ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2008–0664; FRL–9275–8]

RIN 2060–AP11

Protection of Stratospheric Ozone: New Substitute in the Motor Vehicle Air Conditioning Sector Under the Significant New Alternatives Policy (SNAP) Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP) program is expanding the list of acceptable substitutes for use in the motor vehicle air conditioning end-use as a replacement for ozone-depleting substances. The Clean Air Act requires EPA to review alternatives for ozone-depleting substances and to disapprove substitutes that present overall risks to human health and the environment more significant than those presented by other alternatives that are available or potentially available. The substitute addressed in this final rule is for use in new passenger cars and light-duty trucks in the motor vehicle air conditioning end-use within the refrigeration and air conditioning sector. EPA finds hydrofluoroolefin (HFO)–1234yf acceptable, subject to use conditions, as a substitute for chlorofluorocarbon (CFC)-12 in motor vehicle air conditioning for new passenger cars and light-duty trucks. The substitute is a non-ozone-depleting gas and consequently does not contribute to stratospheric ozone depletion.

DATES: This final rule is effective on May 31, 2011. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of May 31, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2008–0664. All documents in the docket are listed on the *http://www.regulations.gov* Web site. 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 either electronically through *http://www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility 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 Air Docket is (202) 566–1742.

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Notices and rulemakings under the SNAP program are available on EPA's Stratospheric Ozone Web site at *http://www.epa.gov/ozone/snap/regulations.html.* The full list of SNAP decisions in all industrial sectors is available at *http://www.epa.gov/ozone/snap.*

SUPPLEMENTARY INFORMATION: This final rule provides motor vehicle manufacturers and their suppliers an additional refrigerant option for motor vehicle air conditioning (MVAC) systems in new passenger cars and light-duty trucks. HFO–1234yf (2,3,3,3-tetrafluoroprop-1-ene), the refrigerant discussed in this final action, is a non-ozone-depleting substance.

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I. Does this action apply to me?

This final rule regulates the use of the chemical HFO–1234yf (2,3,3,3-tetrafluoroprop-1-ene, Chemical Abstracts Service Registry Number [CAS Reg. No.] 754–12–1) as a refrigerant in new motor vehicle air conditioning (MVAC) systems in new passenger cars and light-duty trucks. Businesses in this end-use that might want to use HFO–1234yf in new MVAC systems in the future include:

- Automobile manufacturers.
- Manufacturers of motor vehicle air conditioners.

Regulated entities may include:

TABLE 1—POTENTIALLY REGULATED ENTITIES, BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE

Category	NAICS code	Description of regulated entities
Industry	336111	Automobile Manufacturing.
Industry	336391	Motor Vehicle Air-Conditioning Manufacturing.

This table is not intended to be exhaustive, but rather a guide regarding entities likely to be regulated by this action. If you have any questions about whether this action applies to a particular entity, consult the person listed in the preceding section, **FOR FURTHER INFORMATION CONTACT**.

II. What abbreviations and acronyms are used in this action?

100-yr—one-hundred year time horizon
AEGL—Acute Exposure Guideline Level
AIST—the National Institute for Advanced Industrial Science and Technology of Japan
ASHRAE—American Society for Heating, Refrigerating, and Air-Conditioning Engineers
ATSDR—the U.S. Agency for Toxic Substances and Disease Registry
BAM—Bundesanstalt für Materialforschung und-prüfung (German Federal Institute for Materials Research and Testing)
CAA—Clean Air Act
CAS Reg. No.—Chemical Abstracts Service Registry Number
CBI—Confidential Business Information
CFC—chlorofluorocarbon
CFC–12—the ozone-depleting chemical dichlorodifluoromethane, CAS Reg. No. 75–71–8
CFD—Computational Fluid Dynamics
CFR—Code of Federal Regulations
cm/s—centimeters per second
CO_2—carbon dioxide, CAS Reg. No. 124–38–9
CRP—Cooperative Research Program
DIN—Deutsches Institut für Normung (designation for standards from the German Institute for Standards)
DIY—"do-it-yourself"
DOT—the United States Department of Transportation
EPA—the United States Environmental Protection Agency
EO—Executive Order
FMEA—Failure Mode and Effect Analysis
FR—**Federal Register**
GWP—Global Warming Potential
HF—Hydrogen Fluoride, CAS Reg. No. 7664–39–3
HI—Hazard Index
HFC—hydrofluorocarbon
HFC–134a—the chemical 1,1,1,2-tetrafluoroethane, CAS Reg. No. 811–97–2
HFC–152a—the chemical 1,1-difluoroethane, CAS Reg. No. 75–37–6
HFO—hydrofluoroolefin
HFO–1234yf—the chemical 2,3,3,3-tetrafluoroprop-1-ene, CAS Reg. No. 754–12–1
ISO—International Organization for Standardization
JAMA—Japan Automobile Manufacturers Association
JAPIA—Japan Auto Parts Industries Association
LCA—Lifecycle Analysis
LCCP—Lifecycle Climate Performance
LFL—Lower Flammability Limit
LOAEL—Lowest Observed Adverse Effect Level
mg/L—milligram per liter
MIR—Maximum Incremental Reactivity
mJ—millijoule
mm—millimeter
MOE—Margin of Exposure
MPa—megapascal
MRL—Minimal Risk Level
MVAC—Motor Vehicle Air Conditioning
NAICS—North American Industrial Classification System
ng/L—nanograms per liter
NHTSA—the U.S. National Highway Traffic Safety Administration
NOAEL—No Observed Adverse Effect Level
NOEC—No Observed Effect Concentration
NPRM—Notice of Proposed Rulemaking
NTTAA—National Technology Transfer and Advancement Act
ODP—Ozone Depletion Potential
ODS—zmOzone-Depleting Substance
OEM—Original Equipment Manufacturer
OMB—Office of Management and Budget
OSHA—the United States Occupational Safety and Health Administration
PAG—Polyalkylene Glycol
PMN—Pre-Manufacture Notice
POCP—Photochemical Ozone Creation Potential
POD—Point of Departure
ppm—parts per million
ppt—parts per trillion
psig—pounds per square inch gauge
R–1234yf—ASHRAE designation for refrigerant HFO–1234yf
R–134a—ASHRAE designation for refrigerant HFC–134a
R–152a—ASHRAE designation for refrigerant HFC–152a
R–744—ASHRAE designation for refrigerant CO_2
RCRA—the Resource Conservation and Recovery Act
RFA—Regulatory Flexibility Act
SAE—SAE International, formerly the Society of Automotive Engineers
SBA—the United States Small Business Administration
SIP—State Implementation Plan
SNAP—Significant New Alternatives Policy
SNUN—Significant New Use Notice
SNUR—Significant New Use Rule
SO_2—sulfur dioxide, CAS Reg. No. 7446–09–5
TEWI—Total Equivalent Warming Impact
TFA—Trifluoroacetic acid, CF_3COOH, also known as trifluoroethanoic acid, CAS Reg. No. 76–05–1
TSCA—the Toxic Substances Control Act
TWA—Time-Weighted Average
UBA—Umweltbundesamt (German Federal Environment Agency)
UF—Uncertainty Factor
UMRA—Unfunded Mandates Reform Act
VDA—Verband der Automobilindustrie (German Association for the Automobile Industry)
VOC—Volatile Organic Compound
v/v—volume to volume
WEEL—Workplace Environmental Exposure Limit

III. What is EPA's final decision for HFO–1234yf for motor vehicle air conditioning (MVAC)?

In this final rule, EPA is finding HFO–1234yf acceptable, subject to use conditions, as a substitute for CFC–12 in new MVAC systems for passenger cars and light-duty trucks. This determination does not apply to the use of HFO–1234yf as a conversion or retrofit for existing MVAC systems. In addition, it does not apply to the use of HFO–1234yf in the air conditioning or refrigeration systems of heavy-duty trucks, refrigerated transport, or off-road vehicles such as agricultural or construction equipment.

EPA is not mandating the use of HFO–1234yf or any other alternative for MVAC systems. This final rule is adding HFO–1234yf to the list of acceptable substitutes, subject to use conditions, in new MVAC systems. Automobile manufacturers have the option of using any refrigerant listed as acceptable for this end-use, so long as they meet any applicable use conditions.

Under this decision, the following enforceable use conditions apply when HFO–1234yf is used in a new MVAC system for passenger cars and light-duty trucks:

1. HFO–1234yf MVAC systems must adhere to all of the safety requirements of SAE [1] J639 (adopted 2011), including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers of 20 lbs or greater, use fittings consistent with SAE J2844 (adopted 2011).

2. Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739 (adopted 2009). Manufacturers must keep the FMEA on file for at least three years from the date of creation.

IV. What are the final use conditions and why did EPA finalize these conditions?

Summary of the Use Conditions

The first use condition requires that MVAC systems designed to use HFO–1234yf must meet the requirements of the 2011 version of the industry standard SAE J639, "Safety Standards for Motor Vehicle Refrigerant Vapor Compression Systems." Among other things, this standard sets safety standards that include unique fittings to connect refrigerant containers to the MVAC system; a warning label indicating the refrigerant's identity and indicating that it is a flammable refrigerant; and requirements for engineering design strategies that include a high-pressure compressor cutoff switch and pressure relief devices. This use condition also requires that fittings for refrigerant

[1] Designates a standard from SAE International, formerly the Society of Automotive Engineers.

containers of 20 lbs or greater will be consistent with SAE J2844 (same fittings as for low-side service port in SAE J639).

The second use condition requires the manufacturer of MVAC systems and vehicles (*i.e.,* the original equipment manufacturer [OEM]) to conduct and keep records of a risk assessment and failure Failure Mode and Effects Analysis (FMEA) for at least three years from the date of creation. There is an existing industry standard, SAE J1739, that gives guidance on how to do this. It is standard industry practice to perform the FMEA and to keep it on file while the vehicle is in production and for several years afterwards (U.S. EPA, 2010a).

Reasons for Revised Use Conditions

EPA proposed five use conditions in the Notice of Proposed Rulemaking (NPRM) (October 19, 2009; 74 FR 53445). One use condition required manufacturers to meet all the safety requirements in the standard SAE J639, "Safety Standards for Motor Vehicle Refrigerant Vapor Compression Systems" and required use of unique servicing fittings from that standard. Another use condition required automobile manufacturers to perform Failure Mode and Effect Analysis (FMEA) and to keep records of the FMEA.

The remaining three proposed use conditions specifically addressed risks of flammability of HFO–1234yf and indirectly addressed risks of generating hydrogen fluoride (HF) from combustion of HFO–1234yf. For the first of those proposed use conditions, which addressed the passenger compartment, the concentration of HFO–1234yf was not to exceed the lower flammability limit (LFL) in the free space for more than 15 seconds. For the second proposed use condition, which addressed the engine compartment, the concentration of HFO–1234yf was not to exceed the LFL for any period of time. A third proposed use condition, which also addressed the engine compartment, would have required protective devices, isolation and/or ventilation techniques in areas where there is a potential to generate HFO–1234yf concentrations at or above 6.2% volume to volume (v/v) in proximity to exhaust manifold surfaces and hybrid or electric vehicle electric power sources.

EPA based our determination of the appropriate use conditions to include in the final rule using information in the docket at the time of proposal, comments received on the proposed rule, and additional information we have received since the NPRM was published. We provided additional opportunities for comment on the public comments and additional information we received with them when we re-opened the comment period on the proposed rule (74 FR 68558, December 28, 2009; 75 FR 6338, February 9, 2010). First, SAE International's Cooperative Research Program (hereafter called the SAE CRP) issued a new report on December 17, 2009 assessing risks of HFO–1234yf and carbon dioxide (CO_2) as refrigerants for MVAC. This report found that the risks of HFO–1234yf were low overall, and somewhat less than risks for another potential alternative refrigerant (CO_2, also know as R–744). The December 2009 CRP report found that the greatest risks from HFO–1234yf are likely to come from generation of HF, both from thermal decomposition and from ignition, rather than direct fire risks from ignition of HFO–1234yf (EPA–HQ–OAR–2006–0664–0056.2). (HF is a severe irritant to the skin, eyes, and respiratory system.) The SAE CRP estimates risks of excessive HF exposure at approximately 4.6×10^{-12} occurrences per vehicle operating hour and risks of ignition at approximately 9×10^{-14} occurrences per vehicle operating hour. These correspond roughly to one occurrence in the entire U.S. fleet of passenger vehicles over 2 years for HF risks and one occurrence in the U.S. vehicle fleet every 100 years for flammability risks.[2] For comparison, the risk for excessive HF exposure is less than one ten-thousandth the risk of a highway vehicle fire and one fortieth or less of the risk of a fatality from deployment of an airbag during a vehicle collision (EPA–HQ–OAR–2008–0664–0056.2). Even these estimates may be conservative because they assume that refrigerant could be released in a collision severe enough to rupture the evaporator (under the windshield) while the windshield and windows would remain intact and would prevent ventilation into the passenger cabin in case of a collision (EPA–HQ–OAR–2006–0664–0056.2).

Second, we received a number of public comments regarding the proposed use conditions. Some commenters claimed that the second use condition concerning concentrations in the engine compartment was infeasible because in the event of a leak, there would always be some small volume that would have a concentration over the LFL; these commenters further stated that exceeding the LFL would not necessarily create a risk of ignition, because one could have a leak that is not near a source of heat or flame (EPA–HQ–OAR–2006–0664–0116.2; EPA–HQ–OAR–2006–0664–0060). Some commenters stated that flammability was not a significant risk from use of HFO–1234yf, given the results of the SAE CRP risk assessment (December 17, 2009). These commenters stated that the use conditions limiting refrigerant concentrations were not necessary. These commenters also suggested a number of alternative ways of phrasing the use conditions in order to address risks from HF as well as flammability. Most of these comments suggested relying on the performance of a risk assessment and Failure Mode and Effect Analysis (FMEA) consistent with SAE J1739 to determine appropriate protective strategies. Other commenters stated that the use conditions were not sufficiently protective as proposed because of other risks: (1) Risks due to generation of HF from HFO–1234yf, both from thermal decomposition and from combustion; (2) risks from direct toxicity of HFO–1234yf; and (3) risks from flammability of HFO–1234yf because the LFL becomes lower than 6.2% at temperatures higher than 21 °C (EPA–HQ–OAR–2006–0664–0088, –0054, –0089, –0097 and –0057).

After evaluating the comments and the additional information made available to the public through the re-opened comment period, we have decided not to include the three use conditions that directly address flammability in the final rule. We believe these use conditions are not necessary to ensure that overall risks to human health and the environment from HFO–1234yf will be similar to or less than those of other available or potentially available refrigerants that EPA has already listed or proposed as acceptable for MVAC. This is because of the low overall levels of risk identified for HFO–1234yf from flammability and from ignition of HF (EPA–HQ–OAR–2008–0664–0056.2). The highest risk identified for HFO–1234yf is potential consumer exposure to HF from decomposition and ignition, which is of the same order of magnitude of risks of HF from the current most common automotive refrigerant, hydrofluorocarbon (HFC)–134a[3] (order of magnitude of 10^{-12} events per vehicle operating hour). EPA previously

[2] Assumes a fleet of approximately 250 million passenger vehicles and typical vehicle operation of 500 hours per year. Sources: U.S. Census, *http://www.census.gov/compendia/statab/2010/tables/10s1060.pdf;* SAE J2766, as cited in EPA–HQ–OAR–2008–0664–0056.2.

[3] HFC–134a is also known as 1,1,1,2-tetrafluoroethane or, when used as a refrigerant, R–134a. The Chemical Abstracts Service Registry Number (CAS Reg. No.) is 811–97–2.

found HFC–134a acceptable for use in new and retrofit MVAC systems (59 FR 13044; March 18, 1994; and 60 FR 31092, June 13, 1995), without use conditions addressing risks of HF. Since that time, EPA has heard of no cases where someone has been injured due to exposure to HF from decomposition of HFC–134a from an MVAC system, and a risk assessment from the SAE CRP found no published reports in the medical literature of injuries to fire fighters or vehicle passengers from HF or other decomposition products of HFC–134a (EPA–HQ–OAR–2008–0664–0008). The direct risk of flammability from HFO–1234yf is extremely small. Further, the risks of HFO–1234yf are comparable to or less than the risks from other available or potentially available alternatives in this end-use that EPA has already listed or proposed as acceptable (*e.g.,* HFC–152a,[4] HFC–134a, and CO_2) (EPA–HQ–OAR–2008–0664–0086.1).

We have concluded that the use conditions we are including in the final rule address the risks from both HF and flammability. Industry standard SAE J639 (adopted 2011) provides for a pressure relief device designed to minimize direct impingement of the refrigerant and oil on hot surfaces and for design of the refrigerant circuit and connections to avoid refrigerant entering the passenger cabin. These conditions will mitigate risks of HF generation and ignition. The pressure release device ensures that pressure in the system will not reach an unsafe level that might cause an uncontrolled, explosive leak of refrigerant, such as if the air conditioning system is overcharged. The pressure release device will reduce the likelihood that refrigerant leaks would reach hot surfaces that might lead to either ignition or formation of HF. Designing the refrigerant circuit and connections to avoid refrigerant entering the passenger cabin ensures that if there is a leak, the refrigerant is unlikely to enter the passenger cabin. Keeping refrigerant out of the passenger cabin minimizes the possibility that there would be sufficient levels of refrigerant to reach flammable concentrations or that HF would be formed and transported where passengers might be exposed.

The last proposed use condition, requiring manufacturers to conduct and keep records of FMEA according to the standard SAE J1739, remains unchanged.

The proposed use condition regarding conducting and keeping records of a Failure Mode and Effects Analysis according to the standard SAE J1739 remains unchanged. We have revised the remaining proposed use condition by replacing the reference to SAE J639 (adopted 2009) with a reference to the 2011 version of the standard and to the fittings for large refrigerant containers in SAE J2844 (2011). This is the most recent version of the SAE J639 standard, with new provisions designed specifically to address use of HFO–1234yf.

V. Why is EPA finding HFO–1234yf acceptable subject to use conditions?

EPA is finding HFO–1234yf acceptable subject to use conditions because the use conditions are necessary to ensure that use of HFO–1234yf will not have a significantly greater overall impact on human health and the environment than other available or potentially available substitutes for CFC–12 in MVAC systems. Examples of other substitutes that EPA has already found acceptable subject to use conditions for use in MVAC include HFC–134a and HFC–152a. HFC–134a is the alternative most widely used in MVAC systems today. EPA has also proposed to find CO_2 (R–744) acceptable subject to use conditions in MVAC (September 14, 2006; 71 FR 55140).

All alternatives listed as acceptable for use in MVAC systems in passenger cars and light-duty trucks are required to have unique fittings under use conditions issued previously under the SNAP Program at appendix D to subpart G of 40 CFR part 82 (61 FR 54040, October 16, 1996). Thus, all substitutes for use in MVAC systems in passenger cars and light-duty trucks are subject to those use conditions, at a minimum, if found acceptable and thus are identified as acceptable subject to use conditions. For HFO–1234yf, the unique fittings that must be used for MVAC systems are those required in the industry standard SAE J639 (2011). The fitting for refrigerant containers of 20 lbs or larger is specified in SAE J2844 (2011). The original submitter of HFO–1234yf to the SNAP program has provided EPA with a copy of and a diagram for these unique fittings. As described above, the fittings will be quick-connect fittings, different from those for any other refrigerant. The low-side service port and connections with containers of 20 lbs or greater will have an outside diameter of 14 mm (0.551 inches) and the high-side service port will have an outside diameter of 17 mm (0.669 inches), both accurate to within 2 mm. The submitter has not provided, and the SAE standards do not include, unique fittings for use with small refrigerant containers or can taps.[5] Thus, the final use conditions do not allow use of small containers for servicing MVAC systems.

In addition to the use conditions regarding unique fittings, which apply under appendix D to subpart G of 40 CFR part 82, EPA is requiring use conditions for the safe design of new MVAC systems using HFO–1234yf, consistent with standards of the automotive industry (*e.g.,* SAE J1739, SAE J639). These use conditions are intended to ensure that new cars and light-duty trucks that have MVAC systems that use HFO–1234yf are specifically designed to minimize release of the refrigerant into the passenger cabin or onto hot surfaces that might result in ignition or in generation of HF. The industry standard SAE J1739 gives guidelines on designing vehicles to address these risks.

Cost and Availability

EPA received initial estimates of the anticipated cost of HFO–1234yf from the manufacturer, claimed as confidential business information, as part of the initial SNAP submission (EPA–HQ–OAR–2008–0664–0013 and –0013.1). Initial publicly available estimates on the cost of HFO–1234yf were for approximately $40–60/pound (Weissler, 2008). The first automobile manufacturer to announce its commitment to use HFO–1234yf as a refrigerant has confirmed that the prices in its long-term purchase contracts are in the range that EPA considered at the time of proposal (Sciance, 2010).

In May 2010, two major chemical manufacturers, including the original submitter, issued a press release, committing to building a "world-scale manufacturing facility" to produce HFO–1234yf (EPA–HQ–OAR–2008–0664–0128.1). The same manufacturers have committed to providing HFO–1234yf in time to meet requirements of a European Union directive to use only refrigerants with GWP less than 150 in new automobile designs starting in 2011.

Environmental Impacts

EPA finds that HFO–1234yf does not pose significantly greater risk to the environment than the other substitutes that are currently or potentially

[4] HFC–152a is also known as 1,1-difluoroethane or, when used as a refrigerant, R–152a. The CAS Reg. No. is 75–37–6.

[5] The SAE J639 standard specifies unique fittings for high-side and low-side service ports and the manufacturer of HFO–1234yf supports these fittings. The unique fitting for large containers for use in servicing by professionals (*e.g.,* 20 or 30 lbs) is the same as the fitting for the low-side service port in SAE J639 and is also specified in SAE J2844, "R–1234yf New Refrigerant Purity and Container Requirements Used in Mobile Air-Conditioning Systems." (U.S. EPA, 2010b)

available. In at least one aspect, HFO–1234yf is significantly better for the environment than other alternatives currently found acceptable subject to use conditions. HFO–1234yf has a hundred-year time horizon (100-yr) global warming potential (GWP) of 4 (Nielsen *et al.,* 2007; Papadimitriou *et al.,* 2007), compared to a GWP of 124 for HFC–152a, and a GWP of 1430 for HFC–134a (IPCC, 2007). CO_2, another substitute currently under review in this end-use, has a GWP of 1, which is lower, but comparable to the GWP of HFO–1234yf. Information on the schedule for EPA's final rulemaking on CO_2 as a substitute in MVAC, RIN 2060–AM54, is available in EPA's regulatory agenda at *http://www.reginfo.gov/public/do/eAgendaMain.* A number of other refrigerant blends containing HFCs or HCFCs have been found acceptable subject to use conditions in MVAC that have higher GWPs in the range of 1000 to 2400, such as R–426A, R–414A, R–414B, R–416A, and R–420A. Further, HFO–1234yf has no ozone depletion potential (EPA–HQ–OAR–2008–0664–0013), comparable to CO_2, HFC–152a, and HFC–134a, and has less risk of ozone depletion than all refrigerant blends containing HCFCs that EPA previously found acceptable subject to use conditions for MVAC systems.

EPA also considered the aggregate environmental impact of all anticipated emissions of HFO–1234yf, both for the proposed rule and for this final rule. We performed a conservative analysis that assumed widespread use of HFO–1234yf as the primary refrigerant for MVAC, as well as for other refrigeration and air conditioning uses that were not included in the manufacturer's original submission (ICF, 2009; ICF, 2010a,b,c,e). Thus, we believe that actual environmental impacts are likely to be less than those we considered, either at the proposal or final stage.

Under Clean Air Act regulations (*see* 40 CFR 51.100(s)) addressing the development of State implementation plans (SIPs) to attain and maintain the national ambient air quality standards, HFO–1234yf is considered a volatile organic compound (VOC). Available information indicates that HFO–1234yf has greater photochemical reactivity than HFC–134a, which is exempt from the definition of "VOC" in 40 CFR 51.100(s). Some of the other acceptable substitutes in the MVAC end-use contain VOCs, such as R–406A, R–414A, R–414B, and R–426A. VOCs can contribute to ground-level ozone (smog) formation. For purposes of State plans to address ground-level ozone, EPA has exempted VOCs with negligible photochemical reactivity from regulation (40 CFR 51.100(s)). The manufacturer of HFO–1234yf has submitted a petition to EPA requesting that the chemical be exempted from regulation as a VOC, based on a claim that it has maximum incremental reactivity comparable to that of ethane (EPA–HQ–OAR–2008–0664–0116.1). Separate from this action, EPA is reviewing that request and plans to issue a proposed rule to address it. Information on the schedule for EPA's proposed rulemaking for exemption from regulation as a VOC for HFO–1234yf, RIN 2060–AQ38, is available in EPA's regulatory agenda at *http://www.reginfo.gov/public/do/eAgendaMain.*

Regardless of whether EPA determines to exempt HFO–1234yf from regulation as a VOC for State planning purposes, other analyses available in the docket during the public comment period indicated that the additional contribution to ground-level ozone due to a widespread switch to HFO–1234yf is likely to be around 0.01% or less of all VOC emissions, based on the formation of reactive breakdown products such as OH^- (Luecken *et al.,* 2009). Since issuing the NPRM, we performed an additional analysis that finds a worst-case increase in the Los Angeles region of 0.00080 ppm, or a contribution of only 0.1% of the 1997 8-hour standard for ground-level ozone of 0.08 ppm (ICF, 2010b). Our initial analysis at the proposal stage had estimated a maximum increase in ozone of 1.4 to 4.0% of the standard in the same region (ICF, 2009). The major difference between the 2009 and the 2010 versions of this analysis involved modeling of atmospheric chemistry. The 2010 study was based on the kinetics and decomposition products predicted for HFO–1234yf, rather than using the oxidation of sulfur dioxide (SO_2) as a proxy for decomposition of HFO–1234yf as was done in the 2009 study. The 2010 analysis used updated baseline emission estimates that were 1.5% higher to 5.8% lower than those in the 2009 analysis,[6] depending on the year analyzed (ICF, 2010e). We also evaluated environmental impacts based on alternative emissions estimates from a peer-reviewed journal article provided during the public comment period (Papasavva *et al.,* 2009);[7] these values ranged from 26.3% to 51.1% lower than EPA's estimates in the 2009 analysis (ICF, 2009; ICF, 2010c).

Another potential environmental impact of HFO–1234yf is its atmospheric decomposition to trifluoroacetic acid (TFA, CF_3COOH). TFA is a strong acid that may accumulate on soil, on plants, and in aquatic ecosystems over time and that may have the potential to adversely impact plants, animals, and ecosystems. Other fluorinated compounds also decompose into TFA, including HFC–134a. However, the amount of TFA produced from HFO–1234yf in MVAC is estimated to be at least double that of current natural and artificial sources of TFA in rainfall (Luecken *et al.,* 2009). An initial analysis performed for EPA at the proposal stage found that, with highly conservative emission estimates, TFA concentrations in rainwater could be as high as 1.8 mg/L for the maximum monthly concentration for the Los Angeles area and would be no higher than 0.23 mg/L on an annual basis, compared to a no observed adverse effect concentration of 1 mg/L for the most sensitive plant species (ICF, 2009). This analysis concluded, "Projected levels of TFA in rainwater should not result in a significant risk of ecotoxicity." A more recent analysis by Luecken *et al* (2009) that became available during the initial public comment period reached the conclusion that emissions of HFO–1234yf from MVAC could produce TFA concentrations in rainwater of 1/800th to 1/80th the no-observed adverse effect level (NOAEL) for the most sensitive algae species expected (Luecken *et al.,* 2009). The conclusions in the Luecken study are supported by additional analyses that have become available since we issued the proposed rule. A study from the National Institute of Advanced Industrial Science and Technology (AIST) in Japan, which became available during the re-opened comment period, estimated that concentrations of TFA in surface water would be approximately twice the level in rainwater (Kajihara *et al.,* 2010). This study found that this higher level in surface water would be roughly 1/80th

[6] These changes in estimates reflect ongoing updates to EPA's Vintaging Model, a model that considers industry trends in different end-uses that historically have used ODS.

[7] Analyzed scenarios considered HFO–1234yf emissions from MVAC and from both MVAC systems and stationary air conditioning and refrigeration systems. The analysis also considered scenarios with typical emissions from MVAC systems during the entire year similar to those from current MVAC systems using HFC–134a and another scenario with reduced emissions of HFO–1234yf of approximately 50 g/yr per vehicle, in line with emissions estimates in a study by Papasavva *et al.* (2009) (EPA–HQ–OAR–2008–0664–0114.1). Major differences between the data sources include assumptions of a lower leak rate (5.6% of charge vs. 8% of charge) and a lower annualized rate of leaks during servicing (3.2% of charge vs. 10% of charge) for the Papasavva *et al.* paper compared to assumptions in EPA's Vintaging Model (ICF 2010a).

the NOAEL for the most sensitive algae species, even with assumptions of high emissions levels (*i.e.,* assuming that all types of refrigeration and AC equipment currently using HFCs or HCFCs, not just MVAC systems, would use HFO–1234yf). Kajihara *et al.* (2010) evaluated scenarios specific to Japan, with emissions of approximately 15,172 ton/yr in 2050, compared to a maximum of 64,324 metric tons/yr in 2050 in ICF, 2009 or a maximum of 24,715 metric tons/yr in 2017 in Luecken *et al* (2009). All three studies noted the potential for accumulation in closed aquatic systems.

As we developed the proposed rule, the data we relied on indicated that in the worst case, the highest monthly TFA concentrations in the area with the highest expected emissions, the Los Angeles area, could exceed the no observed adverse effect concentration for the most sensitive plant species, but annual values would never exceed that value. Further, TFA concentrations would never approach levels of concern for aquatic animals (ICF, 2009). In a more recent analysis, ICF (2010a, b, c, e) performed modeling for EPA using the kinetics and decomposition products predicted specifically for HFO–1234yf and considered revised emission estimates that were slightly lower than in a 2009 analysis (ICF, 2009). The revised analysis found a maximum projected concentration of TFA in rainwater of approximately 1,700 ng/L, roughly one-thousandth of the estimate from our 2009 analysis (ICF, 2010b). This maximum concentration is roughly 34% higher than the 1,264 ng/L reported by Luecken *et al.* (2009), reflecting the higher emission estimates we used (ICF, 2010b). A maximum concentration of 1700 ng/L corresponds to roughly 1/600th of the NOAEL for the most sensitive algae species—thus, it is not a level of concern. We find these additional analyses confirm that the projected maximum TFA concentration in rainwater and in surface waters should not result in a significant risk of aquatic toxicity, consistent with our original proposal.

Human Health and Safety Impacts

Occupational risks could occur during the manufacture of the refrigerant, initial installation of the refrigerant into the MVAC system at the car assembly plant, servicing of the MVAC system, or final disposition of the MVAC system (*i.e.,* recycling or disposal). Consumer risks could occur to drivers or riders in the passenger compartment. Risks of exposure to consumers could also occur if they purchase HFO–1234yf and attempt to install or service the MVAC system without proper training or use of refrigerant recovery equipment. In addition, members of the general public, consumers, and first-responders could face risks in the case of a vehicle accident that is severe enough to release the refrigerant.

To evaluate these potential human health and safety impacts, we considered EPA's own risk assessments (EPA–HQ–OAR–2008–0664–0036 and –0038), as well as detailed risk assessments with fault-tree analysis from the SAE CRP for HFO–1234yf and CO_2 (EPA–HQ–OAR–2008–0664–0008 and –0056.2), and scientific data provided in public comments on the topics of health and safety risks.[8] Health and safety risks that we evaluated included direct toxicity of HFO–1234yf, both long-term and short-term; toxicity of HF formed through thermal decomposition or combustion of HFO–1234yf; and flammability of HFO–1234yf.

Occupational Risks

For long-term occupational exposure to HFO–1234yf, EPA compared worker exposures to a workplace exposure limit of 250 ppm[9] over an 8-hour time-weighted average. For short-term occupational exposure to HFO–1234yf, we compared worker exposure to an acute exposure limit of 98,211 ppm, divided by a margin of exposure of 30, for a value of 3270 ppm over 30 minutes.[10,11]

Section 609 of the Clean Air Act requires technicians servicing MVAC systems for consideration (*e.g.,* receiving money, credit, or services in exchange for their work) to use approved refrigerant recycling equipment properly and to have proper training and certification. Therefore, we expect that professional technicians have the proper equipment and knowledge to minimize their risks due to exposure to refrigerant from an MVAC system. Thus, we found that worker exposure would be low. Further, EPA intends to pursue a future rulemaking under Section 609 of the CAA to apply also to HFO–1234yf (*e.g.,* servicing practices, certification requirements for recovery and recycling equipment intended for use with MVACs using HFO–1234yf, any potential changes to the rules for training and testing technicians, and recordkeeping requirements for service facilities and for refrigerant retailers). If workers service MVAC systems using certified refrigerant recovery equipment after receiving training and testing, exposure levels to HFO–1234yf are estimated to be on the order of 4 to 8.5 ppm on an 8-hour time-weighted average (as compared with a 250 ppm workplace exposure limit) and 122 ppm on a 30-minute average (as compared with a short-term exposure level of 98,211 ppm/[margin of exposure of 30] or 3270 ppm). (EPA–HQ–OAR–2008–0664–0036; EPA–HQ–OAR–2008–0664–

[8] On September 30, 2010, we received a final report from the German Federal Environment Agency (UBA) with additional information from testing of HFO–1234yf's potential for flammability and for generating hydrogen fluoride. Although this comment was received too late in the rulemaking process for us to analyze it in depth, our preliminary review found that the procedures they used contain many unrealistic provisions that are not relevant to our decision and in some tests did not provide proper controls (*e.g.,* lacking a comparison to HFC–134a under the same conditions). Concerning flammability risk, the results do not vary significantly from those we are relying on for the final rule. Thus, our preliminary review of the UBA test procedures and results does not suggest that we should re-evaluate our decision to find HFO–1234yf acceptable subject to use conditions.

[9] This was based on a NOAEL of 4000 ppm from the study, "An Inhalation Prenatal Developmental Toxicity Study of HFO–1234yf (2,3,3,3-Tetrafluoropropene) in Rabbits," EPA–HQ–OAR–2008–0664–0041. We used a factor of 1.9 to account for differences in blood concentrations between animals and humans, and a margin of exposure or collective uncertainty factor of 30. Uncertainty factors of 3 were assigned for animal to human extrapolation, and 10 for variability within the human population. The long-term workplace exposure limit was calculated as follows: 4000 ppm (animal exposure) × 1.9 (ratio of estimated human exposure/animal exposure) × ⅓ (UF for animal to human extrapolation) × ⅒ (UF for variability within the human population) exposure) = 250 ppm. This value was compared against 8-hour average concentrations. *See* EPA–HQ–OAR–2008–0664–0036 and EPA–HQ–OAR–2008–0664–0038.

[10] This was based on a NOAEL of 51,690 ppm from the study, "Sub-acute (2-week) Inhalation Toxicity Study with HFO–1234yf in rats," EPA–HQ–OAR–2008–0664–0020 through-0020.4, a factor of 1.9 to account for differences in blood concentrations between animals and humans and a margin of exposure or collective uncertainty factor of 30. Uncertainty factors of 3 were assigned for animal to human extrapolation, and 10 for variability within the human population. The short-term workplace exposure value was calculated as follows: 51,690 ppm (animal exposure) × 1.9 (ratio of estimated human exposure/animal exposure) = 98,211 ppm This value was then divided by the expected exposure in each scenario, and compared against the target margin of exposure of 30. *See* EPA–HQ–OAR–2008–0664–0036 and EPA–HQ–OAR–2008–0664–0038.

[11] For comparison, the SAE CRP used exposure limits of 500 ppm over 8 hours and 115,000 ppm over 30 minutes to evaluate risks for these same time periods. These are based on the 8-hr Workplace Environmental Exposure Limit (WEEL) for HFO–1234yf and for short-term exposure, assuming a NOAEL of approximately 405,800 ppm from the study, "Acute (4-hour) inhalation toxicity study with HFO–1234yf in rats." Note that EPA disagrees with the finding that the acute inhalation toxicity study found a NOAEL. We consider this study to show adverse effects at all levels because of the presence of grey discoloration in the lungs of the test animals. In order to ensure sufficient protection, EPA's risk assessment used a NOAEL from a subacute study instead of a LOAEL from an acute study.

0038). We also analyzed exposure levels during manufacture and final disposition at vehicle end-of-life, and found that they would be no higher than 28 ppm on a 15-minute average or 8.5 ppm on an 8-hour time-weighted average (EPA–HQ–OAR–2008–0664–0038). Therefore, the manufacture, use, and disposal or recycling of HFO–1234yf are not expected to present a toxicity risk to workers.

We did not analyze the risk of generation of HF in the workplace. In its December 17, 2009 *Risk Assessment for Alternative Refrigerants HFO–1234yf and R–744 (CO_2)*, the SAE CRP indicated that "service technicians will be knowledgeable about the potential for HF generation and will immediately move away from the area when they perceive the irritancy of HF prior to being exposed above a health-based limit" (EPA–HQ–OAR–2008–0664–0056.2). Since there is a similar potential to form HF from other MVAC refrigerants that have been used for years, such as CFC–12 or HFC–134a, it is reasonable to assume that service technicians, recyclers, and disposers will handle HFO–1234yf similarly and that use of HFO–1234yf does not pose a significantly greater risk in the workplace with regard to HF generation than the use of those other refrigerants.

In that same report, the SAE CRP also discussed qualitatively the risks for emergency responders, such as firefighters or ambulance workers that respond in case of a vehicle fire or collision. With regard to risk of fire, the CRP report stated that "Due to the low burning velocity of HFO–1234yf, ignition of the refrigerant will not contribute substantially to a pre-existing fire" (EPA–HQ–OAR–2008–0664–0056.2). EPA considers this reasonable, given a burning velocity for HFO–1234yf of only 1.5 cm/s. This is more than an order of magnitude less than the burning velocity of gasoline, which is approximately 42 cm/s (Ceviz and Yuksel, 2005). Concerning first responder exposure to HF, the SAE CRP stated, "Professional first responders also have training in chemical hazards and possess appropriate gear which will prevent them from receiving HF exposures above health-based limits" (EPA–HQ–OAR–2008–0664–0056.2). We agree with this assessment. Other MVAC refrigerants containing fluorine such as CFC–12, which was historically used, and HFC–134a, which is the predominant refrigerant currently in use, also can produce HF due to thermal decomposition or combustion, and smoke and other toxic chemicals are likely to be present in case of an automotive fire (CRP, 2008). Therefore, it is reasonable to expect that first responders are prepared for the presence of HF and other toxic chemicals when approaching a burning vehicle and that they will wear appropriate personal protective equipment.

EPA's risk screen for HFO–1234yf evaluated flammability risks, including occupational risks. Modeling of concentrations of HFO–1234yf in workplace situations such as at equipment manufacture and during disposal or recycling at vehicle end-of-life found short-term, 15-minute concentrations of 28 ppm or less—far below the lower flammability limit (LFL) of 6.2% by volume (62,000 ppm) (EPA–HQ–OAR–2008–0664–0038). The SAE CRP's risk assessments evaluated flammability risks by comparing concentrations of HFO–1234yf with the LFL of 6.2%. The SAE CRP conducted Computational Fluid Dynamics (CFD) modeling of exposure levels in case of a leak in a system in a service shop. The SAE CRP's earlier February 26, 2008 risk assessment found that a leaked concentration of HFO–1234yf exceeded the LFL only in the most conservative simulation, with the largest refrigerant leak and with all air being recirculated within the passenger cabin (EPA–HQ–OAR–2008–0664–0010). Updated CFD modeling performed for the December, 2010 SAE CRP risk assessment found that concentrations of HFO–1234yf sometimes exceeded the LFL, but only within ten centimeters of the leak or less (EPA–HQ–OAR–2008–0664–0056.2). The risk assessment found the risk of this occupational exposure scenario to be on the order of 10^{-26} cases per working hour. We note that HFO–1234yf is less flammable and results in a less energetic flame than a number of fluids that motor vehicle service technicians and recyclers or disposers deal with on a regular basis, such as oil, anti-freeze, transmission fluid, and gasoline. HFO–1234yf is also less flammable than HFC–152a, a substitute that we have already found acceptable for new MVAC systems subject to use conditions. Thus, EPA finds that the risks of flammability in the workplace from HFO–1234yf are similar to or lower than the risk posed by currently available substitutes when the use conditions are met.

Consumer Exposure

EPA's review of consumer risks from toxicity of HFO–1234yf indicated that potential consumer (passenger) exposure from a refrigerant leak into the passenger compartment of a vehicle is not expected to present an unreasonable risk (EPA–HQ–OAR–2008–0664–0036, EPA–HQ–OAR–2008–0664–0038). However, consumer exposure from filling, servicing, or maintaining MVAC systems may cause exposures at high enough concentrations to warrant concern. Specifically, this risk may be due to a lack of professional training and due to refrigerant handling or containment without the use of refrigerant recovery equipment certified in accordance with the regulations promulgated under CAA Section 609 and codified at subpart B of 40 CFR part 82. Consumer filling, servicing, or maintaining of MVAC systems may cause exposures at high enough concentrations to warrant concern (EPA–HQ–OAR–2008–0664–0036). However, this rule does not specifically allow for use of HFO–1234yf in consumer filling, servicing, or maintenance of MVAC systems. The manufacturer's submission specifically addressed HFO–1234yf as a refrigerant for use by OEMs and by professional technicians (EPA–HQ–OAR–2008–0664–0013.1).

The use conditions in this final rule provide for unique service fittings relevant to OEMs and to professional technicians (*i.e.,* unique fittings for the high-pressure side and for the low-pressure side of the MVAC system and unique fittings for large cylinders of 20 lb or more). EPA would require additional information on consumer risk and a set of unique fittings from the refrigerant manufacturer for use with small cans or containers of HFO–1234yf before we would be able to issue a revised rule that allows for consumer filling, servicing, or maintenance of MVAC systems with HFO–1234yf.

EPA has issued a significant new use rule (SNUR) under the authority of TSCA (October 27, 2010; 75 FR 65987). Under 40 CFR part 721, EPA may issue a SNUR where the Agency determines that activities other than those described in the premanufacture notice may result in significant changes in human exposures or environmental release levels and that concern exists about the substance's health or environmental effects. Manufacturers, importers and processors of substances subject to a SNUR must notify EPA at least 90 days before beginning any designated significant new use through a significant new use notice (SNUN). EPA has 90 days from the date of submission of a SNUN to decide whether the new use "may present an unreasonable risk" to human health or the environment. If the Agency does not determine that the new use "may present an unreasonable risk," the submitter would be allowed to engage in the use, with or without certain restrictions. The significant new

uses identified in the SNUR for HFO–1234yf are: (1) Use other than as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles; (2) commercial use other than in new passenger cars and vehicles in which the charging of motor vehicle air conditioning systems with HFO–1234yf was done by the motor vehicle OEM; and (3) distribution in commerce of products intended for use by a consumer for the purposes of servicing, maintenance and disposal involving HFO–1234yf.

Under existing regulations in appendix D to subpart G of 40 CFR part 82, "A refrigerant may only be used with the fittings and can taps specifically intended for that refrigerant and designed by the manufacturer of the refrigerant. Using a refrigerant with a fitting designed by anyone else, even if it is different from fittings used with other refrigerants, is a violation of this use condition." The manufacturer and submitter for HFO–1234yf has provided unique fittings for the high-pressure side and for the low-pressure side of the MVAC system and for large cylinders for professional use (typically 20 lb or more [12]). Therefore, until the manufacturer provides unique fittings to EPA's SNAP Program for use with can taps or other small containers for consumer use and until EPA publishes a final rule identifying such unique fittings, it would be a violation of the use condition in appendix D to use HFO–1234yf in small cans or containers for MVAC. Before issuing a rule allowing use of HFO–1234yf with fittings for small cans or containers for MVAC, we would first need to conclude through either review under TSCA or under the SNAP program that use of these smaller canisters would not pose an unreasonable risk to consumers.

In our review of consumer risks from HFO–1234yf, we considered information concerning consumer exposure to HF from thermal decomposition or combustion of HFO–1234yf. EPA's analysis at the time of the proposed rule focused on the flammability risk to consumers, which at the time we believed to be a significant risk in its own right, as well as a way to prevent consumer exposure to HF from combustion of HFO–1234yf. However, in preparing our proposal, we had available and did consider the SAE CRP's 2008 evaluation of scenarios that might cause consumer or occupational exposure to HF (CRP, 2008). This report stated:

> Decomposition of HFO–1234yf in a fire scenario might, in theory, pose a significant acute health risk to passengers or firemen. But in the event of a fire, other toxic chemicals will be produced by combustion of other automotive components and thus decomposition of the refrigerant may increase the risk for fire fighters and would not introduce an entirely new type of hazard. It is also anticipated that only a small portion of the refrigerant charge will be converted to these decomposition products. In U.S. EPA's assessment of risk of R–152a and CO_2 (R–744), the agency cited a study by Southwestern Laboratories which indicated that a 100% R–134a atmosphere only produced an HF concentration of 10 ppm when passed through a tube heated to 1,000 °F (Blackwell *et al.,* 2006). A search of the medical literature also did not reveal any published reports of injuries to fire fighters or vehicle passengers resulting from exposures to COF_2 or HF produced in fires involving refrigerants. (EPA–HQ–OAR–2008–0664–0008, p. 67)

After the SAE CRP's 2008 evaluation, SAE CRP members conducted tests to measure HF concentrations and to identify factors that were most likely to lead to HF formation (EPA–HQ–OAR–2008–0664–0056.2). One test on HF concentrations inside a car cabin found maximum concentrations were in the range of 0 to 35 ppm in trials both with HFO–1234yf and with HFC–134a, with concentrations dropping to 10 ppm or less after 10 minutes. In a second test of HF generated in the engine compartment, HF concentrations from thermal decomposition of HFO–1234yf reached as high as 120 ppm in the engine compartment in the worst case, with interior passenger cabin values of 40 to 80 ppm. Under the same extreme conditions (flash ignition, temperature of 700 °C, closed hood), HF concentrations from thermal decomposition of HFC–134a reached 36.1 ppm in the engine compartment with interior passenger cabin values of 2 to 8 ppm. The other trials with less extreme conditions found HF concentrations from HFO–1234yf in the engine compartment of 0 to 8 ppm.

The SAE CRP selected an Acute Exposure Guideline Limit (AEGL)−2 of 95 ppm over 10 minutes as its criterion for determining toxicity risk from HF.[13] Thus, even assuming levels inside a passenger compartment reached the highest level that occurred during the tests—80 ppm—a passenger inside a vehicle would at worst experience discomfort and irritation, rather than any permanent effects. HF levels that could result in similar effects were also observed for HFC–134a. The SAE CRP concluded that the probability of such a worst-case event is on the order of 10^{-12} occurrences per operating hour [14] (EPA–HQ–OAR–2008–0664–0056.2). This level of risk is similar to the current level of risk of HF generated from HFC–134a (EPA–HQ–OAR–2008–0664–0086.1). To date, EPA is unaware of any reports of consumers affected by HF generated by HFC–134a, which has been used in automobile MVAC systems across the industry since 1993. Thus, we do not expect there will be a significant risk of HF exposure to consumers from HFO–1234yf.

Depending on the charge size of an HFO–1234yf MVAC system, which may range from as little as 400 grams to as much as 1600 grams (ICF, 2008), it is possible in a worst case scenario to reach a flammable concentration of HFO–1234yf inside the passenger compartment. This could occur in the case of a collision that ruptures the evaporator in the absence of a switch or other engineering mitigation device to prevent flow of high concentrations of the refrigerant into the passenger compartment, provided that the windows and windshield remain intact. As stated in the SAE CRP, ignition of the refrigerant once in the passenger cabin is unlikely (probability on the order of 10^{-14} occurrences per operating hour) because the only causes of ignition within the passenger cabin with sufficient energy to ignite the refrigerant would be use of a butane lighter (EPA–OAR–2008–0664–0056.2). If a passenger were in a collision, or in an emergency situation, it is unlikely that they would choose to operate a butane lighter in the passenger cabin. Additionally, it is unlikely ignition would occur from a flame from another part of the vehicle because automobiles are constructed to seal off the passenger compartment with a firewall. If a collision breached the passenger compartment such that a flame from another part of the vehicle could reach it, that breach would also create ventilation that would lower the refrigerant concentration below the

[12] EPA has issued lists of approved unique fittings for refrigerants in MVAC (*see http://www.epa.gov/ozone/snap/refrigerants/fittlist.html*). These have been issued for the high-side service port, low-side service port, 30-lb cylinders (that is, the most typical size container for use in professional servicing), and small cans (containers typically used by consumers). The label "30-lb cylinders" is not intended to restrict the existence of other container sizes that professional service technicians might use (*e.g.,* 50 lb, 20 lb, 10 lb).

[13] The AEGL–2 is defined as "the airborne concentration of a substance * * * above which it is predicted that the general population, including susceptible individuals could experience irreversible or other serious, long lasting adverse effects or an impaired ability to escape." *http://www.epa.gov/oppt/aegl/pubs/define.htm.*

[14] If we assume 250 million passenger vehicles in the U.S. and typical driving times of 500 hours per year per vehicle, a risk of 4.6×10^{-12} per operating hour equates roughly to one event every 2 years for all drivers in the entire U.S.

lower flammability limit. Similarly, if either a window or the windshield were broken in the collision, the ventilation created would lower the refrigerant concentration below the lower flammability limit. Therefore, EPA finds that flammability risks of HFO–1234yf to passengers inside a vehicle will be low. Further, these risks are likely to be less than those from HFC–152a, another flammable refrigerant that EPA has previously found acceptable subject to use conditions, because HFC–152a has a lower LFL and a lower minimum ignition energy than HFO–1234yf (EPA–HQ–OAR–2008–0664–0008, –0013.4, –0056.2).

Overall Conclusion

EPA finds that the use of HFO–1234yf in new passenger vehicle and light-duty truck MVAC systems, subject to the use conditions being adopted in the final rule, does not present a significantly greater risk to human health and the environment compared to the currently-approved MVAC alternatives or as compared to CO_2, which has been proposed for approval in this end-use.

VI. What is the relationship between this SNAP rule and other EPA rules?

A. Significant New Use Rule

Under the Toxics Substances Control Act, EPA has issued a Significant New Use Rule (75 FR 65987; October 27, 2010) for 1-propene, 2,3,3,3-tetrafluoro-, which is also known as HFO–1234yf. This rule requires persons who intend to manufacture, import, or process HFO–1234yf for a use that is designated as a significant new use in the final SNUR to submit a SNUN at least 90 days before such activity may occur. EPA has 90 days from the date of submission of a SNUN to decide whether the new use "may present an unreasonable risk" to human health or the environment. If the Agency does not determine that the new use "may present an unreasonable risk," the submitter would be allowed to engage in the use, with or without certain restrictions. The significant new uses identified in the final SNUR and subject to the SNUN requirement are: Use other than as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles; commercial use other than in new passenger cars or vehicles and in which the charging of motor vehicle air conditioning systems with HFO–1234yf was done by the motor vehicle OEM; and distribution in commerce of products intended for use by a consumer for the purpose of servicing, maintenance and disposal involving HFO–1234yf. The health concerns expressed in the final SNUR are based primarily on potential inhalation exposures to consumers during "do-it-yourself" servicing, as well as a number of other relevant factors.

B. Rules Under Sections 609 and 608 of the Clean Air Act

Section 609 of the CAA establishes standards and requirements regarding servicing of MVAC systems. These requirements include training and certification of any person that services MVAC systems for consideration,[15] as well as standards for certification of equipment for refrigerant recovery and recycling. EPA has issued regulations interpreting this statutory requirement and those regulations are codified at subpart B of 40 CFR part 82. The statutory and regulatory provisions regarding MVAC servicing apply to any refrigerant alternative and are not limited to refrigerants that are also ODS. This final SNAP rule addresses the conditions for safe use of HFO–1234yf in new MVAC systems. Thus, the requirements in this rule apply primarily to OEMs, except for specific requirements for service fittings unique to HFO–1234yf. MVAC end-of-life disposal and recycling specifications are covered under section 608 of the CAA and our regulations issued under that section of the Act.

VII. What is EPA's response to public comments on the proposal?

This section of the preamble summarizes the major comments received on the October 19, 2009 proposed rule, and EPA's responses to those comments. Additional comments are addressed in a response to comments document in docket EPA–HQ–OAR–2008–0664.

A. Acceptability Decision

Comment: Several commenters supported EPA's proposal to find HFO–1234yf an acceptable substitute for CFC–12 in MVACs. These commenters stated that available information indicates that HFO–1234yf will not pose significant health risks or environmental concerns under foreseeable use and leak conditions and that it has a strong potential to reduce greenhouse gas emissions from motor vehicles. Also, these commenters declared that HFO–1234yf's risks were similar to or less than those of other available alternatives, such as HFC–134a, HFC–152a, and CO_2. A commenter referenced the work of the SAE CRP, which concluded that HFO–1234yf can be used safely through established industry practices for vehicle design, engineering, manufacturing, and service.

Other commenters opposed finding HFO–1234yf acceptable or stated that there was insufficient information to support a conclusion. These commenters stated that the risks of HFO–1234yf were greater than those of other available alternatives, such as HFC–134a, CO_2, and hydrocarbons.

Response: For the reasons provided in more detail above, EPA has determined that HFO–1234yf, if used in accordance with the adopted use conditions, can be used safely in MVAC systems in new passenger vehicles and light-duty trucks. The use conditions established by this final rule ensure that the overall risks to human health and the environment are comparable to or less than those of other available or potentially available substitutes, such as HFC–134a, HFC–152a, or CO_2. EPA did not compare the risks to those posed by hydrocarbons since we have not yet received adequate information for hydrocarbons that would allow us to make such a comparison for use in MVAC.[16]

Comment: Some commenters suggested that EPA should consider other substitutes for CFC–12 in MVAC, such as CO_2 or hydrocarbons. An organization representing the automotive industry stated that the risks from using CO_2 in MVAC systems are below the probability of other adverse events which society considers acceptable and are roughly 1.5 orders of magnitude greater than the risks from using HFO–1234yf.

Response: This rule only concerns EPA's decision on the use of HFO–1234yf in new passenger vehicles and light-duty trucks. In a separate action, EPA has proposed to find CO_2 acceptable subject to use conditions as a substitute for CFC–12 in MVAC systems for new motor vehicles (September 16, 2006; 71 FR 55140). Information on the schedule for EPA's final rulemaking on CO_2 as a substitute in MVAC, RIN 2060–AM54, is available in EPA's regulatory agenda at *http://www.reginfo.gov/public/do/eAgendaMain*. We currently have inadequate information on hydrocarbons to consider adding them to the list of substitutes for MVAC. We

[15] Service for consideration means receiving something of worth or value to perform service, whether in money, credit, goods, or services.

[16] EPA previously reviewed two hydrocarbon blends for use in MVAC and found them unacceptable, stating "Flammability is a serious concern. Data have not been submitted to demonstrate that [the hydrocarbon blend] can be used safely in this end-use." Appendixes A and B to subpart G of 40 CFR part 82.

will review additional substitutes if they are submitted with complete and adequate data to allow an evaluation of whether such substitutes may be used safely within the meaning of section 612 of the CAA as compared with other existing or potential substitutes in the MVAC end-use.

B. Use Conditions

Comment: Several commenters stated that the proposed use conditions limiting concentrations of HFO–1234yf below the lower flammability limit are overly stringent or even impossible to meet and are not needed for safe usage. Some automobile manufacturers suggested relying upon established standards and practices, such as SAE protocols and standards, instead of use conditions. Some commenters suggested alternative language for use conditions. Other commenters expressed concern that the proposed use conditions limiting concentrations of HFO–1234yf would preclude the use of HFO–1234yf by any vehicle that is not initially designed to use this refrigerant.

Response: As described above, EPA agrees that the use conditions, as proposed, require modification. In this final rule, we have removed the first three proposed use conditions, which required design to keep refrigerant concentrations below the LFL. *See* section IV of the preamble, "What are the final use conditions and why did EPA finalize these conditions?" for our basis. With respect to the commenter who suggested that the proposed use conditions limiting concentrations of HFO–1234yf below the LFL would not allow use except in systems initially designed to use this refrigerant, we note that this decision is limited to use in new motor vehicles and light-duty trucks. Further, the proposed use conditions limiting refrigerant concentration are not included in the final rule and thus do not have implications for a future decision concerning retrofits.

Comment: One commenter provided test results from the Bundesanstalt für Materialforschung und –prüfung (BAM—Federal Institute for Materials Research and Testing) that tested various mixtures of HFO–1234yf and ethane (EPA–HQ–OAR–2008–0664–0053.3). The commenter stated that the tests show that explosions can occur at HFO–1234yf concentrations below its lower flammability limit (LFL) of 6.2% when minimal amounts of gaseous hydrocarbons are available. This commenter stated that the maximum concentrations of HFO–1234yf allowed under any use condition need to be far below the 6.2% LFL to ensure safety. Other commenters agreed with these concerns. Yet other commenters looked at the same test data and stated that the testing was not relevant to real-world situations in MVAC because it is unlikely that such large amounts of ethane or other gaseous hydrocarbons (0.8–2.4% by volume) would form in a vehicle. One commenter stated that HFO–1234yf reduces the flammability of ethane compared to ethane alone, and that HFO–1234yf reduces flammability of ethane more than CO_2 or argon, substances used as fire suppressants (EPA–HQ–OAR–2008–0664–0115.1).

Response: We do not believe that the BAM testing of the flammability limits of mixtures of HFO–1234yf and ethane is relevant to assessing the risks of HFO–1234yf as a refrigerant in MVAC. Examples of flammable substances in the engine compartment may include compressor oil mixed with the refrigerant, motor oil, cleaners, anti-freeze, transmission fluid, brake fluid, and gasoline. These are typically liquid and there is no evidence that any vapors that might form would include significant amounts of ethane. These fluids typically contain larger molecules with higher boiling points than ethane (*e.g.,* octane, polyalkylene glycol). It seems more likely, as one commenter suggested, that these flammable fluids would ignite before breaking down into concentrations of ethane considered in the BAM testing. Further, the results of the testing are not surprising; based on a scientifically known chemical equilibrium principle known as Le Chatelier's principle—the lower flammability limit of a mixture of two flammable substances falls between the lower flammability limits of the two individual substances. The range of LFLs for flammable mixtures of ethane and refrigerants HFC–134a, HFO–1234yf, and CO_2 is largest for CO_2 and is similar for HFC–134a and HFO–1234yf (Besnard, 1996).

A more relevant test to compare risks for HFO–1234yf and other alternative refrigerants in MVAC is to consider flammability of a mixture of compressor oil and refrigerant, as occurs in MVAC systems. Such testing, conducted as part of the SAE CRP, found that mixtures of HFO–1234yf and 5% oil and HFC–134a and 5% oil both ignited at temperatures higher than what usually occurs in a vehicle (730 °C or higher for HFO–1234yf and 800 °C or higher for HFC–134a).

Furthermore, we note that the final use conditions do not rely on the lower flammability limit. As explained in more detail in sections IV and V of the preamble, "What are the final use conditions and why did EPA finalize these use conditions?" and "Why is EPA finding HFO–1234yf acceptable subject to use conditions?", we believe that the risks from HFO–1234yf and its decomposition products are very small and are comparable to or less than the risks from other acceptable alternatives available or potentially available for use in MVAC systems. The use conditions established in this final rule require manufacturers to design systems to prevent leakage from refrigerant system connections that might enter the passenger cabin, and to minimize impingement of refrigerant and oil onto hot surfaces, as required by SAE J639 (adopted 2011). These use conditions will further reduce already low risks from flammability and HF generation.

Comment: One commenter provided data from a presentation showing that the lower flammability limit of HFO–1234yf decreases as temperature increases. The commenter stated that the proposed LFL of 6.2% may not be conservative enough.

Response: EPA agrees that the LFL decreases as temperature increases. However, for the analysis relied on for the proposed rule, we considered an LFL relevant to the temperatures that might be expected in a collision or leak scenario and that would not be so high as to be a higher risk factor than exposure to HF. The data provided by the commenter show an LFL of 5.7% at 60 °C (140 °F) and an LFL of 5.3% at 100 °C (212 °F). If a passenger were exposed to temperatures this high in the passenger compartment for any extended period of time, he or she would suffer from the heat before there was a risk of the refrigerant igniting. However, after considering the available information, we find it is not necessary to require a concentration of HFO–1234yf below the LFL to address this refrigerant's risks; rather, risks are sufficiently addressed with the final use conditions. As discussed above in section IV of the preamble, "What are the final use conditions and why did EPA finalize these conditions?", we believe that the flammability risks from HFO–1234yf are very small and overall risks from HFO–1234yf are comparable to or less than the risks from other acceptable alternatives used in MVAC. EPA finds that the use conditions in this final rule are sufficient to manage risks of injury or adverse health effects caused by HFO–1234yf.

Comment: Regarding the first proposed use condition that would limit the concentration of HFO–1234yf below the LFL in the passenger cabin, several commenters stated that the risks of refrigerant leaking into the passenger compartment and exceeding the LFL are

very low. Some automobile manufacturers stated that it may not be possible to keep the concentration below the LFL in the event of a collision; however, the commenters said that even if concentrations in the passenger cabin exceeded the LFL, it would be extremely difficult to ignite the refrigerant. Some commenters stated that the engineering strategies that would be necessary to implement the proposed use condition would actually increase overall risk by increasing the risk of conveying smoke and fumes from the engine compartment into the passenger compartment in the event of an accident. Some commenters suggested alternative language for the use condition to give greater flexibility in engineering responses to allow for differences between vehicles.

Response: As discussed above in section IV of the preamble, EPA is not including the proposed use condition requiring that a specific level of refrigerant concentration inside the passenger cabin is not exceeded.

Comment: One commenter suggested that the use conditions for limiting concentrations in the passenger cabin should require the incorporation of engineering strategies and/or devices "such that foreseeable leaks" rising to the specified concentration levels can be avoided. Similarly, the commenter stated that any use condition limiting concentrations in the engine compartment should be limited to "prevention of ignition caused by foreseeable leaks." The commenter noted that EPA did this in a similar use condition in its final SNAP rule for HFC–152a, another flammable refrigerant for MVAC with greater flammability risk. The commenter stated that this would be consistent with safety requirements of the National Highway Traffic Safety Administration (NHTSA) and would ensure that EPA's use conditions are feasible.

Response: As discussed above in section IV of the preamble, EPA is not including the proposed use condition and is not limiting the refrigerant concentration inside the passenger cabin or the engine compartment.

Comment: A number of commenters did not support the proposed use condition on concentrations of HFO–1234yf in hybrid and electric vehicles. One commenter recommended eliminating this use condition, as the SAE CRP risk assessment concludes there are no real world safety risks. Another commenter suggested referring to the SAE or ISO (International Organization for Standardization) standards in place of a specific use condition. One commenter stated that electric terminals on hybrid vehicles are well protected to prevent fires and should not ignite the refrigerant. Another commenter stated that an accident severe enough to cause refrigerant leakage would also result in damage to the duct between the evaporator [in the MVAC system] and the battery pack, preventing an increase in refrigerant concentrations at the battery pack. One commenter stated that it is difficult to establish generic SNAP use conditions for hybrid vehicles, and individual manufacturers need to understand particular design features of their hybrid vehicles to ensure safe refrigerant application.

Three commenters expressed concern for using HFO–1234yf in hybrid and electric vehicles and stated that the use condition is not conservative enough. One commenter stated that the maximum concentrations of HFO–1234yf need to be far below the 6.2% LFL based on new tests done at the Federal Institute for Materials Research and Testing (BAM) and that they are unsure whether or not additional measures can effectively avoid the risk of explosive mixtures. Another commenter stated that HFO–1234yf would raise concerns in the field of battery cooling needed in electric vehicles because flammability and chemical reactions would pose major risks, which could lead to legal consequences for OEMs.

Response: As discussed above in section IV of the preamble, EPA is not including the proposed use condition and is not requiring protective devices, isolation and/or ventilation techniques where levels of refrigerant concentration may exceed the LFL in proximity to exhaust manifold surfaces or near hybrid or electric vehicle power sources. As discussed above, we do not believe that the BAM testing of the flammability limits of mixtures of HFO–1234yf and ethane is relevant to assessing the risks of HFO–1234yf as a refrigerant in MVAC. Based on information provided by OEMs that manufacture hybrid vehicles, we conclude that there will be sufficient protection against fire risk and generation of HF in the engine compartment for hybrid vehicles because they have protective coverings on power sources that will prevent any sparks that might have enough energy to ignite refrigerant and engine surfaces will not be hotter than those in conventional vehicles (EPA–HQ–OAR–2008–0664–0081.1, –0081.2). Further, we agree that it is reasonable to assume that a collision severe enough to release refrigerant from the evaporator (under the windshield) would also release it in a location far enough away from the battery pack to keep refrigerant concentrations at the battery pack below the LFL. CFD modeling performed for the December, 2010 SAE CRP risk assessment found that concentrations of HFO–1234yf only exceeded the LFL within ten centimeters of the leak or less (EPA–HQ–OAR–2008–0664–0056.2), but the battery pack is typically placed more than ten centimeters away from the evaporator. EPA expects that OEMs will include assessment of risks from the exhaust manifold, hybrid power source, and electric vehicle power source as part of the FMEA required under one of the final use conditions in this rule.

Comment: Some commenters responded to EPA's request for comment as to whether the use conditions should apply only when the car ignition is on. These commenters indicated that it is unnecessary for the use conditions on refrigerant concentrations within the passenger compartment to apply while a vehicle's ignition is off because it is unlikely that a collision would occur, that high temperatures would occur, or that refrigerant would enter the passenger cabin when the ignition, and thus the MVAC system, is off. Another commenter stated that it should be mandatory for all electric power sources to be shut off when the ignition is off.

Response: As discussed above in section IV of the preamble, EPA is not including the proposed use conditions that specified a refrigerant concentration not to be exceeded.

Comment: Several commenters stated that the proposed limits on concentrations of HFO–1234yf in the engine compartment cannot be met, even hypothetically, and that imposition of such a use condition would delay or even prevent the use of HFO–1234yf. Other commenters stated that the engineering required to meet the proposed use condition is almost certain to preclude the use of HFO–1234yf by any vehicle that was not initially designed to use this refrigerant.

Response: EPA is not including in the final rule the proposed use condition that sets a specific limit for refrigerant concentrations inside the engine compartment. *See* section IV of the preamble, "What are the final use conditions and why did EPA finalize these conditions?" for further rationale.

Comment: Several commenters agreed with EPA's proposal to require use of unique fittings and a warning label that identify the new refrigerant and restrict the possibility of cross-contamination with other refrigerants. Other commenters suggested that no use

conditions are necessary because established standards and practices would be adequate for safe use of HFO–1234yf.

Response: The use conditions referenced by the commenters were established in a separate final rule, promulgated in 1996, which applies to all refrigerants used in MVAC (*see* appendix D to subpart G of 40 CFR part 82). EPA has not proposed to modify that existing rule for purposes of its acceptability determination for HFO–1234yf. These requirements indicate to technicians the refrigerant they are using and thus help reduce risks to the technician by ensuring that the technician will handle the refrigerant properly. In addition, these use conditions serve to prevent contamination of refrigerant supplies through unintended mixing of different refrigerants. For purposes of meeting that existing regulatory requirement, this final rule specifies use of fittings for the high-pressure side service port, the low-pressure side service port, and for refrigerant containers of 20 pounds or greater. The submitter for HFO–1234yf has provided these fittings to the Agency and they are consistent with the SAE standard J639. In addition, the final rule retains the requirement for a warning label identifying the refrigerant, consistent with SAE J639.

Comment: Some commenters agreed with EPA's proposal to require a high-pressure compressor cut-off switch, as per SAE J639. Another commenter suggested that the compressor cut-off switch would be useful for all systems in which the discharge pressure can reach the burst pressure, not just those systems with pressure relief devices.

Response: EPA is maintaining the requirement that HFO–1234yf MVAC systems must have a high-pressure compressor cut-off switch by requiring compliance with the SAE J639 standard. The SAE J639 standard requires a pressure relief device on the refrigerant high-pressure side of the compressor for all MVAC systems, and so the compressor cut-off switch will be required for all systems, as suggested by the commenter.

Comment: Several commenters supported the requirement for vehicle makers to conduct and maintain FMEAs. Other automobile manufacturers stated that the final SNAP rule finding HFC–152a acceptable as a substitute for CFC–12 in MVAC included this as a comment rather than as a use condition, and suggested that EPA do the same in the final rule for HFO–1234yf. Another commenter stated that FMEAs for each vehicle design are standard industry practice, and so no use condition is required; this commenter provided language for an alternate use condition should EPA choose to specify a use condition for vehicle design.

Response: EPA is retaining the requirement for FMEAs in the final rule as a use condition, rather than simply as an unenforceable comment. In an FMEA, vehicle designers analyze all the ways in which parts of the MVAC system could fail and identify how they will address those risks in design of the system. In addition, keeping records of an FMEA is important to ensuring safe use because it documents that vehicle designers have complied with the safety requirements of this rule. We believe that it is necessary to retain this requirement as a use condition in order to ensure that OEMs are required to analyze and address the risks and to document those efforts such that this analysis is available to demonstrate compliance to EPA in case of an EPA inspection. Information in the FMEAs complements the safety requirements in SAE J639 and is useful for demonstrating compliance. Because the revised SAE J639 standard refers to use of FMEAs more extensively, risk assessment using FMEAs is more critical for HFO–1234yf than it was for HFC–152a

Comment: A commenter requested that EPA specifically allow manufacturers to perform FMEAs according to equivalent standards developed by organizations other than SAE (*e.g.,* the International Organization for Standardization [ISO], the German Institute for Standards [DIN], or the Japan Automobile Manufacturers Association [JAMA]).

Response: We agree that standards from other standard-setting organizations may provide equivalent assurance of safe use. However, we are not aware at this time of any standards that do so. In order to ensure safe use of HFO–1234yf, we would need to review any other standard to ensure that it provides equivalent assurances of safety before allowing its use in place of the SAE standard. An OEM, for example, could petition EPA's SNAP program and provide copies of the other standard for consideration. If we agree that the other standard is equivalent, then we would add it to the use condition on FMEAs through a rulemaking.

Comment: A commenter expressed that EPA's approach to setting use conditions infringes upon the Department of Transportation's motor vehicle safety jurisdiction and that EPA does not have the authority to protect against any fire risk associated with motor vehicles.

Response: As an initial matter, we note that the commenter does not point to any specific legislative authority that supports his claim. Regardless, EPA disagrees with this commenter. Section 612 of the CAA provides that EPA may find substitutes for ODS acceptable if they present less risk to human health and the environment than other substitutes that are currently or potentially available. Congress did not establish any limits on EPA's authority for ensuring that substitutes are not more risky than other substitutes that are available and EPA has consistently interpreted this provision to allow the Agency to establish use conditions to ensure safe use of substitutes. In this case, we find that HFO–1234yf may be used safely, and with risks comparable to or less than those of other available substitutes for CFC–12 in the MVAC end-use, so long as it is used according to the use conditions established by this action. If the commenter were correct that the Department of Transportation (DOT) has sole authority to address safety risks from MVAC systems, in the absence of standards from DOT addressing HFO–1234yf's risks, EPA would need to determine that HFO–1234yf is unacceptable for use in MVACs.

C. Environmental Impacts

1. Ozone Depletion Potential

Comment: Several commenters agreed with EPA's proposed finding that HFO–1234yf would not contribute significantly to stratospheric ozone depletion, and that the ozone depletion potential (ODP) of HFO–1234yf is at or near zero. Two commenters claimed that the ODP of HFO–1234yf should be stated as "zero" instead of "nearly zero," and one commenter requested that EPA clarify that HFO–1234yf has an ODP less than that of HFC–134a.

Other commenters disagreed with EPA's statement that the ODP of HFO–1234yf is at or near zero. One commenter expressed concern that ODS may be used in the HFO–1234yf manufacturing process, or emissions of HFO–1234yf and its by-products from the manufacturing process may break down into gases with ODPs; this commenter advised EPA against listing HFO–1234yf as an acceptable replacement for HFC–134a in MVACs. Another commenter stated that HFO–1234yf requires further investigation since unsaturated HFCs such as HFO–1234yf might break down into gases that are ozone depleting.

Response: It is generally agreed among scientists that substances that contain chlorine, bromine or iodine may have an ozone depletion potential while those that contain only fluorine effectively have no ODP. In particular, this is because the CF_3 radical produced from HFCs has negligible reactivity (Ravishankara *et al.,* 1993); the same radicals would be expected from HFO–1234yf. HFO–1234yf contains no chlorine, bromine, or iodine. Also, the atmospheric lifetime of HFO–1234yf is estimated at only 11 to 12 days (Orkin *et al.,* 1997; Papadimitrou *et al.,* 2007), further reducing the amount of the chemical that could possibly reach the stratosphere. Unsaturated HFCs, such as HFO–1234yf, have at least one double bond or triple bond between two carbon atoms. Double bonds, like those in HFO–1234yf, are less stable than single bonds. A saturated HFC, such as HFC–134a, has only single bonds between atoms of carbon, and is thus more stable. Although HFO–1234yf may be more unstable than HFC–134a, EPA is not aware of any chemical reactions or decomposition pathways that would cause HFO–1234yf or its breakdown products to lead to ozone depletion and the commenter has provided no technical or scientific support for their claims. For purposes of our determination, whether its ODP is zero or nearly zero, we expect HFO–1234yf to have negligible impact on the ozone layer and we are listing it as acceptable, subject to use conditions.

2. Global Warming Potential

Comment: Several commenters agreed with EPA's statement that HFO–1234yf has a global warming potential (GWP) of 4 over a 100-year time horizon. Some commenters noted the potential environmental benefits of having a lower GWP refrigerant available. Other commenters stated that HFO–1234yf would not be a solution to high global warming impacts because of environmental and health impacts of breakdown products, including HF, trifluoroacetic acid (TFA), and aldehydes.

Response: EPA continues to believe that the 100-yr GWP of HFO–1234yf is 4, as supported by the commenters. We further agree with the commenters who state that there will be an environmental benefit if car manufacturers switch to HFO–1234yf from HFC–134a, a refrigerant with a GWP of 1430 relative to CO_2.

We disagree with the commenters who claim that environmental and health impacts of breakdown products are a major cause for concern or will prevent HFO–1234yf from being a useful solution to high global warming impacts. One commenter mentioned concerns about HF in the atmosphere, but HFO–1234yf does not decompose to form significant amounts of HF in the atmosphere. In fact, HFC–134a and HFC–152a result in more HF in the atmosphere than HFO–1234yf because those two compounds decompose to form both COF_2, carbonyl fluoride (and then HF and CO_2) and CF_3COF, trifluoroacetyl fluoride (and then TFA); in contrast, HFO–1234yf favors forming trifluoroacetyl fluoride (and then TFA) and does not decompose to carbonyl fluoride or to HF (ICF, 2010d). For a discussion on the potential human health impacts of HF, *see* sections V and VII.D.3, "Why is EPA finding HFO–1234yf acceptable subject to use conditions?" and "Toxicity of Hydrogen Fluoride."

The fluorinated breakdown product that we have identified of greatest concern is TFA, because of its persistence and potential impacts on aquatic plants. As discussed above in section V and below in section VII.C.5, "Formation of Trifluoroacetic Acid and Ecosystem Impacts," the projected concentrations of TFA, based on a conservative analysis, will be far below the level expected to cause any adverse impacts on aquatic life.

EPA agrees that the breakdown products from the decomposition of HFO–1234yf will include aldehydes, but we disagree that this is a cause for concern. As part of the analysis of the atmospheric breakdown products of HFO–1234yf, we found that worst-case concentrations of formaldehyde would reach 6 to 8 parts per trillion (ppt) on a monthly basis or an average of 3 ppt on an annual average basis, compared to a health-based limit of 8000 ppt,[17] *i.e.*, a level that is roughly 1000 to 2600 times lower than the health-based limit (ICF, 2010d). Acetaldehyde levels would be even lower, with worst-case concentrations of 1.2 ppt and annual average concentrations of 0.23 ppt, compared to a health-based limit of 5000 ppt[18] (ICF, 2010d). As discussed further below in section VII.D.1 of the preamble, "Toxicity of HFO–1234yf," these concentrations are one to three orders of magnitude less than ambient concentrations of formaldehyde and acetaldehyde without the introduction of HFO–1234yf (ICF, 2010d). Thus, aldehydes that would be decomposition products of HFO–1234yf in the atmosphere would not contribute significantly to adverse health effects for people on earth's surface.

Other fluorinated alternatives that are acceptable in the MVAC end-use, HFC–134a and HFC–152a, also create fluorinated breakdown products, and there is not evidence to show that those from HFO–1234yf create significantly more risk for human health or the environment than breakdown products from other alternatives. Thus, even assuming that risks from breakdown products would exist, based on use of HFO–1234yf in the MVAC end-use, we do not believe those risks are greater than the risks posed by other acceptable alternatives.

3. Lifecycle Emissions of HFO–1234yf

Comment: One commenter stated that HFO–1234yf has the best global lifecycle climate performance (LCCP) and lower CO_2 [equivalent] emissions compared to other alternatives. However, another commenter stated that HFO–1234yf has a lower thermodynamic efficiency than HFC–134a and that its use could lead to increases in CO_2 and other air pollutant emissions. The same commenter stated that there is no assurance that automakers would voluntarily add technologies to maintain current levels of MVAC efficiency when using HFO–1234yf.

Response: We note that EPA has chosen to use GWP as the primary metric for climate impact for the SNAP program, while also considering energy efficiency (March 18, 1994; 59 FR 13044). We have not used specific lifecycle metrics such as Total Equivalent Warming Impact (TEWI), Lifecycle Analysis (LCA) or LCCP as metrics for climate impact, since it is not clear that there is agreement in all industrial sectors or end-uses on which of these measures is most appropriate in which situations or how these metrics are to be calculated (SROC, 2005).

The available information on efficiency, LCCP and lifecycle emissions for MVAC does not raise concern that the indirect climate impacts from HFO–1234yf will cause significantly greater impacts on human health and the environment than other available alternatives. Looking at some of the information referenced by the commenters, we learned that:

- Bench testing for the Japan Automobile Manufacturers Association (JAMA) and the Japan

[17] The Agency for Toxic Substances and Disease Registry (ATSDR) has established a chronic inhalation minimal risk level (MRL) of 0.008 ppm (8,000 ppt) for formaldehyde (ICF, 2010d). MRLs are available online at *http://www.atsdr.cdc.gov/mrls/mrls_list.html.*

[18] EPA has established a Reference Concentration (RfC) of 0.005 ppm (5,000 ppt or 0.009 mg/m^3) for acetaldehyde (ICF, 2010d). A summary of EPA's documentation for its risk assessment and RfC derivation for acetaldehyde is available online at *http://www.epa.gov/ncea/iris/subst/0290.htm.*

Auto Parts Industry Association (JAPIA) found a system efficiency (coefficient of performance) for HFO–1234yf that is roughly 96% of that for HFC–134a (JAMA–JAPIA, 2008)
- LCCP analysis conducted by JAMA found that indirect CO_2 equivalent emissions from less efficient fuel usage due to use of the MVAC system were a few percent higher for HFO–1234yf and roughly 20 to 25% higher for CO_2, compared to HFC–134a (JAMA, 2008)
- JAMA's LCCP analysis found that when both direct emissions of refrigerant and indirect emissions from less efficient fuel usage are considered, HFC–134a has higher total climate impact than either HFO–1234yf or CO_2; in hotter climates like Phoenix, Arizona, HFC–134a has higher total climate impact than HFO–1234yf but slightly lower climate impact than CO_2; and in all cases, HFO–1234yf had the lowest total climate impact of the three alternatives. (JAMA, 2008)
- MVAC systems can be designed to improve efficiency through steps such as changing the compressor, sealing the area around the air inlet, changing the thermal expansion valve, improving the efficiency of the internal heat exchanger, adding an oil separator to the compressor, and changing the design of the evaporator. Optimized new MVAC systems using either HFO–1234yf or CO_2 can reduce fuel usage compared to current MVAC systems using HFC–134a. (Benouali *et al.,* 2008; Meyer, 2008; Monforte *et al.,* 2008)

EPA believes that there is good reason to expect that automobile manufacturers will choose to design new cars using more efficient MVAC components and systems than in the past because of recent regulations. The Department of Transportation has issued new regulations raising the Corporate Average Fuel Economy standards for vehicles and EPA has issued new regulations restricting greenhouse gas emissions from light-duty vehicles (75 FR 25324; May 7, 2010). Thus, in order to ensure that their fleets meet these standards, it is highly likely that automobile manufacturers will include MVAC systems optimized for efficiency in future models, regardless of the refrigerant used.

Comment: Concerning an appropriate rate of emissions for estimating environmental impacts of HFO–1234yf, three commenters recommended that EPA use 50 g per vehicle per year total lifecycle emission rate. These commenters cited the work of Wallington *et al.* (2008) and Papasavva *et al.* (2009).[19] Another commenter stated that HFO–1234yf is very likely to have a lower leak rate than HFC–134a, citing data on permeability for both refrigerants.

Response: EPA agrees that the permeability data indicate that regular leakage emissions of HFO–1234yf, which are released slowly through hoses, are likely to be lower than those from HFC–134a. However, this is only a portion of total emissions expected because emissions may also come through irregular leaks due to damage to the MVAC system, refrigerant loss during servicing, and refrigerant loss at the end of vehicle life. In response to the commenters who suggested that we use an annual emission rate of 50 g/vehicle/yr, we reexamined environmental impacts as part of our final environmental analysis (ICF, 2010c) using the recommended 50 g/vehicle/yr value and compared this to the impacts calculated assuming emissions are similar to those from HFC–134a in MVAC, as we did at the time of proposal (closer to 100 g/vehicle/yr). The emission values from using 50 g/vehicle/yr (*i.e.,* values from the Pappasavva *et al.* (2009) study) were 26.3% to 51.1% less than the emission estimates used in our analysis at the time of proposal (ICF, 2009; ICF, 2010a; ICF, 2010c). In either case, as described more fully in section V above and in sections VII.C.4 and VII.C.5, below, the overall environmental impacts on generation of ground-level ozone and of TFA were sufficiently low and the impacts of HFO–1234yf are not significantly greater than those of other available substitutes for MVAC. For further information, *see* the ICF analyses in the docket (ICF, 2010a,b,c,e).

4. Ground-Level Ozone Formation

Comment: Some commenters expressed concern about a potential increase in ground-level ozone of > 1–4% calculated in EPA's initial assessment (ICF, 2009) of environmental impacts of HFO–1234yf. Other commenters stated that HFO–1234yf will not contribute significantly to ground-level ozone. One commenter suggested that EPA provide an updated assessment of the potential contribution of HFO–1234yf to ground-level ozone, considering the additional information provided in public comments (*e.g.,* Luecken *et al.,* 2009 and Wallington *et al.,* 2009).[20]

Response: We proposed that HFO–1234yf would be acceptable, even with a worst-case increase in ground-level ozone of > 1 to 4%. In response to comments, EPA performed a new analysis that (1) used revised estimates of the expected emissions of HFO–1234yf; and (2) used reactions with ozone formation from hydroxyl radicals rather than using sulfur dioxide (SO_2) as a surrogate for the hydroxyl radical, OH , and rather than making assumptions about the relative reactivity of compounds. Our revised analysis (ICF, 2010b) estimates that emissions of HFO–1234yf might cause increases in ground-level ozone of approximately 0.08 ppb or 0.1% of the ozone standard in the worst case, rather than an increase of 1.4 to 4% as determined in our initial analysis (ICF, 2009). This value also agrees with results from Kajihara *et al.,* 2010 and Luecken *et al.,* 2009. This revised analysis provides additional support that HFO–1234yf will not create significant impacts on ground level ozone formation or on local air quality.

Comment: Some commenters disagreed with EPA's statement that HFO–1234yf has a photochemical ozone creation potential (POCP) comparable to that of ethylene (100), while others agreed with this conclusion. One commenter provided a peer reviewed study that estimated the POCP of HFO–1234yf to be 7 (Wallington *et al.,* 2010).

Response: Based on the comments received and additional studies, EPA believes that the initial assessment that assumed a POCP of 100 to 300 is overly conservative. We have revised our initial analysis to incorporate reaction kinetics specific to HFO–1234yf, consistent with Luecken *et al.,* 2009, which avoids making an assumption of POCP. EPA's revised analysis estimates worst-case increases in ground-level ozone formation of approximately 0.1% (ICF, 2010b). Compared to the uncertainty in the sources of emissions, the uncertainty in the measures that localities will take to meet the ozone standard, and the uncertainty in the analysis, a projected worst-case increase in ozone of 0.1% is not significant for purposes of determining that HFO–1234yf poses substantially greater human health or environmental risk than other alternatives. This provides further support for our proposed determination that the conditioned use of HFO–1234yf does not present a

[19] Papasavva *et al.* (2009) includes several sources of emissions of automobile refrigerant, including regular leaks through hoses, irregular leaks, refrigerant loss during servicing, and refrigerant loss at end of vehicle life.

[20] Prepublication version of Wallington *et al.,* 2010 (Docket item EPA–HQ–OAR–2008–0664–0084.2)

significantly larger risk to human health and the environment compared to HFC–134a, and in many cases likely poses less risk. For further information, *see* the analysis of environmental impacts in section V of the preamble, "Why is EPA finding HFO–1234yf acceptable subject to use conditions?" and *see* the analysis in the docket (ICF, 2010b).

Comment: A commenter provided a link to a paper (Carter, 2009) that found the maximum incremental reactivity (MIR) for HFO–1234yf to be about the same as that for ethane. Based on the MIR value for HFO–1234yf, some commenters stated that EPA should find HFO–1234yf to be exempt from the definition of VOC.

Response: (Note: EPA has previously found certain compounds exempt from the definition of "volatile organic compound" [VOC] for purposes of air regulations in State Implementation Plans, 40 CFR 51.100(s), if they have a MIR equal to or less than that of ethane on a mass basis [69 FR 69298, November 29, 2004; 74 FR 29595, June 23, 2009; also *see* interim EPA guidance at 70 FR 54046, September 13, 2005].) In a separate rulemaking process, EPA is considering whether to list HFO–1234yf under 40 CFR 51.100(s) as exempt from the definition of VOC for purposes of air regulations that States may adopt in State Implementation Plans.

5. Formation of Trifluoroacetic Acid and Ecosystem Impacts

Comment: Several commenters agreed with EPA's proposed finding that the projected maximum concentration of TFA in rainwater from degradation of HFO–1234yf does not pose a significant aquatic toxicity risk. Other commenters raised concern about the potential impacts of TFA on biodiversity, ecosystems, and human health. One commenter questioned the sustainability of HFO–1234yf, so long as there are questions remaining about its environmental fate and degradation. One commenter stated that artificial input of TFA into the environment should be avoided because of its toxicity and chemical properties. Another commenter stated that HFO–1234yf poses additional environmental concerns compared to HFC–134a and advised against finding it acceptable while the issue of TFA production is being further researched.

Response: We continue to conclude for purposes of our decision here that the degradation of HFO–1234yf into TFA does not pose a significant risk of aquatic toxicity or ecosystem impacts. All available research indicates that, assuming emissions are no more than twice the current level of emissions from HFC–134a from MVAC, TFA concentrations in surface water and rainwater will be on the order of 1/800th to 1/80th of the no observed adverse effect level (NOAEL) for the most sensitive known alga (Luecken *et al.,* 2009; Kajihara *et al.,* 2010). We have revised our analysis on TFA concentrations using the known reaction kinetics of HFO–1234yf. The revised estimate of the worst-case TFA concentration in rainwater is approximately 1700 ng/L, similar to the concentrations in Luecken *et al.* (2009) of 1260 ng/L and Kajihara *et al.* (2010) of 450 ng/L. We believe this provides a sufficient margin of protection to find that the use of HFO–1234yf in MVAC will not pose significantly greater risks than other available alternatives in this end-use.

Comment: Some commenters stated that further research on TFA is necessary.

Response: EPA has considered additional studies submitted during the public comment period (Luecken *et al.,* 2009; Kajihara *et al.,* 2010) and has performed further analysis on this issue. Luecken *et al.* (2009) predicted through modeling that in the U.S., HFO–1234yf used in MVAC would result in enough TFA to increase its concentration in rainwater to 1/80th to 1/800th of the NOAEL for the most sensitive plant species considered. Kajihara *et al.* (2010) predicted through modeling that in Japan, HFO–1234yf use in all potential refrigeration uses would increase the TFA concentration in surface water to no more than 1/80th of the NOAEL for the most sensitive plant species considered. This study also found that surface water concentrations were roughly twice those in rainwater. Thus, even with highly conservative modeling that also considered accumulation in surface water, the concentrations of TFA are likely to be at least 80 times lower than a level expected to have no impact on the most sensitive aquatic species.

We also performed a further modeling analysis using refined assumptions on emissions and the mechanisms by which HFO–1234yf might break down. We found that the worst-case concentration of TFA would be approximately 1700 ng/L, similar to the concentrations in Luecken *et al.* (2009) of 1260 ng/L and Kajihara *et al.* (2010) of 450 ng/L (ICF, 2010b). These additional studies and analyses indicate even less risk than the studies available at the time of proposal and thus provide further support that TFA emissions from MVAC system will not pose a significant risk of aquatic toxicity or ecosystem impacts.

We also note that EPA has an obligation to act on submissions in a timely manner under the Clean Air Act (§ 612(d)). Given that research to date has not indicated a significant risk, we disagree that the Agency should delay a final decision to await further studies that may be done in the future. If future studies indicate that HFO–1234yf poses a significantly greater environmental risk than we now believe, section 612(d) provides a process for an interested party to petition the Agency to change a listing decision.

Comment: Two commenters stated that EPA's initial modeling (EPA–HQ–OAR–2008–0664–0037) greatly overestimates the local deposition of TFA from oxidation of HFO–1234yf. In particular, one commenter claimed that the modeling's use of the oxidation of SO_2 to sulfate ion, SO_3^-, as a proxy for the oxidation of HFO–1234yf is overly conservative because a large portion of SO_2 is in aerosol form, unlike for HFO–1234yf. This commenter also referred to the impacts found in the peer-reviewed paper by Luecken *et al.* (2009).

Response: EPA agrees that the use of the oxidation of SO_2 to SO_3^- as a proxy for the oxidation of HFO-1234yf likely results in overestimating TFA concentrations. This is because the sulfate particle is a condensation nucleus in the wet deposition process and it has a very high removal efficiency compared to the gas phase process for wet deposition that acts with HFO–1234yf and its decomposition products. Further, TFA forms more slowly from HFO–1234yf than sulfate forms from SO_2 (ICF, 2010b).

We have repeated the modeling using refined assumptions on emissions and the mechanisms by which HFO–1234yf might break down. This revised assessment (ICF, 2010b) found TFA concentrations roughly one-thousandth those in the earlier assessment (1700 ng/L compared to 1,800,000 ng/L in ICF, 2009). This additional research provides stronger support for our conclusion that the degradation of HFO–1234yf into TFA does not pose a significant risk of aquatic toxicity or ecosystem impacts.

Comment: Some commenters disagreed with a statement in the ICF (2009) analysis concerning TFA concentrations in surface waters, that "the exception to this is vernal pools and similar seasonal water bodies that have no significant outflow capacity." These commenters believe that Boutonnet *et al.* (1999) showed that accumulation of trifluoroacetate, a compound closely related to TFA, was rather limited in seasonal water bodies. The commenters also stated that Benesch *et al.* (2002) conducted an

experimental study of the impacts of TFA on vernal pools, in which no impacts were observed.

Response: The statement from ICF, 2009 in context stated:

NOECs [No-observed effect concentrations] were compared to rainwater TFA concentrations because for most water bodies, it is difficult to predict what the actual TFA concentration will be. This is because concentrations of environmental contaminants in most fresh water bodies fluctuate widely due to varying inputs and outputs to most ponds, lakes, and streams. Comparison of NOECs to rainwater concentrations of TFA is actually more conservative because TFA is expected to be diluted in most freshwater bodies. The exception to this is vernal pools and similar seasonal water bodies that have no significant outflow capacity. (ICF, 2009)

We note that the "exception" described in the analysis is an exception to the expectation that TFA will be diluted more in freshwater bodies than in rainwater. We believe that the available evidence confirms that vernal pools do not dilute TFA as much as freshwater bodies with outflow capacity. Modeling by Kajihara *et al.,* 2010 found surface water concentrations were roughly twice those in rainwater. However, even these concentrations were not high enough to be of significant concern for environmental impacts. As noted previously, even the highest levels of TFA concentrations were at least 80 times less than the NOAEL for the most sensitive aquatic species examined.

D. Health and Safety Impacts

1. Toxicity of HFO–1234yf

Comment: Three commenters stated that there are no toxicity concerns with using HFO–1234yf, and two commenters noted that HFO–1234yf is comparable to HFC–134a in terms of human health effects. One commenter also stated that HFO–1234yf does not present a developmental toxicity or lethality risk. Seven commenters stated that there are potential toxicity concerns with use of HFO–1234yf. One commenter cautioned EPA against listing HFO–1234yf as acceptable for use in MVACs on the grounds of increased concerns over developmental effects and other toxic effects on human health.

Response: EPA continues to believe that HFO–1234yf, when used in new MVAC systems in accordance with the use conditions in this final rule, does not result in significantly greater risks to human health than the use of other available or potentially available substitutes, such as HFC–134a or CO_2. The results of most of the toxicity tests for HFO–1234yf either confirmed no observed adverse health effects, or found health effects at similar or higher exposure levels than for HFC–134a. For example, HFC–134a caused cardiac sensitization at 75,000 ppm but HFO–1234yf did not cause cardiac sensitization even at 120,000 ppm, the highest level in the study (NRC, 1996; WIL 2006). NOAELs from subacute exposure were higher for HFO–1234yf than for HFC–134a (NOAELs of 51,690 for HFO–1234yf with no effects seen in the study, compared to 10,000 ppm for HFC–134a with lung lesions and reproductive effects seen at 50,000 ppm [NRC, 1996; TNO, 2005]). No adverse effects were seen at 50,000 ppm or any other level in subchronic (13-week) studies for both HFO–1234yf and HFC–134a (NRC, 1996; TNO, 2007a).

In mutagenicity testing for HFO-1234yf, the two most sensitive of five strains of bacteria showed mutation; however, this screening test for carcinogenic potential is known to have only a weak correlation with carcinogenicity (Parodi *et al.,* 1982; [21] Kirkland *et al.,* 2005 [22]), so a positive result in this test for the two most sensitive strains is not sufficient reason to consider HFO–1234yf to be a significant health risk. Mutagenicity testing for HFC–134a by the same test found no evidence of mutagenicity. Screening for carcinogenic potential in a genomics study did not identify HFO–1234yf as a likely carcinogen (Hamner Institutes, 2007). A two-year cancer assay for HFC–134a did not find evidence of carcinogenicity (NRC, 1996).

EPA considers the results of developmental testing to date to be of some concern, but not a sufficient basis to find HFO–1234yf unacceptable for purposes of this action under the SNAP program. In a developmental study on rats, cases of wavy ribs were seen in some developing fetuses during exposure to HFO–1234yf (TNO 2007b); however, effects on bone formation were also seen for HFC–134a (NRC, 1996). It is not clear if this effect is reversible or not. Interim results from a two-generation reproductive study did not find an association between exposure to HFO–1234yf and skeletal effects. This two-generation reproductive study for HFO–1234yf finds a NOAEL of 5000 ppm for delayed mean time to vaginal opening in F1 females (females in the first generation of offspring). A subacute (28-day) test for HFC–134a (single generation) found a NOAEL of 10,000 ppm for male reproductive effects (NRC, 1996). A developmental test on rabbits exposed to HFO–1234yf did not find effects on the developing fetus. However, some of the mother rabbits in this study died. The reason for the deaths is not known. The data on developmental effects are inconsistent depending on the test performed and the species tested. The development effects observed in the developmental study on rats are not significantly different from the developmental effects observed for HFC–134a. In any case, as discussed above in section V and below in this section, our risk assessments found that HFO–1234yf would likely be used with exposure levels well below those of concern in the uses allowed under this rule. Thus, we do not find the observed developmental effects sufficient reason for finding HFO–1234yf unacceptable in this rule.

For purposes of this action, we prepared our risk assessment for long-term exposure using the level at which no deaths or other adverse health effects were seen in the rabbit developmental study—a "no observed adverse effect level" or NOAEL—to ensure that exposed people would be protected. The longer-term, repeated exposure in that study would be the exposure pattern (though not necessarily the exposure level) for a worker using HFO–1234yf on a regular basis or for a consumer exposed in a car due to a long, slow leak into the passenger compartment. Using the NOAEL concentration of 4000 ppm as a starting point, we found no situations where we expect exposure to exceed the level that EPA considers safe for long-term or repeated exposure (EPA–HQ–OAR–2008–0664–0036). Thus, we consider the potential toxicity risks of HFO–1234yf for those uses allowed under this action to be addressed sufficiently to list it as acceptable subject to use conditions.

Comment: Based on a risk assessment conducted by one commenter, the commenter concluded that if HFO–1234yf is used under the conditions specified in the commenter's risk assessment, adverse health impacts would not be expected to car occupants, to servicing personnel, or to do-it-yourself (DIY) consumers. This commenter noted differences between the margin-of-exposure approach to

[21] Predictive ability of the autoradiographic repair assay in rat liver cells compared with the Ames test; S. Parodi; M. Taningher; C. Balbi; L. Santi; *Journal of Toxicology and Environmental Health,* Vol. 10, Issue 4 & 5, October 1982, pages 531–539.

[22] Kirkland *et al.* (2005) Evaluation of a battery of three in vitro genotoxicity tests to determine rodent carcinogens and non-carcinogens. I. Sensitivity, specificity and relative predictivity, *Mutation Research,* 584, 1–256.

assessing risk, as in EPA's risk assessment (EPA–HQ–OAR–2008–0664–0036), and the commenter's hazard index (HI) approach. The commenter further stated that in all cases, the predicted hazard index for HFO–1234yf was only one-half of the values predicted for HFC–134a, and in some cases, only one-third of the HFC–134a values, demonstrating from a health perspective that HFO–1234yf is a viable alternative to HFC–134a.

Response: EPA agrees that adverse health impacts would not be expected to car occupants or to servicing personnel, so long as the use conditions of this rule are observed. However, EPA has issued a Significant New Use Rule under TSCA (October 27, 2010; 75 FR 65987) that would require submission of additional information to EPA prior to the manufacture, import or processing of HFO–1234yf for certain uses, including distribution in commerce of products intended for use by a consumer for the purposes of servicing, maintenance and disposal involving HFO–1234yf (*e.g.,* "do-it-yourself" servicing of MVAC systems).

Where available, it is EPA policy to use a NOAEL (No-Observed-Adverse-Effect Level) for the point of departure (POD) for risk assessment. This is the highest exposure level that did not cause an adverse health effect in a study. In this case, EPA selected the POD from an animal (rat 2-week inhalation) study. Because animals may respond to different exposure levels than humans, there is some uncertainty when extrapolating from animals to humans. For this reason, an Uncertainty Factor (UF) is applied when extrapolating from animals to humans—typically a factor of 10 is used but, in this case, since there was a reasonable estimate of the pharmacokinetic component of the uncertainty, this UF was reduced to 3. An additional UF is applied to account for variation in the human population response to a chemical exposure—in this case, a UF of 10 was used. The two UFs give a resultant UF of 30 to yield an acceptable level of health risk. As stated in the final SNUR, EPA's policy for review of new chemicals under TSCA is to divide the POD by the exposure level to obtain the MOE. For HFO–1234yf, the "acceptable level of health risk" would be an MOE of 30 or greater.

The commenter proposed dividing the estimated exposure to HFO–1234yf by the POD levels to obtain a HI. As a result, if the exposure is less than the POD, the HI is < 1 and the commenter considered this an "acceptable level of health risk." The commenter's approach to the hazard index does not factor in uncertainties about extrapolating from animal to human responses, nor does it address variability within the human population with regard to thresholds of response to chemical exposures. EPA has consistently applied the margin of exposure (MOE) approach to evaluations of pre-manufacture notices (and for certain other risk assessments) in order to account for the uncertainties discussed above. The SNAP program considered work performed during evaluation of the pre-manufacture notice (EPA–HQ–OAR–2008–0664–0036), as well as a separate SNAP program risk screen (EPA–HQ–OAR–2008–0664–0038). SNAP program risk screens compare expected exposures to exposure limits that incorporate uncertainty factors based on EPA guidance, rather than calculating either a hazard index or a margin of exposure. Any of these approaches to risk assessment will come to a similar conclusion about whether there is a potential health concern when using the same point of departure, uncertainty factors, and exposure estimates.

The Agency and the commenter disagree on all three of these inputs to the risk assessment and hence have reached different conclusions. Despite these differences, the assessments relied on by both the commenter and EPA show that there is low risk both to car occupants and to service technicians. EPA's risk assessment indicates a potential risk to DIYers (EPA–HQ–OAR–2008–0664–0036). As stated previously in this action, this issue is further addressed through the Agency's authority under TSCA.

Comment: In response to EPA's risk assessment (EPA–HQ–OAR–2008–0664–0036), two commenters disagreed with the use of a 2-week study for evaluating 30 minute exposures and stated that acute toxicity (4-hour test) or cardiac sensitization test results would be more appropriate for acute exposure evaluations.

Response: Commenters have suggested that EPA use data from the 4-hour acute toxicity study or from the cardiac sensitization study as a starting point ("point of departure") for assessing risks of short-term (acute) exposure. However, cardiac sensitization studies are for very short durations—on the order of 10 minutes—and they only address cardiac sensitization. HFO–1234yf does not induce cardiac sensitization. EPA selected the point of departure for acute effects from a multiple-exposure 2-week (subacute) rat inhalation study on HFO–1234yf, reasoning that if no effects were seen in the duration of the study (6 hours per day, 5 days per week for 2 weeks), that no effects would be seen from a single exposure at a similar exposure level, either. Further, the subacute exposure rat study included more thorough pathology examinations than those included in a cardiac sensitization study.

The acute 4-hour exposure study in rats showed some lung effects at approximately 200,000 ppm, the lowest exposure level in the study. Thus EPA considers 200,000 ppm to be a LOAEL (Low-Observed-Adverse-Effect Level). If a LOAEL were used in the risk assessment instead of a NOAEL, EPA would use an uncertainty factor to estimate a NOAEL, which would result in a lower POD than what was used. For example, if EPA had started with the LOAEL of 200,000 ppm, it would have required an additional MOE of 10 to estimate a NOAEL from a LOAEL, for a total MOE of 300 instead of 30. This would have resulted in a more conservative risk assessment than using the NOAEL from the 14-day subacute study. In the 4-hour acute toxicity study, some of the animals had grey, discolored lungs at all exposure levels in the study, and we considered this an adverse effect. Thus, EPA could only determine a lowest observed adverse effect level (LOAEL) from the 4-hour acute study and could not determine a no observed adverse effect level (NOAEL). It is longstanding Agency policy to use the NOAEL where available instead of a LOAEL, because of greater assurance of a safe exposure level. EPA instead used the NOAEL for the next shortest study, the subacute 14-day study, as the endpoint of concern for short term exposure because the LOAEL from the acute 4-hour study is an endpoint showing effects that may not result in safe exposure levels for humans. If we had used the value from the 4-hour acute toxicity study, we would have had to consider additional uncertainty that would have resulted in a more conservative, more restrictive risk assessment than using the NOAEL from the 14-day subacute study.

Further, EPA has uncertainties about using the available single exposure studies on HFO–1234yf to determine the MOEs for different exposure scenarios. As a result of concerns with these studies, EPA calculated single exposure MOEs from the NOAEL in the 2-week inhalation toxicity study of HFO–1234yf in rats. There are some uncertainties in the single exposure (acute) assessments because of the observation of lethality in rabbit dams after multiple exposures to HFO–1234yf in a developmental study. For these reasons, EPA recommended an acute inhalation toxicity study on rabbits in the proposed SNUR to address

the question of whether pregnant rabbits would die from a single exposure (April 2, 2010; 75 FR 16706).

Comment: A commenter asserted that EPA's methodology to estimate the exposure levels associated with the DIY use, using the SAE CRP (2008) Phase II Report, greatly exaggerates the exposure that could be experienced in actual use conditions. Another commenter calculated exposure to a DIYer assuming that the refrigerant fills a garage and concluded that exposure would be less than the manufacturer's recommended exposure limit of 1000 ppm. The first commenter stated that the 30 minute time-weighted average (TWA) value used by the EPA is unrealistic as are the exposure estimates presented in Scenarios 1 and 2 of the supporting document EPA–HQ–OAR–2008–0664–0036. The specific exposure parameters that the commenters questioned were assumptions regarding:

- Garage volume;
- Time the user spent under the hood during recharging operations;
- The size of the space where any leaking gas would disperse;
- The air exchange rate in a service area that should be well-ventilated when the engine is running;
- Use of the refrigerant in a closed garage with no ventilation; and,
- The amount of refrigerant used during recharge operations.

During the comment period for the proposed SNUR, the PMN and SNAP submitter conducted a simulated vehicle service leak testing, using HFC–134a as a surrogate, indicating that exposures from use of a 12-oz can during consumer DIY use are below the Agency's level of concern for HFO–1234yf (Honeywell, 2010a).

Response: Concerning exposure estimates for DIYers, the exposure values in the EPA risk assessment (EPA–HQ–OAR–2008–0664–0036) are bounding estimates of the maximum possible theoretical concentrations. The EPA assessment used the industry-modeled DIY scenarios and assumptions in a 2008 report by Gradient Corporation for the SAE CRP (CRP, 2008) as a starting point for creating the bounding estimates. To do so, EPA assumed that the entire leakage mass of each industry-modeled scenario was released to its corresponding volume with no air exchange. These assumptions are conservative and protective, as intended.

We considered the calculations provided by one commenter that assumed that the refrigerant fills a garage. However, this analysis assumes a longer-term, steady-state concentration after the refrigerant has diffused throughout the garage and uses a long-term, 8-hour time-weighted average exposure recommendation for comparison. EPA's concerns about DIY consumer exposure focuses on short-term acute exposures, including peak exposures over a few minutes near the consumer's mouth and nose because typically a DIY consumer will only need a short period of time to recharge a single MVAC system (Clodic *et al.,* 2008). Thus, the commenter's calculations do not address EPA's concerns.

After reviewing the consumer DIY use exposure study from the SNAP/PMN submitter, EPA responded with a list of clarifying questions (U.S. EPA, 2010c), to which the submitter subsequently responded (Honeywell, 2010b). Although the submitter's responses were helpful, EPA still has concerns about potential exposures to consumers during DIY use and the inherent toxicity of HFO–1234yf. However, since this acceptability determination is limited to use with fittings for large containers, which DIYers would not purchase, our concerns about potential health risk to DIY users need not be addressed in this action. We would plan to evaluate this issue further before taking a final action on a SNAP submission for unique fittings for small containers. We further note that the Agency would analyze this issue in the context of any SNUN filed pursuant to the recently issued SNUR (75 FR 65987). Although we do not reach any conclusion in this final rule regarding safe use by DIYers, we make the following observations about the submitted study. With regards to exposure, the peak concentration values from the submitted study are as high as 3% by volume, equivalent to 30,000 ppm. These peaks appeared to occur in the first one or two minutes of each emission. Accordingly, EPA would need exposure data presented and averaged out over shorter Time Weighted Averages (TWAs) than the 30 minutes currently in the study, because it would appear that a number of these early exposure peaks could result in TWA values that would result in MOEs less than the acceptable Agency level of 30 described above in this section. This is important because the data on HFO–1234yf are insufficient to differentiate whether the toxicity is due to blood level alone from an acute exposure, is due to accumulated exposure over time ("area under the curve"), or is due to some combination of both. Since blood equilibrium levels are reached within minutes, a high level of exposure in a short duration could result in blood levels exceeding a threshold if the mode of action of the toxicity of HFO–1234yf is due to blood levels of the chemical. EPA expects that exposure data with additional TWAs of 3, 5, and 10 minutes would help to resolve these issues of consumer exposure.

Comment: One commenter stated that HFOs could harm the human nervous system. The commenter cited a diagram of breakdown products in a slide presentation given by the Montreal Protocol Scientific Assessment Panel in July 2009 and suggested that the toxic impact of aldehydes formed as breakdown products would be higher than that of carbonic acids.

Response: EPA agrees that the breakdown products from the decomposition of HFO–1234yf will include aldehydes, but we disagree that this is a cause for concern. The aldehydes that would be produced as atmospheric breakdown products of HFO–1234yf are formaldehyde and acetaldehyde (ICF, 2010d). Their health effects include respiratory effects; irritation of the eyes, nose, and throat; and corrosion of the gastrointestinal tract. EPA also considers formaldehyde and acetaldehyde to be probable human carcinogens (U.S. EPA, 2000; ICF, 2010d). The decomposition products of HFO–1234yf are not noted for causing neurotoxic effects, and toxicity tests for HFO–1234yf did not identify this as an effect.

As part of analysis of the atmospheric breakdown products of HFO–1234yf, we found that worst-case concentrations of formaldehyde would reach 6 to 8 parts per trillion (ppt) on a monthly basis or an average of 3 ppt on an annual average basis, compared to a health-based limit of 8000 ppt [23]—*i.e.,* a level that is roughly 1000 to 2600 times lower than the health-based limit (ICF, 2010d). Acetaldehyde levels would be even lower, with worst-case concentrations of 1.2 ppt and annual average concentrations of 0.23 ppt, compared to a health-based limit of 5000 ppt [24] (ICF, 2010d). Thus, aldehydes that would be decomposition products of HFO–1234yf in the atmosphere would not contribute significantly to adverse human health effects (ICF, 2010d).

Aldehydes, including formaldehyde and acetaldehyde, are already present in

[23] The Agency for Toxic Substances and Disease Registry (ATSDR) has established a chronic inhalation minimal risk level (MRL) of 0.008 ppm (8,000 ppt) for formaldehyde (ICF, 2010d). MRLs are available at *http://www.atsdr.cdc.gov/mrls/mrls_list.html.*

[24] EPA has established a Reference Concentration (RfC) of 0.005 ppm (5,000 ppt or 0.009 mg/m^3) for acetaldehyde (ICF, 2010d). A summary of EPA's documentation for its risk assessment and RfC derivation for acetaldehyde is available online at *http://www.epa.gov/ncea/iris/subst/0290.htm.*

the atmosphere in significant amounts from natural sources such as plants, from direct emissions, from combustion products, or from breakdown of other compounds such as hydrocarbons (NRC, 1981; Rhasa and Zellner, 1987). The current background level of formaldehyde in the atmosphere ranges from 80 ppt in pristine areas to approximately 3300 ppt in New York, NY—one to three orders of magnitude more than the worst-case generation of formaldehyde from HFO–1234yf (ICF, 2010d). The maximum incremental acetaldehyde concentration calculated due to use of HFO–1234yf was approximately three orders of magnitude less than the average concentration of acetaldehyde in areas with pristine air quality (ICF, 2010d). Thus, the additional aldehydes created during decomposition of HFO–1234yf in the atmosphere are not likely to have a significant impact on human health.

Comment: Some commenters stated that additional research and review of the available information regarding toxicity of HFO–1234yf needs to be conducted.

Response: EPA has an obligation to act on submissions in a timely manner under the Act (§ 612(d)). Our risk assessments to date have found no significant risk for car passengers or drivers, professional servicing personnel, or workers disposing of or recycling vehicles containing HFO–1234yf. We believe these assessments are sufficient to support this action. We note that these assessments rely on somewhat conservative assumptions.

We note that we expect there will be no toxicity risks to DIYers because EPA must receive and take regulatory action to allow unique fittings for use with small cans of refrigerant before DIYers could be exposed, as per appendix D to subpart G of 40 CFR part 82. Further, because HFO–1234yf is not expected to be introduced into any new cars until late 2011 or later, we expect to have further information and to take further action before DIYers could be exposed. In addition, the final SNUR would not allow distribution in commerce of products intended for use by a consumer for the purposes of servicing, maintenance and disposal involving HFO–1234yf until at least 90 days after submission of a SNUN.

We recognize that more studies will be performed on HFO–1234yf, further addressing risk. EPA's New Chemicals Program has recommended additional testing of acute exposure in rabbits, including pregnant rabbits (April 2, 2010; 75 FR 16706). In addition, the manufacturer is voluntarily conducting a multi-generation reproductive study. If these or other future studies call into question the basis for our decision today, section 612 allows citizens to petition EPA to change or modify a listing decision or EPA could determine on its own to reassess this decision.

Comment: In late comments, a commenter stated that EPA appears to be relying on a SNUR to reduce risks to human health from exposure to HFO–1234yf. This commenter stated that EPA must re-open the comment period on the proposed SNAP rule so that commenters may reassess the extent to which the final restrictions of the SNUR will be effective at limiting adverse human health effects. The same commenter noted that information on new price levels and availability is needed to assess the effectiveness of the SNUR.

Response: EPA's final SNUR addresses potential risks to human health from exposure to HFO–1234yf. However, as discussed above in section V of the preamble, "Why is EPA listing HFO–1234yf as acceptable subject to use conditions?", this final SNAP rule does not allow for the use of HFO–1234yf with small cans or containers (*i.e.,* container sizes that would be purchased by DIY users, such as small cans and containers less than 5 lbs) because it does not contain specifications for unique fittings for can taps and for these smaller containers. Existing SNAP program regulations in appendix D to subpart G of 40 CFR part 82 require the use of unique fittings for specific purposes (*e.g.,* high pressure-side service port, small can taps) for each MVAC refrigerant, as submitted by the refrigerant manufacturer. Before HFO–1234yf can be introduced in small containers typically used by DIYers, the manufacturer must submit unique fittings to EPA, we must conclude that they are unique, and we must issue new proposed and final rules specifying those fittings. In addition, the final SNUR would not allow distribution in commerce of products intended for use by a consumer for the purposes of servicing, maintenance and disposal involving HFO–1234yf until at least 90 days after submission of a SNUN. These and other requirements ensure—to the extent possible, with the information currently available to EPA—that HFO–1234yf has no greater risk overall for human health and the environment than other available refrigerants for MVAC.

Under the final SNUR, it is necessary for EPA to receive and complete its review of a significant new use notice (SNUN) with additional information on consumer exposure risks before—if the Agency so decides—HFO–1234yf may be manufactured, imported or processed for the purpose of use in DIY servicing, with or without other restrictions. We would also consider information in the SNUN before issuing a final rule specifying unique fittings for use with small containers of refrigerant.

In comments EPA received on the proposed SNAP rule, the initial direct final SNUR that was withdrawn and the proposed SNUR, no commenters suggested making the provisions of the SNUR stricter or suggested adding use conditions under the SNAP program for addressing risks to consumers during DIY servicing. A number of commenters stated that no restrictions were needed to address risks to consumers during DIY servicing, while other commenters stated more broadly that EPA should find HFO–1234yf unacceptable because of its toxicity risks. We provided an additional opportunity for comment on the SNAP rule after the direct final SNUR was issued (February 1, 2010; 75 FR 4083), in response to a request to reopen the public comment period (EPA–HQ–OAR–2008–0664–0077.1), in part to allow comment on the relationship between these two rulemakings that both address HFO–1234yf. However, we do not believe that the conditions of the final SNUR are necessary to the determination that we are making here. As noted above, this final rule does not allow for the servicing of HFO–1234yf from container sizes that would be purchased by DIY users because of the lack of an approved unique fitting for smaller containers. Further rulemaking under SNAP will occur prior to such use and any risks can be addressed in that rulemaking package. At that time, we will be able to fully consider the impact of the final SNUR.

2. Flammability

Comment: Five commenters stated that HFO–1234yf has a low likelihood of ignition, especially under the conditions encountered in an automotive application. One commenter stated that the mere presence of high refrigerant concentrations does not contribute to a hazardous condition because an ignition source of sufficient energy must also be present. Another commenter disagreed with EPA's view that a flammability risk exists. Other commenters stated that additional review of the available information regarding flammability of HFO–1234yf needs to be conducted. Some commenters stated that EPA should consider restricting concentrations of HFO–1234yf to much lower concentrations than to the lower flammability limit (LFL) of 6.2%.

Response: The available evidence indicates that HFO–1234yf will not

present a significant risk of flammability and that any risk it poses is not greater than the risk presented by other available alternatives. For example, because of its higher LFL, its considerably higher minimum ignition energy (5000 mJ to 10,000 mJ), and its slower flame speed (1.5 cm/s), HFO–1234yf is less flammable than HFC–152a, a substitute that EPA has already found acceptable subject to use conditions.

Further, an analysis conducted for SAE International's Cooperative Research Program by Gradient Corporation (CRP, 2009) found that there was a very low flammability risk (on order of 10^{-14} occurrences per operating hour or 1 occurrence in 100 years across the entire U.S. fleet of passenger vehicles). This was due to the low probability of achieving a concentration of HFO–1234yf above the LFL at the same time as having a sufficiently high energy source to cause the refrigerant to ignite. Further, even that low probability of ignition of HFO–1234yf may be overstated, because it assumes that a vehicle collision severe enough to crack open the evaporator (located under the windshield and steering wheel) is not severe enough to crack the windshield or windows that would hold refrigerant in the passenger compartment. In a sensitivity analysis, the SAE CRP considered how the flammability risk would change if a refrigerant release into the passenger compartment only occurs in a collision causing damage to more than the MVAC system. That analysis estimated that the risk of exposure to an open flame would then be reduced by a factor of 23,000, to approximately 4×10^{-19} occurrences per vehicle operating hour (EPA–HQ–OAR–2008–0664–0056.2).

For the reasons provided above in sections IV and VII.B of the preamble, "What are the final use conditions and why did EPA finalize these use conditions?" and "Use conditions," EPA does not believe it is necessary to establish a use condition limiting refrigerant concentrations, whether at 6.2% or some other, lower value. We believe the final use conditions sufficiently address flammability risks.

Comment: Three commenters stated that HFO–1234yf is flammable and that the proposed regulation does not offer any restrictions to protect those persons handling HFO–1234yf, nor does it restrict its sale and use by the general public.

Response: The purpose of the use conditions is to ensure that HFO–1234yf will not pose a greater risk to human health or the environment than other available or potentially available substitutes. For all of the reasons provided in sections IV and V above, EPA has determined that HFO–1234yf will not pose a greater risk than other substitutes for MVAC. As explained above, EPA proposed restricting concentrations of the refrigerant below the LFL of 6.2% as a use condition. Based on comments and additional analysis, EPA has concluded that it is not necessary to require use conditions limiting refrigerant concentrations to below the LFL; rather, the use conditions now specify design parameters for MVAC systems and require an FMEA. This will ensure that systems are designed to minimize risk not only from flammability, but also from exposure to HF.

We will address use by service personnel through a rulemaking under section 609 of the CAA. Although these rules will further address issues of interest to service personnel and others that might handle HFO–1234yf used in MVAC systems, we note that our risk assessments of use of HFO–1234yf found that significant flammability risks do not exist for personnel installing the refrigerant at equipment manufacture, professional servicing personnel, and personnel working with automobiles at equipment end-of-life (EPA–HQ–OAR–2008–0664–0036 and –0038). Moreover, we note that an industry-sponsored analysis of risks found the risk of ignition of HFO–1234yf to a technician is extremely small, on the order of 10^{-26} occurrences per working hour (EPA–HQ–OAR–2008–0664–0056.2).

As we have explained above, this rule only addresses the use of large containers for professional use (typically 20 lbs or larger) and thus HFO–1234yf may not be used in small container sizes that would be the type purchased by the general public. We will address the issue of risk to DIY users through a future rulemaking under SNAP if we receive a request for unique fittings for smaller containers from the refrigerant manufacturer. We also are addressing risks to DIY users through the Significant New Use Rule under the Toxic Substances Control Act (October 27, 2010; 75 FR 65987).

Comment: One commenter stated that compared with HFC–134a, the explosion probability of HFO–1234yf is much higher based on testing done at the Federal Institute for Materials Research and Testing (Bundesanstalt für Materialforschung und-prüfung, BAM). Other commenters disagreed with those flammability conclusions, finding the testing results to be expected but not representative of real-world use in MVAC. These commenters stated that the flammability risks of HFO–1234yf were not significant and that the mixtures of HFO–1234yf and ethane used in the testing would not be seen in MVAC in actual operations.

Response: As explained above in section VII.B, we do not believe that these tests are relevant for assessing the flammability risks of HFO–1234yf as used in MVAC systems because they evaluated flammability based on the presence of ethane, a substance that should not be present in any situation that might cause flammability risks for MVAC systems.

3. Toxicity of Hydrogen Fluoride (HF)

Comment: Two commenters stated that there is low risk due to exposure to HF. One of these commenters stated that (1) for vehicles that do not discontinue the use of the blower after collision, the risk due to exposure to HF from use of HFO–1234yf is approximately twice the risk with the current use of HFC–134a, and (2) for vehicles that discontinue the use of the blower after collision, the risk due to exposure to HF when using HFO–1234yf is approximately the same as that with the current use of HFC–134a (on order of 10^{-12} occurrences per operating hour, or one in one trillion). The second commenter stated that there is no need for concentration limits to protect against exposure to HF because the risks from exposure to HF from HFO–1234yf are similar to what would be experienced with HFC–134a. One commenter also stated that concentrations of HF as low as 0.3 ppm cause a sensation of irritation. The commenter stated that this characteristic would deter someone from remaining exposed to excessive concentrations from an open hood.

Other commenters stated that there is a high probability of HF generation in cars from HFO–1234yf. One commenter stated that the flammability of HFO–1234yf makes the production of HF more likely and increases the risk of HF exposure to vehicle passengers, to workers at chemical facilities, automotive manufacturing facilities, vehicle servicing facilities, and to the general public. Two commenters stated that various health and safety concerns related to HF generation and its toxicity are well studied and documented, and three commenters stated that use of HFO–1234yf is unacceptable as there is increased potential for HF exposure and related casualties.

Response: EPA has considered the potential for generation of HF from HFO–1234yf, including the SAE CRP's evaluation of scenarios that might cause workplace and consumer exposure to HF (EPA–HQ–OAR–2008–0664–0056.2). SAE CRP members conducted

tests to measure HF concentrations and to identify factors that were most likely to lead to HF formation. One set of tests conducted in a car found that HF measurements inside the passenger cabin were 35 ppm or less (EPA–HQ–OAR–2008–0664–0056.2). This highest value occurred during release of the entire charge of refrigerant of 1000 g into the passenger cabin with ignition started by a butane lighter augmented with an additional spark—a highly conservative scenario. (A more typical charge would be 575 g, and it would be unlikely to have the amount of ignition energy that occurred artificially in the experiment with use of both a butane lighter and an additional spark source.) A second set of tests focusing on HF in the engine compartment tried to simulate a major rupture in the AC system that would release 12 g/s of refrigerant across 5 cm onto an artificial hot surface at temperatures of 450 °C (typical of the exhaust manifold) and 700 °C (most extreme case), with the car hood in various positions. This testing found HF concentrations as high as 120 ppm at the hot surface in the engine compartment in the worst case, with interior passenger cabin values of 40 to 80 ppm in the worst case (EPA–HQ–OAR–2008–0664–0056.2). This test was conservative for the following reasons: The temperature was high, representing extreme conditions; the refrigerant was released extremely close to the hot surface; the hood was closed; and the refrigerant ignited briefly. The other test trials under less extreme conditions resulted in HF concentrations of a few ppm. The test trials also found somewhat lower concentrations of HF generated during testing of HFC–134a using the same procedures and apparatus, with maximum concentration of 36 ppm in the engine compartment and concentrations of less than 8 ppm in the passenger compartment in the worst case. The SAE CRP selected an Acute Exposure Guideline Limit (AEGL)–2 [25] of 95 ppm over 10 minutes as its criterion for determining excessive risk. This limit was developed to protect against irreversible health effects when exposure remains below the limit of 95 ppm over 10 minutes, but short-term discomfort or irritation could still occur. Thus, even assuming a passenger inside a vehicle was exposed to HF at the highest level found in the test of 80 ppm, exposure at this level would at worst cause discomfort and irritation, rather than permanent or disabling health effects.

For both HFO–1234yf and for HFC–134a, HF concentrations in the passenger compartment fell between the level that would protect against all adverse health effects (AEGL–1 of 1.0 ppm for 10 minutes to 8 hours) and the level that would protect against irreversible or disabling health effects (AEGL–2 of 95 ppm over 10 minutes) (NRC, 2004). The SAE CRP concluded that the probability of such a worst case event is on the order of 10^{-12} occurrences per operating hour (EPA–HQ–OAR–2008–0664–0056.2). Commenters provided information indicating that this level of risk for HF generation is the same order of magnitude for both HFC–134a and for HFO–1234yf. EPA considers the risk level presented by HFO–1234yf to be similar to that of the refrigerant currently being used by automobile manufacturers, HFC–134a. Therefore, there is no reason to regulate HFO–1234yf more stringently to protect against HF exposure than for HFC–134a.

Comment: One commenter stated that testing with HFOs commissioned by the environmental organization Greenpeace in 2001 hinted at a multitude of decomposition products with high reactivity. The commenter stated that apparently even lubricants (polyalkylene glycol—PAG) break down to HF when in contact with HFO–1234yf in a MVAC system. The commenter further expressed that BAM testing showed that burning HFO–1234yf resulted in concentrations of HF greater than 90 ppm in the engine compartment. The commenter concluded that the tests prove that in a standard system with standard charge (900 grams) and oil, the risk for humans would be incalculable.

Response: The commenter has not provided sufficient information on the testing commissioned by Greenpeace in 2001 for the Agency to determine what the results were or whether the testing conditions are relevant to this action. Concerning the BAM testing, EPA has not seen a testing report or a detailed description of the experimental method that allows for a full evaluation. Based on the information provided by the commenter, the temperature of the released substance reached 600 °C and HF concentrations of over 90 ppm were measured in the engine compartment. According to a risk assessment from an automobile manufacturer, such a high temperature is unlikely and could only be achieved on the exhaust manifold under heavy engine loads such as when a vehicle is climbing a hill, and the temperature of the exhaust manifold would drop in a minute or so during deceleration (EPA–HQ–OAR–2008–0664–0081.1). It is not clear what the conditions were for the study mentioned by the commenter. For example, it is not clear if the refrigerant was mixed with compressor oil as it normally would be in an MVAC; inclusion of oil with a relatively low flashpoint would be expected to lead to ignition at lower temperatures (EPA–HQ–OAR–2008–0664–0056.2; EPA–HQ–OAR–2008–0664–0118.1). It also is not clear if the compressor fan was operating during the test. During normal vehicle operation, the fan would cool down the compressor and the engine compartment, avoiding the temperature of 600 °C on hot surfaces in the engine.

Other tests have found that HF concentrations in the engine compartment were approximately 5 ppm or less and only in the worst case (hot surface temperature of 700 °C, closed hood on engine compartment) did HF concentrations attain a value of approximately 120 ppm in the engine compartment (OAR–2008–0664–0056.2). This level is slightly higher than the AEGL–2 of 95 ppm on a 10-minute average and is lower than the AEGL–3 for HF of 170 ppm on a 10-minute average, the value that would protect against life-threatening exposure but would not necessarily prevent long-term health effects. However, we note that we do not anticipate any circumstance where a person would be exposed to these levels in an engine compartment because such conditions would not occur during vehicle servicing, but rather during vehicle operation. Further, in the case of a collision resulting in a fire, we would expect that professional first responders have training in chemical hazards and possess appropriate gear which would prevent them from receiving HF exposures above health-based limits (EPA–HQ–OAR–2008–0664–0056.2) and an interested by-stander would quickly back away from a fire or from irritating HF vapors, thus preventing excessive HF exposure. The concentration measured in the passenger compartment in the same worst-case situation was in the range of 40 to 80 ppm, less than the concentration in the engine compartment and less than the AEGL–2 intended to protect against long-term health effects. Thus, we disagree with the commenter's assertion that HF exposures from thermal decomposition or combustion of refrigerant would be likely to result in fatalities. We further

[25] An AEGL–2 is intended to apply to an emergency situation where someone would try to move away from the hazard in a short period of time and may suffer some temporary irritation, but no permanent health damage. Irreversible or disabling but non-fatal health effects could occur between the AEGL–2 and the higher AEGL–3.

note that the HF concentrations found in the passenger compartment were lower than the health-based limit, the AEGL–2 of 95 ppm over 10 minutes.

We also note that the risks presented by HFO–1234yf are not significantly different than the risk posed by HFC–134a, the refrigerant currently in use in MVAC systems. Mixtures of HFC–134a and compressor oil also combust and generate HF. Testing performed using HFC–134a under worst-case conditions in the engine compartment (hot surface temperature of 700 °C, closed hood on engine compartment) found HF concentrations as high as 36 ppm in the engine compartment and 2 to 8 ppm in the passenger compartment. The amount of HF generated from a typical charge of HFC–134a, if it all burned or decomposed, could be even more than for the expected charge of HFO–1234yf because charge sizes using HFO–1234yf are expected to be smaller (EPA–HQ–OAR–2008–0664–0056.2). The SAE CRP considered potential risks of HF exposure from both HFO–1234yf and from HFC–134a. Both presented potential risks on the order of 10^{-12} occurrences per operating hour (EPA–HQ–OAR–2008–0664–0056.2, –0096.1). This corresponds to less than one case per year across the entire fleet of motor vehicles in the U.S. Although there is no specific testing data on HF production from HFC–152a, another acceptable refrigerant for MVAC, since this compound contains fluorine, it presents risks of HF generation as well. As discussed above in Section IV of the preamble, we are not requiring specific use conditions that regulate production of HF, either directly or indirectly, because of the low level of risk. However, the final use conditions in this rule address the risks of HF production, as well as risks of flammability, by requiring certain design safety features of MVAC systems using HFO–1234yf and by requiring risk analysis for each car model through FMEAs.

Comment: A commenter provided results from a test by IBExU on the decomposition of HFO–1234yf under heat (EPA–HQ–OAR–2008–0664–0053.3). This commenter strongly warned against a decision in favor of HFO–1234yf because it would form highly toxic HF when burning. Three commenters disagreed that the results of the IBExU testing were relevant because test conditions did not represent realistic conditions. One commenter said that the SAE risk assessment, which used actual vehicle test data for HF formation, found that actual HF formation rates are far below the levels [from the IBExU test results] cited by the first commenter, the Federal Environmental Agency (Umweltbundesamt—UBA).

Response: The IBExU testing of HF generation from HFO–1234yf is not relevant to assessing the risks of HFO–1234yf as a refrigerant in MVAC. Laboratory tests concerning the nature of HF generation on hot surfaces found that this depends on the contact time of reactants on the hot surface, the temperature of the hot surface and the movement of refrigerant in diluted concentrations due to airflow (EPA–HQ–OAR–2008–0664–0056.2; EPA–HQ–OAR–2008–0664–0116.2). The IBExU testing involved heating the refrigerant steadily in a sealed flask. Thus, the contact time in that test was far greater than would occur in an engine compartment and the movement of refrigerant in that test was essentially zero, unlike in an engine compartment where there would be constant air movement.

Comment: Another test from BAM reported by UBA examined HF formation from HFO–1234yf and from HFC–134a (EPA–HQ–OAR–2008–0664–0080.1). Fifty grams of refrigerant was streamed through a hole of 2 mm diameter onto a hot metal surface. The study found that pure HFO–1234yf exploded on the hot surface whereas pure HFC–134a did not. The study also found that when HFO–1234yf was mixed with 3% oil, it exploded at 600 °C. The commenter stated that handling of HFO–1234yf in the presence of hot metal surfaces results in HF formation in concentrations far above allowed workplace concentrations.

Response: These results are not consistent with results from hot-plate tests conducted by an automobile manufacturer and by a chemical manufacturer for the SAE CRP (EPA–HQ–OAR–2008–0664–0056.2; EPA–HQ–OAR–2008–0664–0115.1). Those manufacturers found that neither HFO–1234yf nor HFC–134a alone ignited at 900 °C. One of these tests found that HFO–1234yf mixed with PAG oil combusted starting at 730 °C, while HFC–134a mixed with PAG oil ignited at 800 °C and above; the other test observed no ignition of a blend of each refrigerant with PAG oil at 800 °C, but both blends ignited at 900 °C. Based on the lack of reproducibility of the specific ignition temperature, it appears that the specific ignition temperature may depend on variables in the testing (*e.g.,* flash point of the oil used, amount of mixture used, angle of application, and air flow available). This information also shows that mixtures of refrigerant with compressor oil can combust at lower temperatures than pure refrigerant and that mixtures of HFO–1234yf and oil and mixtures of HFC–134a and oil present similar risks of ignition and HF generation. Thus, we concluded that the risks of toxicity from HF exposure due to combustion or decomposition of HFO–1234yf are comparable to those from HFC–134a.

Further, the risks from toxicity of HF posed by both refrigerants are small. The SAE CRP estimates this risk on the order of 10^{-12} cases per operating hour (EPA–HQ–OAR–2008–0664–0086.1). This is equivalent to less than one event per year across the entire fleet of motor vehicles in the U.S. For comparison, this is less than one ten-thousandth the risk of a highway vehicle fire and one fortieth or less of the risk of a fatality from deployment of an airbag during a vehicle collision (EPA–HQ–OAR–2008–0664–0056.2).

E. Retrofit Usage

Comment: Several commenters stated that HFO–1234yf should be allowed initially in new vehicles but should not be used to retrofit vehicles using HFC–134a, or at least not unless there are industry standards to guide such a process. Other commenters stated that it is critical to allow a natural phase-out of the fleet of cars using HFC–134a as the refrigerant, rather than requiring retrofitting existing cars with HFO–1234yf. A commenter expressed concern that retrofitting of HFC–134a MVAC systems with HFO–1234yf would result in cases of cross-contamination of refrigerant, while another commenter contested this statement and found it unsupported. Other commenters opposed obstacles that would prevent older MVACs from being retrofitted to the new refrigerant. These commenters mentioned the potential for greenhouse gas benefits when retrofitting systems currently using HFC–134a with HFO–1234yf.

Response: The submitter did not request review of HFO–1234yf for retrofitting vehicles and thus EPA did not review HFO–1234yf as acceptable (or acceptable subject to use conditions) for retrofitting in MVAC in this rulemaking. Consistent with the request submitted to the Agency, we proposed to find HFO–1234yf acceptable for use subject to use conditions in new MVAC systems and evaluated its risks only for use in new systems. We will consider the retrofit use of HFO–1234yf in MVAC systems if we receive a submission that specifically addresses retrofitting and the risks that are unique to retrofitting. In response to the commenter who raised a concern about a "phase-out" of HFC–134a and the potential that we would "require" use of HFO–1234yf, we

note that our rulemakings under SNAP do not require use of any specific substitute. Rather, under SNAP, we have established lists of substitutes that are acceptable for use in various end-uses (such as for MVACs) and end-users are free to choose which substitute to use, but must do so consistent with any use conditions that apply. As stated in the rule establishing the SNAP program, "The Agency * * * does not want to intercede in the market's choice of available substitutes, unless a substitute has been proposed or is being used that is clearly more harmful to human health and the environment than other alternatives." 59 FR 13046, March 18, 1994. We further note that this rulemaking does not change the status of HFC–134a, which remains an acceptable substitute for use in MVACs, subject to use conditions.

F. Use by "Do-it-Yourselfers"

Comment: Some commenters raised concerns about EPA's statements in the proposed rule about potential health effects that might occur without professional training and the use of CAA Section 609 certified equipment. These commenters stated that the studies and testing in the docket support a finding that use of HFO–1234yf by non-professionals is safe and do not offer valid technical support for EPA's concerns.

Response: EPA's risk assessment and risk screen both indicated that worst-case exposure levels expected during servicing by do-it-yourselfers are of potential concern (EPA–HQ–OAR–2008–0664–0036 and EPA–HQ–OAR–2008–0664–0038). In both documents, this was based upon estimated exposure levels from a 2008 risk assessment by Gradient Corporation for the SAE CRP (EPA–HQ–OAR–2008–0664–0008). In EPA's risk assessment (EPA–HQ–OAR–2008–0664–0036), we found that the level that EPA determined did not cause health effects in laboratory animals might be only 2 to 3 times higher than the exposure predicted for that use (the "margin of exposure"). Our risk assessment indicated a higher, more protective margin of exposure of at least 30 was needed to account for uncertainty in the extrapolation from animals to humans and for variability in the human population. In other words, we found that based on worst-case assumptions, a do-it-yourselfer's exposure could be 10 or more times the level that EPA considered safe. The margin of exposure was calculated using a conservative estimated exposure level of 45,000 ppm over 30 minutes and a human equivalent concentration of 98,211 ppm from a no-observed adverse effect level that we selected as the point of departure for risk assessment (EPA–HQ–OAR–2008–0664–0036).

However, under this final rule, unique fittings have only been submitted for servicing fittings for the high-side and low-side ports and for large containers of HFO–1234yf and thus the acceptability listing is limited to use of HFO–1234yf with the unique fittings specified (*e.g.,* for large containers of 20 pounds or more). We expect these containers would not be purchased by DIYers because of their expense ($800 or more per container) and because they would contain enough refrigerant for 10 charges or more. We will continue to review the issue of safe use for DIYers if and when we are requested to review unique fittings for a smaller container size. In addition, EPA is further addressing the issue of risks to DIYers in the Significant New Use Rule for 1-propene-2,3,3,3-tetrafluoro- (75 FR 65987, October 27, 2010). This SNUR requires submission of a SNUN at least 90 days before sale or distribution of products intended for use by a consumer for the purpose of servicing, maintenance and disposal involving HFO–1234yf.

EPA's proposed rule on the use of HFO–1234yf as a substitute for CFC–12 in new MVAC systems did not propose to establish use conditions for servicing vehicles by certified professionals, but our analyses indicate that there is not significant risk to certified professionals, because HFC–134a, which is currently used in most MVAC systems, presents similar risks and professionals have the knowledge and equipment to mitigate any risks. We plan to further address servicing by professionals when we develop a new rule under section 609 of the Clean Air Act for servicing and maintenance of MVAC systems.

Comment: Some commenters supported prohibiting sale of HFO–1234yf in small containers. Other commenters stated that only certified technicians should be allowed to purchase and use refrigerants, including HFC–134a and HFO–1234yf. Other commenters found no data to support restrictions on the sale of HFO–1234yf to non-professionals.

Response: As noted previously, the submission only addressed unique fittings for large containers (*e.g.,* 20 lbs or larger) of HFO–1234yf. If anyone is interested in using HFO–1234yf in small cans or other small containers, they would need to contact the refrigerant manufacturer to submit unique fittings for approval under the SNAP program. Thus, under this final rule, we believe that only certified technicians will purchase HFO–1234yf because the larger containers are likely to be prohibitively expensive for individuals performing DIY servicing ($800 or more for a 20 lb cylinder) and are likely to be too large for most individuals to use, containing enough refrigerant for 10 or more charges.

We also note that in a separate final rule under the authority of TSCA (October 27, 2010; 75 FR 65987), EPA requires among other things, that notice must be given to EPA 90 days before (1) HFO–1234yf is used commercially other than in new passenger cars and vehicles in which the charging of motor vehicle air conditioning systems with HFO–1234yf was done by the motor vehicle OEM or (2) sale or distribution of products intended for use by a consumer for the purpose of servicing, maintenance and disposal involving HFO–1234yf.

Comment: A commenter stated that banning DIY use of HFO–1234yf will mean that car owners will be forced to have professionals perform service work on their AC systems at a significantly higher cost. This commenter stated that millions of lower-income motorists may be forced to go without air conditioning each year or may seek out lower-cost alternatives such as propane or HFC–152a.

Response: While this final rule effectively prohibits DIY use because the final use conditions do not include unique fittings allowing for use with small refrigerant containers, we are not making any final determination about whether HFO–1234yf may be safely used by DIYers. As we noted above, we have not yet received a submission for DIY use or received unique fittings for small containers from the manufacturer, but would evaluate such submissions when we receive one. We note that because it is unlikely that any cars will have MVAC systems with HFO–1234yf before the 2013 model year, we believe the availability of small containers for DIY use will not be of concern until such cars are sold and there is a need to recharge a new MVAC system on a model year 2013 vehicle. The separate final Significant New Use Rule that the Agency has issued under TSCA (75 FR 65987; October 27, 2010) requires submission of a Significant New Use Notice at least 90 days before sale or distribution of products intended for DIY use.

With respect to the commenter who suggests that some people may seek lower cost alternatives, presumably to repair an existing MVAC, we note that under current EPA regulations in appendix D to subpart G of 40 CFR part 82, it is not legal to top-off the

refrigerant in an MVAC system with a different substitute refrigerant.

G. Servicing Issues

Comment: Several commenters stated that appropriate training and certification should be required to purchase HFO–1234yf for use in MVACs. Four commenters also stated that the final regulation should include a provision requiring proof of certification in order to purchase HFO–1234yf, and recommended that current AC systems tests (*i.e.,* for CAA section 609 certification) be updated.

Some commenters disagreed with EPA's statement that HFO–1234yf may cause serious health effects when used in servicing and maintaining MVACs without professional training. Another commenter stated that EPA is limiting productivity by only allowing dealerships to perform refrigerant maintenance, and that independent MVAC service shops should be allowed to be certified. The commenter also questioned who will monitor "certified" technicians employed by dealerships that may do work on the side. A commenter representing automobile dealerships specifically opposed mandatory requirements for certification of technicians because of potential costs and burden on small businesses.

Response: As background for the public comments, we note that under EPA's regulations implementing section 609, one must be a section 609 certified technician in order to purchase CFC–12 or other ODS for use in MVAC (40 CFR 82.34(b)). Section 609(e) of the CAA itself specifically prohibits sale of small containers less than 20 pounds with Class I or Class II substances suitable for use as a refrigerant in MVAC, except for individuals performing service for consideration in compliance with section 609. However, there is no comparable restriction on the sale of HFC–134a or on other substitutes for MVAC that do not contain Class I or Class II ODS, such as HFO–1234yf.

In the NPRM (74 FR 53449), EPA stated that any specific training and certification requirements would be adopted through a rulemaking under the authority of CAA section 609 and would be codified in subpart B of 40 CFR part 82, which contains the regulations implementing section 609. We will address concerns regarding certification and training requirements during that separate rulemaking process. We note, however, that the CAA itself mandates that persons performing service for consideration that involve the refrigerant must be properly trained and certified. Furthermore, as noted previously, we believe that there is not a significant health risk to professionals from HFO–1234yf because they will have the knowledge and equipment to mitigate any risks. Also, because HFC–134a presents similar risks to HFO–1234yf, and the flammability risks of HFO–1234yf are less than those for HFC–152a, the health risks of HFO–1234yf are not significantly greater than those of other available substitutes.

With regard to whether independent service shops could service MVACs with HFO–1234yf or whether service would be limited to "dealerships," we note that neither this rule nor any other CAA regulation would limit servicing to dealerships. The comment may concern the withdrawn SNUR, 75 FR 4983 (February 1, 2010), which referred to the "original equipment manufacturer"; the commenter may have interpreted this term to mean an automobile dealership. The final SNUR (October 27, 2010; 75 FR 65987) requires a significant new use notice to EPA at least 90 days before "commercial use other than in new passenger cars and vehicles in which the charging of motor vehicle air conditioning systems with the PMN substance [HFO–1234yf] was done by the motor vehicle original equipment manufacturer." This requirement restricts commercial use of HFO–1234yf to use for vehicles that were initially charged with HFO–1234yf by the automobile's manufacturer, as opposed to allowing commercial use of HFO–1234yf for vehicles initially charged with a different refrigerant. The term "original equipment manufacturer" refers to the automobile manufacturer, not to dealerships.

Comment: Commenters indicated that SAE International is developing standards for safety and servicing of alternative refrigerant HFO–1234yf MVAC systems. Another commenter stated that there are appropriate mechanisms within the industry for training. One commenter representing automobile dealerships objected to mandatory Section 609 technician certification and training for use of HFO–1234yf, stating that because dealerships already train technicians on flammable substances in accordance with hazard communication standards of the Occupational Safety and Health Administration (OSHA), and since the risks associated with HFO–1234yf are similar to those that already exist in MVAC service facilities, mandatory training and proof of training is not necessary. To enable training pursuant to the OSHA hazard communication standard, the commenter stated that MVAC system and refrigerant suppliers should provide dealerships with sufficient information on the hazards posed by HFO–1234yf.

Response: EPA is issuing use conditions in this final rule that reference relevant SAE technical standards on safety. This rule does not, however, include a use condition requiring technician training and does not refer to specific training standards. We agree with the commenter that current technician training generally should be sufficient to ensure that professional technicians will use HFO–1234yf safely. Although this SNAP determination does not contain a use condition regarding technician training, as noted above, section 609 of the CAA requires technician training for persons servicing for consideration. EPA will consider in a separate rulemaking under section 609, whether it is necessary to modify our existing regulations under section 609 to include additional specifications for HFO–1234yf.

Comment: A commenter representing automobile dealerships opposed mandatory requirements for recycling and containment of the refrigerant because of potential costs and minimal environmental benefits.

Response: This rulemaking does not impose requirements for recycling or containment of the refrigerant. A separate rulemaking under CAA section 609 will address practices required in the servicing of MVAC systems using HFO–1234yf, including recycling and recovery. Further, EPA notes that Section 608 of the CAA prohibits the intentional release of any refrigerant during the maintenance, repair, service, or disposal of refrigeration and air conditioning equipment, unless the Administrator determines through rulemaking that such release does not pose a threat to the environment. We have not made such a determination for HFO–1234yf.

H. Cost, Availability, and Small Business Impacts

Comment: One late commenter stated that there was insufficient information in the record on the cost, terms of availability and anticipated market share of HFO–1234yf for EPA to make the required statutory findings that HFO–1234yf "reduces the overall risk to human health and the environment" by comparison to other alternatives that are already available. The commenter stated that this information is necessary in order for EPA to assess anticipated environmental effects adequately. The same commenter stated that EPA's environmental analysis is based on price assumptions that were not disclosed and are no longer valid, and thus, EPA should subpoena the

information from the manufacturer and reopen the public comment period.

Response: EPA believes that there was sufficient information in the record at the time of proposal for us to complete a meaningful environmental analysis, even in the absence of definitive cost information. At the time of proposal, we had available both estimates from a trade magazine provided by the manufacturer (Weissler, 2008), as well as estimates of price provided in the initial submission from the manufacturer (EPA–HQ–OAR–2008–0664–0013). The estimates of price provided by the manufacturer were claimed as confidential business information and thus were not available in the record to the public.

We typically use this type of information for purposes of determining market penetration for a particular substance, so that we can evaluate how much of the substitute will likely be used and thus the environmental risks it might pose. In this case, however, because the automobile industry tends to prefer use of a single substitute, information on the cost of the substitute was not critical to our analysis. Thus, in conducting our environmental analysis, we took a conservative approach, assuming that all new MVAC systems began using HFO–1234yf by 2020 (*i.e.,* full market penetration). We also considered an even more conservative scenario, in which HFO–1234yf would be the only refrigerant used for stationary air conditioning and for refrigeration as of 2020, as well as for MVAC. Even with these highly conservative assumptions, we found that there would not be sufficient negative environmental impacts due to emissions of HFO–1234yf to warrant finding it unacceptable.

In the proposal, we mentioned a cost estimate for HFO–1234yf of $40–$60/lb (Weissler, 2008). More recently, the first automobile manufacturer announcing its intention to use HFO–1234yf confirmed that this range does not underestimate prices of HFO–1234yf and is consistent with the manufacturer's long-term purchase contracts (Sciance, 2010). Thus, the most recent information shows costs to be similar to those we considered at the time of proposal. This data contradicts the late commenter's assertion that the manufacturer's effective monopoly would result in significantly different, higher costs that would invalidate EPA's earlier analysis. In any event, assuming that costs were higher as suggested by the commenter, then we expect that use of HFO–1234yf would be less than assumed for our health and environmental risk analysis. As mentioned in the proposal, emissions, and thus the resulting environmental effects such as impacts on local air quality or on production of TFA, would be expected to be less under a scenario with higher prices and less use of HFO–1234yf. Our analysis assumes widespread use and thus its results would be protective.

We note that where a new chemical is introduced, there is some uncertainty in the price. At best, the manufacturer can provide rough estimates of price and of market share before the chemical is produced in commercial quantities and becomes subject to supply and demand pressures. EPA's requirement for information on cost, anticipated availability in the market, and anticipated market share (40 CFR 82.178(a)(14) through (16)) should not be construed as requiring precise, detailed cost estimates based upon a well-defined methodology. As noted above, we use these numbers for the purposes of predicting market penetration and thus how much of a particular substitute might be used and thus pose an environmental risk. As we did for HFO–1234yf, we typically take an environmentally-protective approach to our evaluation, assuming use at least as high as that the cost and availability information may indicate.

Comment: A late commenter stated that the information in the record is insufficient for EPA to make a statutory finding that HFO–1234yf is "currently or potentially available." The commenter stated that a previous decision by the United States Court of Appeals for the District of Columbia Circuit (*Honeywell International, Inc.* v. *EPA,* 374 F.3d 1363 (D.C. Cir. 2004)) implied that an interpretation of the term "available" in CAA section 612(c)(2) could potentially consider economic factors if EPA adopted such an approach as a reasonable interpretation of the statutory language. The commenter states that EPA should obtain information as to the anticipated cost of HFO–1234yf if the manufacturer does not grant licenses to produce.

Response: The CAA does not require that EPA find a substitute to be available or potentially available when finding it acceptable. Section 612(c) states: "* * * It shall be unlawful to replace any class I or class II substance with any substitute substance which the Administrator determines may present adverse effects to human health or the environment, where the Administrator has identified an alternative to such replacement that—reduces the overall risk to human health and the environment; and is currently or potentially available. * * *"

This section makes clear that it is not the substitute under review that must be available or potentially available, but rather alternative replacements for ODS that EPA determines pose less overall risk to human health and the environment than the substitute being reviewed. Thus, if there are alternatives to the substance under review that are currently or potentially available and that pose less risk, EPA cannot find the substitute under review acceptable. Section 612(c) establishes no requirement that EPA must determine that the substitute under review is "available." *See also* 40 CFR 82.180(b) (describing types of listing decisions EPA can make in reviewing substitutes [26]). We note that even if EPA was required to determine that the substitute under review is available or potentially available before it could make an acceptability determination, we believe that the available information supports that HFO–1234yf is potentially available. EPA's definition of "potentially available" at 40 CFR 82.172 provides that "potentially available" is defined as any alternative for which adequate health, safety, and environmental data, as required for the SNAP notification process, exist to make a determination of acceptability, and which the Agency reasonably believes to be technically feasible, even if not all testing has yet been completed and the alternative is not yet produced or sold. This definition makes explicit that it is not necessary to have perfect information on a substitute nor is it necessary for the substitute to be produced or sold in order for EPA to consider it "potentially available." Instead, it is necessary for EPA to find the health, safety and environmental data adequate to make a determination of acceptability, and for the Agency to reasonably believe that the alternative is "technically feasible," in order for the alternative to be potentially available. We believe the record contains adequate information showing that HFO–1234yf

[26] The regulations for the SNAP program include cost and availability as one of the criteria for review as to whether a substitute is acceptable or unacceptable as a replacement for ozone depleting substances (82.180(a)(7)(vii)), along with a number of criteria for different aspects of health and environmental impacts. Cost and availability are included as criteria because they affect assumptions we may make about a substitute regarding its risks, *i.e.,* we need to know its cost and availability so we can make assumptions about the risk it might pose. In this case, we assumed that HFO–1234yf would be used widely across the industry in new MVACs because widespread use of a single refrigerant in new car models has been the industry practice with MVAC systems. Thus, more detail on cost and availability of the substitute was not necessary in order to identify assumptions we should make for estimating risk.

is potentially available. The manufacturer has submitted the information required under 40 CFR 82.178 (*e.g.,* pre-manufacture notice form and TSCA/SNAP addendum form containing: Name and description of the substitute, physical and chemical information, information on ODP and global warming impacts, toxicity data, data on environmental fate and transport, flammability, exposure, cost and estimated production). The submitter has also provided unique fittings as required under appendix D to subpart G of 40 CFR part 82. Thus, we believe that there is "adequate health, safety, and environmental data." Even if the commenter were correct about claims that higher costs would result if the manufacturer does not grant licenses for production, as discussed above, this does not affect the adequacy of the health, safety, and environmental data for HFO–1234yf, because we have protectively assumed widespread use that would result in more emissions and greater environmental impacts. In addition, based on the experimental work conducted by the automobile industry, we reasonably believe that HFO–1234yf is technically feasible as a refrigerant. Thus, HFO–1234yf would still be "potentially available" under the SNAP program's definition.

One commenter points to *Honeywell International, Inc.* v. *EPA,* 374 F.3d 1363 in urging EPA to explicitly include cost as a consideration in determining whether a substitute is "potentially available." In that case, the court vacated and remanded a SNAP decision in which EPA listed a foam blowing substitute as acceptable subject to "narrowed use limits" on the basis that for some niche foam blowing uses, the substitutes that were already listed as acceptable might not be available. Under the narrowed use limits, the end-user would need to demonstrate and document that other substitutes were not technically feasible for a particular use. The court vacated and remanded EPA's rule on the basis that EPA had considered cost in concluding that already listed substitutes might not be available based on "technical" feasibility, and that EPA had not attempted to justify the rule on the ground that the statute allows it to consider economic factors in making its SNAP determinations. The court left open the question of whether EPA could attempt to interpret the term "available" in section 612(c) as allowing for consideration of costs.

Again, we note that "available or potentially available" applies only to the substitutes against which the substitute at issue is being compared. The Agency has not decided whether consideration of the cost of other substitutes should be a factor to consider in determining whether they are available or potentially available and thus should (or should not) be used for comparison to a substitute under review. However, we note that for purposes of the substitute under review, the Agency firmly believes that cost should not be the primary or sole basis for finding a substitute unacceptable. EPA's role is to determine the health and environmental risk associated with the use of substitutes and the market should serve to address the issue of costs. Costs will necessarily be a factor considered by the automobile manufacturers in deciding which substitute to use.

Comment: Two commenters stated that EPA needed to perform further analysis on the potential small business impacts and costs of EPA's regulations and the introduction of HFO–1234yf. A commenter representing recyclers of automobiles and scrap metal expressed concern about the regulatory burden and costs that automotive recyclers are likely to incur if they must manage flammable refrigerants that are regulated as hazardous waste under EPA's regulations implementing the Resource Conservation and Recovery Act (RCRA). The same commenter also suggests that the RCRA subtitle C regulations would need to be changed to alleviate the hazardous-waste management requirements for handling HFO–1234yf. The other commenter mentioned the costs to service and repair shops, end-of-life vehicle recyclers, and automobile dealerships, and stated that EPA needed to analyze costs to these small businesses under the Regulatory Flexibility Act (RFA). This latter commenter stated that EPA should determine if a significant change in price and supply expectations would affect the way that these businesses handle and deal with automobile repairs and recycling.

Response: The RFA applies only when there are small entities subject to the requirements of the proposed or final rule. 5 U.S.C. § 604(a)(3). We believe the potential burden of complying with RCRA regulations placed on those recycling or recovering a substitute is generally not pertinent to a decision of whether HFO–1234yf should be found acceptable under SNAP. To the extent the commenters are suggesting that we must evaluate such costs for purposes of the Regulatory Flexibility Act, we note that under the RFA we evaluate costs imposed by the enforceable regulations being promulgated. To the extent the costs referred to by the commenter are already imposed under RCRA, they would not be new costs, but costs associated with the relevant RCRA regulations. Moreover, under this SNAP final rule, EPA is not requiring the use of HFO–1234yf, and thus the costs associated with its use are not due to enforceable regulatory requirements under SNAP. To the extent there are enforceable requirements for those persons who choose to use this new substitute, those requirements (the "use conditions") apply primarily to manufacturers of automobiles and MVAC systems, because they concern design of MVAC systems. The one use condition of the rule that applies to servicing of MVAC systems, and thus, could apply to small businesses, is the requirement for specific unique service fittings. However, EPA's existing SNAP regulations at appendix D to subpart G of 40 CFR part 82 already require unique service fittings as specified by the refrigerant manufacturer. Thus, the costs of purchasing new unique fittings for this refrigerant are imposed by the pre-existing regulation. This rule specifies the requirements for the type of unique fitting, in accordance with the fittings provided to EPA by the manufacturer. These fittings are part of the SAE J639 standard. It is not clear that there would be any cost differential between these specific unique fittings and others that the automotive industry could adopt instead. For these reasons, EPA is able to certify that this regulation will not create a significant impact on a significant number of small entities.

Regulations concerning disposal of refrigerant from MVAC systems and other refrigerant-containing appliances under section 608 of the CAA are at subpart F of 40 CFR part 82. Cost and benefit estimates for these regulations are at *http://www.regulations.gov*, docket EPA–HQ–OAR–2003–0167. EPA notes that there may be costs of servicing or of disposal (end-of-life) to small businesses under future regulations under section 609 or 608 of the CAA. We will conduct an analysis of such costs, and any potential significant impacts on small entities, as necessary, as part of those future rulemakings.

Comment: A commenter stated that to comply with requirements of the Unfunded Mandates Reform Act (UMRA), EPA needed to perform further analysis on the potential costs of EPA's SNAP regulations for HFO–1234yf to determine if the rule would result in the expenditure of $100 million or more per year by the private sector. In particular, the commenter stated that EPA must obtain more information on pricing and

the effect of the manufacturer's patent to analyze this.

Response: UMRA applies only to "enforceable duties" imposed on State, local, and Tribal governments or on the private sector. The SNAP rule does not impose duties on governments. As we have noted previously, the SNAP program does not mandate the use of any specific substitute for ozone depleting substances. Rather, through this action, we are expanding the choices of MVAC refrigerants available to the private sector. The issue raised by the commenter concerning the cost of the refrigerant and the effect of the manufacturer's patent on pricing is not related to any requirement of the rule, and thus, EPA is not required to consider that cost under UMRA.

VIII. How does the SNAP program work?

A. What are the statutory requirements and authority for the SNAP program?

Section 612 of the Clean Air Act (CAA) requires EPA to develop a program for evaluating alternatives to ozone-depleting substances (ODS). EPA refers to this program as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

1. Rulemaking

Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (*i.e.,* chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, methyl bromide, and hydrobromofluorocarbon) or class II (*i.e.,* hydrochlorofluorocarbon) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

2. Listing of Unacceptable/Acceptable Substitutes

Section 612(c) requires EPA to publish a list of the substitutes unacceptable for specific uses and to publish a corresponding list of acceptable alternatives for specific uses. The list of acceptable substitutes is found at *http://www.epa.gov/ozone/snap/lists/index.html* and the lists of "unacceptable", "acceptable subject to use conditions", and "acceptable subject to narrowed use limits" substitutes are found at subpart G of 40 CFR part 82.

3. Petition Process

Section 612(d) grants the right to any person to petition EPA to add a substance to, or delete a substance from, the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, EPA must publish the revised lists within an additional six months.

4. 90-Day Notification

Section 612(e) directs EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

5. Outreach

Section 612(b)(1) states that the Administrator shall seek to maximize the use of Federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

6. Clearinghouse

Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

B. What are EPA's regulations implementing section 612?

On March 18, 1994, EPA published the original rulemaking (59 FR 13044) which established the process for administering the SNAP program and issued EPA's first lists identifying acceptable and unacceptable substitutes in the major industrial use sectors (subpart G of 40 CFR part 82). These sectors include: Refrigeration and air conditioning; foam blowing; cleaning solvents; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors compose the principal industrial sectors that historically consumed the largest volumes of ODS.

Section 612 of the CAA requires EPA to list as acceptable only those substitutes that do not present a significantly greater risk to human health and the environment as compared with other substitutes that are currently or potentially available.

C. How do the regulations for the SNAP program work?

Under the SNAP regulations, anyone who plans to market or produce a substitute to replace a class I or II ODS in one of the eight major industrial use sectors must provide notice to the Agency, including health and safety information on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative. This requirement applies to the person planning to introduce the substitute into interstate commerce,[27] typically chemical manufacturers, but may also include importers, formulators, equipment manufacturers, or end-users [28] when they are responsible for introducing a substitute into commerce.

The Agency has identified four possible decision categories for substitutes: acceptable; acceptable subject to use conditions; acceptable subject to narrowed use limits; and unacceptable. Use conditions and narrowed use limits are both considered "use restrictions" and are explained below. Substitutes that are deemed acceptable with no use restrictions (no use conditions or narrowed use limits) can be used for all applications within the relevant end-uses within the sector. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. It is illegal to replace an ODS with a substitute listed as unacceptable, unless certain exceptions (*e.g.,* test marketing, research and development) provided by the regulation are met.

After reviewing a substitute, the Agency may determine that a substitute is acceptable only if certain conditions in the way that the substitute is used are met to minimize risks to human health and the environment. EPA describes such substitutes as "acceptable subject to use conditions." Entities that use these substitutes without meeting the

[27] As defined at 40 CFR 82.104 "interstate commerce" means the distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or District of Columbia. The entry points for which a product is introduced into interstate commerce are the release of a product from the facility in which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance.

[28] As defined at 40 CFR 82.172 "end-use" means processes or classes of specific applications within major industrial sectors where a substitute is used to replace an ozone-depleting substance.

associated use conditions are in violation of section 612 of the Clean Air Act and EPA's SNAP regulations.

For some substitutes, the Agency may permit a narrowed range of use within an end-use or sector. For example, the Agency may limit the use of a substitute to certain end-uses or specific applications within an industry sector. The Agency requires a user of a narrowed use substitute to demonstrate that no other acceptable substitutes are available for their specific application by conducting comprehensive studies. EPA describes these substitutes as "acceptable subject to narrowed use limits." A person using a substitute that is acceptable subject to narrowed use limits in applications and end-uses that are not consistent with the narrowed use limit is using the substitute in an unacceptable manner and is in violation of section 612 of the CAA and EPA's SNAP regulations.

The Agency publishes its SNAP program decisions in the **Federal Register** (FR). EPA publishes decisions concerning substitutes that are deemed acceptable subject to use restrictions (use conditions and/or narrowed use limits), or for substitutes deemed unacceptable, as proposed rulemakings to allow the public opportunity to comment, before publishing final decisions.

In contrast, EPA publishes decisions concerning substitutes that are deemed acceptable with no restrictions in "notices of acceptability," rather than as proposed and final rules. As described in the rule initially implementing the SNAP program (59 FR 13044), EPA does not believe that rulemaking procedures are necessary to list alternatives that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

Many SNAP listings include "comments" or "further information" to provide additional information on substitutes. Since this additional information is not part of the regulatory decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements so listed are binding under other regulatory programs. The "further information" classification does not necessarily include all other legal obligations pertaining to the use of the substitute. While the items listed are not legally binding under the SNAP program, EPA encourages users of substitutes to apply all statements in the "further information" column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building-codes or standards. Thus, many of the statements, if adopted, would not require the affected user to make significant changes in existing operating practices.

D. Where can I get additional information about the SNAP program?

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, refer to EPA's Ozone Depletion Web site at *http://www.epa.gov/ozone/snap/index.html.* For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the SNAP final rulemaking published March 18, 1994 (59 FR 13044), codified at subpart G of 40 CFR part 82. A complete chronology of SNAP decisions and the appropriate citations are found at *http://www.epa.gov/ozone/snap/chron.html.*

IX. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action." It raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. Today's action is an Agency determination. It contains no new requirements for reporting. The only new recordkeeping requirement involves customary business practice. Today's rule requires minimal record-keeping of studies done to ensure that MVAC systems using HFO–1234yf meet the requirements set forth in this rule. Because it is customary business practice that OEMs conduct and keep on file Failure Mode and Effect Analysis (FMEA) on any potentially hazardous part or system from the beginning of production of a car model until three or more years after production of the model ends, we believe this requirement will not impose an additional paperwork burden. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations in subpart G of 40 CFR part 82 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control numbers 2060–0226. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; for NAICS code 336111 (Automobile manufacturing), a small business has < 1000 employees; for NAICS code 336391 (Motor Vehicle Air-Conditioning Manufacturing), a small business has < 750 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant adverse economic impact on a substantial number of small entities. The only new requirement on small entities in this final rule is a requirement specifying the type of unique service fittings required when servicing MVAC systems using the refrigerant HFO–1234yf. Existing regulations at appendix D to subpart G of 40 CFR part 82 already require that there be unique service fittings for each refrigerant used in MVAC systems. Thus, the costs of purchasing new unique fittings for this refrigerant have already been imposed by the pre-existing regulation. This rule specifies the requirements for which type of unique fitting, in accordance with the fittings provided to EPA by the manufacturer. These fittings are part of the SAE J639 standard. It is not clear that there would be any cost differential between these specific unique fittings

and others that the automotive industry could adopt instead. Thus, cost impacts of this final rule on small entities are expected to be small. This final rule is expected to relieve burden for some small entities, such as car repair shops, by allowing them the flexibility to use a new refrigerant that otherwise would have been prohibited under previous requirements at appendix B to subpart G of 40 CFR part 82 and by allowing them to use the easy-to-use "quick-connect" fittings for this refrigerant. Other final rule requirements apply to original equipment manufacturers, which are not small entities. These final rule requirements are the least burdensome option for regulation.

Original equipment manufacturers are not mandated to move to MVAC systems using HFO–1234yf. EPA is simply listing HFO–1234yf as an acceptable alternative with use conditions in new MVAC systems. This rule allows the use of this alternative to ozone-depleting substances in the MVAC sector and outlines the conditions necessary for safe use. By approving this refrigerant under SNAP, EPA provides additional choice to the automotive industry which, if adopted, would reduce the impact of MVACs on the global environment. This rulemaking does not mandate the use of HFO–1234yf as a refrigerant in new MVACs.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Today's rule does not affect State, local, or Tribal governments. The enforceable requirements of today's rule related to system design and documentation of the safety of alternative MVAC systems affect only a small number of original equipment manufacturers. Further, those requirements are consistent with requirements that the automotive industry has already adopted through consensus standards of SAE International. We expect that most manufacturers of automobiles and MVAC systems would attempt to meet those requirements or something very similar, even in the absence of EPA's regulations. The only requirement that is applied more widely than for original equipment manufacturers is a requirement specifying the type of unique service fittings required when servicing MVAC systems using the refrigerant HFO–1234yf. Existing regulations at appendix D to subpart G of 40 CFR part 82 already require that there be unique service fittings for each refrigerant used in MVAC systems. The fittings required in this final rule are part of the SAE J639 standard. Thus, the costs of this rule are consistent with standard industry practice and are expected to be much less than $100 million per year.

This action provides additional options allowing greater flexibility for industry in designing consumer products. The impact of this rule on the private sector will be less than $100 million per year. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. This regulation applies directly to facilities that use these substances and not to governmental entities. This rule does not mandate a switch to HFO–1234yf and the limited direct economic impact on entities from this rulemaking is less than $100 million annually.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that 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."

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, as specified in Executive Order 13132. This regulation applies directly to facilities that use these substances and not to governmental entities. Thus, Executive Order 13132 does not apply to this rule.

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

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (59 FR 22951, November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This final rule does not have Tribal implications, as specified in Executive Order 13175. It does not significantly or uniquely affect the communities of Indian Tribal governments, because this regulation applies directly to facilities that use these substances and not to governmental entities. Thus, Executive Order 13175 does not apply to this rule.

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

This action is not subject to EO 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in EO 12866, and because the Agency does not believe the environmental health or safety risks

addressed by this action present a disproportionate risk to children. This action's health and risk assessments are discussed in sections V and VII.D of the preamble and in documents EPA–HQ–OAR–2008–0664–0036 and HQ–OAR–2008–0664–0038 in the docket for this rulemaking.

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

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action could impact manufacturing and repair of MVAC systems using an alternative refrigerant. This rule does not mandate a switch to HFO–1234yf. Preliminary information indicates that these new systems are more energy efficient than currently available systems in some climates. Therefore, we conclude that this rule is not likely to have a significant adverse effect on energy supply, distribution or use.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking involves technical standards. EPA has decided to use SAE International's most recent version of the SAE J1739 and SAE J639 standards. These standards can be obtained from *http://www.sae.org/technical/standards/.* These standards address safety and reliability issues in motor vehicle design, including MVAC systems using alternative refrigerants.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. HFO–1234yf is a non-ozone-depleting substance with a low GWP. Based on the toxicological and atmospheric work described earlier, HFO–1234yf will not have any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This final rule requires specific use conditions for MVAC systems, if car manufacturers chose to make MVAC systems using this low GWP refrigerant alternative.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective May 31, 2011.

X. References

The documents below are referenced in the preamble. All documents are located in the Air Docket at the address listed in section titled **ADDRESSES** at the beginning of this document. Unless specified otherwise, all documents are available in Docket ID No. EPA–HQ–OAR–2008–0664 at *http://www.regulations.gov.*

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List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: February 24, 2011.

Lisa P. Jackson,

Administrator.

For the reasons set out in the preamble, 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart G—Significant New Alternatives Policy Program

■ 2. Appendix B to Subpart G of Part 82 is amended as follows:

■ a. By adding one new entry to the end and by adding a note at the end of the first table.

■ b. By revising the entry for "CFC–12 Motor Vehicle Air Conditioners (Retrofit and New Equipment/NIKs)" in the table titled "Refrigerants—Unacceptable Substitutes".

The additions and revisions read as follows:

Appendix B to Subpart G of Part 82—Substitutes Subject to Use Restrictions and Unacceptable Substitutes

REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS

Application	Substitute	Decision	Conditions	Comments
*	*	* *	* *	*
CFC–12 Automobile Motor Vehicle Air Conditioning (New equipment in passenger cars and light-duty trucks only).	HFO–1234yf as a substitute for CFC–12.	Acceptable subject to use conditions.	Manufacturers must adhere to all of the safety requirements listed in the Society of Automotive Engineers (SAE) Standard J639 (adopted 2011), including requirements for: unique fittings, flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices. For connections with refrigerant containers of 20 lbs or greater, use fittings consistent with SAE J2844. Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739 (adopted 2009). Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. Observe requirements of Significant New Use Rule at 40 CFR 721.10182. HFO–1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No 754–12–1).

* * * * *

Note: The use conditions in this appendix contain references to certain standards from SAE International. The standards are incorporated by reference and the referenced sections are made part of the regulations in part 82:

1. SAE J639. Safety Standards for Motor Vehicle Refrigerant Vapor Compression Systems. February 2011 edition. SAE International.

2. SAE J1739. Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA). January 2009 edition. SAE International.

3. SAE J2844. R–1234yf (HFO–1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems. February 2011 edition. SAE International.

The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from SAE Customer Service, 400 Commonwealth Drive, Warrendale, PA 15096–0001 USA; e-mail: *CustomerService@sae.org;* Telephone: 1–877–606–7323 (U.S. and Canada only) or 1–724–776–4970 (outside the U.S. and Canada); Internet address: *http://store.sae.org/dlabout.htm.*

You may inspect a copy at U.S. EPA's Air Docket; EPA West Building, Room 3334; 1301 Constitution Ave., NW.; Washington, DC or at the National Archives and Records Administration (NARA). For questions regarding access to these standards, the telephone number of EPA's Air Docket is 202–566–1742. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

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REFRIGERANTS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Comments
*	* *	*	* * *
CFC–12 Motor Vehicle Air Conditioners (Retrofit and New Equipment/NIKs).	R–405A	Unacceptable	R–405A contains R–c318, a PFC, which has an extremely high GWP and lifetime. Other Substitutes exist which do not contain PFCs.
	Hydrocarbon Blend B	Unacceptable	Flammability is a serious concern. Data have not been submitted to demonstrate it can be used safely in this end-use.
	Flammable Substitutes, other than R–152a or HFO–1234yf in new equipment.	Unacceptable	The risks associated with using flammable substitutes (except R–152a and HFO–1234yf) in this end-use have not been addressed by a risk assessment. R–152a and HFO–1234yf may be used in new equipment with the use conditions in appendix B to this subpart.

[FR Doc. 2011–6268 Filed 3–28–11; 8:45 am]

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