition to designate a new application as eligible for priority access to allowances; reporting and recordkeeping requirements relevant for narrow revisions to the methodology used to allocate allowances to ASA holders for calendar years 2026 and beyond; and other limited reporting and recordkeeping revisions, such as for the proposal to authorize an entity to produce regulated substances for export.

All information sent by the submitter electronically is transmitted securely to protect information that is CBI or claimed as CBI consistent with the confidentiality determinations made in the Allocation Framework Rule and the proposed confidentiality determinations described in Section IX of this preamble, if finalized as proposed. The reporting tool guides the user through the process of submitting such data. Documents containing information claimed as CBI must be submitted in an electronic format, in accordance with the recordkeeping requirements.

Respondents/affected entities: Respondents and affected entities will be individuals or entities that produce, import, export, reclaim, recycle for use as a fire suppressant, distribute, destroy, transform, use HFCs as a process agent, or produce for export, certain HFCs that are defined as a regulated substance under the AIM Act. Respondents and affected entities will also be any entity issued or conferred ASAs.

Respondent's obligation to respond: Mandatory (AIM Act).

Estimated number of respondents: 342.

Frequency of response: Quarterly, biannual, annual, and as needed depending on the nature of the report.

Total estimated burden: 36,248~~36,238~~ hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $5,485,736 ~~5,484,707~~ (per year), includes $1,037,950 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. The EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. OMB

must receive comments no later than **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities (SISNOSE) under the RFA. The small entities subject to the requirements of this action are entities that hold HFC allowance allocations (including production, consumption, and application-specific allowances), entities that applied for but did not receive set-aside allowances in 2022, entities that previously imported HFCs between 2017 and 2019 but did not receive 2022 allowance allocations, and entities that recover and reprocess HFCs. Given there are co-proposals for two applications, EPA conducted this preliminary screening analysis based on the pathway that could lead to the highest cost burden on small entities; therefore, this analysis assumes for analytical purposes that the defense sprays and SCPPU foam for marine and trailer uses applications will not be renewed. The Agency has determined that four of the 276 affected small businesses or 1.4 percent of all affected small businesses could incur costs in excess of one percent of annual sales, and three of those four small businesses or 1.1 percent of all affected small businesses could incur costs in excess of 3 percent of annual sales. The four entities that could incur costs in excess of one percent of annual sales are all entities that currently receive ASAs in the defense sprays and SCPPU foam for marine and trailer uses applications. These costs are primarily driven by these entities no longer being exempted from Technology Transition Program restrictions. Further dDetails of this analysis are presented in *Economic Impact Screening Analysis for Phasedown of Hydrofluorocarbons: Review and Renewal of Eligibility for Application-specific Allowances*, which is available in the docket for this action (EPA–HQ–OAR–2024–0196).

Commented [EO 12866135]: Please see reviewer's related comments on the economic impact screening. If any changes are made as a result, please also make sure they are reflected here.

Commented [EPA136R135]: Understood. The text aligns.

Commented [EO 12866137]: Please provide a summary of the analysis. Small entities should be able to access all of the information they need without finding additional documents in the docket.

Commented [EPA138R137]: Added

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate of $100 million (adjusted annually for inflation) or more (in 1995 dollars) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments and the costs involved in this action are estimated not to exceed $183 million in 2023$ ($100 million in 1995$ adjusted for inflation using the GDP implicit price deflator) or more in any one year~~or the private sector~~.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. EPA is not aware of Tribal businesses engaged in activities that would be directly affected by this action. Based on the Agency's assessments, EPA also does not believe that potential effects, even if direct, would be substantial. Accordingly, this action will not have substantial direct effects on Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

EPA periodically updates Tribal officials on air regulations through the monthly meetings of the National Tribal Air Association and has shared information on this rulemaking through this and other fora.

Commented [EO 12866139]: Assuming the HFC Framework Rule included unfunded mandates on the private sector, and this rule's impacts are captured in the HFC Framework Rule's RIA (and others that followed), would it be more appropriate to say that the unfunded mandates imposed by this action have been contemplated and addressed in the previous rulemakings?

Commented [EPA140R139]: Thank you for the comment. EPA has revised the text.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order.

Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, EPA's Policy on Children's Health also does not apply.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action applies to certain regulated substances and certain applications containing regulated substances, none of which are used to supply or distribute energy.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns.

Although this action does not concern human health or environmental conditions because it is not changing the HFC phasedown schedule, the EPA identified and addressed environmental justice concerns associated with the HFC phasedown within the Allocation Framework Rule (86 FR 55116, October 5, 2021) and the 2024 Allocation Rule (88 FR 46836, July 20, 2023). In these rulemakings, EPA identified and addressed environmental justice concerns by assessing available information to analyze baseline human health or environmental conditions, conducting updated analyses based on more recently available data, and providing meaningful participation opportunities for communit~~e~~ies with environmental justice concerns ~~people of color, low-income populations and/or Indigenous peoples or tribes~~. EPA carefully evaluated available information on HFC production facilities and the characteristics of nearby communities. Based on EPA's analysis, EPA found evidence of environmental justice concerns near HFC production facilities from cumulative exposure to existing environmental hazards in these communities.

Commented [EO 12866141]: recommend employing EO 14096 term of art if accurate.

Commented [EPA142R141]: Thank you for flagging. Edit accepted.

For the reasons set out in the preamble, 40 CFR part 84 is proposed to be amended as follows:
PART 84 - PHASEDOWN OF HYDROFLUOROCARBONS

1. The authority citation for part 84 continues to read as follows:

Authority: Pub. L. 116-260, Division S, Sec. 103.

Subpart A-[Amended]

2. Amend § 84.3 by adding the definitions "healthcare system need," "responsible corporate officer," and "responsible official" in alphabetical order to read as follows:

§ 84.3 Definitions.

* * * * *

Healthcare system need means circumstances where an increase in demand for MDIs used to treat asthma, chronic obstructive pulmonary disease, and other respiratory diseases may occur because of a change in market conditions that otherwise would not be included in calculated rates of growth.

Commented [EO 12866143]: Has HHS/FDA contributed to this definition?

Commented [EPA144R143]: Similar to the response on page 107, EPA did not consult with FDA/HHS on this specific proposal prior to submitting this rule for interagency review. EPA seeks to confirm that FDA/HHS has seen this proposed change and welcomes a call if helpful to confirm this need for this type of provision.

* * * * *

Responsible corporate officer means a person who is authorized by the regulated entity to make representations on behalf of, or obligate the company as ultimately responsible for, any activity regulated under 40 CFR part 84, subpart A.

Responsible official means a person who is authorized by the regulated entity to make representations on behalf of, or obligate the company as ultimately responsible for, any activity regulated under 40 CFR part 84, subpart A.

* * * * *

3. Amend § 84.5 by:

a. In paragraph (a)(1), adding ", unexpended production for export allowances," after "unexpended production allowances and consumption allowances".

b. Revising paragraph (c)(2).

c. In paragraph (d), adding "production for export," after "All production, consumption," and adding "production for export," after "confer a production, consumption,".

d. Revising paragraph (f).

e. Adding paragraph (k).

The revisions and additions read as follows:

§ 84.5 Prohibitions relating to regulated substances.

* * * * *

(c) * * *

(2) No person may use a regulated substance produced or imported by expending application-specific allowances for any purpose other than those for which the application-specific allowance was allocated, and as set forth in this paragraph (c). Application-specific allowances are apportioned to a person under §§ 84.13 and 84.15 for the production or import of regulated substances solely for the individual application listed on the allowance.

* * * * *

(f) ***Sale and distribution.*** No person may sell or distribute, or offer for sale or distribution, any regulated substance that was produced or imported in violation of paragraphs (a) through (d) of this section, except:

(1) for such actions needed to re-export the regulated substance; or

(2) if the regulated substance was purchased at a government auction authorized by the United States Customs and Border Protection and consumption allowances were expended in the requisite quantity to cover the regulated substances at issue.

Every kilogram of a regulated substance sold or distributed, or offered for sale or distribution, in contravention of this paragraph constitutes a separate violation of this subpart. Sale or distribution, or offer for sale or distribution, of less than one kilogram of regulated substance in contravention of this paragraph constitutes a separate violation of this subpart.

* * * * *

(k) ***Production for export allowances.*** No person may use a regulated substance produced by expending production for export allowances for any purpose other than those for which the production for export allowance was allocated, aligning with the applications as listed in § 84.13(a).

4. Amend § 84.9 by:

a. In paragraph (b)(3) adding “and 3,000.0 MTEVe allowances to be allocated pursuant to §84.18,” after “§ 84.13”.

b. Redesignating paragraph (c) as (d).

c. Adding paragraph (c) to read as follows:

§ 84.9 Allocation of calendar-year production allowances.

* * * * *

(c) Starting with the allocation of 2026 calendar year allowances, the relevant Agency official will withhold ten percent of production allowances otherwise calculated under paragraph (b) of this section from any entity that produced regulated substances in any calendar year 2011 through 2019 for a separate entity that is being issued application-specific allowances in accordance with § 84.13, except for mission-critical military end uses. If there are remaining production allowances after distribution from the set-aside under § 84.15, the relevant agency official will distribute such allowances to the entity from which they were withheld.

Commented [Round 3145]: what is this withholding for? Same question elsewhere where referenced in reg text

* * * * *

5. Amend § 84.11 by:

a. Redesignating (c) as (d).

b. Adding paragraph (c) to read as follows:

§ 84.11 Allocation of calendar-year consumption allowances.

* * * * *

(c) Starting with the allocation of 2026 calendar year allowances, the relevant Agency official will withhold ten percent of consumption allowances otherwise calculated under paragraph (b) of this section from any entity that imported regulated substances in any calendar year 2011 through 2019 for a separate entity that is being issued application-specific allowances in accordance with § 84.13, except for mission-critical military end uses. If there are remaining consumption allowances after distribution from the set-aside under § 84.15, the relevant agency official will distribute such allowances to the entity from which they were withheld.

* * * * *

6. Amend § 84.13 by:

a. In paragraph (a), replacing “2022, 2023, 2024, and 2025” with “as designated”.

b. In paragraph (a)(1), adding “for calendar years 2022–2030” after “metered dose inhalers”

c. In paragraph (a)(2), adding “for calendar years 2022–2025” after “defense sprays”

d. In paragraph (a)(3), adding “for calendar years 2022–2030” after “trailer use”

e. In paragraph (a)(4), adding “for calendar years 2022–2030” after “semiconductor manufacturing sector”

f. In paragraph (a)(5), adding "for calendar years 2022–2030" after "end uses"

g. In paragraph (a)(6), adding "for calendar years 2022–2030" after "fire suppression"

h. In paragraph (b)(1), adding ", including supporting documentation that verifies this need" after the phrase "this section" in the first sentence.

i. In paragraph (b)(1)(ii) delete "or" after "facility or facilities;".

j. In paragraph (b)(1)(iii), replacing "A global pandemic or other public health emergency that increases" with "A global pandemic, other public health emergency, or other healthcare system needs related to increased" and replacing "." with ";".

Commented [EO 12866146]: Official designation? (Would want HHS to weigh in here)

Commented [EPA147R146]: This is not intended to be limited to only officially designated public health emergencies. We have added clarifying language in Section VII.B (p. 106) of the preamble.

k. Adding paragraphs (b)(1)(iv) and (v).

l. In paragraph (b)(2) replacing "[Reserved]" with "Entities must provide an estimate of the total quantity of regulated substances they expect to purchase in the following calendar year based on their expected eligibility for allowances."

m. Redesignating (c)(1) as (c)(7).

n. Adding paragraph (c)(1).

o. Adding paragraphs (c)(4) through (6).

p. In the newly designated (c)(7), replacing "Taking the higher of the use of regulated substances by the company in the specific application in the prior year multiplied by" with "For all other entities, multiplying the use of regulated substances by the company in the specific application in the prior year by the higher of".

q. Removing paragraph (e).

r. Redesignating (f) through (h) to (e) through (g), respectively.

s. Adding paragraph (h).

The additions read as follows:

§ 84.13 Allocation of application-specific allowances.

* * * * *

(b) * * *

(1) * * *

(iv) Economic disruption outside the immediate control of the applicant; or

(v) Buildup of a stockpile of a specific regulated substance in the event of a production cessation. Requests for this unique circumstances must include: a letter from the applicant's supplier signed by a responsible corporate officer stating that the supplier is ceasing all production of the regulated substance at issue within three years; certification that the applicant has regulatory requirements beyond this part that limit ability to switch suppliers or there are no other suppliers that could meet their needs; and evidence that the applicant has a restricted HFC supply chain.

* * * * *

(c) * * *

(1) Accounting for verified changes in inventory in calculating growth rates and purchase amounts, except:

(i) for applications for mission-critical military end uses; and

(ii) if the applying entity provides a rationale deemed acceptable by the relevant agency official as to why inventory buildup should not be accounted for;

* * * * *

(4) Subtracting out quantities reported under § 84.31(h)(1)(x) in calculating growth rates and purchase amounts;

(5) Allocating allowances equivalent to the highest verified purchase amount measured in exchange value equivalent from the prior three years for entities that meet any of the following criteria:

(i) entity purchased less than 100 kilograms of regulated substances in at least one of the last three years, and the average growth rate of use for the company over the past three years calculated under subparagraph (7)(i) is equal to or greater than 200 percent;

(ii) entity had zero purchases in one of the last three years for reasons other than newly using regulated substances; or

(iii) entity purchased equal to or less than 100 kilograms of regulated substances in each of the past three years;

(6) For the application of structural composite preformed polyurethane foam for marine use and trailer use, utilizing the exchange value for HFC-152a in calculating the allowance allocation, regardless of what regulated substance was used by an entity;* * * * *

(h) Any entity receiving an allocation of allowances pursuant to this section may voluntarily choose to return any quantity of allowances to EPA up to, and including, June 30 of the calendar year in which the allowances can be expended. If any allowances are so returned, those

allowances will be distributed to the persons who meet the criteria listed in §§ 84.9 and 84.11 proportionate to entities' market share as calculated in §§ 84.9(b)(2) and 84.11(b)(5).

7. Amend subpart A by adding § 84.14 to read as follows:

§ 84.14 Petition for designation of an application as eligible for application-specific allowances.

(a) Petitions filed pursuant to 42 U.S.C. § 7675(e)(4)(B)(ii) must include:

(1) A description of the application, including an explanation of what the application is, what purpose or function it achieves, and what populations or commercial products benefit from the application;

(2) A list of regulated substance(s) and description of their use in the application and an explanation as to why regulated substances are required in the application;

(3) Evidence that no safe or technically achievable substitute is or is expected to be available, and that the petitioner has conducted research to evaluate substitutes for the regulated substance(s);

(4) Evidence that supply of the regulated substance(s) used in the application is insufficient to accommodate the application;

(5) A signed and notarized certification from a responsible corporate officer at the requesting entity that the application cannot use recovered and reprocessed regulated substance in conjunction with or in place of virgin regulated substance, either due to demonstrated lack of technical achievability or insufficient supply, and an explanation and evidence documenting why recovered and reprocessed regulated substance cannot be used for the application;

(6) Total quantity (in kilograms) of all regulated substances acquired by each entity submitting the petition for the application specified in the petition in each of the previous three years, including records documenting that quantity;

(7) The name of the entity or entities supplying regulated substances and contact information for those suppliers over the past three years;

(8) Total quantity (in kilograms) of each regulated substance held in inventory by each entity submitting the petition as of the date the petition is submitted;

(9) An estimate of the total quantity of regulated substances the petitioner expects to purchase in the first year it would be eligible for ASAs;

(10) Data on the proportion of the overall cost of the product or system that reflects the cost of regulated substances for each entity;

(11) Historic and projected sales for the product or system for each entity;

(12) Evidence of research into design changes to decrease the amount of regulated substance used in the product or system;

(13) An explanation regarding whether the use of the regulated substance(s) is necessary for the health, safety, or is critical for the functioning of society (encompassing cultural and intellectual aspects);

(14) An explanation regarding steps taken to minimize the use of the regulated substance and any associated emission of the HFC(s); and

(15) Information on regulatory restrictions related to possible alternatives and substitutes.

(b) If the petition does not include the required information listed in paragraph (a), the petition will be deemed incomplete and EPA will notify the entity submitting the petition.

(c) In the event that an application becomes eligible to receive application-specific allowances:

(1) EPA will allocate allowances to entities in a new application in accordance with § 84.13; and

(2) A new application would be eligible to receive application-specific allowances for no longer than the latest calendar year included in § 84.13(a).

8. Amend § 84.15 by adding paragraph (h) to read:

§ 84.15 Set-aside of application-specific allowances, production allowances, and consumption allowances.

* * * * *

(h) Consumption and production allowances from § 84.9(c) and § 84.11(c) are available in the form of application-specific allowances to entities that request them no later than April 30 of the calendar year in which the allowances may be expended that:

(1) qualify for application-specific allowances under § 84.13;

(2) provide supporting documentation that verify a need to purchase regulated substances in the present calendar year beyond what is reflected by the rates of growth calculated in § 84.13(c)(1);

(3) are facing a situation that qualifies as a unique circumstance as defined in § 84.13(b)(iii); and

(4) demonstrate to the satisfaction of the relevant agency official that the situation described in subparagraph (3) was unknowable at the time the entity made its request for application-specific allowances pursuant to § 84.13(b).

9. Amend § 84.17 by:

a. Adding ", except for the export of regulated substances produced with a production for export allowance" after "a foreign country in accordance with this section".

b. Revising paragraph (a)(5).

The revision reads as follows:

§ 84.17 Availability of additional consumption allowances.

* * * * *

(a) * * *

(5) The source of the regulated substances and whether the date purchased was before or after January 1, 2022;

* * * * *

10. Amend subpart A by adding § 84.18 to read as follows:

§ 84.18 Authorization of production for export allowances.

(a) EPA will allocate 3,000.0 MTEVe of production for export allowances to Iofina Chemical by October 1 of the calendar year prior to the year in which the allowances may be used for calendar years 2026, 2027, 2028, 2029, and 2030.

(b) Production for export allowances cannot be transferred.

(c) Any regulated substances produced with production for export allowances must be exported in the same calendar year it was produced.

11. Amend § 84.31 by:

a. In the introductory text of paragraph (a), removing the phrase "in the six applications listed in subsection (e)(4)(B)(iv) of the AIM Act".

b. Redesignating (d)(1)(vii) and (d)(1)(viii) to (d)(1)(viii) and (d)(1)(ix), respectively.

c. Adding paragraph (d)(1)(vii).

d. In paragraph (h)(1)(i), adding ", including a copy of the sales records, invoices, or other records documenting that quantity" after the word "months";

e. In paragraph (h)(1)(ii), adding ", including a copy of the sales records, invoices, or other records documenting that quantity" after the word "months";

f. In paragraph (h)(1)(iii), adding ", including a copy of the sales records, invoices, or other records documenting that quantity" after the parenthetical "(i.e., from the open market)";

g. In paragraph (h)(1)(iv), adding ", including a copy of inventory records documenting that quantity;" after the word "use";

h. In paragraph (h)(1)(viii), removing the last "and" after the phrase "additional need";

i. In paragraph (h)(1)(ix), replacing "." with "; and";

j. Adding paragraphs (h)(1)(x);

k. In paragraph (h)(2)(iv), adding ", including a copy of inventory records documenting that quantity;" after the phrase "current year";

l. In the introductory text of paragraph (h)(4), striking out ", except for the conferral of allowances for mission-critical military end uses,";

m. In paragraph (h)(7)(i), replacing "annual" with "biannual";

n. Redesignating (h)(7)(iii) through (h)(7)(vi) to (h)(7)(iv) through (h)(7)(vii), respectively;

o. Adding paragraph (h)(7)(iii);

p. Redesignating paragraph (l) as paragraph (n~~m~~); and

q. Adding paragraph (l) and (m).

The revision and additions read as follows:

§ 84.31 Recordkeeping and reporting.

* * * * *

(d) * * *

(1) * * *

(vii) Internal Transaction Numbers for all shipments, except shipments where an exemption from the requirements for the filing of Electronic Export Information (EEI) is provided in 15 CFR Part 30 Subpart D;

* * * * *

Commented [EO 12866148]: Is this intended to mean every other year, or twice per year? Please clarify, since there are two definitions supported by Merriam Webster, e.g.

Commented [EPA149R148]: It is clear in 84.31 that these biannual reports must be submitted July 31 and January 31 every year, so EPA feels there is sufficient context for a reader. This edit here is fixing a typo in the CFR and aligns with the framing used elsewhere.

(h) * * *

(1) * * *

(x) If allowances are allocated for a unique circumstance under § 84.13(b)(1)(v), the quantity (in kilograms) of each regulated substance purchased with the intent to build inventory during the prior six-month period, including a copy of records documenting that quantity.

* * * * *

(7) * * *

(iii) A copy of confirmation notices when conferring allowances for application-specific use;

* * * * *

(l) ***Holders of production for export allowances.*** Any person allocated production for export allowances must comply with the following recordkeeping and reporting requirements:

(1) Quarterly Reporting. Within 45 days after the end of each quarter, each holder of production for export allowances must submit to the relevant Agency official a report containing the following information:

(i) The quantity (in exchange value equivalent) of production for export allowances expended for each regulated substance and the quantity (in kilograms) of each regulated substance produced for export;

(ii) The quantity (in kilograms) of each regulated substance produced using production for export allowances that was exported;

(iii) The quantity (in kilograms) of each regulated substance produced with production for export allowances held in inventory at the end of the quarter;

(iv) Internal Transaction Numbers for all exports of regulated substances produced with production for export allowances;

(v) The country or countries to which regulated substances produced using production for export allowances were exported

(2) Annual Reporting. Within 45 days after the end of the fourth quarter, each holder of production for export allowances must submit to the relevant Agency official a report containing the following information:

(i) Signed certifications by a responsible corporate officer from all foreign customers and supply intermediaries attesting that any regulated substances produced using production for export allowances will only be used in an application as listed in § 84.13(a). Each certification must

include the name and address of the foreign entity, and a contact person's name, email address, and phone number;

(ii) A description of how the use identified in the signed certifications provided pursuant to paragraph (i) aligns with the applications as listed in § 84.13(a).

(3) Recordkeeping. Entities who receive production for export allowances must maintain the following records for ~~five~~ three years:

(i) A copy of all certifications reported pursuant to paragraph (2)(i); and

(ii) Records demonstrating due diligence undertaken to verify and ensure that all regulated substances produced with production for export allowances and exported are being used in an application as listed in § 84.13(a).

(m) ***Purchasers of HFCs at a government auction.*** Any entity purchasing regulated substances at a government auction authorized by the United States Customs and Border Protection must report such purchase as if they were an import consistent with the applicable provisions under this section, except for the following adjustments.

(i) ***Quarterly reporting.*** The date that filing for that entry was accepted by a United States Customs and Border Protection-authorized electronic data interchange system, such as the Automated Broker Interface, must be reported as the date on which the regulated substances were imported for purposes of paragraph (c)(1)(v). Unless otherwise unavailable, all requirements of paragraph (c)(1) must be reported. If a data element is unavailable, the auction purchaser must contact EPA and state that fact in writing by the time they make their filed report.

(ii) ***Recordkeeping.*** In addition to the records specificied in paragraph (c)(2), the auction purchaser must maintain records of the auction purchase, including the accepted bid, confirmation of payment, certification by the entity that they expended allowances, container composition testing to verify the regulated substances contained within the cylinder, and all other final documentation of the auction purchase. Unless otherwise unavailable, all requirements of paragraph (c)(2) must be met. If a data element is unavailable, the auction purchaser must contact EPA and state that fact in writing by the time they make their filed report.

(iii) ***Advance notification.*** The auction purchaser must report the information specified in paragraph (c)(7) prior to the HFCs entering U.S. commerce. The requirement in paragraph (c)(7)(xvi) does not apply if a certificate of analysis is not available at the time of submitting the information in paragraph (c)(7). The entity must complete all required sampling and testing required in this subpart prior to sale in U.S. commerce and maintain such records consistent with 84.31.

* * * * *

12. Amend § 84.54 by revising paragraph (a)(16)(i)(O) and adding (a)(16)(i)(P) as follows:

Commented [EO 12866150]: Consistent with 5 CFR 1320.5, OMB cannot approve an information collection that includes a records retention of >3 years unless the agency can demonstrate that such a long records retention is necessary. Please provide such a demonstration in the preamble or remove the requirement from this proposal

Commented [EPA151R150]: See prior response on the same comment around p.100.

Commented [Round 3152R150]: EPA's response is unsatisfactory. Revising the regulatory text accordingly unless EPA can provide better justification.

Commented [Round 2153]: Are the added reporting requirements in the regulatory text reflected in the costs and hour burdens discussed/reflected in the Paperwork Reduction Act section of the preamble?

Commented [EPA154R153]: Thank you for flagging, we have updated the preamble and cost-benefit memo to incorporate recordkeeping costs for HFC purchasers at government auctions into the costs of the rule. Additional costs are expected to be minimal given a purchaser of HFCs at auction would likely be an existing importer and allowance holder. As a result, burden is already accounted for, e.g., they already have to file quarterly importer reports.

§ 84.54 Restrictions on the use of hydrofluorocarbons.

(a) * * *

(16) * * *

(i) * * *

(O) Products for removing bandage adhesives from skin; and

(P) Defense sprays as defined at § 84.3.

* * * * *

13. Amend § 84.60 by adding paragraph (a)(7) and (b)(7) as follows:

§ 84.60 Recordkeeping and reporting.

(a) *Reporting.*

* * *
(7) Effective [DATE], this paragraph shall apply to defense sprays as defined at § 84.3 and structural composite preformed polyurethane foam as defined at § 84.3.

* * *
(b) *Recordkeeping.*

* * *
(3) Effective [DATE], this paragraph shall apply to defense sprays as defined at § 84.3 and structural composite preformed polyurethane foam as defined at § 84.3.
* * * * *

Page 59: [1] Commented [EPA53R52] EPA 6/12/2024 5:13:00 PM

The stranded inventory concerns raised under the Technology Transition Rule are for Variable refrigerant flow air conditioning systems used in large buildings, and residential unitary split air conditioning units in the residential air conditioning subsector. Both of these types of equipment are not subject to a manufacturing or import restriction and sell through date, but instead are subject to an installation restriction. Under the TT rule products that are fully complete when they leave the factory such as aerosols are products and subject to a manufacturing and import restriction with a three year sell through. We have not received any letters or concerns from the aerosol industry concerned about stranded inventory since the final rulemaking.

In this rule, EPA is proposing that defense sprays would be subject to the existing aerosol subsector restrictions, which also has the effect that defense sprays would be subject to the framework of restrictions under the Technology Transitions program, which includes the sell through provision that was established in the 2023 Technology Transitions Rulemaking. Given how the two aerosol subsectors are laid out in the regulatory text, we are clarifying in the regulatory text which set of compliance dates would apply. EPA is not proposing to reopen the framework of restrictions in the existing program, including the compliance date for the restriction on sale and distribution.

Reliance solely on a manufacturing compliance date was one suggested path to avoiding stranded inventory that EPA received in comments primarily in relation to the refrigeration and air conditioning sector in the TT Rulemaking. However, as explained in that rule, that path also posed increased risk of non-compliant products with fraudulent manufacturing or import dates remaining on the market. The sell-through period, the length of which EPA tripled in the final rule in order to minimize the possibility of stranded inventory, ensures that there is a clear compliance date by which regulated entities, consumers, and Agency enforcement officials can be sure that no products that do not meet the restrictions are on the market. Concern about stranded inventory due to the proposed one-year sell-through period was not a point that was widely raised by the aerosol industry during the TT comment period.

Page 59: [2] Commented [EPA55R52] EPA 7/18/2024 2:30:00 PM

EPA is not supportive of adding a request for comment on the timing of the sell-through period. EPA finalized a 3 year sell through for all aerosol products in the Technology Transitions (TT) rule. EPA understands the point the commenter is making, which EPA understands could be relevant for other applications that are not considered in this rulemaking. This section solely concerns an application within the aerosols sector. Since the issuance of the final TT rule, EPA has not heard any concerns from the relevant trade associations or manufacturers of aerosols regarding the three-year sell-through contained in the final rule.

Page 67: [3] Commented [EPA64R61] EPA 7/17/2024 11:17:00 AM

The ultimate timing driver for this rule is that if we do not get this rule done, the result will be that these applications do not receive ASAs, which are necessary for the priority access that Congress intended. ASAs are available to entities for calendar years 2022, 2023, 2024, and 2025. *See* 40 CFR 84.13(a). Under EPA's regulation, EPA cannot allocate ASAs to any entity for calendar year 2026 until this rule is finalized. EPA wants to ensure that this rulemaking is completed on time to ensure that ASAs meeting the statutory criteria for renewal will receive priority access to allowances in calendar year 2026. As noted, EPA must allocate those allowances no later than October 1, 2026. Given we are bound by the timing for annual issuance of allowances, and we want to ensure priority access is provided where the criteria are met, we have taken the approach discussed in this proposed rule.

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

This document does not contain Confidential Business Information (CBI) and, therefore, may be disclosed to the public. Brackets [ ] represent redacted CBI content. Redacted content includes elements EPA has determined are CBI and elements where an entity has claimed CBI.

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Figures

Tables

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

[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).

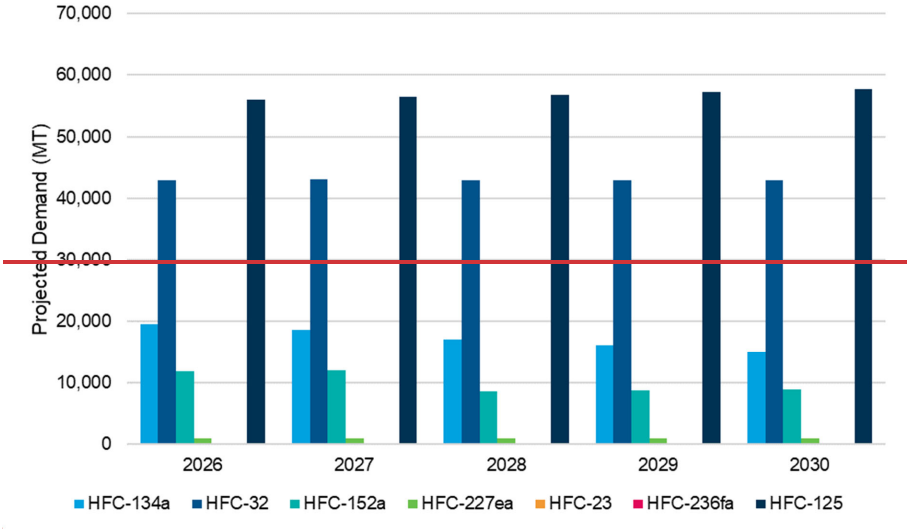
Other HFCs used by the six applications, such as HFC-41 and HFC-23, have little to no use in sectors and subsectors restricted by EPA's Technology Transitions Program, and continue to have projected demand from non-impacted sectors.[2] Furthermore, for other HFCs the Technology Transitions Program may have countervailing effects on demand, potentially resulting in relatively stable consumption overall despite changes in use. For example, demand

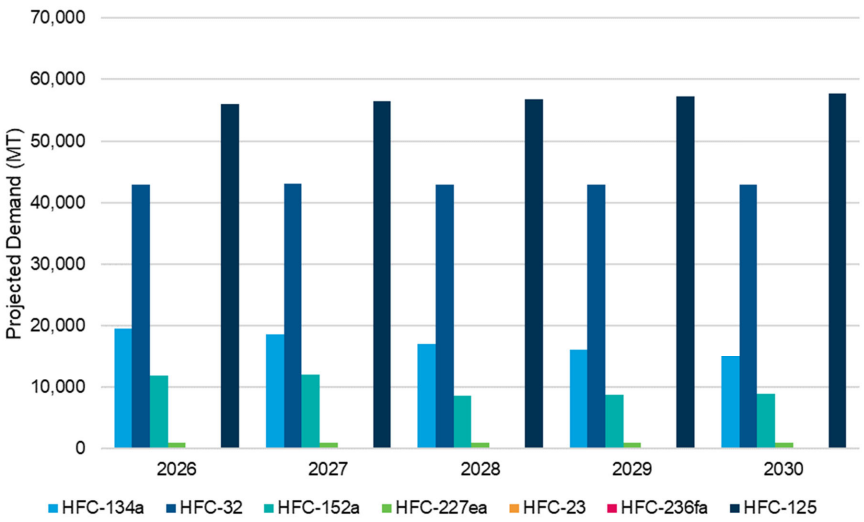
importers multiply the quantity of the HFC they seek to produce or import by its exchange value. For example, an importer would need to expend 143 consumption allowances to import 100 kilograms of HFC-134a. Given the variation in exchange values, one would need to expend 5.3 allowances to import 100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

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

for HFC-32 as a component of R-410A (a relatively higher-GWP blend) is anticipated to fall, while demand for neat HFC-32 or HFC-32 in lower-GWP blends is anticipated to increase. Figure 1~~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

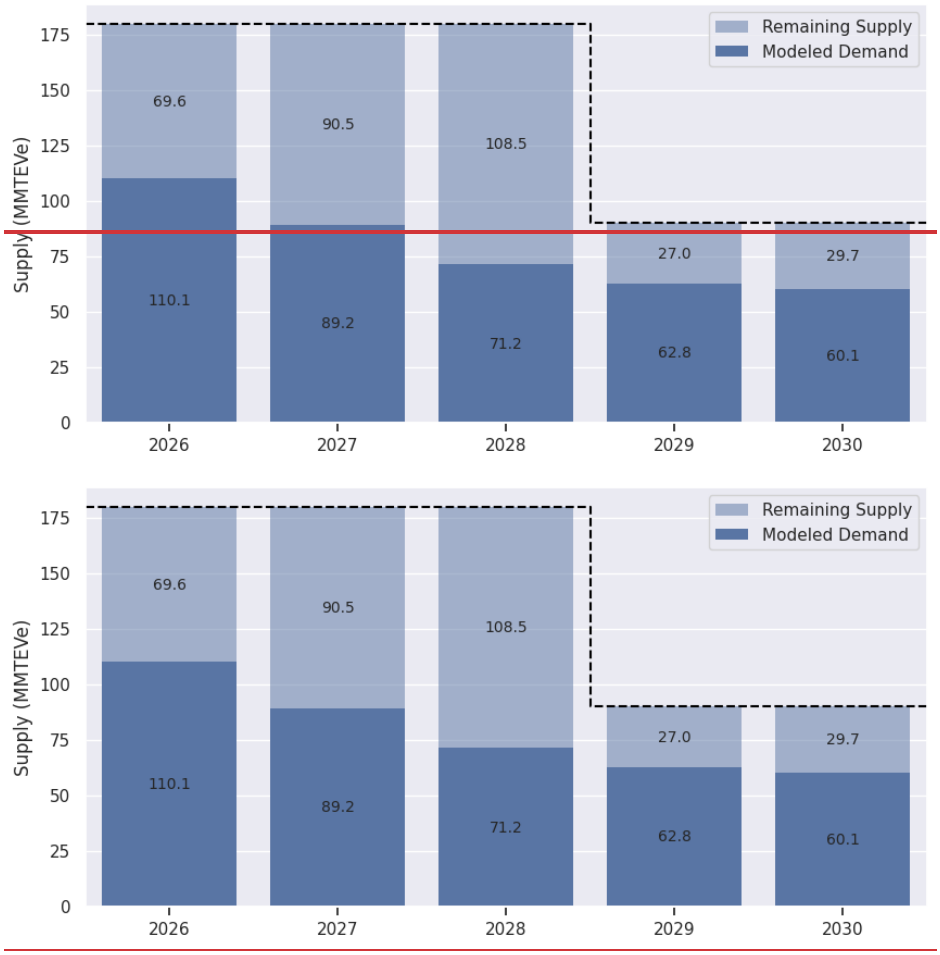




Note: HFC-23 and HFC-236fa demand estimates are too small to be shown. Estimates for HFC-23 range from 11 to 12 MT over the time series. Estimates for HFC-236fa range from 190 to 212 MT over the time series. In addition, HFC-41 is not modeled in EPA's Vintaging Model.

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~~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

[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.

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		
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

[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).

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).
- 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,

[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.

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.

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.

[9] TSCA section 8(a)(7)
[10] See https://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1113&item=5&snum=130
[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 (FDA, 2023). 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 (ICF, 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

[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).

in MDIs is not as prevalent as the use of HFC-134a as it is costly and has a higher GWP (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.

Commented [EO 128661]: Suggest adding a statement on the impact to patient access and pricing that occurred due to phase-out of CFCs and MDI transition:

Jena, Anupam B., et al. "The impact of the US Food and Drug Administration chlorofluorocarbon ban on out-of-pocket costs and use of albuterol inhalers among individuals with asthma." JAMA internal medicine 175.7 (2015): 1171-1179.

Wouters, Olivier J., William B. Feldman, and S. Sean Tu. "Product hopping in the drug industry—lessons from albuterol." New England Journal of Medicine 387.13 (2022): 1153-1156.

Commented [EPA2R1]: A sentence was added to the footnote here.

[18] HFC products clog more easily, and the plume has slower velocity and is less cold compared to CFC products (FDA, 2023). Additionally, there were documented impacts to patient access due to the transition (Anupam, 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	~~Ventolin®~~Flovent HFA	Fluticasone Propionate	5/14/2004~~4/19/2001~~
GlaxoSmithKline	Prasco Laboratories	Authorized Generic Fluticasone Propionate Inhaler	~~Albuterol Sulfate~~ 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

Commented [EO 128663]: The API for Ventolin is Albuterol Sulfate

Commented [EO 128664]: GSK Fluticasone Propionate HFA approved 5/14/2004 Tradename Flovent

Commented [EO 128666]: API should be Fluticasone Propionate

Commented [EO 128665]: If this is an authorized generic, I suggest we omit from here and/or specify that it is authorized generic and/or use the brand name for it. An authorized generic is marketed under the NDA and not an ANDA

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
~~Aurobindo Pharma USA[h]~~	~~Aurobindo Pharma USA~~	~~[ ]~~	~~[ ]~~	~~Application Filed[h]~~
Unspecified				
Catalent Pharmaceuticals[ih]	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] Aurobindo Pharma USA has filed an application with FDA, which is not yet listed in FDA's Drugs@FDA database (i.e., list of drugs approved for human use in the United States), and has five additional MDI products [ ] under development (Motilal Oswal, 2020; EPA, 2024).~~
[ih] 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

Commented [Round 29]: Re-inserting a comment from round 1:

The first cited source (Motilal Oswal, 2020) discloses that Aurobindo filed an application for a MDI generic, but is it public information that the proposed MDI uses HFC-134a (instead of HFC-227ea or other propellant)? If no, I'd suggest either redacting Aurobindo's name in first two columns or moving row down to "unspecified" section.

Commented [EPA10R9]: Suggestion to remove information accepted.

Commented [Round 27]: Re-inserting a comment from round 1:

I suggest to omit as it is not a marketed product and moreover, we do not disclose if an ANDA has been submitted. And this calls out a specific company, one of many who may have submitted ANDAs for these products

Commented [EPA8R7]: Edit accepted.

Commented [Round 211]: Is the fact of importation itself confidential information, or is only the name of the source confidential (and thus redacted)? Same question for the domestic R&D column. If it is the fact of importation or domestic R&D, I'd suggest redacting all rows because the redaction or lack thereof would confirm one or the other.

Commented [EPA12R11]: We have deleted the additional two columns and changed the title of this table. Thank you for this comment.

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

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

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 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 (Koura, 2021a). 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). [ ] 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 ~~that reformulate an MDI product by switching propellants may need to make other formulation changes, as vapor pressure, stability, and reactivity could be affected. Because of this, the use of an alternative MDI propellant will require FDA evaluation of the product for approval.~~intending to market an MDI containing ~~a LGWP~~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).

~~New MDI drug products are subject to the approval requirements under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations, which include requirements on chemistry, manufacturing, and controls. MDIs must also meet, among other requirements, FDA *Current Good Manufacturing Practice* (CGMP) requirements to ensure safety and functionality of the product (FDA, 2020a).~~

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. ~~For New Drug Applications (NDAs), FDA requires new toxicological and clinical studies to ensure the safety and efficacy of the products (FDA, 1995; FDA, 2015). Before the drug sponsor~~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) ~~can~~

Commented [EPA13]: Accepted edits in this paragraph with one change. We replaced "LGWP" with the more general "alternative propellant", which is a term we use earlier in this chapter. While we are proposing to only consider substitutes with a lower GWP to be safe substitutes, we are looking at substitutes for currently used HFCs, not necessarily only LGWP propellants.

Commented [Round 214]: Revised the introductory sentence to focus on the purpose of an IND. The remainder of the paragraph contains a good description on the elements of an IND submission.

Commented [EPA15R14]: Edit accepted.

~~conduct drug studies in humans, they~~developing MDIs with ~~a low GWP~~an alternative propellant must ~~submit~~have an IND application that is reviewed by FDA and a local ~~institution~~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, 2022d). ~~Following submission, review, and approval of the~~Once an IND ~~application, drug~~goes into effect, sponsors can conduct clinical (human) trials to assess the safety and efficacy of the drug product. During development, ~~drug~~ sponsors can request meetings to seek feedback and guidance from FDA. The clinical development program ~~typically takes~~may take many years to complete, e.g. ranging from over a year to six or more years (FDA, 2018b).

4.2.2.1.2 New Drug Applications

~~The drug sponsor formally requests~~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 ~~U.S~~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 ~~preserve the drug's identity, strength, quality, and purity~~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 ~~has 60 days~~will conduct a filing review to ~~determine whether~~ensure that the application is sufficiently complete to ~~file the NDA for~~permit a substantive review. If filed, FDA reviews the NDA ~~to determine that the drug is safe and effective for the proposed context of use and that the benefits of the drug outweigh the potential risks.~~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 ~~must~~may also conduct an inspection of the drug manufacturing facilities to ensure that drugs are manufactured in accordance with CGMP ~~and that the marketed product is the same as the product tested in clinical trials. If approving an NDA, FDA also reviews a drug's label to ensure that necessary information is provided for health care professionals and consumers.~~. Once the drug is approved by FDA, the drug sponsor must conduct post-marketing monitoring to ~~ensure continued~~monitor safety (FDA, 2015; FDA, 2017a; FDA, 2016).

Commented [EO 1286616]: Suggested edit: …..FDA *Current Good Manufacturing Practice* (CGMP) requirements to ensure safety, quality and ~~functionality~~ reliable performance (e.g., drug delivery) of the product (FDA, 2020a)

Commented [EPA17R16]: Incorporated this suggested edit

Commented [Round 218]: Comment reinserted from 1st round:

Depends on type of application, so would make general.

Commented [EPA19R18]: Edit accepted.

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 ~~a duplicate of~~presumed to be therapeutically equivalent to a previously approved drug product~~. An ANDA relies on FDA's finding that the previously approved drug product~~, i.e., ~~the~~its reference listed drug (RLD~~), is safe~~). Products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and ~~effective~~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 ~~guidance~~guidances, which for orally inhaled products like MDIs, ~~has~~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 ~~meet~~consult with the Agency both before and after ANDA submission ~~to discuss~~regarding, among other things, a generic ~~manufacturer's~~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 ~~will~~committed to review 90% of standard original 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, 2018c). After mixing, MDI canisters are filled with the formulation, the constituent parts of the device are assembled, and the MDIs are packaged (FDA, 2018c).

[24] MDIs approved under ANDAs may also be marketed as brand-name products.
[25] Certain prioritized ANDAs receive an 8-month goal date as set forth in the GDUFA III Commitment Letter.

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 ~~components~~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. ~~FDA CGMP requirements for drug components include those related to storage and handling, sampling and testing, and compliance with appropriate purity and quality specifications.~~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 (~~21 CFR 211~~; ;Daikin Industries, Ltd., n.d.). These facilities may also be periodically inspected to ensure that they meet ~~regulatory~~ 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 ~~purification~~ HFC manufacturing facility (FDA, 2018c).

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 ~~and~~, product quality data of the new propellant source ~~and~~, 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 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. ~~While not required for approval, industry uniformly follows FDA's When finalized this guidance, will reflects FDA's current thinking on this topic. FDA's guidance documents do not establish legally enforceable responsibilities, 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. Industry has told EPA that they uniformly follow the draft guidance.~~ Per this draft guidance ~~issued by FDA~~, from a safety standpoint, propellants used in MDIs are recommended~~, but~~ (though not required for approval~~,~~). to have a greater purity of at least 99.99% (FDA, 2018c~~), which is generally stricter than those~~

Commented [EO 1286620]: We don't have CGMP regulations for the manufacturing of components as we do for drug products, however we have statutory coverage under 501(a). As such we should despecify the requirements to a level that's more consistent with statute. Additionally, we can introduce the regulations in 211 as requirements for manufacturers when using components in their drug products.

Commented [EPA21R20]: Edits accepted. This is helpful background for the edits.

Commented [EO 1286622]: Recommend we delete this reference unless the purification is happening inside the drug manufacturer who uses the HFC

Commented [EPA23R22]: Deleted as the purification occurs outside of the MDI drug manufacturing facilities.

Commented [EO 1286624]: Change to CGMP per comment above

Commented [EPA25R24]: Accepted with the addition of a comma after the phrase "including audits by FDA" to keep it distinct from "inspections by other non-U.S. health authorities."

Commented [EPA26]: Modified for clarity.

Commented [EPA27]: EPA has accepted most of the edits in this paragraph, but has kept in the sentence that states that industry uniformly follow's FDA's draft guidance (with some alterations). EPA understands this to be standard practice based on conversations with an industry trade association. This information provides additional context on what role the draft guidance actually plays for industry in maintaining a certain level of and consistency in quality in the manufacture of MDIs.

Commented [Round 228R27]: Reviewing agency struck the revised sentence in 2nd round review

Commented [EPA29R27]: EPA has updated this text based on suggested edits from the reviewer on 7/22/2024.

Commented [EO 1286630]: Recommend edits to avoid implying that the expectation is for industry to follow draft guidance.

Commented [EPA31R30]: Edits accepted.

~~for other industries~~) compared to other industrial uses~~.~~ (e.g., AHRI 700 requires a purity of 99.5% for refrigerants). FDA has also ~~included example~~recommended acceptance criteria for total impurities in these propellants at ≤1,000ppm for HFC-134a and ≤20 ppm for HFC-227ea (FDA, 2018c). 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. ~~Industry~~An industry trade association has told EPA that ~~they~~industry uniformly follows the ~~draft~~ 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 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).

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

4.3.2 Use of Recovered and Reprocessed Material

[ ] (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 ~~guidelines~~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~~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).

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~~Table 5~~). However, their use in MDIs

[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.

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***

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] [ ]

[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]

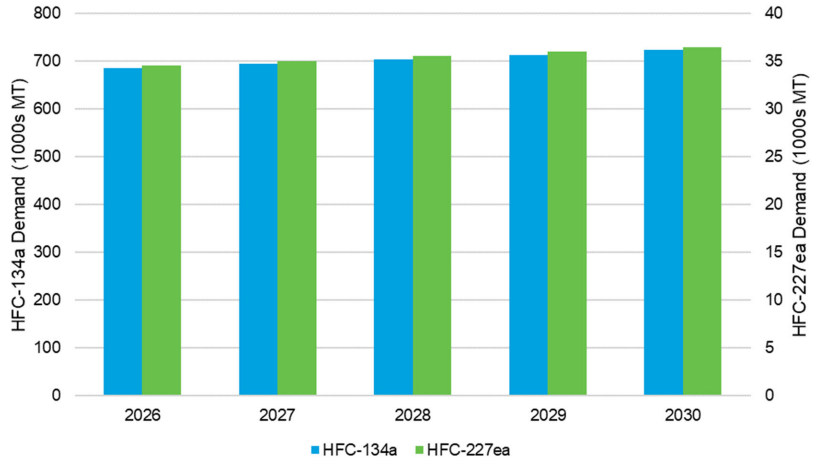
[c] Boehringer Ingelheim did not receive 2023 allowances [ ].

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~~Figure 3~~) (EPA, 2023). Projected HFC demand is conservatively based on average 2021 to 2023 purchases, which were primarily HFC-134a and HFC-227ea.

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



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

While Figure 3~~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, 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).

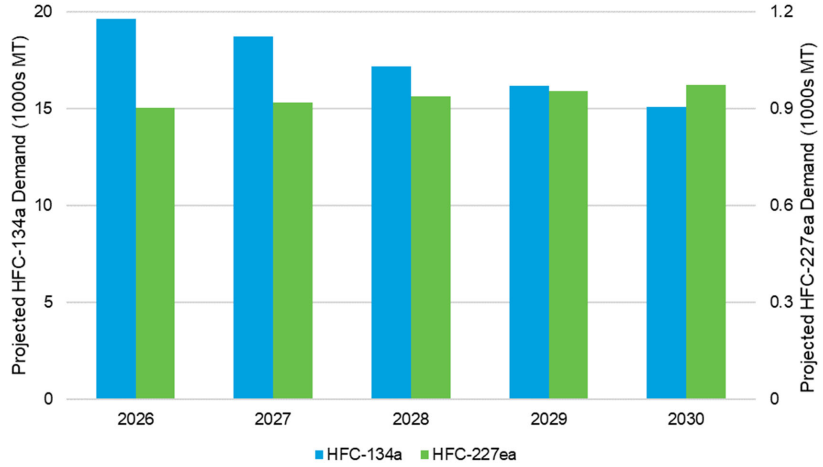
EPA regulations under the AIM Act, planned transitions out of HFC-134a, and market trends generally are estimated to reduce demand for HFC-134a through 2030; modeling under existing AIM Act regulations estimates demand for HFC-134a will reduce by approximately 24,800 MT

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

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~~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~~Table 6~~).

In addition, Table 6~~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~~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~~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	3.7%	46.6%

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~~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~~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~~Table 9~~. HFC-134a has a higher vapor pressure and lower boiling point than these alternatives. Early

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

manufacturer 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), which received approval under FIFRA regulations [ ] ([ ]) and one bear spray [ ] uses HFC-152a. [ ]. Honeywell has also indicated that it indirectly sells HFO-1234ze(E) into the personal defense spray market, and the end customer is in Canada. In addition, [ ].

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).

[ ]

[ ] (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

[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

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. 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.

[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, 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

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

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~~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 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,

[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.

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~~.

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~~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~~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 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

[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).

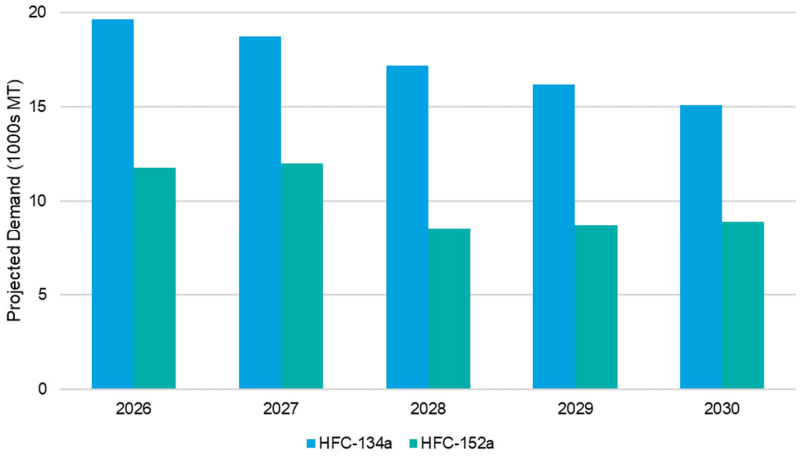
comparison to the same volume of higher-EV HFCs. For example, an importer would need to expend 143 consumption allowances to import 100 kg of HFC-134a compared to 12.4 allowances to import 100 kg of HFC-152a—a greater than 90% reduction.

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 soon 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. If finalized as proposed, this 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. 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.

Commented [Round 332]: EPA should soften this language as this rule is under review.

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~~).

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~~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.

Error! Not a valid bookmark self-reference. 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~~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 (BASF, 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, 2022b; 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 (BASF, 2021; 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 (BASF, 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; NCMS, 2023).

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 (BASF, 2021).

6.1.4.3 Trailer Manufacturers

There are multiple domestic trailer manufacturers (Table 13~~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~~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).

[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.

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.

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, [ ] (EPA, 2024a). [ ]. 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).

[ ] (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~~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 (BASF, 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~~).

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~~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~~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~~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).

[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~~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~~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~~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.
[l] 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 fluorinated, chlorinated, and other reactive gases used during the etching and CVD chamber cleaning processes of semiconductor manufacturing~~. 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~~is likely~~ 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).

Commented [EPA33]: Clarification added to show that this standard would not apply to non-hazardous HFCs.

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% (Arkema, 2021).

7.3.2 Use of Recovered and Reprocessed Material

[ ] (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 95%HKW%93:-n-8.-m). 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). **Error! Reference source not found.** 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)

[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, 17,762 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~~Table 21~~ for a summary of HFC use in kilograms). This trend is reflected by the change in the

[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						

[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						

Company Name	2018	2019	2020	2021	2022[a]	2023[a]
Northrop Grumman Corporation						
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***

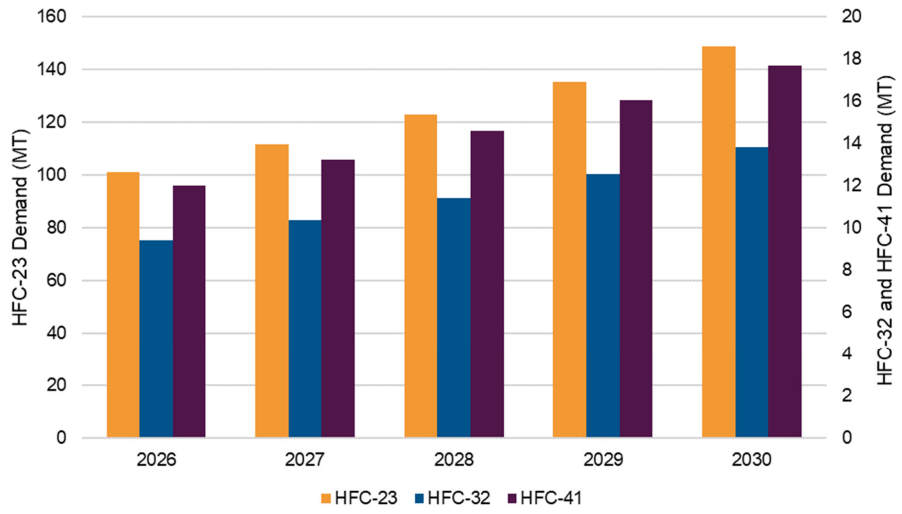
Source: EPA (2024a).
[a] Calculated as the sum of HFC held in inventory (previous period) + HFC acquired through conferrals + HFC imported using allowances + HFC purchased – HFC held in inventory (current period).

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~~).

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).

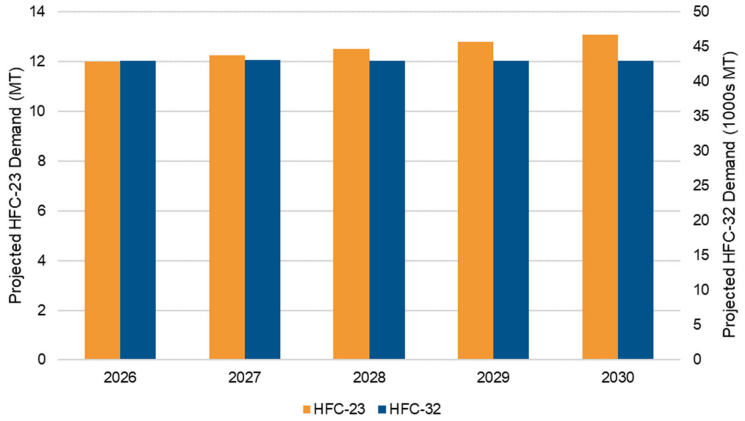
National security interests and global competition within the semiconductor industry has resulted in recent regulations limiting the trade of domestic product. In October 2023, the U.S. Commerce Department announced two new rules that update and expand the Export Administration Regulations (EAR) controls, 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~~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. **Error! Not a valid bookmark self-reference.**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	50%	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; Jensen Hughes Inc., 2015; 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; Jensen Hughes Inc., 2015):

- **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

[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).

[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~~used~~s~~d 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 (Jensen Hughes, Inc., 2020; Jensen Hughes, Inc., 2021b). 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).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~~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

~~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 (Jensen Hughes, Inc., 2021a).[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.

[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.

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 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).

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

[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 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 (Jensen Hughes, Inc., 2023; 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 (Jensen Hughes, Inc., 2023). [ ] (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

Standard	Title	Description
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 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 American Society of Testing and Materials (ASTM) 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]

[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.

- 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.

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 (Jensen Hughes, Inc., 2023). [ ] (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 –*

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

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]
- 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

[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.
[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.

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-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).

[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.

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 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).

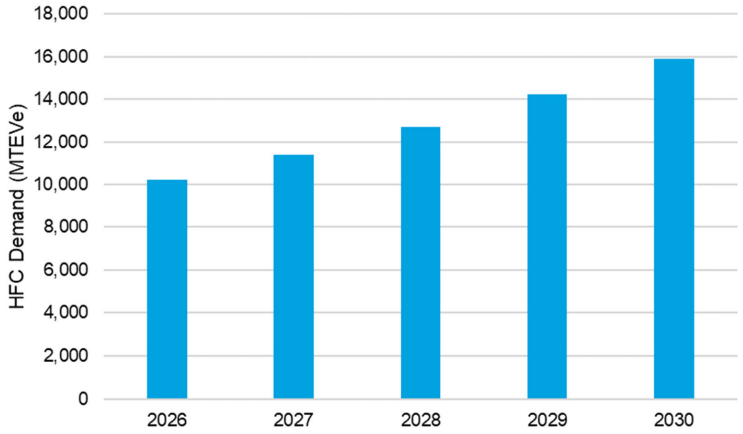
Boeing predicts that the global aviation market will grow at a compound annual growth rate of 2.5% from 2022-2042 with the Americas and Europe accounting for 24% and 23% of the market, respectively (Boeing, 2023b). However, even if this estimate were taken at face value, this growth in the overall market 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.

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

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 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 8~~Figure 8~~).

[ ]

Figure 8. 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

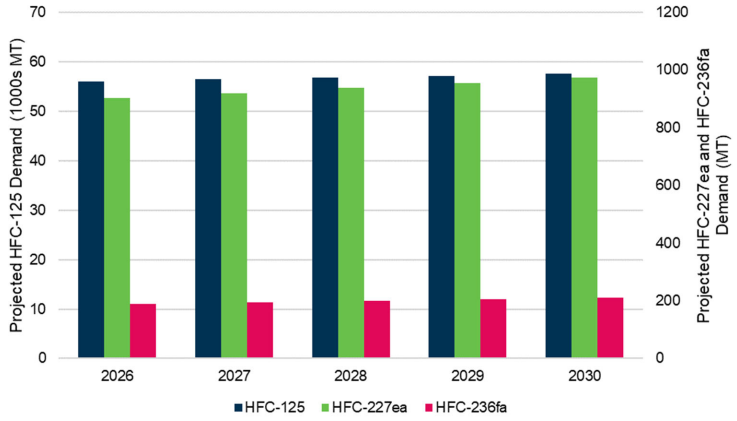
As noted in Section 3.1.2, EPA's 2023 Technology Transitions Rule established GWP limits, which in turn will limit the use of HFC-236fa and blends containing HFC-125 (e.g., R-410A, R-404A) in many sectors and subsectors as early as 2025. As noted in Section 4.3.5, HFC-227ea is used primarily in MDIs 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 9 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 9. 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.

Error! Not a valid bookmark self-reference.~~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 **Error! Not a valid bookmark self-reference.**~~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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