



REGULATORY MANAGEMENT OPTION ANALYSIS FOR SELECTED F-GASES

Report for: European FluoroCarbons Technical Committee (EFCTC)

Ref. CN02875

Ricardo ref. ED16656

Issue: 2

19 September 2023

Customer:

European FluoroCarbons Technical Committee
(EFCTC)

Customer reference:

CN02875

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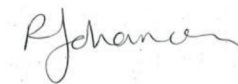
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EXECUTIVE SUMMARY

This Study has been commissioned by the European FluoroCarbons Technical Committee (EFCTC) to provide an independent Regulatory Management Option Analysis (RMOA) of eight fluorinated gases (F-gases) placed on the market in the European Economic Area (EEA). The analysis covers both producers and importers of F-gases and downstream users. This analysis will be used to support a response to the European Chemicals Agency's (ECHA) consultation on the proposed REACH restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS).

The intention to submit a proposal for a REACH restriction on the manufacture, placing on the market and use of PFAS was identified by EFCTC as being potentially significantly impactful for the F-gas sector. These impacts provide justification for this RMOA, in order to identify whether or not there are potentially more proportionate regulatory management options that could address the concerns.

F-gases are man-made substances used in numerous industrial, commercial and residential applications. F-gases include a broad range of chemical compounds, including but not limited to, hydrofluorocarbons (HFCs), hydrofluoro-olefins (HFOs), hydrochlorofluoro-olefins (HCFOs), perfluorocarbons (PFCs), sulphur hexafluoride (SF₆), and nitrogen trifluoride (NF₃). This Study focuses on eight substances – four HFCs, three HFOs and one HCFO (See Table 0-1).

Table 0-1 Substance Identifiers

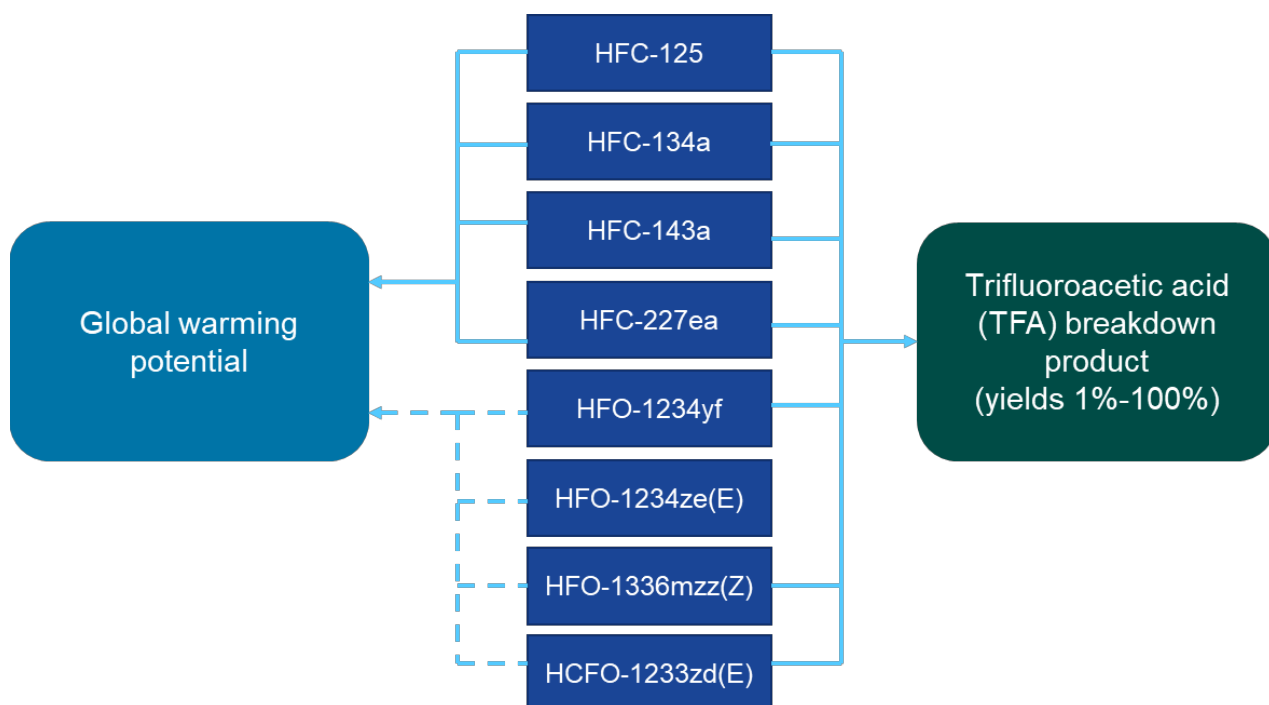
Name	Other names	CAS #	EC #
Pentafluoroethane	HFC-125	354-33-6	206-557-8
1,1,1,2-Tetrafluoroethane	HFC-134a	811-97-2	212-377-0
1,1,1-trifluoroethane	HFC-143a	420-46-2	206-996-5
1,1,1,2,3,3,3-heptafluoropropane	HFC-227ea	431-89-0	207-079-2
2,3,3,3-Tetrafluoroprop-1-ene	HFO-1234yf	754-12-1	468-710-7
1-Propene, 1,3,3,3-tetrafluoro-	HFO-1234ze(E)	1645-83-6	471-480-0
2-Butene, 1,1,1,4,4,4-hexafluoro-, (2Z)-	HFO-1336mzz(Z)	692-49-9	700-651-7
(1E)-1-chloro-3,3,3-trifluoroprop-1-ene	HCFO-1233zd(E)	102687-65-0	700-486-0
(E)-1-chloro-3,3,3-trifluoroprop-1-ene		2730-43-0	

F-gases are already a highly regulated group of substances, with legislation targeting their manufacture, use and end-of-life. Although F-gases tend not to exhibit hazards to human health or the environment, according to the PFAS Restriction Proposal submitters, beyond their global warming potential (GWP) there remains concerns regarding the high GWP of certain F-gases and the degradation product trifluoroacetic acid (TFA) (CAS # 76-05-1, EC # 200-929-3)¹, which require further regulatory management in order to prevent their potentially negative impacts on the environment throughout the lifecycle of F-gases.

As can be seen in Figure 0-1, a number of the F-gases in scope have the potential to degrade to TFA in the environment and so regulatory management options (RMOs) are needed to address this in all cases. Four out of the eight F-gases in scope have GWP greater than 1000, whilst those linked with a dashed line have GWP of less than 5. As can be seen from the alternatives assessment (Section 3), a number of the potential alternative refrigerants to F-gases also have GWP of less than 5. This suggests that there is a more immediate need to address the manufacture, use and end-of-life management of those F-gases with higher GWP.

¹ To note, The UNEP Environmental Effects of Stratospheric Ozone depletion, UV radiation, and interactions with climate change: 2022 Assessment report suggests that although TFA is included in the class of PFAS, it should be treated as a unique chemical for the purposes of regulation due to the widely differing physical, chemical and biological properties of perfluorinated alkanic acids. Available at: <https://ozone.unep.org/system/files/documents/EEAP-2022-Assessment-Report-May2023.pdf>

Figure 0-1 Focus Areas



The above focus areas require consideration of a variety of RMOs, each of which will have their own strengths and weaknesses. Some will be able to target both the GWP and degradation products of the F-gases in scope, whilst others will only be able to focus on one concern. A systematic review has been carried out to identify a longlist of potential RMOs. This review considered:

- How the RMO addresses the concerns i.e. does it address the GWP/ degradation products of the F-gases directly or indirectly
- Whether the RMO operates in isolation or does it work in combination with other RMOs
- The uses and lifecycle stages that the RMO addresses
- The target of the RMO i.e. human health or the environmental compartment.

The systematic review provides the criteria for screening of the RMOs, evidencing the conclusion of their relevance in addressing the concerns. The following RMOs have been taken forward for assessment based on the aforementioned systematic review:

- RMO 1: Substance evaluation under REACH
- RMO 2: REACH restriction – similar to the proposed restriction on the manufacture, placing on the market and use of PFAS
- RMO 3: REACH authorisation
- RMO 4: Regulatory proposal for amendment of F-gas Regulation
- RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF
- RMO 6: Substitution (industry initiative)

A qualitative scoring framework has been used to allow clear comparison of the RMOs taken forward for further assessment. The final scores are provided in Table 0-2.

Table 0-2 Qualitative Assessment of Overall Proportionality (weighted score)

RMO	Overall effectiveness	Overall practicability	Overall consistency	Overall economic impact	Overall human health impact	Overall environmental impact	Overall proportionality	Final ranking
RMO 1: Substance evaluation	0	-3	5	-2	0	0	0	Not ranked
RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS	9.125	-7.5	2	-6	-1	-2	-5.4	5
RMO 3: REACH Authorisation	5.125	-6.5	3	-4	-1	-1	-4.4	4
RMO 4: Regulatory proposal for amendment of F-gas Regulation	7.125	-.2	6	0	-1	-0.5	9.6	3
RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	4.5	1	2	6	0	3	16.5	1
RMO 6: Substitution (industry initiative)	5.875	-1	6	0	1	3	14.9	2

The analysis has concluded that there is no single RMO that would effectively address the concerns related to the lifecycle of F-gases. As such, it is suggested that a combination of measures could be the most proportionate way forward. RMO 1 – substance evaluation, is considered to be a separate but complementary ongoing RMO which could produce continuing valuable evidence for further regulatory management considerations, should a concern be identified under REACH. As all refrigerants are already registered under REACH, this does not require new registrations. In order to address concerns related to GWP and the TFA degradation product, the analysis suggests a combination of RMO 4, 5, and 6 would be the most proportionate option. RMO 4 is the overarching measure that would address the production, containment, use and end-of-life treatment of the F-gases in scope. It further strengthens the current F-gas Regulation and so seeks to bring about greater control and reduction in emissions of F-gases, whilst ensuring that key initiatives, such as REPowerEU, are not compromised. RMO 5 is a complementary measure, in that it supports the actions under the proposed amendment to the F-gas Regulation, increasing regulatory pressure to reduce emissions and move to lower GWP refrigerants. The combination of the three RMOs would likely see a move to non-fluorinated refrigerants, where possible, within a timeline that is feasible for industry and will not place undue burden on industry or regulators. RMO 6 relies on industry efforts to substitute F-gases for alternatives that are not of regulatory concern. As noted in the assessment, there are a number of drivers for substitution and regulatory pressure is only going to increase. Should industry (both F-gas manufacturers and importers, and F-gas downstream users) dedicate their R&D efforts to find alternatives and make the switch early enough, there may be a first mover advantage and potential mitigation of the costs associated with innovation. It is noted that manufacturers of F-gases would likely need to decommission their plants and build a new installation to be able to manufacture alternatives. By combining RMO 6 with RMO 4 and 5, it may be possible for the reduction in manufacture and use of F-gases to be reduced faster than is legally required under the F-gas Regulation phase-down. It must be noted that substitution should not be rushed as this increases the chances of regrettable substitution, but that increased investment early on could be beneficial overall.

RMO 2 – REACH restriction, has been found to be effective at reducing risk yet significant limitations remain regarding the practicability of enforcement (e.g., enforceability of illicit imports) and ease of implementation (e.g., limited knowledge of the feasibility of alternatives for many uses at the time that derogations are defined). When combined with the economic impacts (i.e., loss of business for F-gas manufacturers and importers when alternatives are not feasible for them, and loss of business for downstream users when their products are not feasible without the use of or without containing F-gases), which in the absence of alternatives propagate through the supply chain, this raises questions over the potential overall negative impacts from its implementation. RMO 3 – REACH authorisation, is marginally more proportionate, with similar concerns regarding practicability of enforcement and ease of implementation, but slightly lower economic impact, although still negative. Neither have been identified as appropriate regulatory management options to address the concerns.

As F-gases are so key to the functioning of society at present, it is recommended that further evaluation is carried out to assess the proportionality of the REACH restriction proposal to ensure that an undue burden is not placed on industry, regulators or wider society.

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Glossary

AIM	American Innovation and Manufacturing
BAT	Best available technique
BREF	Best available technique reference document
C&L	Classification and Labelling
CAA	Clean Air Act
CAGR	Compound Annual Growth Rate
CCH	Compliance check evaluations
CFC	Chlorofluorocarbon
CLH	Harmonised classification and labelling
CoRAP	Community rolling action plan
CSR	Chemical Safety Report
EC	Effect Concentration
EEA	European Environmental Agency
eMSCA	Evaluating Member State Competent Authority
EPA	Environmental Protection Agency
EQS	Environmental quality standards
F-gases	Fluorinated gases
FTE	Full time equivalent
GHG	Greenhouse gas
GVA	Gross Value Added
GWP	Global Warming Potential
HCFC	Hydrochlorofluorocarbon
HCFO	hydrochlorofluoroolefin
HFC	Hydrofluorocarbon
HFO	Hydrofluoro-olefin
HVAC	Heating, ventilation, and air conditioning
IAPP	International Air Pollution Prevention
IED	Industrial Emissions Directive
IFA	Institute for Occupational Safety and Health of the German Social Accident Insurance
IMO	International Maritime Organization
LC	Lethal Concentration
MAC	Mobile air conditioning
MARPOL	The International Convention for the Prevention of Pollution from Ships
MDI	Metered Dose Inhalers
MMR	Monitoring Mechanism Regulation
MPHE	Methoxytridecafluoroheptene
MS	Member State
MSCA	Member State Competent Authority
NAAQS	National Ambient Air Quality Standards
NACE	Nomenclature of Economic Activities
NEEAP	National energy efficiency action plan
NOAA	National Oceanic and Atmospheric Administration
ODS	Ozone depleting substances
OEL	Occupational exposure limit
OPEX	Operating expenditure
OR DEQ	Oregon Department of Environmental Quality
PBT	Persistence, bioaccumulative, toxic
PFAS	Per- and polyfluoroalkyl substances
PFC	Perfluorocarbon
PFOA	Perfluorooctanoic acid
PNEC	Predicted No Exposure Concentration
RACH	Refrigeration, air conditioning, and heating
RACHP	Refrigeration, air conditioning and heat pump
RCR	Risk characterisation ratio
REDII	The Renewable Energy Directive 2018/2001/EU
RMO	Regulatory Management Option
ROMOA	Regulatory Management Option Analysis
SME	Small and medium-sized enterprise
SNAP	Significant New Alternatives Policy

STOT SE	Specific target organ toxicity - single exposure
UNFCCC	United Nations Framework Convention on Climate Change
vPvB	very persistent, very bioaccumulative
VRF	Variable refrigerant flow

1. INTRODUCTION

This Study has been commissioned by the European FluoroCarbons Technical Committee (EFCTC) to provide an independent Regulatory Management Option Analysis (RMOA) of eight fluorinated gases (F-gases) placed on the market in the European Economic Area (EEA). The analysis covers both producers and importers of F-gases and downstream users. This analysis will be used to support a response to the European Chemicals Agency's (ECHA) consultation on the proposed REACH restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS).

The report is structured into five sections:

- Section 1: Scope of the RMOA, identity of the substances in scope, and the regulatory status
- Section 2: Available information on substances – volumes and uses, hazards, exposure and risk, socio-economic assessment
- Section 3: Alternatives Assessment
- Section 4: Regulatory Management Options (RMOs)– identification, assessment, and selection of RMOs
- Section 5: Conclusions.

1.1 SCOPE OF THE RMOA

In July 2021, a group of four EU Member States (Sweden, Germany, the Netherlands and Denmark) plus Norway submitted a joint intention for a REACH restriction of PFAS due to concerns about their persistence in the environment. The restriction proposal was submitted to ECHA on 13th January 2023 and published on 7th February 2023. The definition of PFAS in the REACH restriction proposal is broad² and covers over 10,000 substances, with most F-gases being included in the scope. One of the main concerns related to PFAS is their persistence in the environment, and, although F-gases do not present the same persistence concerns, the degradation product of some F-gases, Trifluoroacetic acid (TFA), has persistent properties.

Production and consumption of F-gases, specifically hydrofluorocarbons (HFCs), has increased considerably over the last 30 years as they have been widely used as substitutes for ozone depleting substances (ODS). The Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) entered into force in 1989, with the aim to reduce the emission of ODS globally. The Montreal Protocol initially required the parties to phase out the use of ODS such as chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs). The Montreal Protocol has been effective in protecting the ozone layer and thus further amendments have been made to address additional atmospheric issues.

However, in response to the phase-out of ODS, many applications increased their use of F-gases. The Kigali Amendment was introduced to the Montreal Protocol in 2016, with the aim to phase down the use of HFCs due to their GWP, with entry into force in 2019. HFCs often have a high GWP, some of them more than 1,000 times greater than carbon dioxide (CO₂). Increasingly, lower GWP F-gases such as hydrofluoroolefins (HFOs), hydrochlorofluoroolefins (HCFOs) and other lower GWP products are being developed and used to replace higher GWP F-gases (in particular through the quota system and prohibitions put in place by the F-gas Regulation ((EU) No. 517/2014)³).

The scope of this RMOA takes into account the concerns raised by the Dossier Submitters related to the GWP of F-gases and their degradation product TFA, and seeks to identify and evaluate the possible regulatory management options that could address the aforementioned concerns. The objective of this assessment is to evaluate all publicly available data related to the socio-economic importance of the F-gases in scope, as well as scientific evidence and data obtained through stakeholder consultation to conclude on the best option to adequately control the risk, whilst ensuring proportionality.

² Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the proposed restriction:

CF₃-X or X-CF₂-X',

where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R''',

and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-).

³ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases

The stakeholder consultation ran from 15th November 2022 to 31st January 2023 and targeted manufacturers, importers and downstream users of F-gases to obtain detailed information on the socio-economic contribution of F-gases in the EEA. All data has been treated as confidential and has been aggregated and anonymised according to the European Chemicals Industry Council (Cefic) statistical rules to ensure that all data remains confidential and cannot be reverse engineered.

1.2 IDENTITY OF THE SUBSTANCES IN SCOPE

F-gases are man-made substances used in numerous industrial, commercial and residential applications. F-gases include a broad range of chemical compounds, including but not limited to, HFCs, hydrofluoro-olefins (HFOs), HCFOs, perfluorocarbons (PFCs), sulphur hexafluoride (SF₆), and nitrogen trifluoride (NF₃). This Study focuses on eight substances – four HFCs, three HFOs and one HCFO (See Table 1-1).

Table 1-1 Substance Identifiers

Name	Other names	CAS #	EC #
Pentafluoroethane	HFC-125	354-33-6	206-557-8
1,1,1,2-Tetrafluoroethane	HFC-134a	811-97-2	212-377-0
1,1,1-trifluoroethane	HFC-143a	420-46-2	206-996-5
1,1,1,2,3,3,3-heptafluoropropane	HFC-227ea	431-89-0	207-079-2
2,3,3,3-Tetrafluoroprop-1-ene	HFO-1234yf	754-12-1	468-710-7
1-Propene, 1,3,3,3-tetrafluoro-	HFO-1234ze(E)	1645-83-6	471-480-0
2-Butene,1,1,1,4,4,4-hexafluoro-, (2Z)-	HFO-1336mzz(Z)	692-49-9	700-651-7
(1E)-1-chloro-3,3,3-trifluoroprop-1-ene	HCFO-1233zd(E)	102687-65-0	700-486-0
(E)-1-chloro-3,3,3-trifluoroprop-1-ene		2730-43-0	

1.2.1 Manufacturing Process

The F-gases in scope have varying manufacturing processes, as outlined below.

1.2.1.1 HFC-125

HFC-125 is synthesized in a closed reactor by hydrofluorination of chlorotetrafluoroethane (HFC-124) and subsequent purification by distillation.⁴

1.2.1.2 HFC-134a

HFC-134a can be manufactured via several of routes. The fluorination of trichloroethene using hydrogen fluoride in a gas phase process over a heterogeneous catalyst is most commonly used. Other manufacturers may instead use hydrogenolysis of CFC-114a.⁵

1.2.1.3 HFC-143a

HFC-143a can be produced by hydrofluorination of 1,1-dichloroethylene or 1,1,1-trichloroethane. The degree of fluorination of the raw material is controlled by varying the reaction conditions i.e. hydrogen fluoride (HF) - reactant ratio, temperature and use of a catalyst.⁶

⁴ OECD (2005) SIDS Initial Assessment Report - 1,1,1,2,2-pentafluoroethane. Available at: <https://hpvchemicals.oecd.org/UI/handler.axd?id=997b57cc-6912-432e-8885-49076cd65a08>

⁵ McCulloch, A. & Lindley, A. A (2003) From mine to refrigeration: a lifecycle inventory analysis of the production of HFC-134a. International Journal of Refrigeration. 26, 865-872. Available at: <https://www.sciencedirect.com/science/article/pii/S0140700703000951?via%3Dihub>

⁶ ECETOC (2006) ECETOC JACC Report No. 52: Trifluoroethane (HFC-143a). Available at: <https://www.ecetoc.org/wp-content/uploads/2014/08/JACC-052.pdf>

1.2.1.4 HFC-227ea

To produce HFC-227ea, HCFC-22 is pyrolyzed in a closed reactor at high temperature to give tetrafluoroethylene and hexafluoropropene (HFP). Hexafluoropropene (HFP) is a co-product in the synthesis of TFE from HCFC-22 (chlorodifluoromethane). HFP yield can be increased, in lieu of TFE production, by altering the reaction conditions such as reduction in the pyrolysis temperature and use of steam as diluent of the reactants.⁷ HFP is reacted with Hydrogen fluoride in a closed system to give HFC-227ea.⁸

1.2.1.5 HFO-1234yf

There are multiple production pathways that can be used for the manufacture of HFO-1234yf.

- 1 Chloroform and HF are the starting materials to produce HFP, which is further converted to HFO-1225ye (1,2,3,3,3-pentafluoropropene) via hydrogenation then dehydrofluorination. HFO-1225ye is converted to HFO-1234yf via hydrogenation then dehydrofluorination. All our steps are in vapor phase under pressure they are flow through reactor.
- 2 TFE (produced from Chloroform and HF) is reacted by catalytical reaction with HCFC-21 (dichlorofluoromethane) to produce HCFC-225ca. The HCFC-225ca isomer is convert to 1214ya by reaction with KOH in liquid phase, then 1214ya is hydrogenation to 1234yf in vapor phase with Pd/C catalyst.
- 3 This involves the reaction of ethylene with carbon tetrachloride (CTC) as a starting point to manufacture HCC-250fb (1,3,3,3-tetrachloropropane) which then, then 250fb is convert to 1243zf by vapor phase hydrofluorination, then 1243zf is chlorinated to 243db catalytical liquid phase or photochlorination, 243db dehydrochlorination to 1233xf in liquid phase and 1233xf hydrofluorination (liquid phase) to 244bb, last 244bb dehydrochlorination to HFO-1234yf in vapor phase.⁹

1.2.1.6 HFO-1234ze(E)

Vinyl chloride (CH₂=CHCl), and carbon tetrachloride (CCl₄) are reacted together at about 100C and under pressure using a catalyst to give 1,1,1,3,3-pentachloropropane (HCC-240fa). The process to continuously produce 1,1,1,3,3-pentafluoropropane (HFC-245fa) from 1,1,1,3,3-pentachloropropane (HCC-240fa) involves the substitution of the chlorine atoms in HCC-240fa with fluorine atoms using anhydrous HF as the fluorine source and a halogen exchange catalyst such as antimony pentahalide.¹⁰ HFC-245fa is converted to HFO-1234ze isomers by dehydrofluorination in the liquid phase in the presence of alkali. An isomerisation catalyst is used to maximise the yield of HFO-1234ze(E).¹¹

1.2.1.7 HFO-1336mzz(Z)

1,1,1-trifluorotrichloroethane (CFC-113a) is reacted with hydrogen in the presence of a catalyst to produce 2,3 dichlorohexafluorobut-2-ene (HCFO-1316mxx). Hydrodechlorination of HCFO-1316mxx via 2-chlorohexafluorobut-2-ene (HCFO-1326mxx) over a catalyst then produces HFO-1336mzz.¹²

⁷ Ebnesajjad, S. (2011). Chapter 4 Introduction to Fluoropolymers, Applied Plastics Engineering Handbook.

⁸ Vapor phase production of 1,1,1,2,3,3,3-heptafluoropropane from hydrogen fluoride and hexafluoropropylene United States Patent 6900362. [Vapor phase production of 1,1,1,2,3,3,3-heptafluoropropane from hydrogen fluoride and hexafluoropropylene - E. I. du Pont de Nemours and Company \(freepatentsonline.com\)](https://freepatentsonline.com)

⁹ Sherry, D., Nolan, M., Seidel, S., & Anderson, S. O. (2017) HFO-1234yf: An Examination of Projected Long-Term Costs of Production. Available at: <https://www.c2es.org/wp-content/uploads/2017/04/hfo-1234yf-examination-projected-long-term-costs-production.pdf>

¹⁰ McCulloch, A. (2010) : Life Cycle Inventory Analysis of the Production of a High performance Foam Blowing Agent HFC-245fa (1,1,1,3,3-pentafluoropropane), JOURNAL OF CELLULAR PLASTICS Volume 46, 0021-955X/10/01 0057-16 \$10.00/0 DOI: 10.1177/0021955X09349130

¹¹ Manufacturing Process for HFO-1234ze, United States Patent Application 20100022809. [Manufacturing Process for HFO-1234ze - HONEYWELL INTERNATIONAL, INC. \(freepatentsonline.com\)](https://freepatentsonline.com)

¹² Integrated process for the production of Z-1,1,1,4,4,4-hexafluoro-2-butene. United States Patent 9758452. Integrated process for the production of Z-1,1,1,4,4,4-hexafluoro-2-butene - THE CHEMOURS COMPANY FC, LLC (freepatentsonline.com)

1.2.1.8 One process for preparing HCFO-1233zd is via the reaction of 1,1,1,3,3-penta-chloropropane (HCC-240fa) with hydrogen fluoride (HF).¹³ HCFO-1233zd(E)¹⁴

Vinyl chloride (CH₂=CHCl), and carbon tetrachloride (CCl₄) are reacted together at about 100C and under pressure using a catalyst to give 1,1,1,3,3-pentachloropropane (HCC-240fa).¹⁵

1.3 REGULATORY STATUS

Table 1-2 presents a summary of the European legal requirements that are applicable to F-gases. Further detail is provided below.

Table 1-2 Overview of Legal Requirements Applicable to F-gases - European legislation

Jurisdiction	Legal text	Regulatory Implications
EEA	Regulation (EU) 2018/1999 on the Governance of the Energy Union and Climate Action ("Monitoring Mechanism Regulation", MMR) ¹⁶ and Commission Implementing Regulation (EU) No 2020/1208 sets the requirements for national reporting under Regulation (EU) 2018/1999 ¹⁷	MMR sets out the mechanism for monitoring and reporting greenhouse gas emissions in Europe, which is implemented via Regulation No 2020/1208.
	Regulation (EC) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases ¹⁸	The main mechanism through which the EU complies with the Kigali Amendment to the Montreal Protocol. The 'F-gas Regulation' includes several measures, most notably the phase-down and restrictions/prohibitions, which hand-in-hand seek to reduce the use of high-GWP HFCs. The Regulation also has measures concerning: leakage checks and control, technician certification, F-Gas reporting and recovery.
	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ¹⁹	REACH establishes procedures for collecting and assessing information on the properties and hazards of substances that are manufactured or imported into EU quantities of one tonne or more per year. Companies that manufacture or import substances into the EU in quantities of one tonne or more per year must be registered and demonstrate to ECHA how the substance can be

¹³ [PROCESS FOR MAKING HCFO-1233ZD - European Patent Office - EP 3294697 B1 \(storage.googleapis.com\)](#) AND US20130261353A1 United States Integrated process to coproduce trans-1-chloro-3,3,3-trifluoropropene, trans-1,3,3,3-tetrafluoropropene, and 1,1,1,3,3-pentafluoropropene. US20130261353A1 - Integrated process to coproduce trans-1-chloro-3,3,3-trifluoropropene, trans-1,3,3,3-tetrafluoropropene, and 1,1,1,3,3-pentafluoropropene - Google Patents

¹⁴ Source: US Patent US20160332936A1

¹⁵ Ibid footnote 11

¹⁶ European Commission (2018) Regulation (EU) 2018/1999 of the European Parliament and of the Council of 11 December 2018 on the Governance of the Energy Union and Climate Action, amending Regulations (EC) No 663/2009 and (EC) No 715/2009 of the European Parliament and of the Council, Directives 94/22/EC, 98/70/EC, 2009/31/EC, 2009/73/EC, 2010/31/EU, 2012/27/EU and 2013/30/EU of the European Parliament and of the Council, Council Directives 2009/119/EC and (EU) 2015/652 and repealing Regulation (EU) No 525/2013 of the European Parliament and of the Council ELI: <http://data.europa.eu/eli/reg/2018/1999/2021-07-29>

¹⁷ European Commission (2020) COMMISSION IMPLEMENTING REGULATION (EU) 2020/1208 of 7 August 2020 on structure, format, submission processes and review of information reported by Member States pursuant to Regulation (EU) 2018/1999 of the European Parliament and of the Council and repealing Commission Implementing Regulation (EU) No 749/2014. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1208>

¹⁸ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 Text with EEA relevance. Accessible under: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0517>

¹⁹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>

Jurisdiction	Legal text	Regulatory Implications
		safely used. Companies must communicate the risk management measures to downstream users via safety data sheets. If the risks cannot be managed, authorities can ban or restrict the use of substances in different ways.
	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP) ²⁰	Requirement for the self-classification of substances and mixtures by companies and compliance with any associated labelling and packaging requirements before placing them on the market. Establishes the list of harmonised classifications and the Classification and Labelling Inventory as required by REACH.
	Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste ²¹	Prohibits the export of wastes in Annex V (inc HFC and HCFC) which are destined for recovery in countries to which the OECD Decision (control of transboundary movements of wastes destined for recovery operations) does not apply.
	Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles (MAC Directive) ²²	Since 2017 fluorinated greenhouse gases with GWP over 150 have been banned from new vehicles placed on the EU market.
	Directive 2001/95/EC of the European Parliament and of the Council on general product safety (The General Product Safety Directive) ²³	Businesses are responsible for ensuring the products placed on the EU market are safe and/or consumers are informed of the risks associated with the product.
	Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles ²⁴	Sets out the way in which waste from vehicles must be disposed, including air-conditioning system fluids.
	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) ²⁵	Sets out the way in which WEEE should be collected and treated, setting requirements for recovery and recycling.
	Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards	Organisations which use or store substances identified in the Seveso Directive need to report to the relevant Member States on the safety measures implemented.

²⁰ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>

²¹ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1013>

²² Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC. ELI: <http://data.europa.eu/eli/dir/2006/40/oj>

²³ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. ELI: <http://data.europa.eu/eli/dir/2001/95/2010-01-01>

²⁴ Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles. ELI: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32000L0053>

²⁵ Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) . Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012L0019-20180704>

Jurisdiction	Legal text	Regulatory Implications
	involving dangerous substances (The Seveso III Directive) ²⁶	
	Proposal ²⁷ for a Directive of the European Parliament and of the Council on the protection of the environment through criminal law and replacing Directive 2008/99/EC ²⁸	Proposed criminalisation of the illegal production, placing on the market, import, export, use, emission, or release of fluorinated greenhouse gases (as defined by Article 2 (1) of Regulation 517/2014).
	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) ²⁹	The main EU instrument for regulating polluting emissions from industrial installations. Based on several pillars with the integrated approach taking whole environmental performance of an installation into account.
	Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption ³⁰	Concerns the access to and quality of water intended for human consumption.

1.3.1 Status of substance under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation)

The REACH Regulation is comprised of 4 main components, Registration, Evaluation, Authorisation and Restriction. F-gases are not currently subject to all requirements and so only registration and evaluation are presented below.

a) Registration

Single components of F-gases (not blends), which are either manufactured or imported into the EU, in quantities of one tonne or more per year must be registered under REACH. This entails compiling and submitting a registration dossier to ECHA. It is stated in the legislation that the registration dossier should include the following details:

- Information on the manufacturer or importer;
- Information on the intrinsic properties of the substance;
- Substance identity;
- Classification and labelling of the substance;
- Details on the intended uses of the substance;
- Guidance on its safe use;
- Chemical safety report if the substance is manufactured or imported of more than 10 tonnes or more per year;
- The manufactured or imported tonnage range for the substance per year³¹.

²⁶ Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances. ELI: <http://data.europa.eu/eli/dir/2012/18/oj>

²⁷ Proposal for a Directive of the European Parliament and of the Council on the protection of the environment through criminal law and replacing Directive 2008/99/EC. Available from: https://ec.europa.eu/info/files/proposal-directive-european-parliament-and-council-protection-environment-through-criminal-law-and-replacing-directive-2008-99-ec_en

²⁸ Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008L0099>

²⁹ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast). Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0075-20110106>

³⁰ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast). Available from: <https://eur-lex.europa.eu/eli/dir/2020/2184/oj>

³¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>

A fee according to Commission Regulation (EC) 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency³² should accompany the dossier submission. The fees payable to ECHA depend on the tonnage band of the registration and can vary if the registrant is a small or medium-sized enterprise (SME).

b) Evaluation

REACH evaluation is two-fold:

- Dossier evaluation
 - Compliance check evaluations (CCH) – Conducted by ECHA.
Compliance with the standard information requirements under REACH are reviewed and further information may be required from the registrant. These checks can be expected across all registered substances, ECHA is currently aiming to have at least 20% of registration dossiers in each tonnage band checked for compliance, which represents 30% of all registered substances. As of 2022 (the last reported progress check), ECHA have yet to reach their goal of compliance checks for tonnage bands of less than 100 (1-10t/y = 4%; 10-100t/y = 11%), but aim to have these completed by December 31 2027³³.
 - The examination of testing proposals- Conducted by ECHA.
ECHA is required to review the testing proposals for studies on vertebrate animals if listed in Annexes IX and X of REACH to ensure the tests are necessary for the information requirements.
- Substance Evaluation – Conducted by Member States.
This is required when a specific substance has been listed in the Community rolling action plan (CoRAP)³⁴, the risks posed by the substance to human health or the environment are assessed and further information may be required.

Table 1-3 provides an overview of the REACH registration and evaluation status of the substances in scope.

³² Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ELI: <http://data.europa.eu/eli/reg/2008/340/2021-06-21>

³³ ECHA (2022). Progress in evaluation. Available at: [https://echa.europa.eu/progress-in-dossier-evaluation/Compliance%20check%20evaluations%20\(CCH\)](https://echa.europa.eu/progress-in-dossier-evaluation/Compliance%20check%20evaluations%20(CCH))

³⁴ Community rolling action plan (CoRAP) lists substances for priority evaluation, these substances will be evaluated over three years. The substances are prioritised due to hazard concerns. For more information: <https://www.echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan>

Table 1-3 The registration and evaluation status of the F-gases in scope of this assessment, as of April 2022. Source: ECHA³⁵.

Substance Name	CAS Number	REACH Registration	Dossier Evaluation Status	Substance Evaluation Status
HFC- 125	354-33-6	Joint Submission ≥ 10,000 to < 100,000 tonnes	Concluded Compliance Check Evaluation (CCH) - Comprehensive	No evaluation
HFC-134a	811-97-2	Joint Submission ≥ 10,000 to < 100,000 tonnes	Concluded Compliance Check Evaluation (CCH) – Targeted	No evaluation
HFC-143a	420-46-2	Joint Submission ≥ 1,000 to < 10,000 tonnes	Concluded Compliance Check Evaluation (CCH) – Targeted and Comprehensive	No evaluation
HFC-227ea	431-89-0	Joint Submission ≥ 1,000 to < 10,000 tonnes	Concluded Compliance Check Evaluation (CCH) - Comprehensive	No evaluation
HFO-1234yf	754-12-1	Joint Submission ≥ 1,000 to < 10,000 tonnes	Concluded Compliance Check Evaluation (CCH) – Targeted and Comprehensive	Concluded
HFO-1234ze(E)	1645-83-6	Joint Submission ≥ 1,000 to < 10,000 tonnes	Concluded Compliance Check Evaluation (CCH) – Targeted	No evaluation
HFO-1336mzz(Z)	692-49-9	Joint Submission ≥ 100 to < 1,000 tonnes	No evaluation	No evaluation
HCFO-1233zd(E)	102687-65-0 2730-43-0	Joint Submission ≥ 1,000 to < 10,000 tonnes	No evaluation	No evaluation

³⁵ Data sourced from [PACT - Public Activities Coordination Tool - ECHA \(europa.eu\)](#) in April 2022.

1.3.2 Description of other legal requirements

1.3.2.1 Regulation (EC) No 1272/2008 - on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation)

All manufacturers, importers, and downstream users in the EU must comply with the CLP Regulation³⁶ (unless exempt under Article 1(2)).

a) Classification

Manufacturers, importers, and downstream users are required to 'self-classify' their substances under the CLP Regulation. Self-classification is required when a substance, which has hazardous properties, is not listed under Annex VI of the CLP Regulation with a harmonised classification or if an additional hazardous property is identified, not covered by the harmonised classification. The classifications may include exposure considerations, however an exposure assessment is not required for classification as it is based on the intrinsic properties of the substance. The self-classifications resulting from the application of Titles I and II of the CLP Regulation should be included in REACH registration dossiers. Manufacturers, importers, and downstream users are responsible for keeping their notifications up-to-date according to scientific advances in testing and new information on their substances.

b) Labelling

The identified hazardous properties of a substance must be communicated according to the labelling and packaging requirements under the CLP Regulation. The following information must be included on the product label if the product includes substances with identified hazards:

- The identity and contact information of the supplier;
- the nominal quantity of the substance or mixture in packages made available to the general public;
- the identity of the hazardous substance;
- the relevant hazard pictograms and statements, signal words, precautionary statements and any additional information as dictated by complementary legislation³⁷.

There are also strict packaging requirements to ensure safe containment and transport of substances. The packaging of hazardous substances must be strong, resistant to damage and possible to open and reseal without the substance escaping. Additional requirements under CLP restrict the packaging design to prevent attracting children to the hazardous product. All of the F-gases in scope have hazard classifications listed in the Classification and Labelling (C&L) Inventory and REACH registered classifications, meaning all of these substances are subject to the labelling and packaging requirements mentioned.

1.3.2.2 Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases

Regulation (EU) No 517/2014³⁸ (colloquially known as 'the F-gas Regulation') sets out several measures to reduce the use and emissions of F-gases. This includes HFCs, PFCs, SF₆ as well as other fluorinated compounds. All of them contribute to climate change as they exhibit global warming potential once emitted to the atmosphere. Regulation (EU) No 517/2014 replaced Regulation (EC) No 842/2006 when it entered into force on 1 January 2015. The original 2006 F-gas Regulation contained provisions related to certification of technicians and companies dealing with F-gases, reporting on F-gases, leakage checking and recovery requirements for F-gas containing equipment, placing on the market bans for certain products and equipment containing or relying on F-gases as well as prohibitions of the use of certain F-gases in specific applications. The level of ambition of the revised Regulation (EU) No 517/2014 was significantly expanded beyond the 2006 F-gas Regulation, to include among other regulatory measures, an HFC phase-down schedule and HFC quota allocation system, additional certification and reporting requirements, an additional set of placing on the market and use bans, and expanded recovery provisions.

³⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>

³⁷ [Labelling and packaging - ECHA \(europa.eu\)](http://data.europa.eu/eli/reg/2008/1272/oj)

³⁸ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0517>

1.3.2.3 Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles

Directive 2006/40/EC³⁹ ("MAC Directive") relating to emissions from air conditioning systems in passenger cars, complements the F-gas Regulation by introducing a prohibition on the use of F-gases with a GWP of over 150 in new mobile air conditioning systems from 1 January 2017. The objectives of the Directive are to control the leakage of the specific fluorinated greenhouse gases in the air-conditioning systems fitted to passenger vehicles. While the Directive specially targets the use of HFC 134a which has a GWP of 1530 (AR6), it applies to all F-gases (with a GWP over 150).

The Directive applies to all new passenger cars and light commercial vehicles up to 1.305 tonnes that utilise mobile air conditioning systems containing F-gases, that are placed on the EU market.

1.3.2.4 Directive (EU) 2018/844 of the European Parliament and of the Council of 30 May 2018 amending Directive 2010/31/EU on the energy performance of buildings and Directive 2012/27/EU on energy efficiency

Directive (EU) 2018/844⁴⁰ which amends Directive 2010/31/EU on the energy performance of buildings and Directive 2012/27/EU on energy efficiency, was introduced in order to update policy framework targets and help meet the European Union's ambitious commitment of reducing greenhouse gas emission by at least 40% by 2030, and by at least 80-95% by 2050, compared to 1990, under the new 'Clean energy for all Europeans package'⁴¹. The amended Directive 2018/844 requires EU Member States to draw up long-term strategies to support the renovation of both residential and non-residential buildings into highly energy-efficient and decarbonised building stock by 2050. The strategies should include a roadmap with indicative milestones for 2030, 2040 and 2050, in order to report the expected output of their long-term renovation strategies and how they contribute to achieving the EU's energy efficiency targets in accordance with Directive 2012/27/EU. Consequently, in accordance with the objectives of the Directive and Member State strategies, demand for thermal insulation has increased. Included in the increased demand for thermal insulation materials are insulation foams containing H(C)FOs.

1.3.2.5 Energy Efficiency Directive (2012/27/EU) & Directive on Energy Efficiency (2018/2002)

Directive 2012/27/EU⁴² established a set of binding measures to help the EU reach its 20% energy efficiency target by 2020. Under the Directive, all EU Member States are required to produce National Energy Efficiency Action Plans to improve energy use efficiency at all stages of the energy chain, including energy generation, transmission, distribution, and end-use consumption. EU Member States must draw up these plans every three years and they must report the progress achieved towards their national energy efficiency targets on an annual basis. This indirectly impacts end-use consumption of F-gases in the refrigeration, air conditioning, and heating (RACHP) sector, as greater efficiency energy measures such building insulation will reduce dependency on heating and cooling systems. Furthermore, the efficiency targets may promote R&D investment in more efficient RACH systems that utilise less F-gases, or technology that does not rely on F-gases entirely.

In the context of the Directive's objectives and F-gas use, a number of important measures have been adopted throughout the EU including⁴³:

- EU countries making energy efficient renovations to at least 3% per year of buildings owned and occupied by central governments;
- national long-term renovation strategies for the building stock in each EU country (Directive (EU) 2018/844);
- mandatory energy efficiency certificates accompanying the sale and rental of buildings;
- the preparation of national energy efficiency action plans (NEEAPs) every three years; and

³⁹ Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0040>

⁴⁰ Directive (EU) 2018/844 of the European Parliament and of the Council of 30 May 2018 amending Directive 2010/31/EU on the energy performance of buildings and Directive 2012/27/EU on energy efficiency. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32018L0844>

⁴¹ European Commission (n.d.). Clean energy for all Europeans package. Available at: https://energy.ec.europa.eu/topics/energy-strategy/clean-energy-all-europeans-package_en

⁴² Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0027>

⁴³ European Commission (n.d.). Energy efficiency directive. Available at: [https://energy.ec.europa.eu/topics/energy-efficiency/energy-efficiency-targets-directive-and-rules/energy-efficiency-directive_en#:~:text=Directive%202012%2F27%2FEU%20established,\(following%20the%20UK's%20withdrawal\).](https://energy.ec.europa.eu/topics/energy-efficiency/energy-efficiency-targets-directive-and-rules/energy-efficiency-directive_en#:~:text=Directive%202012%2F27%2FEU%20established,(following%20the%20UK's%20withdrawal).)

- the introduction of Amending Directive on Energy Efficiency (2018/2002).

Amending Directive on Energy Efficiency (2018/2002)⁴⁴ was introduced in December 2018 as part of the ‘Clean energy for all Europeans package’, to update the policy framework targets to 2030. It set binding targets of increasing energy efficiency over current levels by at least 32.5% by 2030. The Directive also included an extension to the energy savings obligation in end use, which was introduced in the prior amended Directive 2012/27/EU. Under the amending Directive, EU Member States are obligated to achieve new energy savings of 0.8% each year of final energy consumption for the 2021-2030 period, except Cyprus and Malta that will have to achieve 0.24% each year.

1.3.2.6 Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources

The Renewable Energy Directive 2018/2001/EU⁴⁵, (also known as REDII), is a recast and repeal of Directive 2009/28/EC (REDI). The recast Directive was made as part of the ‘Clean energy for all Europeans package’ and establishes a common framework for the promotion of energy from renewable sources in the EU. It sets a binding target of 32% for the overall share of energy from renewable sources in the EU's gross final consumption of energy in 2030. It also lays down rules on financial support to enhance the use of renewable energy usage, particularly in heating and cooling, electricity, and transport sectors. In the context of F-gases, the Directive's encouragement of Member States to support “innovative” heating and cooling technologies such as heat pumps, can be seen to be in part responsible for the growth in heat pump installations, for which many if not most, utilise F-gases as refrigerants.

1.3.2.7 Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products

Directive 2009/125/EC⁴⁶ which repealed Directive 2005/32/EC in November 2009, sets out a framework for the setting of eco-design requirements to be met by energy-related products in order to be placed on the EU market and put into service. The Directive's aim is to increase product energy efficiency while ensuring at the same time a high level of environmental protection. It impacts all energy-related products sold within the EU. The European Commission states that an energy-related product, is any energy-using product or energy-saving product “having an impact on energy consumption during use” as well as any parts intended to be incorporated into energy-related products covered by Directive 2009/125/EC. Heaters, air conditioners and refrigerating appliances are some of the many energy-related products with Implementing Regulations under the Directive's framework⁴⁷.

1.3.2.8 Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles

Directive 2000/53/EC⁴⁸ covers vehicles and end-of life vehicles, including their components and materials, and sets out targets for the way in which waste from vehicles must be removed, recovered, or disposed. Annex I of the Directive states that “air-conditioning system fluids and any other fluid contained in the end-of-life vehicle” are subject to treatment operations for depollution of end-of-life vehicles under the treatment requirements set out in Article 6 (unless the fluids are necessary for the re-use of the parts concerned), and the reuse and recovery requirements and targets set out in Article 7. The air-conditioning fluids in question includes F-gases such as HFCs and HFOs.

⁴⁴ Directive (EU) 2018/2002 of the European Parliament and of the Council of 11 December 2018 amending Directive 2012/27/EU on energy efficiency. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2018.328.01.0210.01.ENG

⁴⁵ Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (recast). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.328.01.0082.01.ENG

⁴⁶ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009L0125>

⁴⁷ European Commission (n.d.) .Energy-efficient products. Available at: https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-label-and-ecodesign/energy-efficient-products_en

⁴⁸ Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32000L0053>

1.3.2.9 Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

The Waste Electrical and Electronic Equipment Directive 2012/19/EU⁴⁹ ('WEEE Directive') covers equipment containing gases which have a GWP >15, which applies, with exceptions, to many gases covered by the F-gas Regulation. The electrical and electronic equipment containing HFCs which are in the scope of the WEEE Directive includes: large household appliances (large cooling appliances, refrigerators, freezers, clothes dryers, air conditioners), medical devices (freezers), automatic dispensers for cold bottles or cans. The WEEE Directive complements the F-gas Regulation in that it sets out requirements for Member States to minimise disposal of WEEE in unsorted municipal waste to ensure correct treatment. HCFCs and HFCs are specifically stated in Article 8(2) as being required to be removed as a minimum, and in a way that re-use and recycling of components or whole appliances is not hindered. The Directive also requires the extraction and treatment of equipment containing gases with a GWP of > 15 (including aforementioned HCFCs and HFCs) from foams and refrigeration circuits, such as those used as insulation in domestic and small commercial refrigeration appliances (although foams do not require recovery under Article 8 of the Regulation, Article 12 does require their presence being noted on the label, enabling treatment under the WEEE Directive).

1.3.2.10 Directive 2001/95/EC⁵⁰ - on general product safety

Producers are responsible for ensuring the products they place on the EU market are safe, or that consumers are informed of the risks associated with the product, this applies to any F-gas products placed on the EU market.

1.3.2.11 Directive 2012/18/EU -on the control of major-accident hazards involving dangerous substances

In addition to REACH and CLP requirements, certain F-gases meet the conditions of Annex I of the Seveso Directive III (Directive 2012/18/EU⁵¹). For example, HFO-1234yf (CAS 754-12-1) and HFC-143a (CAS 420-46-2) both fall into the category P2 of Part 1 of Annex I due to hazard classifications of flammable gas categories 1 and 2 (H220, H221)^{52,53}. This requires the organisations responsible for industrial processes involving HFC-143a (CAS 420-46-2) and HFO-1234yf (CAS 754-12-1) or the storage of large quantities of the substance to submit information to the relevant Member State Competent Authorities (MSCA). Information must be provided on the locations where the substance is stored and used, the internal emergency plans, safety reports, accident prevention policies and additional information on actions in case of accidents.⁵⁴ All these requirements aim to reduce the risk and severity of large-scale chemical accidents and minimise human health and environmental impacts if they do occur.

1.3.2.12 Proposal for a Directive of the European Parliament and of the Council on the protection of the environment through criminal law and replacing Directive 2008/99/EC

Part of the wider package of initiatives under the European Green Deal, the proposal aims to improve how Member States address the most serious environmental offences by amending Directive 2008/99/EC. Directive 2008/99/EC provides minimum rules to criminalise environmental crime. However, offences related to the illegal production, placing on the market, import, export, use, emission or release of fluorinated greenhouse gases are not yet covered by this Directive and are thus proposed to be included.

1.3.2.13 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (IED)

The IED requires the use of permits that cover emissions to air, water, land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents and restoration of site upon closure. The emission limit values in the permit must be based on Best Available Techniques (BAT) which are presented in the BAT Reference Documents (BREFs). There are currently 35 BREFs covering a range of activities from common

⁴⁹ Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast). Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0019>

⁵⁰ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32001L0095>

⁵¹ Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0018>

⁵² Polyhaloalkene Brief profile. Available at: <https://echa.europa.eu/brief-profile/-/briefprofile/100.104.879>

⁵³ 1,1,1-trifluoroethane Brief profile. Available at: <https://echa.europa.eu/brief-profile/-/briefprofile/100.006.361>

⁵⁴ Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances. ELI: <http://data.europa.eu/eli/dir/2012/18/oj>

wastewater and waste gas treatment/ management systems in the chemical sector, to manufacture of specific chemicals. F-gas use is included under a number of BREFs, including the Food, Drink and Milk Industries and the Slaughterhouses and Animals By-products Industries where there are BAT to control refrigerant use.

1.3.2.14 Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (Drinking Water Directive)

Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption sets parametric values for both 'PFAS Total' and 'Sum of PFAS' of 0.5 µg/l and 0.1 µg/l respectively. With 'PFAS Total' defined as the totality of per- and polyfluoroalkyl substances and 'Sum of PFAS' is defined as the sum of per- and polyfluoroalkyl substances considered a concern as listed in point 3 of Part B of Annex III. These values depend on the confirmation of technical guidelines on the methods of analysis and monitoring of these substances by the Commission which, in the Directive, has been stated as due by the 12 January 2024.

1.3.3 Regulatory activities outside of EU

Table 1-4 presents a summary of the legal requirements that are applicable to F-gases within an international context. Further detail is provided below.

Table 1-4 Overview of Regulatory Requirements for F-gases - International

Jurisdiction	Legal text	Regulatory Implications
International	United Nations Framework Convention on Climate Change (UNFCCC) - The Kyoto Protocol ⁵⁵	Parties to the Protocol must achieve greenhouse gas emission reduction targets. Emission reporting is also required annually from the Parties.
	The Kigali Amendment to The Montreal Protocol on Substances that Deplete the Ozone Layer (The Montreal Protocol) ⁵⁶	The Montreal Protocol requires all parties to phase out various ozone depleting substances (ODS) and provide data on emissions and trade of ODS. The Kigali Amendment to the Protocol requires the Parties to phase down their use of hydrofluorocarbons (HFCs), which were widely introduced as an alternative to ODS.
	The International Convention for the Prevention of Pollution from Ships (MARPOL) Annex VI Prevention of Air Pollution from Ships	IMO has used the Montreal Protocol as the base and developed Regulation 12 with main aim of phasing out the harmful ODS used by ships. Other than hydrochlorofluorocarbon (HCFC) all other ODS were banned in new ships from 19 May 2005 (Reg.12.3.1). HCFC were banned in new ships from 1 January 2020 (Reg.12.3.2). Supplement to IAPP Certificate - Maintain a list of equipment containing ODS (Reg.12.5). Ships are required to complete an ODS Record Book (Reg. 12.6) for rechargeable systems.
	Japan	Act on Rational Use and Proper Management of Fluorocarbons Act No. 64 of June 22, 2001 ⁵⁷ , most recently updated in 2018, and supported for domestic appliances through the "Home Appliance Recycling Act".

⁵⁵ The United Nations (1998) Kyoto Protocol To The United Nations Framework Convention On Climate Change. Available from: [kpeng.pdf \(unfccc.int\)](https://unfccc.int/kyoto_protocol/)

⁵⁶ The United Nations, (1987), The Montreal Protocol on Substances that Deplete the Ozone Layer. Available from: [Preamble | Ozone Secretariat \(unep.org\)](https://www.unep.org/montreal-protocol/)

⁵⁷ Ministry of the Environment Government of Japan (2016). Act on Rational Use and Proper Management of Fluorocarbons. Available at: <https://www.env.go.jp/content/900451359.pdf>

Jurisdiction	Legal text	Regulatory Implications
USA		Act on the Protection of the Ozone Layer Through the Control of Specified Substances, etc. and Other Measures Act No. 53 of May 20, 1988 ⁵⁸ .
		High Pressure Gas Safety Act No. 204 of June 7, 1951 ⁵⁹ .
	Australia	Ozone Protection and Synthetic Gas Management Act 1989 & Ozone Protection and Synthetic Greenhouse Gas Management Regulation 1995.
	USA	Clean Air Act (CAA).
		Significant New Alternatives Policy (SNAP) Program.
		American Innovation and Manufacturing (AIM) Act.
		State of California – Senate Bill No. 1206 ⁶⁰ .
		State of Maine – Revised Statutes Title 38 § 1613 ⁶¹ .

1.3.3.1 United Nations Framework Convention on Climate Change (UNFCCC) - The Kyoto Protocol

F-gas emissions have long been addressed by international conventions such as the United Nations Framework Convention on Climate Change (UNFCCC) and its Kyoto Protocol. As a party to the Kyoto Protocol, the EU must report on the status of the reduction commitments made under the UNFCCC and in relation to EU legislation on greenhouse gas (GHG) emission reductions. Regulation (EU) 2018/1999 on the Governance of the Energy Union and Climate Action (“Monitoring Mechanism Regulation”, MMR)⁶² stipulates the overarching mechanism for monitoring and reporting greenhouse gas emissions. In more detail, Commission Implementing Regulation (EU) No 2020/1208 sets the requirements for national reporting under Regulation (EU) 2018/1999⁶³.

1.3.3.2 The Montreal Protocol on Substances That Deplete the Ozone Layer⁶⁴ – Kigali Amendment

Recognising the potency of F-gases, specifically HFCs, to global climate change, the international community decided in 2016 in Kigali (Rwanda) on an Amendment to the Montreal Protocol. The so-called Kigali Amendment entered into force on 1 January 2019 and implements a global HFC phase-down by cutting the HFC production and consumption by more than 80 % over the next 30 years. There are different baseline years and HFC reduction schedules for Article 5 and non-Article 5 countries, with developed countries starting first and developing countries taking on reduction commitments in the medium-term, in addition to the ODS phase-out also regulated under the Montreal Protocol. The phase-down of HFCs requires the development and uptake of suitable alternative refrigerants with lower global warming potential, which can substitute for HFCs. Beyond the specific reduction schedules, the Kigali Amendment introduced import/export licensing and

⁵⁸ An English translation of the Act is available here: <https://www.japaneselawtranslation.go.jp/en/laws/view/3457/en>

⁵⁹ An English translation of the Act is available here: <https://www.japaneselawtranslation.go.jp/en/laws/view/1974>

⁶⁰ <https://legiscan.com/CA/text/SB1206/id/2609359#:~:text=This%20bill%20would%20prohibit%20a,lower%20global%20warming%20potential%20limits>

⁶¹ <https://legislature.maine.gov/statutes/38/title38sec1613-2.pdf>

⁶² Regulation (EU) 2018/1999 of the European Parliament and of the Council of 11 December 2018 on the Governance of the Energy Union and Climate Action, amending Regulations (EC) No 663/2009 and (EC) No 715/2009 of the European Parliament and of the Council, Directives 94/22/EC, 98/70/EC, 2009/31/EC, 2009/73/EC, 2010/31/EU, 2012/27/EU and 2013/30/EU of the European Parliament and of the Council, Council Directives 2009/119/EC and (EU) 2015/652 and repealing Regulation (EU) No 525/2013 of the European Parliament and of the Council (Text with EEA relevance). Accessible under: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1999>

⁶³ Commission Implementing Regulation (EU) 2020/1208 of 7 August 2020 on structure, format, submission processes and review of information reported by Member States pursuant to Regulation (EU) 2018/1999 of the European Parliament and of the Council and repealing Commission Implementing Regulation (EU) No 749/2014 (Text with EEA relevance). Accessible under: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1208>

⁶⁴ The United Nations, (1987), The Montreal Protocol on Substances that Deplete the Ozone Layer. Available from: Preamble | Ozone Secretariat (unep.org)

reporting requirements for HFCs. By extending the scope of controlled substances to HFCs, the Montreal Protocol took an important step towards the long-term goals set by the Paris Climate Agreement. As identified in the evaluation of the F-gas Regulation⁶⁵, the EU policy played an important role in facilitating convergence towards a potential future agreement to phase down HFCs under the Montreal Protocol.

1.3.3.3 The International Convention for the Prevention of Pollution from Ships (MARPOL)

The MARPOL Convention was adopted on 2 November 1973 at the International Maritime Organization (IMO). It was later revised by the protocol in 1978 and has since been updated by amendments (Annexes). Its purpose is to prevent the pollution of marine environments by preventing the discharge of harmful substances from ships. Each Annex focuses on a different pathway or type of pollution (e.g. oil, sewage, waste, air). Annex VI concerns the “Prevention of Air Pollution from Ships” which entered into force 19 May 2005. The Annex limits the main air pollutants contained in ships exhaust gas, including sulphur oxides and nitrous oxides, and prohibits deliberate emissions of ozone depleting substances (ODS)⁶⁶. In 2010 the Annex was revised and included significantly tighter limits on emissions, with the aim of phasing out the emissions of ODS completely. Included within the definition of ODS are CFCs and halons used in older refrigeration and fire-fighting systems, portable equipment, and insulation foams⁶⁷. HCFC were permitted to be used in installations onboard ships until 2020, when they were prohibited from being used in any new ship installations alongside all other ODS. Furthermore, Regulation 12 of Annex VI states that emissions arising from leaks of an ozone-depleting substance, whether or not the leaks are deliberate, may be regulated by Parties to the Kyoto Protocol of 1997.

While this piece of legislation does not directly govern or restrict emissions of the F-gases in this study, the aim of Annex VI of MARPOL is to prevent emissions of environmental pollutants from ships, and the high GWP values of certain HFCs such as HFC-125, HFC-134a, and HFC-143a (even though they are not ozone depleting) may deem it necessary for ship use of HFCs to be phased out under MARPOL; MARPOL is dynamic piece of legislation that displays a pattern of phasing out climate polluting substances and their substitutes.

1.3.3.4 Japan

Act on Rational Use and Proper Management of Fluorocarbons Act No. 64 of June 22, 2001⁶⁸

Since 2001, CFCs, HCFs and HFCs have been recovered and either recycled or destroyed from commercial refrigerators and air conditioners at the time of disposal under the “Law Concerning the Recovery and Destruction of Fluorocarbons”. In 2015, this law was amended and renamed with the “The Act on the Rational Use and Proper Management of Fluorocarbons”, which aims to further reduce the consumption and use of fluorocarbons (in particular HFCs) by F-gas producers, product manufacturers, and end users of F-gases (e.g. in heating, ventilation, and air conditioning HVAC systems). Furthermore, the act also provides provisions for end-of-life operators such as those who recycle, destroy, and collect F-gases and their appliances.

The “Act on Rational Use and Proper Management of Fluorocarbons”, most recently updated in 2018, and supported for domestic appliances through the “Home Appliance Recycling Act”. This legislation collectively requires measures throughout the lifecycle of fluorocarbons to minimise emissions, including recovery of ODS and HFCs from home appliances, vehicles, and commercial/industrial equipment at their end of useful life. Recovered ODS/HFCs must be recycled or destroyed. Under the authority of the Ministry of Environment and Ministry of Economy, Trade and Industry, the operation of recovery and EOL ODS/HFCs management is administered through members of the national refrigeration servicing association (Japan Association of Refrigeration and Air Conditioning Contractors (JARAC)) and the electrical appliance recycling industry. The operational system involves a nation-wide network of 25 licenced recycling operators and 60 licenced destruction locations.⁶⁹

⁶⁵ Öko-Institut e.V., Ricardo, and Öko-Recherche (2022). Support contract for an Evaluation and Impact assessment for amending Regulation (EU) No 517/2014 on fluorinated greenhouse gases. Available at: https://climate.ec.europa.eu/system/files/2022-04/f-gas_evaluation_report_en.pdf

⁶⁶ IMO (n.d.). Prevention of Air Pollution from Ships. Available at: <https://www.imo.org/en/ourwork/environment/pages/air-pollution.aspx>

⁶⁷ IMO (n.d.). Ozone-depleting substances (ODS) – Regulation 12. Available at: [https://www.imo.org/en/OurWork/Environment/Pages/Ozone-depleting-substances-\(ODS\)-%E2%80%93-Regulation-12.aspx](https://www.imo.org/en/OurWork/Environment/Pages/Ozone-depleting-substances-(ODS)-%E2%80%93-Regulation-12.aspx)

⁶⁸ Ministry of the Environment Government of Japan (2016). Act on Rational Use and Proper Management of Fluorocarbons. Available at: <https://www.env.go.jp/content/900451359.pdf>

⁶⁹ UNEP (2022) Medical and Chemical Technical Options Committee: 2022 Assessment Report. Available from: <https://ozone.unep.org/system/files/documents/MCTOC-Assessment-Report-2022.pdf>

One notable aspect of the Act is that instead of imposing restrictions on the use of specific high GWP refrigerants in certain applications (e.g. as per the EU F-Gas Regulation), the law sets GWP targets per product group, which each manufacturer needs to reach by a certain target year.

Act on the Protection of the Ozone Layer Through the Control of Specified Substances, etc. and Other Measures Act No. 53 of May 20, 1988⁷⁰

The Act regulates the production and consumption of CFC, HCFC, and HFCs. Its purpose is to set measures for controlling the manufacture, reducing the emissions, and rationalising the use of specified substances (e.g. F-gases), in order to ensure the implementation of the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer. The act was revised in 2018 to include the implementation of Montreal Protocol Kigali amendment.

High Pressure Gas Safety Act No. 204 of June 7, 1951⁷¹

The High Pressure Gas Safety Act regulates the production, storage, sale, transportation, and other matters related to the handling of high pressure gases, their consumption, as well as the manufacture and handling of their containers. Its purpose is to encourage businesses to carry out voluntary safety activities that contribute to public safety, by preventing accidents and disasters caused by high pressure gases. The act covers all high-pressure gases including F-gases, and the act classifies a “High Pressure Gas” as any compressed gas greater than or equal to 1MPa (0.2MPa for compressed acetylene gas and liquefied gas).

1.3.3.5 Australia

Ozone Protection and Synthetic Gas Management Act 1989 & Ozone Protection and Synthetic Greenhouse Gas Management Regulation 1995

Since 1989, the Australian government has implemented a number of acts aimed at ozone depleting substances and greenhouse gases; known as the Ozone acts⁷². The first and central act is the Ozone Protection and Synthetic Gas Management Act 1989; enacted in response to the Montreal Protocol. The key aims of this Act are to: control the manufacture, import, export, use and disposal of ODS; achieve a faster and greater reduction in the levels of production and use of ODS than are required under the Montreal Protocol; and promote responsible management and handling of ODS and synthetic greenhouse gases to minimise their impact on the atmosphere. The Ozone Acts are also supported by the Ozone Protection and Synthetic Greenhouse Gas Management Regulation 1995, and subsequent related regulations, which control major uses of ODS and synthetic GHG. The 1995 Regulation also prevents the recharging of refrigeration and air conditioning equipment with a higher global warming potential refrigerant than the equipment was designed to use, which was introduced under a 2020 amendment⁷³.

These Acts and Regulations are the controlling legislation in which Australia has implemented a phase out of HCFCs (starting 1996)⁷⁴ and more recently HFCs (starting 2018)⁷⁵, through banning their manufacturing and importation within Australia. However, presently the HFC phase-down covers only imports of bulk gas, such as in cylinders, and does not cover gas imported in pre-charged equipment such as air-conditioners or refrigerators.

1.3.3.6 United States of America

Clean Air Act (CAA)

The Clean Air Act (CAA), enacted in 1963 and revised in 1990, is a federal law that regulates air emissions from stationary and mobile sources. Inter alia, this law permits the Environmental Protection Agency (EPA) to establish National Ambient Air Quality Standards (NAAQS) to regulate emissions of hazardous air pollutants in order to protect public health and welfare.

⁷⁰ An English translation of the Act is available here: <https://www.japaneselawtranslation.go.jp/en/laws/view/3457/en>

⁷¹ An English translation of the Act is available here: <https://www.japaneselawtranslation.go.jp/en/laws/view/1974>

⁷² Australian Government, Department of Climate Change, Energy, the Environment and Water (n.d.). Ozone Protection and Synthetic Greenhouse Gas Management Legislation. Available at: <https://www.dcceew.gov.au/environment/protection/ozone/legislation>

⁷³ Australian Government, Department of the Environment and Energy (2020). New rules on charging refrigeration and air conditioning equipment. Available at: <https://www.dcceew.gov.au/environment/protection/ozone/rac/new-rules-charging-rac-equipment>

⁷⁴ Australian Government, Department of the Environment and Energy (2018). R22 PHASE OUT. Available at: <https://www.agriculture.gov.au/sites/default/files/documents/fs-r22-phase-out.pdf>

⁷⁵ Australian Government, Department of the Environment and Energy (2018). AUSTRALIA'S HFC PHASE-DOWN. Available at: <https://www.dcceew.gov.au/sites/default/files/documents/hfc-phase-down-factsheet.pdf>

Section 608 of the Clean Air Act was established to prohibit the intentional release of ozone depleting substances, such as refrigerants (CFCs and HCFCs) and their substitutes (HFCs), during maintaining, servicing, repairing, or disposing of refrigeration or air-conditioning equipment. For example, in 2016 under Section 608 the EPA extended the refrigerant management program to include HFC-125, 134a, 143a, 227ea, HFO-1234yf, and HFO-1234ze(E) (40 CFR Part 82, Subpart F)⁷⁶.

Section 612 of the Clean Air Act requires the EPA to identify alternatives to Class I and Class II ozone depleting substances such as CFC, HCFCs, and HFCs, and to publish lists of acceptable and unacceptable substitutes. This section of the Clean Air Act was later enacted into federal law under the Significant New Alternatives Policy (SNAP) Program.

Significant New Alternatives Policy (SNAP) Program

The EPA Significant New Alternatives Policy (SNAP) program⁷⁷ implements Section 612 of the amended Clean Air Act of 1990, which requires the EPA to identify and evaluate substitutes for ozone-depleting substances based on their end use, to reduce the overall risk to human health and the environment. For example, under Rules 20 and 21, SNAP lists certain high-GWP HFC refrigerants as unacceptable for end-uses in the aerosols, refrigeration and air conditioning, retail food refrigeration, household refrigeration, and foam blowing sectors. This means alternatives to these HFCs must be used. The legality of the SNAP program is however contested, as in 2017 the SNAP rules were vacated at the federal level on the grounds of the EPA exceeding its statutory authority. Since then some states have voluntarily implemented the SNAP rules at State level.

American Innovation and Manufacturing (AIM) Act

Enacted in late 2020 and directed by the EPA, the American Innovation and Manufacturing (AIM) Act⁷⁸ aims to address HFC emissions through three main legislative activities:

1. Initiate the phase down of the production and consumption of the listed HFCs in the US by 85% by 2036, in order to match the Kigali Amendment.
2. Establish regulatory requirements for the management of refrigerants and their substitutes.
3. Facilitate the transition to next generation technologies.

⁷⁶ Code of Regulations. Subpart F - Recycling and Emissions Reduction. Available at: <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-82/subpart-F>

⁷⁷ EPA (n.d.). Significant New Alternatives Policy (SNAP) Program. Available at: <https://www.epa.gov/snap>

⁷⁸ EPA (n.d.). AIM Act. Available at: <https://www.epa.gov/climate-hfcs-reduction/aim-act>

2. AVAILABLE INFORMATION ON SUBSTANCES

The main source of evidence for the volume of F-gases that are placed on the EU market annually is the European Environmental Agency (EEA) F-gas Report. The latest F-gas Report, available at the time of writing, was published in November 2022 and contains data on volumes in tonnes and in CO₂-equivalent (CO₂-e) tonnes placed on the market for 5 of the 8 F-gases in scope, up to 2021. These are taken as baseline volumes in this Study.

2.1 VOLUMES AND USES

2.1.1 Tonnage

As outlined above in Section 1.3.1, all of the substances in scope of this Study are registered under REACH. The REACH registration data on volumes placed on the market is supplemented by more accurate data from the EEA, who are responsible for monitoring the progress of the HFC phase-down schemes of the F-gas Regulation and the Montreal Protocol every year. As can be seen from Table 2-1, the tonnes placed on the market in 2021 did not entirely align with the tonnage bands under which some of the F-gases are registered. In particular, HFC-125, HFC-143a and HFC-227ea were placed on the market below the registered tonnage, suggesting that the placing on the market of these F-gases has already declined with respect to their registered amounts. Information on certain F-gases is censored in the published statistics due to confidentiality reasons (i.e., HFO-1234ze, HFO-1336mzz and HCFO-1233zd), as a very limited number of producers or importers place them on the market, and confidential data could be identified.

Table 2-1 Tonnes placed on the market for the F-gases in scope in 2021. Source: European Environment Agency ⁷⁹ F-gas report (2022), REACH registration dossiers.

F-gas	Tonnes placed on the market (2021)	REACH registered tonnage
HFC-125	8,407	≥ 10,000 to < 100,000 tonnes
HFC-134a	27,357	≥ 10,000 to < 100,000 tonnes
HFC-143a	845	≥ 1,000 to < 10,000 tonnes
HFC-227ea	451	≥ 1,000 to < 10,000 tonnes
HFO-1234yf	9,741	≥ 1,000 to < 10,000 tonnes
HFO-1234ze	C	≥ 1,000 to < 10,000 tonnes
HFO-1336mzz	C	≥ 100 to < 1,000 tonnes
HCFO-1233zd	C	≥ 1,000 to < 10,000 tonnes

'C': censored for confidentiality.

The figure below shows the historic evolution of the supply of each of the F-gases in scope in the EU-27. It can be argued that 2021 is a normal baseline year, as the HFC phase-down imposed by the F-gas Regulation in force is already binding and has been for some years. Therefore, no additional decreases in the supply as a result from the restrictions that were active during the first two years of the Covid-19 pandemic can be identified.

The continuation of the HFC phase-down until 2030 determines the composition of the supply of the F-gases in scope in the baseline scenario, and is shown in Figure 2-2. In the baseline, HFCs in scope are modelled to decrease proportionally following the phase-down; H(C)FOs are modelled to continue their historical trends and increase their proportion of the total F-gas supply, as substitutes of the phased-down HFCs. Figures of the baseline projections of the supply of the 8 F-gases in scope, and of business measures associated to them can be found in Section 2.5.1.

⁷⁹ EEA, 2022. ETC CM report 2022/03: Fluorinated Greenhouse Gases 2022. Accessible under: <https://www.eionet.europa.eu/etcs/etc-cm/products/etc-cm-report-2022-03>

Figure 2-1 Historic evolution of the EU supply of F-gases in scope. The supply of 'All HFCs' is included for reference of the HFC phase-down (HFO-1234yf not subject to the phase-down). Source: EEA⁸⁰ F-gas report (2022).

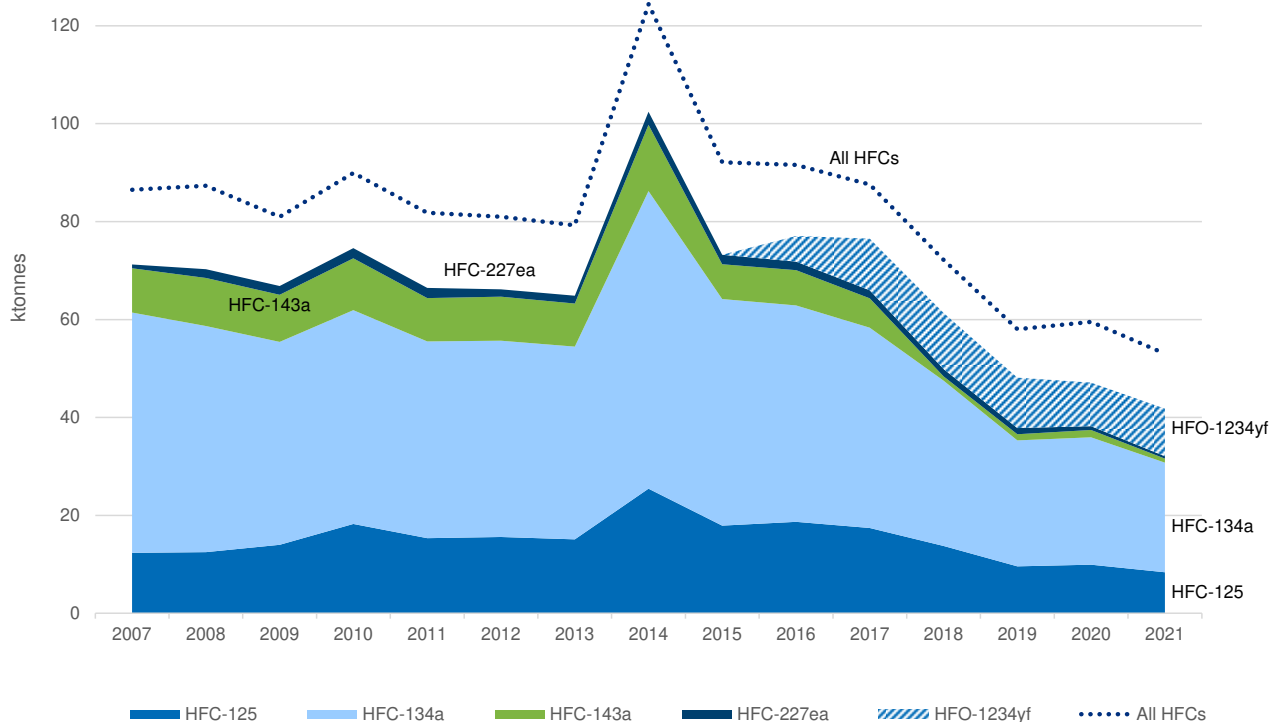
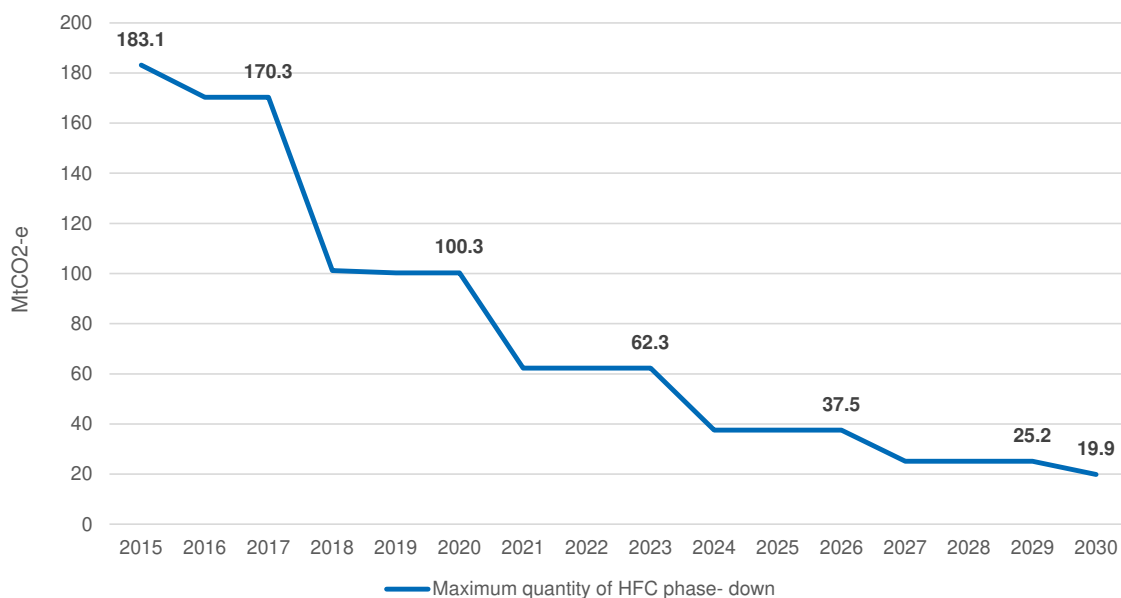


Figure 2-2 HFC phase-down. Million tonnes of CO₂-e jointly for all HFCs. Source: own elaboration with EEA data⁸¹.



⁸⁰ Ibid footnote 79.

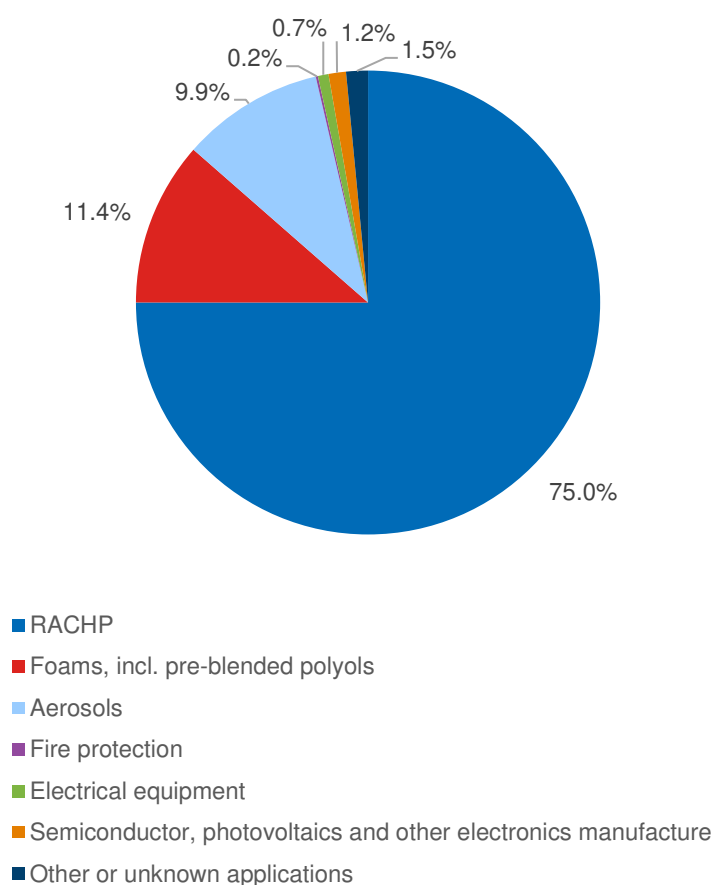
⁸¹ Ibid., EEA, 2020. Fluorinated Greenhouse Gases 2020. Accessible under: <https://www.eea.europa.eu/data-and-maps/data/fluorinated-greenhouse-gases-aggregated-data-2>, and EEA, 2021. Fluorinated Greenhouse Gases 2021. Accessible under: <https://www.eea.europa.eu/publications/fluorinated-greenhouse-gases-2021>.

2.1.2 Overview of Uses

The latest EEA F-gas Report⁸² provides a breakdown of the EU-27 total supply of F-gases by intended application of use in 2021, as reported by manufacturers and importers of F-gases.

Figure 2-3 shows the percentage split by said applications of use, providing an overview of intensity of use by sector. The main sector of intended destination of the whole F-gas supply in the EU-27 in 2021 is refrigeration, air conditioning and heating and other heat transfer fluids (RACHP), with three-quarters of the total supply. Foams and aerosols take up 20 percentage points of the remaining 25%, while other sectors of use only represent, as provided by this 'intended application of use' data, between 0.2% and 1.5% of the total F-gas supply each.

Figure 2-3 Total EU-27 F-gas supply by intended application of use. Source: EEA Fluorinated Greenhouse Gases 2022⁸³.



A consultation of F-gas manufacturers and importers, and F-gas downstream users from 23 different application sectors carried out for this Study has allowed Ricardo to obtain a detailed picture of the use of F-gases by application for each of the eight F-gases in scope of this Study. Table 2-2 combines, information reported by F-gas manufacturers/importers on the destination of their F-gas sales, and information reported by downstream users from each application sector on the F-gases they use.

Comparing the supply of F-gases in scope in 2021 provided in the survey and the supply in 2021 from the EEA F-gas Report from 2022, a deviation of only 7% was found, and therefore the sample is considered to be representative of the market for the F-gases in scope. Business figures related to the manufacture and supply of those F-gases, which cannot be contrasted with public information or statistics, were correspondingly corrected by that factor of deviation.

⁸² Ibid footnote 81.

⁸³ Ibid footnote 81.

Table 2-2 Application uses of each of the F-gases in scope of the assessment, as reported by participants in consultation activities. Dark green cells represent uses confirmed by both manufacturers and downstream users; light green cells represent uses only reported by downstream users. Blank cells represent F-gases for which there is no evidence of use in a given application.

Application sector	HFC-125	HFC-134a	HFC-143a	HFC-227ea	HFO-1234yf	HFO-1234ze	HFO-1336mzz	HCFO-1233zd
Mobile Air Conditioning								
Foam blowing agent (closed cell)								
Industrial Refrigeration								
Transport Refrigeration								
Fire Protection								
Propellants (Non-MDI)								
Foam blowing agent (Open cell)								
Domestic refrigeration								
Solvents								
Cover gas for magnesium casting								
Metered Dose Inhalers (MDI)								
Foam Products								
Skin coolers used in beauty shops								
Hermetically sealed standalone un. (Comm. refriger.)								
Condensing units (Commercial Refrigeration)								
Centralised systems (Commercial refrigeration)								
Moveable room air conditioning								
Stationary air conditioning: Single split systems								
Air conditioning: Multi split systems (VRF)								
Chillers								
Heat Pumps								
Industrial heat pumps and power generation								
Other								

2.2 HAZARDS

2.2.1 Ecotoxicity and PBT Assessment

HFCs, HFOs and H(C)FOs

The HFCs in scope (HFC-125, HFC-134a, HFC-143a, and HFC-227ea) are neither toxic to terrestrial plants or aquatic organisms such as algae, invertebrates, and fish⁸⁴. They are subsequently not classified as being of short-term (acute) or long-term (chronic) toxicity to aquatic life⁸⁵. For example, standard acute toxicity tests of HFC-134a for algae, daphnia (aquatic invertebrate) and fish resulted in an Effect Concentration (EC₅₀)⁸⁶ range between 450 and 980 mg/L⁸⁷. Under the CLP Regulation⁸⁸ a substance is deemed Category 1 Acute toxic (and possibly chronic)⁸⁹ to aquatic life if it has a L(E)C₅₀ value of <1 mg/L. HFO-1234yf, HFO-1234ze, and HFO-1336mzz(Z) are also not classified under the CLP Regulation as having acute or chronic toxicity to aquatic life⁹⁰. However, HCFO-1233zd has a REACH registered classification of Aquatic Chronic 3 toxicity, based on a 96-h LC₅₀ of 38 mg/L in fish (*O. mykiss*) and a chronic aquatic endpoint 72-h no-observed-effect-concentration-growth-rate NOErC of 115 mg/L for freshwater algae (*P. subcapitata*). Meaning it is harmful to aquatic life with long lasting effects. The associated hazard statement for a Chronic Aquatic Classification Category 3 is H412: Harmful to aquatic life with long lasting effects.

Substances may persist in the environment for long periods of time, or have a high potential for accumulation in biota. This is of concern as the long-term effects if such substances can be unpredictable and even where emissions have ceased, exposure can continue. Annex XIII of the REACH Regulation sets the criteria for persistence, bioaccumulative, toxic (PBT) and very persistent, very bioaccumulative (vPvB) substances. PBT assessments are required for all registered substances for which a chemical safety assessment has been carried out (substances manufactured or imported in volumes of 10 tonnes or more per year⁹¹). The assessment status of the eight F-gases in scope of this Study are outlined in Table 2-3.

Table 2-3 Outcome of PBT Assessment⁹²

Substance	Assessment status/ outcome
HFC-125	The substance is not PBT/ vPvB
HFC-134a	The substance is not PBT/ vPvB
HFC-143a	The substance is not PBT/ vPvB
HFC-227ea	The substance is not PBT/ vPvB
HFO-1234yf	The substance is not PBT/ vPvB
HFO-1234ze	The substance is not PBT/ vPvB
HFO-1336mzz	The substance is not PBT/ vPvB
HCFO-1233zd	The substance is not PBT/ vPvB

Although all of the F-gases have been determined to not meet the criteria for PBT/vPvB there are additional considerations for some.

⁸⁴ Tsai, W.-T., 2005. An overview of environmental hazards and exposure risk of hydrofluorocarbons (HFCs). Chemosphere, 61(11), pp. 1539-1547

⁸⁵ ECHA REACH dossiers

⁸⁶ Effect Concentration 50 - How much concentration of a chemical is required to 'affect' 50% of the test population.

⁸⁷ Berends, A. G., de Rooij, C. G., Shin-ya, S., Thompson, R. S., 1999. Biodegradation and Ecotoxicity of HFCs and HCFCs. pp.146-151.

⁸⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. Available at: <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32008R1272>

⁸⁹ Highest and most severe classification category of acute toxicity under the CLP Regulation

⁹⁰ ECHA REACH Dossiers.

⁹¹ Unless exempted.

⁹² REACH registration dossiers.

HFC-143a is noted as fulfilling the criterion for very persistent as it is expected to be stable in the environment. It does meet the criterion for bioaccumulation (log Kow is <1.35) and does not exhibit toxicity to aquatic or human life as the lowest available EC/LC50 is given as >40mg/l and the PNEC is 0.35mg/l.⁹³

HFO-1234yf has been found to not be readily biodegradable and could be considered as potentially persistent. Although there are no persistence criteria for the air compartment, the life time of HFO-1234yf is 10 days which suggests it would not be persistent in the air. The criterion for bioaccumulation is also not met (log Kow = 2) and the aquatic toxicity values do not indicate toxicity (lowest NOEC >100mg/l).⁹⁴

HFO-1234ze is not readily biodegradable and is likely to partition to water rather than soil or sediment due to the low partition and adsorption coefficients (log Kow = 1.6 and Koc = 71.1 l/kg respectively). It will however volatilise rapidly from water to air due to the high vapour pressure (427.1 kPa) and Henry's Law constant (8.7E=04 Pa*m³/mol). Based on the log Kow and estimated BCF value in aquatic organisms of 4.57 l/kg, the substance is not considered to meet the criterion for P/vP or B/vB. The substance is also not toxic to aquatic organisms or humans and so does not meet the T criterion.⁹⁵

2.2.2 Human Health Hazard

The effects of HFCs, HFOs, H(C)FOs and their degradation products on human health has been studied and reported in scientific literature. This section draws upon peer-reviewed and established studies within the toxicology discipline and provides application specific context as to the potential perceived risks to humans, including professionals and consumers. Due to the inherent physical properties of certain potential alternatives to F-gases, physical health effects such as flammability have also been reviewed based on available literature but not included in the human health assessment.

2.2.2.1 HFC-125

HFC-125 has a low potential for acute and sub-chronic toxicity even in concentrations as high as 20,000ppm, as shown in studies with rats⁹⁶. Furthermore, HFC-125 shows a low acute toxicity via inhalation, in exposure levels exceeding 500,000ppm (4-h acute toxicity studies in rats), as reported in its respective REACH registration dossier⁹⁷. Tsai⁹⁸, who summarises exposure levels/limits for workplace exposure of HFCs, states that HFC-125 has a reported exposure level/limit of 1000ppm⁹⁹, a NOAEL of 7.5v/v%, a LOAEL of 10v/v%, and a LC₅₀/ACL of 80v/v%.

2.2.2.2 HFC-134a

HFC-134a has been shown to have low to no effect of exposure on human tests after a 2-hour exposure at 300-500ppm 2-hour (with exercise) exposure¹⁰⁰. In studies with rats, Dekant¹⁰¹ showed that even at high concentrations (up to 20,000ppm), HFC-134a has a low potential for acute and sub-chronic toxicity. The National Research Council (US) suggests that HFC 134a's low acute inhalation toxicity is partly due to its rapid elimination and low uptake, with most of the compound being exhaled unchanged¹⁰². Tsai⁹⁸ reports that HFC-134a has an exposure level/limit of 1000ppm¹⁰³ and a LC₅₀/ACL of 80v/v%; NOAEL (v/v%) and LOAEL (v/v%) values are not reported by Tsai in their study.

⁹³ REACH registration dossier for 1,1,1-trifluoroethane. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15086/2/3>

⁹⁴ REACH registration dossier for Polyhaloalkene. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/16012/2/3>

⁹⁵ REACH registration dossier for 1-Propene, 1,3,3,3-tetrafluoro. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/31292/2/3>

⁹⁶ Dekant, W., 1996. Toxicology of Chlorofluorocarbon Replacements. Environmental Health Perspectives, 104(1), pp. 75-83.

⁹⁷ HFC-125. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15415>

⁹⁸ Tsai, W.-T., 2005. An overview of environmental hazards and exposure risk of hydrofluorocarbons (HFCs). Chemosphere, 61(11), pp. 1539-1547.

⁹⁹ American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Limits (WEEL) based on 8h time-weighted average (TWA).

¹⁰⁰ Gunnare et al., 2006. Toxicokinetics of 1,1,1,2-tetrafluoroethane (HFC-134a) in male volunteers after experimental exposure. Toxicology Letters, 167(1), pp. 65-65.

¹⁰¹ Dekant, W., 1996. Toxicology of Chlorofluorocarbon Replacements. Environmental Health Perspectives, 104(1), pp. 75-83.

¹⁰² National Research Council (US), 2002. Acute Exposure Guideline Levels for Selected. 2 ed. Washington (DC): National Academies Press (US).

¹⁰³ Maximum workplace concentration (MAK) (DFG, Germany) and American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Limits (WEEL) based on 8h time-weighted average (TWA).

Much like many HFCs, HFC-134a is not classed as flammable in the traditional sense, but as shown by Ural¹⁰⁴, there is potential for greater flammability if exposed to increased room temperature and pressure in the presence of air.

To note, the process of reformulating pharmaceutical MDIs began over 40 years ago with the proposed shift from CFCs to HFC-134a and HFC-227ea. The HFCs were subject to extensive toxicological testing and deemed safe for use at that time.¹⁰⁵

2.2.2.3 HFC-143a

In human tests after a 2-hour exposure at 300-500ppm 2-hour (with exercise) exposure, HFC-143a was found to have a low to no effect¹⁰⁶. Additionally, the REACH registration dossier for HFC-143a reports a low acute toxicity via inhalation, as shown by exposure to levels exceeding 500,000ppm (4-h acute toxicity studies in rats)¹⁰⁷. In the study by Tsai⁹⁸ HFC-143a is shown to have an exposure level/limit of 1000ppm¹⁰⁸ and a LC₅₀/ACL of 54v/v%. NOAEL (v/v%) and LOAEL (v/v%) are not reported by Tsai in their study. HFC-143a has a REACH registered classification of flammable gas¹⁰⁹ and as such poses an inherent physical health risk to humans, although it is only used in non-flammable blends which are ISO 817 classified as A1 – non-flammable.

2.2.2.4 HFC-227ea

Within its REACH registration dossier, it is reported that HFC-227ea has low acute toxicity via inhalation, in exposure levels exceeding 500,000ppm (4-h acute toxicity studies in rats)¹¹⁰. Tsai⁹⁸ reports that HFC-227ea has an exposure level/limit of 1000ppm¹¹¹, a NOAEL of 9v/v%, a LOAEL of 10.5v/v%, and a LC₅₀/ACL of 78.9v/v%.

Although HFC-227ea is classed as non-flammable¹¹², increased room temperature and pressure can lead to greater flammability potential with the air¹¹³. Furthermore, an increase in pressure can potentially double the upper flammability limit if it increases above 60psi. For example, Ural¹⁰⁴ estimates that HFC-227ea may form an explosive mixture with the air at room temperature if the pressure is above 60psi. This is of particular relevance as HFC-227ea includes applications for fire protection, and therefore carries a greater risk to human health. However, Ural¹⁰⁴ points out that while this behaviour does not affect the intended use and performance of these agents, recognising this property, and determining the critical pressure are vital to establishing safety procedures that can avoid accidental explosions.

As noted in Section 2.2.2.2, HFC-227ea has been subject to extensive toxicological testing and deemed safe for use in pharmaceutical MDIs.

2.2.2.5 HFO-1234yf

In a 4-h acute inhalation screening study, mice were exposed to HFO-1234yf up to a concentration of 101,850ppm and rats up to 405,800ppm, which produced no lethality. A similar result is reported in the ECHA REACH registration dossier of HFO-1234yf¹¹⁴ with a no mortality finding following 4 hours acute inhalation exposures as high as 405,000ppm in rats. Furthermore, rats exposed to HFO-1234yf at levels in the range of 5000-50,000ppm over 6 hours, 5 days a week for 2-4 weeks, and for 90 days (repeat dose studies) showed no treatment-related adverse effects, or biologically significant reproductive toxicity effects^{115,116}. No lethality

¹⁰⁴ Ural, E. A., 2003. Flammability potential of halogenated fire suppression agents and refrigerants. *Process Safety Progress*, 22(1), pp. 65-73.

¹⁰⁵ Ibid footnote 69

¹⁰⁶ Gunnare et al., 2007. Experimental exposure to 1,1,1-trifluoroethane (HFC-143a): uptake, disposition and acute effects in male volunteers. *Toxicology Letters*, 172(3), pp. 120-130.

¹⁰⁷ HFC-143a. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15086>

¹⁰⁸ American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Limits (WEEL) based on 8h time-weighted average (TWA).

¹⁰⁹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1907>

¹¹⁰ HFC-227ea. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/1989>

¹¹¹ Acceptable exposure limit (AEL) (DuPont Co., USA).

¹¹² HFC-227ea. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/1989>

¹¹³ Ural, E. A., 2003. Flammability potential of halogenated fire suppression agents and refrigerants. *Process Safety Progress*, 22(1), pp. 65-73.

¹¹⁴ HFO-1234yf. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16012/1/1>

¹¹⁵ Tveit et al., 2013a. The acute, developmental, genetic and inhalation toxicology of 2,3,3,3-tetrafluoropropene (HFO-1234yf). *Drug and Chemical Toxicology*, 36(4), pp. 412-420.

¹¹⁶ Rusch, G. M., 2018. The development of environmentally acceptable fluorocarbons. *Critical Reviews in Toxicology*, 48(8), pp. 615-665.

or clinical signs of toxicity resulted following exposures of up to 100,000 ppm HFO-1234yf for 1 hour to pregnant rabbits¹¹⁶.

It is important to note that HFO-1234yf (2,3,3,3-tetrafluoroprop-1-ene) was added to the Community Rolling Action Plan (CoRAP) for evaluation of possible carcinogenic and mutagenic properties and for possible identification as a Substance of Very High Concern (SVHC). However, CoRAP concluded in December 2021¹¹⁷ that HFO-1234yf does not qualify as a SVHC and does not require classification/labelling for mutagenicity or carcinogenicity.

80% (40)¹¹⁸ of notifiers to the C&L inventory report¹¹⁹ that HFO-1234yf meets the criteria for Flammable Gas 1 (H220), and its REACH registration dossier reports a lower flammability limit of 9% and an upper flammability limit of >11%¹¹⁴. However, a combustion study¹²⁰ of HFO-1234yf found that the risk of fire is low due to the high temperatures required for ignition. Although, HFO-1234yf does pose a greater risk to humans through its thermal decomposition products of carbonyl difluoride and hydrogen fluoride which are both highly corrosive to the skin, eyes and respiratory tract¹²⁰.

2.2.2.6 HFO-1234ze(E)

HFO-1234ze is consistent with having very low toxicity as demonstrated in acute and repeated dose toxicity studies in rats. In an acute exposure study at exposure concentrations of 100,000-207,000 ppm over 4 hours, no signs of lethality in rats were observed¹²¹. The ECHA REACH registration dossier also suggests low toxicity, which reports a LC₅₀ exceeding 207,000ppm in 4-h acute inhalation studies of rats¹²². In a 13-week inhalation toxicity study, no treatment related changes were observed relating to body weight gain, food consumption and food conversion efficiency in rats exposed to exposure concentrations up to 15,000 ppm 6 h/day, 5 days/week of HFO-1234ze¹²³. However, multifocal mononuclear cell infiltrates in the heart of both sexes at 15,000 ppm were observed during microscopic examination in the same study. Thus, the study considered a LOAEL of 15,000ppm and a 5000ppm NOEL for HFO-1234ze¹²³.

No genotoxic, prenatal developmental toxicity, or reproductive toxicity effects are associated with exposure to HFO-1234ze as demonstrated by animal studies^{123,124}.

2.2.2.7 HFO-1336mzz(Z)

HFO-1336mzz(Z) is consistent with having very low toxicity as demonstrated in acute and repeated dose toxicity studies in rats¹²⁵. It is neither an acute dermal or eye irritant and has very low acute toxicity via inhalation exposure¹²⁶. An acute toxicity study showed a 4-h LC₅₀ of >102,000 ppm and a NOAEL and LOAEL of 12,500ppm and 25,000 ppm (respectively) for cardiac sensitisation in dogs¹²⁶. 13-week repeat-dose inhalation studies in male and female rats at concentrations of 0, 500, 1500, and 10,000 ppm, showed no treatment related effects other than reductions in body weight, food consumption and efficiency at 10,000 ppm in both males and females. HFO-1336mzz(Z) is not shown to be genotoxic/mutagenic in *in vitro* and *in vivo* studies¹²⁶.

2.2.2.8 HCFO-1233zd(E)

Toxicity data for HCFO-1233zd demonstrates a low potential for toxicity. In a 4h acute toxicological study, HCFO-1233zd was shown to have a 4h LC₅₀ of 120,000ppm in rats, and a NOEL of 25,000ppm (cardiac sensitisation study) in beagle dogs¹²⁷. Repeated dose inhalation studies in rats over 14 days (20,000ppm), 28

¹¹⁷ COPRAP, 2021. SUBSTANCE EVALUATION CONCLUSION as required by REACH Article 48 for Polyhaloalkene EC No 468-710-7 CAS RN 754-12-1. Available at: <https://echa.europa.eu/documents/10162/a794e3ad-c358-b7f8-bc74-268bfea135e7>

¹¹⁸ As of 10/10/2022.

¹¹⁹ HFO-1234yf. C&L Inventory report. Available at: <https://echa.europa.eu/substance-information/-/substanceinfo/100.104.879>

¹²⁰ Magnusson et al., 2016. Identification and brief toxicological assessment of combustion products of the refrigerant HFO-1234yf, Stockholm: FOI.

¹²¹ Rusch et al., 2013. The acute, genetic, developmental and inhalation toxicology of trans-1,3,3,3-tetrafluoropropene (HFO-1234ze). Drug and Chemical Toxicology, 36(2), pp. 170-180.

¹²² HFO-1234ze. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/31292/7/3/1>

¹²³ Rusch, G. M., 2018. The development of environmentally acceptable fluorocarbons. Critical Reviews in Toxicology, 48(8), pp. 615-665.

¹²⁴ ECHA, REACH Registration dossiers

¹²⁵ HFO-1336mzz-Z. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/10030/7/3/1>

¹²⁶ Toxicology and Industrial Health, 2019. Cis-1,1,1,4,4,4-hexafluoro-2-butene (HFO-1336mzz-Z) (2018). Toxicology and Industrial Health, 35(3), pp. 180-188.

¹²⁷ Tveit et al., 2013b. The acute, genetic, developmental and inhalation toxicology of trans-1-chloro,3,3,3-trifluoropropene (HCFO-1233zd(E)). Drug and Chemical Toxicology, 37(1), pp. 83-92.

days (10,000ppm), and 90 days (4000ppm) showed no adverse treatment related effects. Tviet also found that in a 4-week study in which rats were exposed to 0, 2000, 4500, 7500 and 10000ppm¹²⁷, the only observed effect was an increase in potassium of mid-to-high exposure males. Furthermore, tests showed no genetic toxicity (rats) and no developmental toxicity in rabbits¹²⁷.

2.2.3 Harmonised Classification under CLP Regulation

None of the substances within scope of this RMOA have harmonised classifications under the CLP Regulation. For the REACH registration self-classified classification and labelling, see Section 2.2.4 below.

2.2.4 Self-Classification

The majority (eight out of ten) of the F-gases of focus in this report have REACH registered classifications for H280-Contains gas under pressure; may explode if heated. Two of the F-gases are flammable to varying levels of severity (H221, H225) and one is classified as harmful to aquatic life with long lasting effects (H412). Table 2-4 presents an overview of the self-classifications reported in the REACH registration dossiers for each substance.

Table 2-4 REACH registered classifications¹²⁸.

F-Gas	Physical hazard	Health hazard	Environmental hazard
HFC-125	H280 – Pressurised gas: Compressed gas	Not classified	Not classified
HFC-134a	H280 – Liquified gas	Not classified	Not classified
HFC-143a	H221 – Flammable Gas 1A H280 – Liquified gas	Not classified	Not classified
HFC-227ea	H280 – Liquified gas	Not classified	Not classified
HFO-1234yf	H221 – Flammable gas 1B H280 – Liquified gas	Not classified	Not classified
HFO-1234ze(E)	H280 – Liquified gas	Not classified	Not classified
HFO-1336mzz(Z)	Not classified	Not classified	Not classified
HCFO-1233zd(E)	H280 – Liquified gas	Not classified	H412 – Aquatic Chronic 3

2.2.5 Degradation Products

Trifluoroacetic acid (TFA) can be produced from the degradation of certain HFCs, HFOs and H(C)FOs in the atmosphere and can be considered to be a ubiquitous contaminant of the hydrosphere, due to its widespread recorded presence in air and water samples around the world¹²⁹.

Amongst the studies which have been undertaken, TFA is not considered highly toxic to mammals via the inhalation or the oral route. TFA has also been reported to be non-mutagenic and it is unlikely that it is a reproductive or developmental toxicant^{130,131}. Mammalian toxicity studies have shown that TFA is not metabolised in mammalian systems, and it has a half-life of only 16h in humans. A 4-hour OECD 403 guideline study in rats reports that TFA induced no mortality at the tested concentrations of up to 300 mg/m³¹³².

¹²⁸ Information obtained from their respective REACH registration dossiers.

¹²⁹ Solomon et al., 2003. Changes in tropospheric composition and air quality due to stratospheric ozone depletion. Photochemical and Photobiological Sciences, 2(1), pp. 62-67.

¹³⁰ Tang et al., 1998. Changes in tropospheric composition and air quality. Journal of Photochemistry and Photobiology B: Biology, 46(1), pp. 83-95.

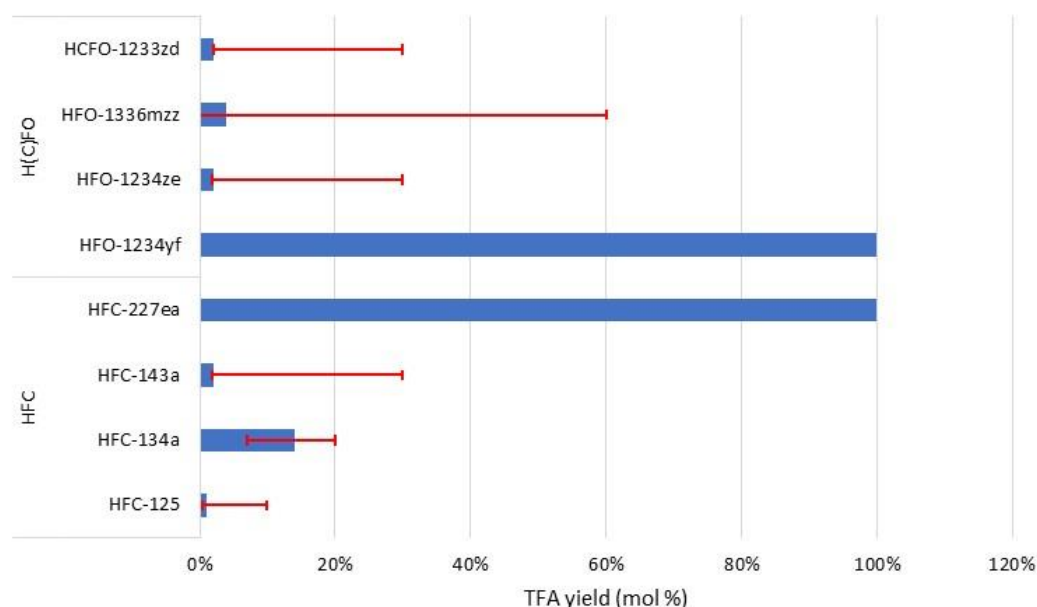
¹³¹ TFA. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/5203/7/1>

¹³² Information obtained from their respective REACH registration dossiers.

HFC-125, HFC-134a, HFC-143a, HFC-227ea, HFO-1234yf, HFO-1234ze(E), HFO 1336mzz(Z) and HCFO-1233zd(E) all degrade to TFA¹³³. However, the yields of TFA produced by each F-gas varies with some producing 100% and others significantly less. For example, HFO-1234yf entirely (100%) degrades to TFA, whereas the TFA yield of HFC-134a is around five times less at approximately 7-20%^{134,135}.

UNEP (2023) reviewed and estimated the yields of TFA from individual compounds based on evaluations of the available literature. These are shown in Figure 2-4, reproduced in part from UNEP 2023.¹³⁶ Error bars represent both experimental uncertainties and upper and lower yield ranges due to competing reaction channels that depend on environmental conditions.

Figure 2-4 TFA yields. Source: reproduced from UNEP (2023)¹³⁷



UNEP (2023) quotes estimated TFA yields for HFOs and H(C)FOs as:

- HFO-1234yf, 100%
- HFO-1234ze(E), 2%
- HFO-1336mzz(E/Z), 4%
- HCFO-1233zd(E), 2%

HFO-1234ze(E), HFO-1336mzz(E/Z), and HCFO-1233zd(E) degrade in the atmosphere via CF_3CHO . The yield of TFA from CF_3CHO may depend on whether it remains in gaseous form. The reaction of OH radicals with the hydrated form of CF_3CHO in the gas phase is known to be an effective route for formation of TFA (100%); however, to what extent CF_3CHO could be removed from the atmosphere through wet scavenging and undergo multiphase chemistry is unknown. The Chapter 6 Appendix¹³⁸ of UNEP (2023) states “*Thus, the TFA yield from processing of CF_3CHO is estimated at 2% with an upper theoretical limit of ~ 30%.*” The atmospheric degradation of HFC-143a also results in CF_3CHO as an intermediate product. For HFC-125, a minor reaction pathway can lead to a low yield of TFA.¹³⁹

¹³³ UNEP (2023) Environmental Effects of Stratospheric Ozone depletion, UV radiation, and interactions with climate change: 2022 Assessment report. Available at: <https://ozone.unep.org/system/files/documents/EEAP-2022-Assessment-Report-May2023.pdf>

¹³⁴ Ibid footnote 133

¹³⁵ Luecken et al., (2010). Ozone and TFA impacts in North America from degradation of 2,3,3,3-Tetrafluoropropene (HFO-1234yf), a potential greenhouse gas replacement. Environmental Science & Technology, 44(1), pp. 343-348.

¹³⁶ Ibid footnote 133

¹³⁷ Ibid footnote 133

¹³⁸ Ibid footnote 133

¹³⁹ Ibid footnote 133

TFA is stable and persistent in the environment and can enter ecosystems through generation in the troposphere and subsequent precipitation. Due to TFA being a strong acid, it readily bonds with minerals in soil and surface waters to create trifluoroacetate salts. It is also water soluble and so accumulates in dry-lakes (playas), land-locked lakes, and the ocean, where it combines with cations such as sodium, potassium, calcium, and magnesium¹⁴⁰, where it behaves very similarly to other salts and minerals. TFA found in the environment as a salt, typically has a no-observed-effect-concentration (NOEC) for aquatic species of >10,000 µg/L¹⁴¹.

The environmental effects of TFA have been summarised by the Environmental Effects Assessment Panel, 2022 Assessment Report¹⁴². The paper reports that TFA is produced by the environmental degradation of several HFCs and H(C)FOs and is found in low concentrations within the environment and not at concentrations likely to have adverse toxicological consequences. UNEP (2023) and WMO (2022)¹⁴³ have the same forecasts for the global generation and deposition of TFA, based on the assumption that 50% of the future emissions of low-GWP alternatives are related to HFOs, from which it is assumed that 50% is HFO-1234yf, with a conversion rate of 100% to TFA. The calculation also assumes that the formation of TFA from HFC-134a is based on its expected mixing ratio and its lifetime of 14 years. Conversion rates from the destroyed HFC-134a amounts to TFA 7–20%. Releases of other potential sources of TFA were not included but are expected to be much smaller.

The emissions of TFA, from HFO-1234yf and HFC-134a, are estimated to increase concentrations in the global oceans from the nominal value of 200 ng acid equivalent/ L (equivalent to 239 ng TFA sodium salt/ L) in 2020, to 266–284 ng sodium salt/L in 2100, if evenly distributed across all oceans. UNEP (2023) state that *“it should be noted that the geographic distribution of TFA released into the atmosphere across the globe has changed with the introduction of refrigerants and blowing agents such as HFOs with short atmospheric lifetimes (days). The longer atmospheric lifetimes of the older generation HFCs allowed wider and more even distribution of parent HFCs and deposition of TFA, across the globe. The HFOs will be degraded by tropospheric OH radicals closer to the source of release with resulting steeper gradients of concentration depending on wind direction and velocity. As a result of this uneven deposition, concentrations of TFA in surface waters will vary with flow rates and volumes of water.”*¹⁴⁴

UNEP (2023) also suggest that the presence of TFA in precipitation and flowing waters is likely to fluctuate and will be driven by release from precursors, other sources and hydrology. It is expected that concentrations in oceans will fluctuate less, and this shall depend on the rates of input from precipitation and rivers. Concentrations in oceans shall be influenced by the rate of input of fresh water as well as the current and mixing of water in the oceans.

It has been concluded that for current and projected (to 2100) ocean concentrations of TFA the margin of exposure (i.e. the ratio of the NOAEL to the actual/projected dose concentration) is large enough that, when compared to the dose level at which the TFA could have an effect on health or environment, the expected effects are minimal. It should be noted that uncertainty remains for the environmental toxicity values of TFA as only two marine species are captured by the toxicity data set for aquatic species, with marine macrophytes having not been tested.¹⁴⁵

Testing for the presence and concentration of TFA is relatively simple. An analysis of 1187 samples of rainwater collected from 8 locations across Germany found a median and a precipitation-weighted mean concentration of TFA of 0.210 µg/L and 0.335 µg/L, respectively (2018-2019)¹⁴⁶.

Aquatic toxicity tests¹⁴⁷ have found no effects of TFA at 1,200mg/L on *Daphnia magna* (water flea) and *Danio rerio* (Zebra fish). Moreover, a 7-day study on *Lemna gibba* G3 (duckweed) displayed a NOEC of 300mg/L and toxicity tests on various species of algae all showed an EC₅₀ value higher than 100mg/L. Furthermore,

¹⁴⁰ UNEP Ozone Secretariat, 2015. Ecological Issues on the feasibility of managing HFCs: Nairobi, UNEP Ozone Secretariat.

¹⁴¹ Neale, R. E., Barnes, P. W., Robson, T. M., Neale, P. J., Williamson, C. E., Zepp, R. G., et al. (2021), ““Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: UNEP Environmental Effects Assessment Panel, Update 2020”, Photochemical & Photobiological Sciences <https://doi.org/10.1007/s43630-020-00001-x>. See sections 7.8 to 7.11 for Trifluoroacetic acid (TFA). Open access paper.

¹⁴² Ibid footnote 133

¹⁴³ World Meteorological Organization (WMO). (2022) Scientific Assessment of Ozone Depletion: 2022, GAW Report No. 278. Available at <https://ozone.unep.org/science/assessment/sap>

¹⁴⁴ Ibid footnote 133

¹⁴⁵ Ibid footnote 133

¹⁴⁶ Ibid 141.

¹⁴⁷ Berends et al., (1999). Toxicity of Trifluoroacetate to Aquatic Organisms Environmental Toxicology and Chemistry. 1053-1059, 18, 5.

TFA exposure tests conducted on the seeds of 10 terrestrial plant species¹⁴⁸ resulted in a no effect concentration of 1000 mg/L (the maximum of the study). UNEP (2023)¹⁴⁹ reported one new toxicity test for an aquatic organism. This was a retest of the most sensitive alga (*Raphidocelis subcapitata*). The study protocol followed OECD guideline 201, with effect values based on growth. A NOEC of 2.5 mg acid equivalent/L (2,500,000 ng/L) was reported based on inhibition of growth. The detailed report of the study was reviewed by ECHA and was classified as “*reliable without restriction*”, hence it has been used here in the characterisation of the toxicity of TFA to aquatic organisms. “The margin of exposure between the distribution of no observed effect concentrations (NOEC) of trifluoroacetic acid salt from a range of studies and the observed and expected concentrations in the oceans and endorheic basins is several orders of magnitude and is indicative of *de minimis* risk”¹⁵⁰.

Under the CLP Regulation TFA does not meet the criteria for any short-term or long-term aquatic toxicity classifications.

While the aforementioned studies have all indicated to some degree that TFA does not adversely affect the environment, ECHA's evaluation of Polyhaloalkene (CAS 754-12-1) did deem that emissions to the environment of sources of TFA should be minimised based on the persistency and mobility of TFA¹⁵¹.

Presently there is no evidence to suggest that exposure of TFA to humans results in any adverse health effects¹⁵². TFA salts are also of low acute toxicity to mammals under conditions relevant to environmental exposure. UNEP (2023) reviewed a report on the potential effects of TFA in mammals, considering the effects of exposure via drinking water in male laboratory rats. The tests followed OECD guidelines (Tests 417 and 452) and exposures were for 90, 370, and 412 days at concentrations in the drinking water of 0 (control), 30, 120, and 600 mg¹⁵³ TFA acid equivalent/L. The responses measured included: activity of the enzymes alanine-amino-transferase (ALT) and glutamate-pyruvate-transferase (GPT) in the blood. The tests observed no significant effects at 30 mg/L for any length of exposure. However, a significant increase in ALT activity at 120 and 600 mg TFA acid equivalent/L was observed at 370 days, but not at 412 days. No effects on GPT were reported. In a second study with exposures for 14, 28, and 90 days to 0, 600, 1200, and 2400 mg TFA acid equivalent/L, no significant effects on ALT were observed. It was concluded that the reported effect does not change the conclusion that TFA is of low toxicity in mammals as “*increases in the activity of enzymes in or originating from the liver are considered as compensatory unless accompanied by physiological responses such as loss of weight.*”¹⁵⁴

An extensive review of the potential effects of TFA published by the German Environmental Agency did not identify any risks other than persistence in the environment. Persistence is currently a legislative criterion and not toxicological.¹⁵⁵

Furthermore, historical and current measurements of TFA in soil and surface-water indicate minimal risks when compared to NOECs in laboratory and field-based testing^{156,157}.

UNEP (2023) has concluded that TFA should not be grouped with longer chain PFAS based on persistence alone. TFA has biological properties that differ significantly from longer chain PFAS and even within the subclass of perfluorinated alkanic acids, the physical, chemical and biological properties differ widely, mostly related to the alkyl chain length.

148 Thompson, R. S. & Windeatt, A. J., (1994). Sodium trifluoroacetate: Effects on seed germination (ten species, by aqueous exposure), s.l.: Brixham Environmental Laboratory.

149 Barnes, Paul W., Bornman, Janet F., Pandey, Krishna K., Bernhard, Germar H., Bais, Alkiviadis F., Neale, Rachel E., Robson, Matthew and et. al. (2023) *Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: 2022 assessment report*. Available at: <https://ozone.unep.org/environmental-effects-stratospheric-ozone-depletion-uv-radiation-and-interactions-climate-change>

150 Ibid footnote 149.

151 ECHA (2021). Substance evaluation conclusion for Polyhaloalkene EC No 468-710-7 CAS RN 754-12-1. Available at: <https://www.echa.europa.eu/documents/10162/a794e3ad-c358-b7f8-bc74-268bfea135e7>

152 Ibid footnote 151141

153 Equivalent to a daily intake of 37.8 mg TFA/kg (body mass).

154 Ibid footnote 133133

155 UBA Final report (2021). Persistent degradation products of halogenated refrigerants and blowing agents in the environment: type, environmental concentrations, and fate with particular regard to new halogenated substitutes with low global warming potential | Umweltbundesamt, Table 14. Available at: <https://www.umweltbundesamt.de/publikationen/persistent-degradation-products-of-halogenated>

156 Ibid 129.

157 Ibid 141.

2.3 EXPOSURE AND RISK

The Chemical Safety Reports (CSRs) of seven F-gases in scope of this project were evaluated for potential refinement that would mean that no further regulatory action was needed for the substance(s). For each substance, information relating to the uses, risk characterisation ratios (RCRs), hazard assessment values, and exposure and emissions was extracted and reviewed to map the areas of concern and identify whether any risks could be further addressed. As part of this, the following was considered:

- Was any key information missing?
- Were RCRs greater than 1 robust, or were they potentially overly conservative and could be reconsidered?
- Could RCRs under but close to 1 be discussed, particularly with the upcoming introduction of the mixture assessment factor?
- Could Predicted No Exposure Concentrations (PNECs) for the environment be reconsidered, e.g. by using experimental data instead of predicted data, or lower assessment factors?
- Could Derived No-Effect Levels (DNELs) for human health be reconsidered, e.g. based on an alternative exposure limit value?
- Could exposure be improved, e.g. via implementation of additional or more effective Risk Management Measures?

RCRs were not available for three of the F-gases as they are not classified according to Directive 67/548/EEC¹⁵⁸ and Regulation (EC) No. 1272/2008¹⁵⁹. Of the four F-gases that had RCRs available, none of them were above 1, indicating exposure of the substances poses no significant risk to human health or the environment. The highest RCRs for the F-gases ranged between 0.4 and just below 1, and were all related to systematic inhalation for workers (3 long-term, 1 acute). To note, these RCRs are substance specific and should not be applied to all F-gases. Although these RCR values are indicative of 'safe use', it was still considered if there was potential for further refinements to reduce the RCRs. There was no obvious scope to improve the no-observed-adverse-effect concentrations and the assessment factors, while high, were those recommended by ECHA for the data used, thus the DNELs could not be refined. Further, the duration of use (exposure during worker activities) was already low and unlikely to be feasibly lowered further. The only scope for improvement, if needed in future, was to implement risk management measures to improve ventilation and respiratory protection.

For the F-gases without an exposure assessment (and related risk characterisation), commentary was provided relating to the expected areas of concern based on the properties of the substances and their known uses. For the environment, none of the F-gases were emitted to the aquatic environment or to sewage treatment plants during their manufacturing and use. Their Henry's Law Constants and organic carbon partition coefficient (K_{oc}) values indicated high potential to partition into the air rather than soil, sediment or water if released to the environment during manufacture, use or end-of-life. For human health, oral intake and dermal uptake were considered unlikely exposure routes. Therefore, exposure to air and thus exposure via inhalation, were relevant for the environment and human health, respectively.

Tsai¹⁶⁰ summarises exposure levels/limits for workplace exposure. The summary includes No-observed-adverse-effect level (NOAEL) values, Lowest-observed-adverse-effect level (LOAEL) values, and Lethal Concentration 50(LC₅₀) values or Approximate Lethal Concentration (ALC) values compiled from HFC manufacturer's material safety data sheets and available references (primarily the United States). According to the American Industrial Hygiene Association, DuPont Co. (USA), and Deutsche Forschungsgemeinschaft (Germany) the majority of the in-scope HFCs have relatively high occupational exposure limits, with limits of 1000ppm. CO₂ exists in air at around 400ppm.

¹⁵⁸ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A31967L0548>

¹⁵⁹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272>

¹⁶⁰ Ibid Footnote 98.

Table 2-5 Summary of exposure limits, NOAEL, LOAEL, LC50 and ALC values of HFCs¹⁶¹

HFCs	Exposure level/limit (ppm)	NOAEL (v/v%) ^a	LOAEL (v/v%) ^b	LC50 or ALC (v/v%) ^c
HFC-125	1000 ^e	7.5	10.0	80
HFC-134a	1000 ^{e,f}	NA ^d	NA ^d	50
HFC-143a	1000 ^e	NA ^d	NA ^d	54
HFC-227ea	1000 ^g	9.0	10.5	78.9

** 2021 Time weighted average workplace environmental exposure limit TWA WEEL value of 225 ppm¹⁶²

a. No observed adverse effect level.

b. Lowest observed adverse effect level.

c. The concentration lethal to 50 percent of a population (rat) by 4 h inhalation; ALC: approximate lethal concentration.

d. No available data.

e. American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Limits (WEEL) based on 8h time-weighted average (TWA).

f. Maximum workplace concentration (MAK) (DFG, Germany).

g. Acceptable exposure limit (AEL) (DuPont Co., USA).

2.3.1 Application specific risks

The majority of toxicological studies of HFCs, HFOs and H(C)FOs have mainly focused on inhalation as the primary route of exposure as it is most relevant to their physico-chemical properties (e.g. gaseous). Furthermore, the primary applications of these F-gases include refrigerant gases, aerosols and foam blowing agents, which by nature can result in a greater risk of inhalation exposure through unintentional discharge.

Foam insulation work in which a foam blowing agent such as HFC-227ea, or HFC-134a is used to form a thick layer of insulating foam in building work, is likely to have a reduced level of risk of inhalation. This is due to its application being mostly carried out by professionals with the appropriate Personal Protective Equipment (PPE) (e.g. mask/respirator). However commercial refrigerants such as HFC-134a, HFC-125, HFC-143a, and HFO-1234yf have a (albeit negligible) potential to expose unprotected humans, (e.g. a supermarket or warehouse). The EU F-gas Regulation has pushed for the reduction of the leaks of F-gases. Some studies in Poland showed that in 2020 the average leaks in commercial and industrial refrigeration has dropped to 3.7% (from 16.2% in 2015)¹⁶³.

It is important also to remember the appropriate risks associated with decomposition products of F-gases such as HF which potentially poses a greater level of risk to human health than its parent compounds. However, these decomposition products and their elevated health risk may only present themselves during certain applications and circumstances such as welding repair work, fire protection, and automotive accidents.

2.4 CLIMATE CHANGE

When F-gases are released into the atmosphere they cause the earth's average temperature to rise, contributing to anthropogenic climate change. Since the onset of the industrial revolution, HFCs have contributed about 1.1% of radiative forcing (ability of all greenhouse gases to trap heat), according to the US NOAA (National Oceanic and Atmospheric Administration)¹⁶⁴. The emissions of greenhouse gases (GHGs) including F-gases drive global warming, which has been observed to lead to rising sea levels, more frequent and severe floods, droughts, and wildfires¹⁶⁵. This has severe impacts on all of earth's ecosystems, subsequently triggering impacts on the health and well-being of populations¹⁶⁶. The impacts of climate change

¹⁶¹ Ibid Footnote 9898.

¹⁶² Toxicology and Industrial Health, 2021, Vol. 37(8) 441–450. Available at: <https://journals.sagepub.com/doi/pdf/10.1177/07482337211019860>

¹⁶³ EFCTC (2022). Focus on refrigerant containment. Available at: <https://www.fluorocarbons.org/news/focus-on-refrigerant-containment/>

¹⁶⁴ NOAA Global Monitoring Laboratory, 2022. *THE NOAA ANNUAL GREENHOUSE GAS INDEX (AGGI)*. Available at: <https://gml.noaa.gov/aggi/aggi.html>

¹⁶⁵ IPCC, 2021. Climate Change 2021, The Physical Science Basis, Summary for Policymakers. P.5. Accessible under: https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_SPM_final.pdf

¹⁶⁶ Ibid., p.8.

will cause ecosystem disruption and loss of biodiversity due to multiple factors, including, disruption of food chains, and changes in reproduction cycles¹⁶⁷.

Greenhouse gases trap solar radiation (by absorbing infrared (IR) radiation) and redirect that radiant energy toward the Earth's surface. This so-called positive radiative forcing effect contributes to global warming. Some GHGs are more effective than others at absorbing IR radiation and contributing to global warming, and for each GHG a GWP has been developed to allow comparisons of the global warming impacts of different gases. The GWP of an individual GHG depends upon (1) its atmospheric lifetime, (2) its ability to absorb infrared radiation, and (3) which infrared wavelengths the gas absorbs. The impact of an individual GHG released in the atmosphere depends upon the substance's GWP value and the amount of the substance released. GHGs include carbon dioxide (CO₂), methane (CH₄), nitrous oxide (N₂O), and fluorinated gases (F-gases).

Anthropogenic greenhouse gas emissions have risen since the industrial revolution in the 18th century¹⁶⁸. Unlike other GHGs, F-gases are synthetic and therefore have been used and released to the atmosphere over a shorter period. Significant production and emissions of HFCs in the scope of this study began in the past three decades.

Current global emissions of F-gases are uncertain¹⁶⁹, although atmospheric concentrations of all the main HFCs are measured and reported¹⁷⁰. However, analysis suggests growing demand for heating and cooling technologies means global emissions of F-gases are projected to rise¹⁷¹. One study projects global emissions of F-gases to rise from 700 MT CO₂-e in 2005 to 3,700 MT CO₂-e in 2050¹⁷². A more recent report from the WMO Scientific Assessment Panel, which takes into account updated trends in consumption and emissions, the provisions of the Kigali Amendment and national regulations including the EU F-gas Regulation and MAC Directive, the HFC phasedown in the USA, and Regulations in Japan, predicts global emissions of HFCs will decrease from approximately 2035 onward. HFC emissions from this scenario are projected to be 0.9–1.0 Pg CO₂-e/yr in 2050, and the corresponding radiative forcing is predicted to decrease from a 2018 “without control measures” scenario value of 0.22–0.25 W/m² to a value of 0.09–0.10 W/m² in 2050. The EU(+UK) share of global HFC emissions is rapidly decreasing, and even without additional measures under a revised F-gas Regulation, EU (EU+UK) is forecast to contribute only 4% to global HFC emissions as CO₂-e in 2050.¹⁷³

It should be noted that the atmospheric lifetimes of HFOs are small and so their emissions do not contribute perceptibly to climate change. WMO (2022) states that “*since the previous Assessment, updated projections, have been made of HFC emissions assuming adherence to the Kigali Amendment (excluding HFC-23). The projected emissions and the associated radiative forcing and temperature change are smaller than estimated previously. The revised projections are based on extended atmospheric observations from 2014 to 2020, updated UNFCCC national emission inventory reports, updated activity data from Annex I countries, and new consumption data from some non-Annex I countries.*”

The EU National Inventory Report for GHG emissions¹⁷⁴, shows that overall GHG emissions increased in 2021 by 193 million tonnes, or 6.2 % compared to 2020, to reach 3,311 million tonnes CO₂ equivalent in 2021. In contrast HFC emissions decreased by 3 million tonnes CO₂ equivalent, or 4.3% compared to 2020. Total EU GHG emissions are reported as 3,311 MtCO₂e and HFC emissions are reported at 70 MtCO₂e, which is 2.1% of total GHG emissions.

The GWP of the F-gases in the scope of this study are detailed in Table 2-6. Values for F-gases in the scope of this study were taken from the 2014 F-gas Regulation¹⁷⁵ (derived from the IPCC's AR4 Climate Change Report, 2007). The IPCC AR6 report¹⁷⁶ (Table 7.SM.7) was also consulted to identify additional variations of

¹⁶⁷ Ibid.

¹⁶⁸ Ritchie, H. & Roser, M., 2022. CO₂ emissions. Our World In Data. Accessible Under: <https://ourworldindata.org/co2-emissions>

¹⁶⁹ UNDP, 2017. Assessments of HFC emissions. United Nations Development Programme. Accessible under: <https://www.undp.org/publications/assessments-hfc-emissions>

¹⁷⁰ See for example Atmospheric histories, growth rates and solubilities in seawater and other natural waters of the potential transient tracers HFO-22, HFO-141b, HFO-142b, HFC-134a, HFC-125, HFC-23, PFC-14 and PFC-116, Pingyang Li, Jens Mühle, Stephen A. Montzka, David E. Oram, Benjamin R. Miller, Ray F. Weiss, Paul J. Fraser, and Toste Tanhua, Ocean Sci., 15, 33–60, 2019 <https://doi.org/10.5194/os-15-33-2019>

¹⁷¹ IPCC, 2021. Technical Summary. Accessible under: https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_TS.pdf

¹⁷² Purohit, P. and Höglund-Isaksson, L., 2017. Global emissions of fluorinated greenhouse gases 2005–2050 with abatement potentials and costs. Atmospheric Chemistry Physics. 17, 2795–2816. Accessible under: <https://doi.org/10.5194/acp-17-2795-2017>

¹⁷³ Ibid footnote 143

¹⁷⁴ UNFCCC (2022) European Union. 2022 National Inventory Report (NIR). Available at: <https://unfccc.int/documents/461931>

¹⁷⁵ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 Text with EEA relevance. Accessible under: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0517>

¹⁷⁶ Intergovernmental Panel on Climate Change 2021. Climate Change 2021 The Physical Science Basis: Working Group I Contribution to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change. Accessible under: https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_Full_Report.pdf

the F-gases in the scope of the study and to show how the 100-year GWPs of F-gases in scope of the evaluation have changed between AR4 and AR6. Table 2-6 shows that the HFCs in scope have relatively high GWPs, between 1530 and 5810 (IPCC AR6) times the 100-year GWP of CO₂. By comparison, the HFOs and the H(C)FOs have relatively small GWPs.

Table 2-6 100-year GWP of F-Gases within the scope of the study. Values for F-Gases which were included in the 2014 F-Gas Regulation¹⁷⁷ (derived from the IPCC's AR4 Climate Change Report, 2007) were used. The IPCC AR6 report (Table 7.SM.7) was also consulted to identify additional variations of the F-Gases in the scope of the study and to compare 100-year GWPs¹⁷⁸.

Group	Name	100-year GWP (AR4 & F-gas Regulation)	100-year GWP (AR6)
HFC	HFC-125	3500	3740
	HFC-134a	1430	1530
	HFC-143a	4470	5810
	HFC-227ea	3220	3600
HFO	HFO-1234yf	4 ^a	0.501
	HFO-1234ze(Z)	7 ^a	0.315
	HFO-1234ze(E)		1.37
	HFO-1336mzz(Z)	9 ^a	2.08
H(C)FO	HCFO-1233zd(Z)	4.5 ^a	0.454
	HCFO-1233zd(E)		3.88

a. Not evaluated at the time of the IPCC AR4 report. Values taken from the F-gas Regulation.

2.5 SOCIO-ECONOMIC ASSESSMENT

Consultation activities carried out for this Study sought to collect business data from F-gas manufacturers and importers, and downstream users, including how their businesses would be impacted upon a restriction of the F-gases they place on the market or use, or any other regulatory management options.

Information collected via survey is complemented with publicly available statistics by sector to construct business baseline figures and projections. Business figures representing the current values (from 2019¹⁷⁹) and baseline projections for F-gas manufacturers and importers and F-gas downstream users are presented in the subsections below. The subsequent Socio-Economic Assessment of each RMO in Section 4.2.8.1 analyses the impacts of RMOs against these baseline figures.

Numbers in this study differ from the numbers in the SEA carried out in 2022 for two main reasons:

1. Scope: this RMOA is limited to the 8 F-gases in scope, while the SEA (2022) had a scope of 10 substances. Additionally, some business figures were asked at the level of the F-gas, mainly turnover and other figures measured in terms of turnover value, such as degree of potential substitution, potential derogations, etc.
2. Sample: the composition of survey participants was slightly different in the survey to F-gas manufacturers, and a significantly larger sample was gathered to participate in the survey to F-gas downstream users. In both cases, this led to a higher sales value on aggregate for each sample.

¹⁷⁷ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 Text with EEA relevance. Accessible under: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0517>

¹⁷⁸ Intergovernmental Panel on Climate Change 2021. Climate Change 2021 The Physical Science Basis: Working Group I Contribution to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change. Accessible under: https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_Full_Report.pdf

¹⁷⁹ 'Current' values referred to 2019 in consultation questions to ease participation from all companies that had already participated in our consultation to the Socio-Economic Assessment of the Value of F-gases one year prior to the current study, and to facilitate combining information from both consultations by the team of analysts. 2019 is taken as the reference year to avoid using 2020, which was not considered a representative year due to the effects of the pandemic, and 2021 being too recent to obtain official figures at the time of the first study.

2.5.1 Business figures of F-gas suppliers

Economic statistics specifically for the F-gas sector alone are not publicly available, in part as this industry does not have its own defined NACE code, but has activities spread across several NACE codes which are in turn combined with non-F-gas activities. Therefore, the baseline economic and business figures for the F-gas industry in this section has been gathered from the stakeholder consultation. A check on the volume of F-gases placed on the market by survey respondents against the volume reported by the EEA of the F-gases in scope suggests that the survey results can be used directly with a high level of accuracy, requiring only minor adjustments: tonnes of F-gases in scope placed on the market by survey participants are found to differ from the total volume of F-gases in scope placed on the market as reported by EEA by only 7% jointly. Figures from the survey that appear in this Study are adjusted individually by F-gas wherever possible, or by the joint percentage adjustment of 7% when individual figures are not available, to account for this margin of reporting error. Additionally, data from Eurostat's Survey of Business Statistics at the level of the Industrial Gases sector (NACE Rev. 2 Class C20.11¹⁸⁰) has been used to complement the context around the impact of the pandemic and expected rhythm of recovery, as well as to contrast respondents' expectations with the wider sector's trends.

The F-gas supply¹⁸¹ (i.e., 'the sector', or 'the F-gas industry') comprises a limited number of companies in the EEA. A stakeholder consultation of 9 producers and importers of F-gases in 2021, and another consultation to 8 producers and importers of F-gases carried out in 2022-2023, saw only one of the companies reporting as a SME. As such, the figures for this subgroup cannot be reported without breaching anonymity, so they will be reported on aggregate for the whole sector.

Most of the F-gases in the EEA are supplied through imports, with companies importing around 85% of the sales volume in tonnes of F-gases in basic form¹⁸², and then formulating other mixtures and/or articles. In 2019, the turnover accrued by these F-gas producing and importing companies from their F-gas related sales was around €2.8 billion¹⁸³ (referred to the 8 F-gases in scope only), based on the survey to F-gas manufacturers and importers in the EEA conducted by Ricardo. According to the same survey data, the F-gas sector's contribution to the Gross Value Added (GVA) of the EEA's economy (i.e., the direct contribution of F-gas production and imports to Gross Domestic Product (GDP), measured as the value of production minus the value of purchases of intermediate consumptions used in production) is estimated to be around €0.9 billion in 2019. Most of the surveyed companies have wider activity scopes, and the aggregate reported turnover across all producers and/or importers and their F-gas and other activities was around €4.3 billion in 2019. As reported in the consultation, the F-gas industry (i.e., production and import of F-gases and their mixtures and/or articles, and not limited to the ones in scope) employs close to 850 workers, and more than 13,000 employees when considering their full scope of activities.

Regulatory costs that the F-gas sector is subject to are also a part of the analysis. A 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU-27 chemical industry¹⁸⁴ suggests that the regulatory burden affecting the wider chemicals sector represents 2.3% of their turnover¹⁸⁵. This also represents 30% of the industry's Gross Operating Surplus, which suggests that this burden plays a role in shaping the sector's profitability. The existing chemicals-specific legislation in the EU-27 is estimated to generate around a third of this total burden. For the F-gas industry, this regulatory burden is estimated to represent 3.7% of their turnover according to the 2016 study, as an industry that produces specialty chemicals, i.e. those used for specific purposes due to their specialist properties.

¹⁸⁰ This class includes: manufacture of liquefied or compressed inorganic industrial or medical gases: elemental gases, liquid or compressed air, refrigerant gases, mixed industrial gases, inert gases such as carbon dioxide, isolating gases. This class excludes: extraction of methane, ethane, butane or propane, see 06.20 – manufacture of fuel gases such as ethane, butane or propane in a petroleum refinery, see 19.20 – manufacture of gaseous fuels from coal, waste etc., see 35.21 – manufacture of gas. Source: Eurostat, (2008). Statistical classification of economic activities in the European Community. NACE Rev. 2. Eurostat Methodologies and Working papers. Available from: <https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF/dd5443f5-b886-40e4-920d-9df03590ff91> (europa.eu)

¹⁸¹ Whenever 'F-gas supply' is used as a term and nothing else is specified, it refers to all F-gases, beyond the 8 F-gases in scope.

¹⁸² EEA, 2022. ETC CM report 2022/03: Fluorinated Greenhouse Gases 2022. Accessible under: <https://www.eionet.europa.eu/etcs/etc-cm/products/etc-cm-report-2022-03>

¹⁸³ Ricardo survey to F-gas manufacturers and importers, 2023.

¹⁸⁴ Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission), Technopolis Group, VVA. (2016). Cumulative Cost Assessment for the EU Chemical Industry. European Commission. Available from: <https://op.europa.eu/en/publication-detail/-/publication/8eb1b47a-ee94-11e6-ad7c-01aa75ed71a1/language-en>

¹⁸⁵ The study assessed costs across the EU-28 between 2004 and 2014, so it should be understood as an indicative reference or approximation, given that this considers the burden within the EU-27 for the period 2008-2018 and projects this forward as part of the baseline.

2.5.1.1 F-gas producers and importers: trends and baseline projections

In this Section, projections of the main business and economic figures associated with the manufacture and import of the 8 F-gases in scope are presented. All baseline projections of growth for the F-gas industry are estimated based on publicly available data at the level of the wider EU Industrial Gases sector, and then applied to the figures reported by the F-gas industry members in consultation, in the following way (see Annex B1):

- The historical data from Eurostat's Survey of Business Statistics on the turnover of the Industrial Gases sector was included in a model that related it to overall economic trends in the EEA, namely GDP and population, from Eurostat. Historical series for the F-gas sector are extrapolated from these wider-scope figures.
- Long-term macroeconomic projections by the OECD¹⁸⁶ for real GDP and population were then used to project forward the turnover of the Industrial Gases sector from 2021 to 2040.
- The resulting growth rates estimated for the period 2022-2040 were applied to the F-gas level figures reported in consultation by F-gas producers and importers. The exception was HFCs, for which the phase-down from the F-gas Regulation was applied as future pathway instead.

The expected growth for the sector over the next decade, as reported by surveyed F-gas producers and importers (i.e., 'the sector', or 'the F-gas industry'), is consistent with the growth projected by the study team for the wider industrial gas sector¹⁸⁷, based on past trends and future macroeconomic projections from the OECD as mentioned above. On average, the overall F-gas sector expects their turnover to grow at a Compound Annual Growth Rate (CAGR) of 3.3%, including inflation, while projections by the study team deliver a 3.1% growth rate including inflation. Based on this, the external and independent projections by the study team will be used to form the future baseline scenario for the F-gas sector and the figures presented here, referring, beyond turnover, to employment, capital expenditure, operating expenditure, and regulatory costs. From this point forward, all monetary measures will be presented in constant euros based on 2021 prices (i.e., presented in real prices), thus removing the effects of inflation.

Over the last decade, the turnover (i.e., revenue) from the EEA's F-gas industry is estimated to have grown between 0.9% and 1.5% per year, on average, to 2019¹⁸⁸. The Covid-19 pandemic, however, has likely had an impact on the operations of the sector, which has been estimated to be around a 21% drop in production and turnover in 2020¹⁸⁹. That said, the sector is anticipated to have somewhat recovered since: following the European Commission's estimations of GDP recovery¹⁹⁰, the sector revenue is estimated to have grown by 10% in 2021 and 6% in 2022. Thereafter, the sector is expected to continue on its longer-term growth trend (i.e., at a compound average growth rate similar to the decade before 2020).

Most of the sector's sales volume coming from F-gases (reported in the survey as around 85%) is represented by imports of F-gases in basic form. That is also consistent and in line with the EEA's reports (75%).

The split of this turnover by each of the F-gases in scope is of special relevance, since some of them will be phased down by the current F-gas Regulation that is in place in the EU in the baseline scenario. That is the case for HFCs, while H(C)FOs are not affected by this phase-down. Figure 2-5 below shows the split of the total turnover attributable to the F-gases in scope of this Study, by F-gas. F-gases for which information was provided by less than 5 respondents were grouped into a single category.

¹⁸⁶ OECD. Long-term baseline projections, No. 95 (Edition 2014). Accessible from: https://www.oecd-ilibrary.org/economics/data/oecd-economic-outlook-statistics-and-projections/long-term-baseline-projections-no-95_data-00690-en

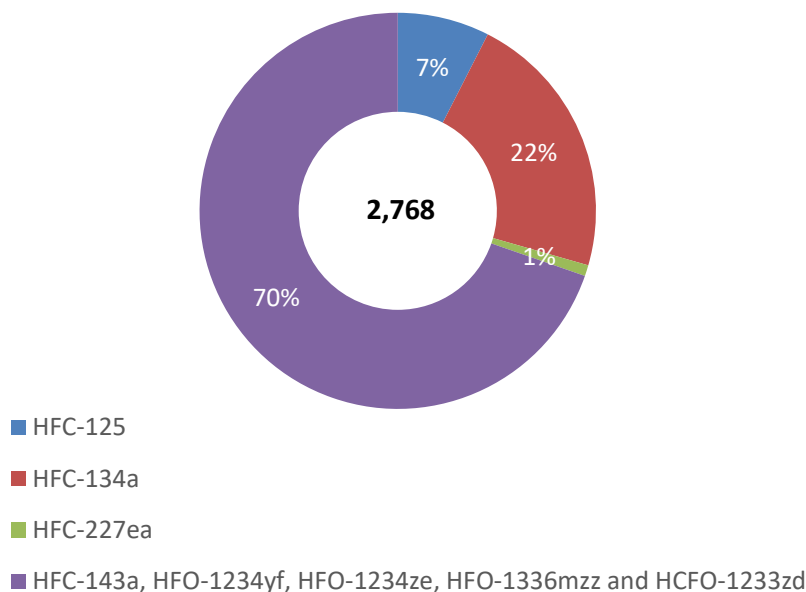
¹⁸⁷ Business figures by F-gas in scope are not publicly available, and neither for the F-gas manufacture and import overall. Hence, an approximation to the trends of the F-gas industry is made from the Survey of Business Statistics using the Industrial Gas sector as reference (NACE Rev. 2 code C20.11). Business figures themselves, such as market size and employment, are taken as valid from the survey; coverage from survey respondents is estimated to be above 90% of the tonnes of F-gases in scope (comparison with EEA figures), so the margin of error is low.

¹⁸⁸ This and other historical trends are estimated by the study team based on current (2019) data provided in consultation by F-gas producers and importers and on past trends observed for the wider 'Industrial gases' sector. The underlying assumption is that overall trends will have been similar.

¹⁸⁹ Ricardo own estimations from econometric regressions relating the output of the EEA Industrial Gases sector to EEA's GDP and population.

¹⁹⁰ European Commission. (2022). Winter 2022 Economic Forecast. Available from: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_926

Figure 2-5 Total turnover attributed to the F-gases in scope in 2019 (2021 € million), split by F-gas. Source: Ricardo estimation based on consultation to industry members.



Over the coming decades, overall past trends introduced above are assumed to continue if no further regulatory action is taken (i.e. This is the baseline or 'Do nothing' scenario, i.e., a counterfactual case in which the proposed restriction of PFAS including F-gases is not implemented and no other RMOs which restrict the use of F-gases, on top of the F-gas Regulation in force). That is, it is understood that members of this market have taken into account the current F-gas Regulation phase-down in their own expectation of business volume, and further, business projections solely based on the sector's history and the anticipated macroeconomic environment for the coming decades are aligned with the expectations reported by the industry. These baseline scenario projections and trends are considered for seven different business indicators:

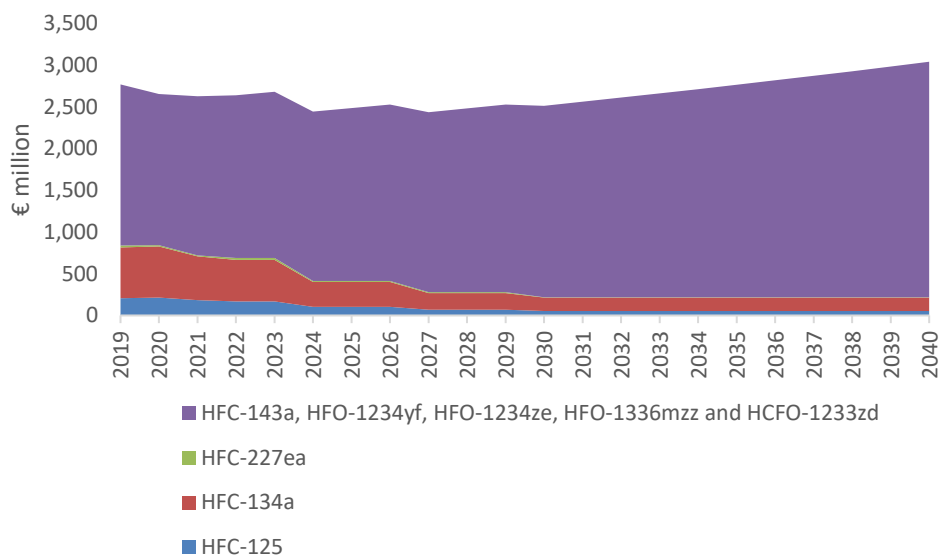
- Turnover and volume (tonnes)
- Gross Value Added
- Intermediate consumption and operating expenditure
- Capital expenditure
- Research and development
- Regulatory burden
- Employment.

I. Turnover and tonnes of the F-gases in scope in the EEA

The EEA turnover from placing on the market the F-gases in scope is projected to grow at a CAGR of 0.4% over the next two decades in real terms (i.e. excluding inflation), as depicted in Figure 2-6 below. This estimate is based on the current and expected growth for the European economy, the overall business context and the policy baseline (especially the F-gas Regulation in place), and is in line with stakeholders' expectations, as provided in consultation. These projections are in line with the growth that may be expected from a mature and well-established industry, stable but moderate, and amounts to a cumulative growth close to 14% from 2023 to 2040 in real terms.

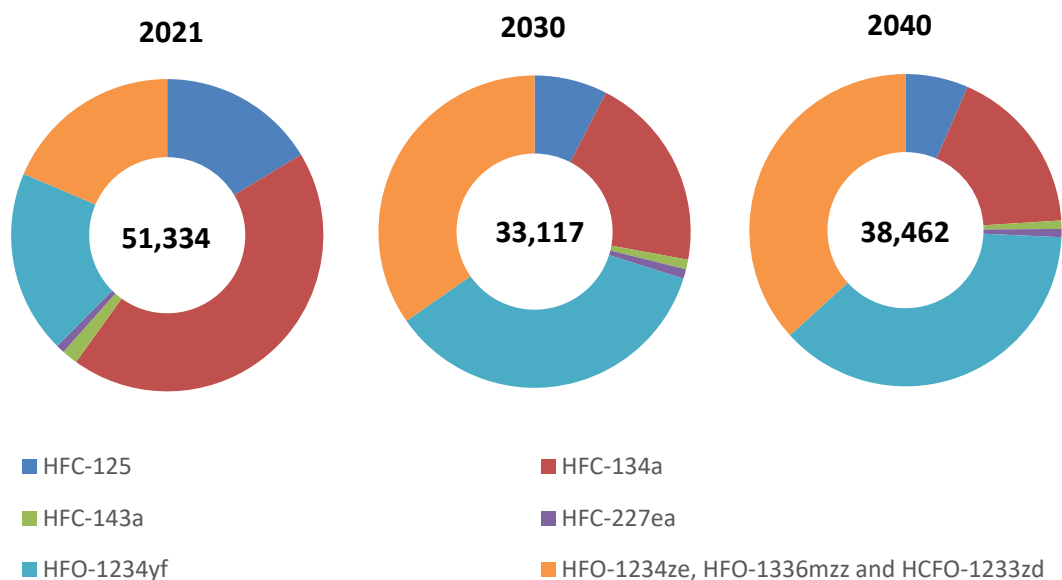
Regarding the phase-down established by the current F-gas Regulation, the 0.4% growth accounts for the switch from higher GWP F-gases towards unsaturated, low GWP H(C)FOs. This is reflected in an initial decrease in turnover or market value during the first half of the 2020s, and then an increase that is supported entirely by H(C)FOs. Volumes reported for each of the F-gases in scope for the baseline scenario in 2030 are shown below.

Figure 2-6 Turnover associated with EEA supply of F-gases in scope, 2019 to 2040. Source: Ricardo estimation based on consultation to industry members, data from Eurostat¹⁹¹, and phase-down for HFCs from the F-gas Regulation.



The volumes in tonnes of F-gases placed on the market are shown in Figure 2-7 for 2021, as reported by industry in consultation, combined with information from the EEA F-gas Report (2022), and for 2030 and 2040 as projected by the study team, taking into account the HFC phase-down in the F-gas Regulation. Overall, tonnes of the F-gases in scope are projected to jointly decrease at a CAGR of 4.8% over the next decade, or a cumulative 35%. This trend, along with the change in distribution of tonnes placed on the market (POM) from HFCs to unsaturated H(C)FOs highlights the continued expected effect of the F-gas Regulation driving a reduction in GWP of the F-gases placed on the market. This expected transition from HFCs POM towards H(C)FOs, that have much lower GWP, can be observed in Figure 2-7 below.

Figure 2-7 Tonnes of each of the F-gases in scope placed on the market in 2021 (EEA F-gas Report 2022) and own estimation in 2030 and 2040 according to the phase-down imposed by the F-gas Regulation.



Additionally, companies in the F-gas industry report a larger current turnover when economic activities other than production and/or import of the F-gases in scope are included. This could be other F-gases and/or additional business beyond F-gases, such as other chemicals. This will be an important aspect when evaluating business impacts of the RMOs, as being involved in other activities may help mitigate any potential

¹⁹¹ Ibid footnote 180188.

losses. However, for the purposes of assessing impacts of different RMOs in this report, only impacts affecting the F-gases in scope and the associated businesses (i.e., downstream users, see Section 2.5.2) were addressed in consultation and can be assessed here. Moreover, the majority of the surveyed F-gas manufacturers and importers' business scope is 100% F-gas production and/or import.

II. Gross Value Added of the F-gases in scope in the EEA

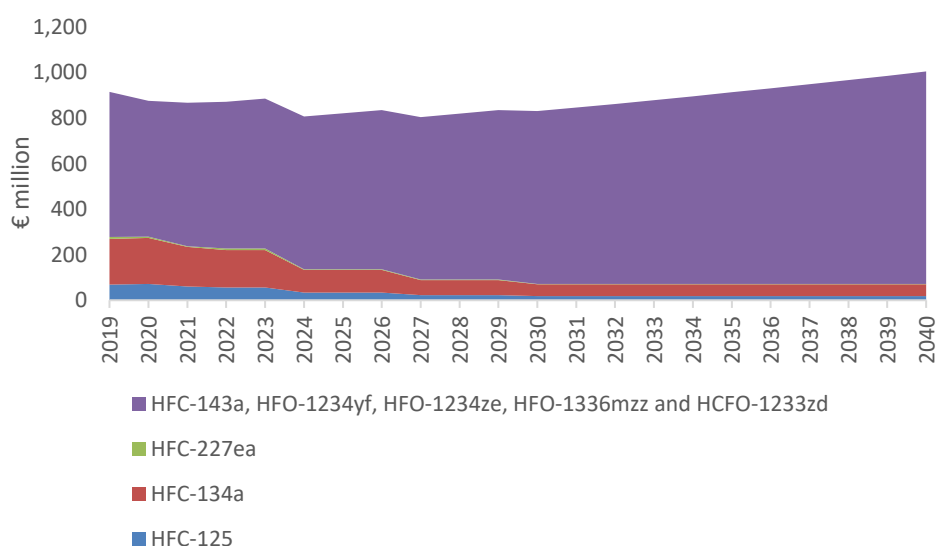
The GVA associated to the manufacture and import of the F-gases in the scope of this Study, more technically defined as the value of output or production minus intermediate consumption of goods and services (gross, i.e., before taxes), refers to their contribution to Gross Domestic Product (GDP). The stakeholder consultation allowed the retrieval of GVA as the difference between production value and intermediate consumption, and the projection of both was then used to obtain baseline projections of GVA as a difference.

The GVA of the sector amounted to around €900 million in 2019, equivalent to 33% of its economic output. GVA increased in the 10 years between 2009 and 2019 at a CAGR of 2.2%¹⁹², which is slightly higher than the sector's output growth. Based on the responses received to the survey, although not directly linked by respondents, the study team considers that two trends have potentially contributed to this:

- Intermediate costs (OPEX) have grown at a slightly slower pace than output (1.3% vs 1.5% per year, based on wider sector trends from Eurostat) over the last decade.
- The sector's expenditure on R&D has grown more rapidly than output (2.7% vs 1.5% based on wider sector trends from Eurostat). The sector's innovation has likely translated into higher value added in the sector.

In the baseline scenario, these trends are not assumed to deepen; OPEX will remain proportional to production volume, thus producing growth for GVA at a CAGR of 0.4%, as shown below in Figure 2-8. It is assumed that in the baseline scenario, actions, such as investing in some production lines and reducing the output of others, to face and adjust to the HFC phase-down in force have already been planned and at least partially taken in advance.

Figure 2-8. Gross value added associated with EEA supply of F-gases in scope, 2019 to 2040. Source: Ricardo estimation based on consultation to industry members, data from Eurostat¹⁹³, and phase-down for HFCs from the F-gas Regulation.



III. Operating expenditure of the F-gases in scope in the EEA

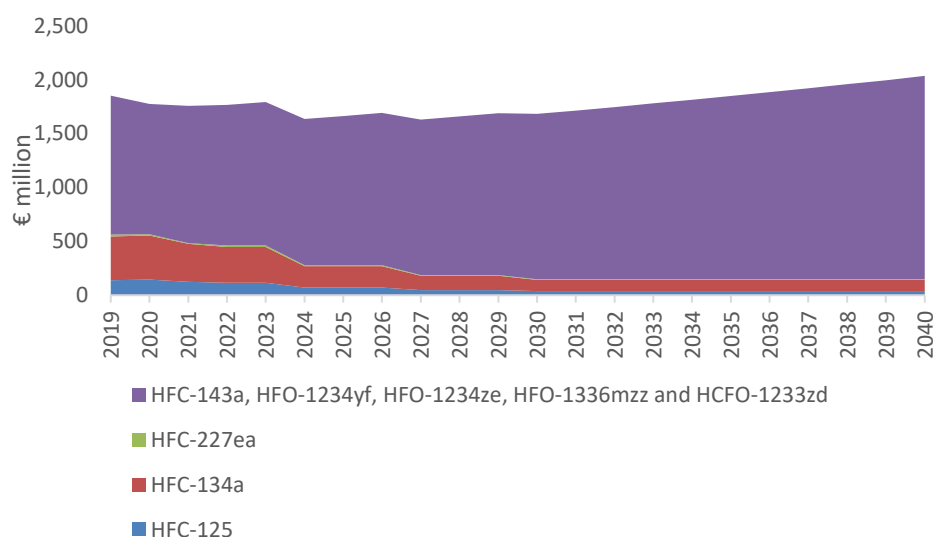
The operating expenditure of producers and importers of F-gases within the scope of this study refers to the value of costs incurred by the industry to maintain operations. The stakeholder consultation provided data on

¹⁹² Ibid footnote 188.

¹⁹³ Ibid footnote 180188.

operating expenditure for 2019. Between 2009 and 2019, OPEX grew at a CAGR of 1.3% in the last decade. This growth in OPEX, together with a past growth rate for turnover of 1.5% per year during that period, means that intermediate consumption per unit of revenue has declined. Growth in OPEX is expected to continue in line with turnover growth, as this type of costs are generally proportional to production, with a CAGR of 0.4%, as showcased in Figure 2-9 below.

Figure 2-9. Operating expenditure (OPEX) associated with EEA supply of F-gases in scope, 2019 to 2040. Source: Ricardo estimation based on consultation to industry members, data from Eurostat¹⁹⁴, and phase-down for HFCs from the F-gas Regulation.



IV. Capital expenditure of the F-gases in scope in the EEA

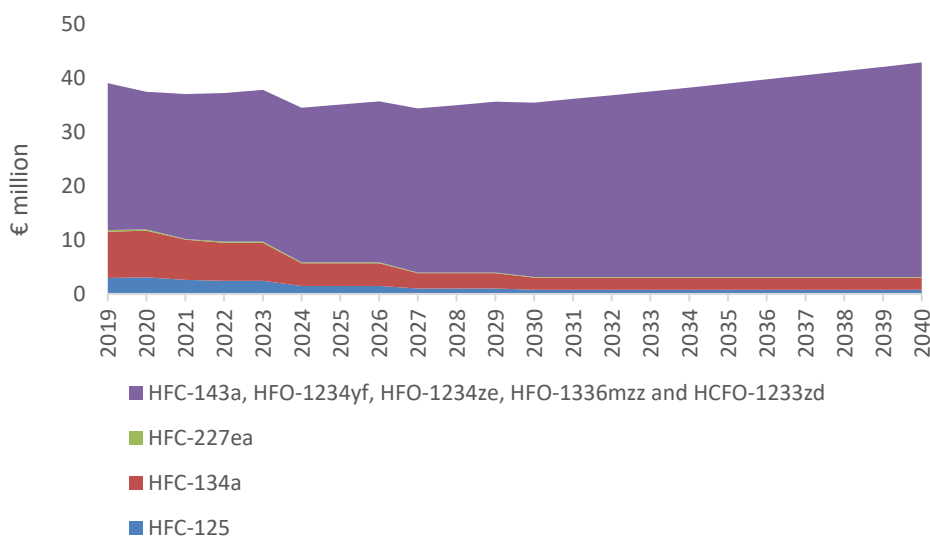
In this study, capital expenditure (CAPEX) refers to the money spent on acquiring assets. Between 2009 and 2019, CAPEX grew at a CAGR of 1.8%¹⁹⁵. In line with the wider chemicals sector, the energy transition that has been achieved so far has likely implied a large growth in investment to renew energy sources and systems within the industry, as well as to improve the energy efficiency of many processes. According to Cefic's Facts and Figures 2023¹⁹⁶, the energy intensity of the chemicals industry has almost halved from 1990 to 2020, and its overall energy consumption has declined by 22% in the same period. More recent developments, such as the increasing focus in moving faster towards climate neutrality and other demands on the sector, may require faster growth in the capital expenditure of F-gas producers and importers as they seek to increase their production capacity of lower GWP F-gases to meet the anticipated increase in demand. Future projections of capital expenditure for the EEA attributed to the F-gases in scope are shown in Figure 2-10. For the next two decades, the observed growth trend in capital expenditure is assumed to continue at a lower rate than in the previous decade in the absence of further policy drivers, at 0.4%, in line with turnover growth based on macroeconomic projections. Part of this growth is also estimated to contain R&D and innovation investment.

¹⁹⁴ Ibid footnote 180 188.

¹⁹⁵ Ibid footnote 180 188.

¹⁹⁶ Cefic (2023). *Facts and Figures*.

Figure 2-10. Capital expenditure (CAPEX) associated with EEA supply of F-gases in scope, 2019 to 2040. Source: Ricardo estimation based on consultation to industry members, data from Eurostat¹⁹⁷, and phase-down for HFCs from the F-gas Regulation.



V. Regulatory cost of the F-gases in scope in the EEA

Regulatory burden estimates capture the administrative costs generated by EU chemicals legislation, which includes the cost of the preparation and submission of information for registrations, the issue of permits, and information for product users (e.g., labels). In the baseline scenario between 2009 to 2019, on average regulatory burden is considered to be between 3.7% of turnover¹⁹⁸ and 4.5% of turnover¹⁹⁹, with a CAGR of 1.5%. This level of burden is assumed to grow between 2023 and 2040 with a CAGR of 0.4%, in line with turnover growth.

VI. Employment of the F-gases in scope in the EEA

Overall, the chemicals industry typically employs highly qualified and highly paid professionals. Employment compensation in the chemicals industry is among the highest out of EU industries, and the same is found for the F-gas industry. As the EEA F-gas sector continues to expand in the future, this is likely to be complemented by an increase in labour demand. However, this relationship between the sector's output and employment has some particularities:

- In the short run, employment has historically been less volatile than sectoral output or production. For example, when output drops, employment declines with lower intensity and, usually, with a time lag. The adjustment in employment is also likely to spread over a longer period than for output. This is driven by the relative rigidity of the labour market in the EU-27 when compared to the market of goods and services, meaning that production is more easily and immediately adjusted than employment.
- In the long run, however, employment and production are assumed to follow similar trends, unless any significant technological and/or production process changes substantially affect this relationship between production and employment. As these changes are uncertain, they have not been considered in the baseline projections below.

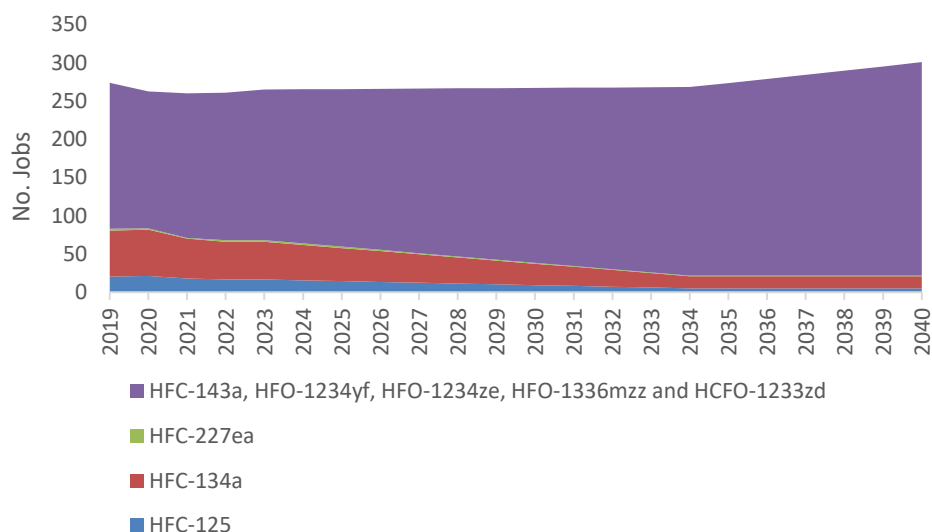
Based on these considerations, the contraction in 2020 and following recovery has been modelled *ad-hoc*, after which employment is assumed to grow in line with turnover at a CAGR of 0.4% per year between 2023 and 2040. This is shown below in Figure 2-11 for the sample of F-gases in scope only. This is an estimation of jobs directly attributable to each F-gas, while other jobs in general F-gas manufacture and import, adding up to 850 jobs in total, have been excluded from this picture.

¹⁹⁷ Ibid footnote 180188.

¹⁹⁸ Ibid footnote 180 196.

¹⁹⁹ Estimate from the targeted survey to F-gas manufacturers and importers.

Figure 2-11. Employment figures associated with EEA supply of F-gases in scope, 2019 to 2040. Source: Ricardo estimation based on consultation to industry members, data from Eurostat²⁰⁰, and phase-down for HFCs from the F-gas Regulation.



2.5.2 F-gas downstream users: trends and baseline projections

F-gases are used for a wide range of downstream applications which are important for the continued functioning of society, including applications such as refrigeration, air conditioning, heating, insulation, metered dose inhalers. Together, these represent multi-billion EUR industries. However, a monetary valuation does not reflect their full social value.

Many of these applications rely on the use of F-gases to develop their activities and products. In the absence of alternatives, any fully restrictive measure on the placing on the market and use of F-gases would have an immediate impact on these essential products and services, including: the cold food supply chain, heating and cooling the built environment (especially significant in hot climates), and people who require medicines to treat respiratory problems. This would have negative social and economic impacts for most people in EEA societies who rely on these products.

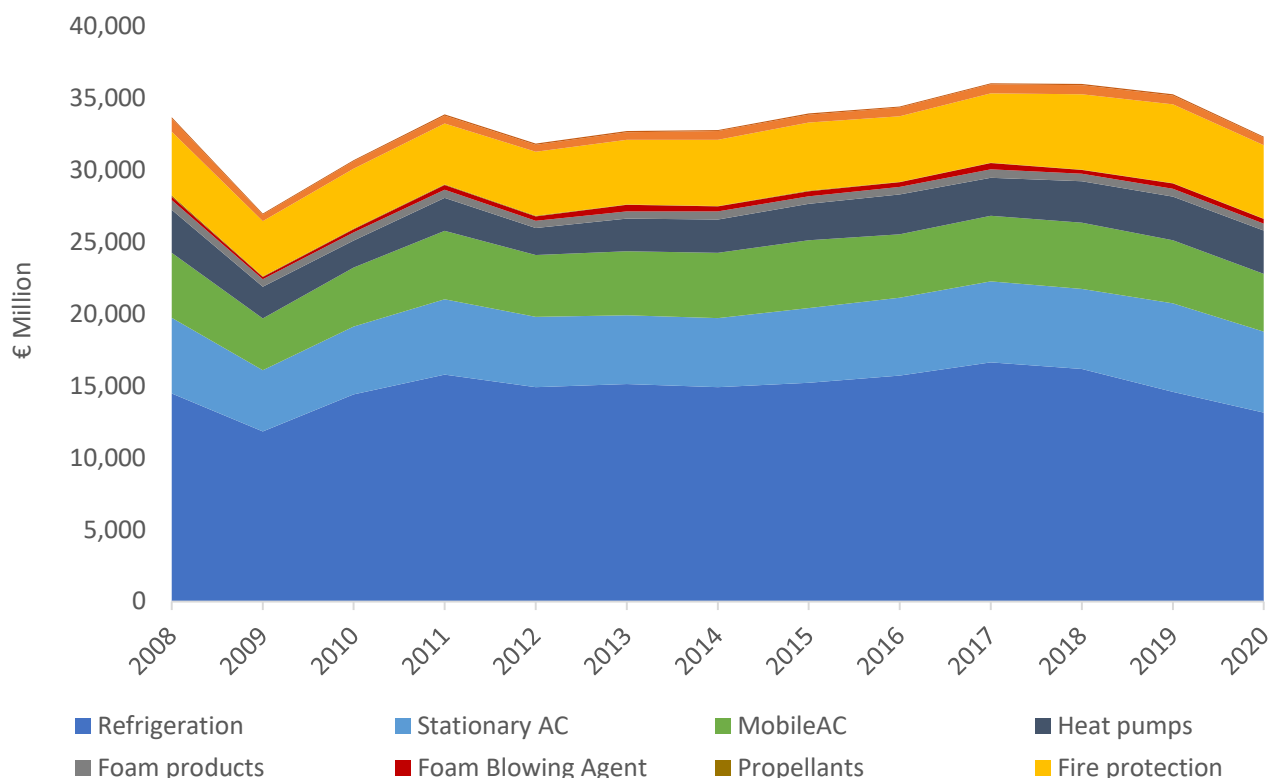
The graph below displays the aggregate production value of all the downstream user applications for each category over the period 2008-2020. Overall, the production of downstream user application sectors has grown at a CAGR of 2.3% between 2015 and 2019²⁰¹, afterwards dropping from almost €35 billion to €32 billion in 2020 when the Covid-19 recession hit.

Figure 2-12 shows that the greatest production value for F-gas applications is linked to refrigeration, which is also the largest end use of F-gases. Its share of the overall value of downstream user applications has decreased over the last decade from a maximum of 47% in 2010 to its current 41%. Other application sectors, namely the ones related to fire protection, stationary air conditioning, and heat pumps, have grown more rapidly.

²⁰⁰ Ibid footnote 188.

²⁰¹ The same reference years as in previous sections on the F-gas market are used for consistency and comparability. 2020 is considered an anomalous year due to the effects of the pandemic and lockdowns during that year.

Figure 2-12 Production value by relevant product application (€ Billion, constant 2021 prices), historical data. Source: Prodcom database (2008-2020).



2.5.2.1 F-gas downstream users: trends and baseline projections

The results of the F-gas Evaluation²⁰² show that manufacturers have been able to continue their business as usual and will continue to grow even in the face of the F-gas phase-down, assuming they will have enough preparation time and/or resources to acquire alternative substances/technologies, including low GWP F-gases that are not subject to the phase-down imposed by the F-gas Regulation. The results of the Impact Assessment to the F-gas Regulation also found the impact on the macroeconomy of the F-gas Regulation was small as the changes included concerns only related to limited areas of the economic system²⁰³. Respondents to the survey conducted for this Study also indicated they will not be significantly impacted by the F-gas phase-down coordinated by the F-gas Regulation.

Therefore, in order to obtain baseline projections of the business figures of F-gas downstream users, the historical data from Prodcom on the production value of each downstream user application was included in a model that related it to overall economic trends in the EEA, namely GDP and population, from Eurostat. Long-term macroeconomic projections by the OECD²⁰⁴ for real GDP and population were then used to project forward production values of each of the F-gas downstream user applications from 2021 to 2040. The resulting growth rates estimated for the period 2022-2040 (2022 is considered the first year after the effect of the COVID-19 pandemic and restrictions are overcome) are varied, but overall moderate.

Economic impacts from each RMO on downstream users of F-gases will be compared against this baseline.

The downstream user application sectors that are projected to grow the most (i.e., between 1.6% and 2.3% per year on average as a result of the abovementioned projections) are heat pumps, foam products, solvents, and fire protection equipment, based on their historic growth and relationship with overall GDP and population. For the other applications, the growth that results from baseline projections is below 1.0% per year on average.

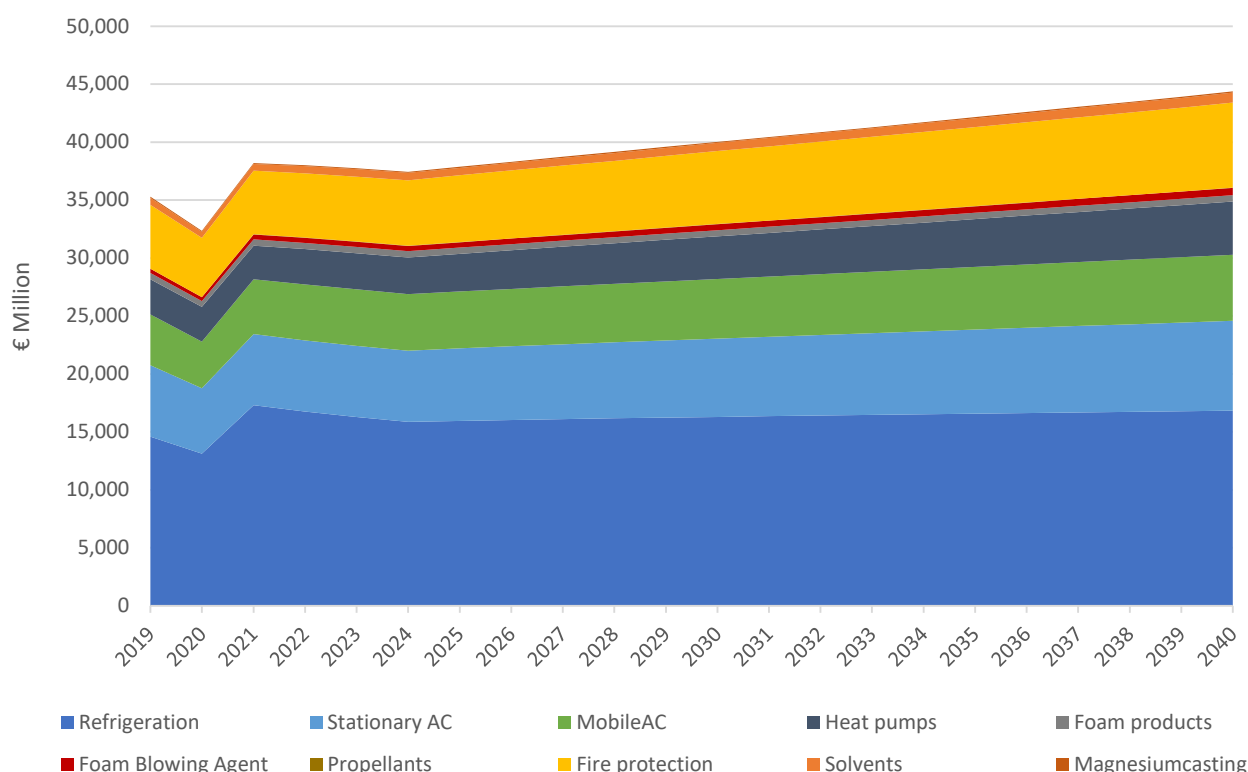
²⁰² Öko-Recherche, 2019. Support contract for an Evaluation and Impact assessment for amending Regulation (EU) No 517/2014 on fluorinated greenhouse gases, CLIMA.A2/ETU/2019/0016, Evaluation Final Report. European Commission: DG Climate. Available from: https://ec.europa.eu/clima/system/files/2022-04/f-gas_evaluation_report_en.pdf.

²⁰³ Öko-Recherche and Ricardo, 2021. Support contract for an Evaluation and Impact Assessment for amending Regulation (EU) No 517/2014 on fluorinated greenhouse gases. Own copy.

²⁰⁴ OECD. Long-term baseline projections, No. 95 (Edition 2014). Accessible from: https://www.oecd-ilibrary.org/economics/data/oecd-economic-outlook-statistics-and-projections/long-term-baseline-projections-no-95_data-00690-en

Figure 2-13 below shows the resulting baseline projections for each downstream user sector's production value.

Figure 2-13 Baseline projections of the selected downstream using sector applications' production value (€ Million, constant 2021 prices). Own elaboration based on Prodcorn data.



The characterisation of the remaining economic variables of the downstream user application sectors in the rest of this section rely on the figures provided by industry members in consultation. 41 F-gas downstream users manufacturing products belonging to 21 different application categories responded to the consultation. The 21 categories that were surveyed in the consultation all belong to the 10 applications represented in Figure 2-13. Downstream application categories contain finer product divisions for which this information, beyond the production value figures shown above, is not publicly available in aggregate. Survey responses cover around 70% of the joint value of all applications as shown in Figure 2-13 for 2019. Hence, our survey responses will be considered representative, on aggregate, of this baseline group of downstream user applications (i.e., joint conclusions can be extrapolated to the whole group in general²⁰⁵, but for individual application categories, sample representativeness is varied, and therefore, some individual sectors are underrepresented).

The product application categories covered in our RMOA survey, along with their respective number of respondents are presented in Table 2-7 below. Categories with less than 5 respondents are not carried forward for quantitative analysis, but qualitative information is considered to the extent possible.

Table 2-7 Product application categories covered in RMOA consultation with F-gas downstream users, and response numbers.

Application category	No. Respondents	Included in quantitative assessment (Y/N)
Mobile air conditioning	8	Y
Moveable room air conditioning	5	Y

²⁰⁵ Impacts from the restriction on downstream users' economic figures will also be calculated using the sample as reference, and extrapolations will be commented where possible, with the caveat that those extrapolations will be heavily impacted by the sample composition. Capturing what could happen to that many sectors on aggregate requires either oversimplifying assumptions or a much larger sample that was not possible to obtain.

Application category	No. Respondents	Included in quantitative assessment (Y/N)
Stationary air conditioning	9	Y
Air conditioning: Multi split systems (VRF)	9	Y
Chillers	11	Y
Heat pumps	13	Y
Industrial heat pumps and power generation	6	Y
Industrial refrigeration	10	Y
Transport refrigeration	9	Y
Hermetically sealed standalone units (Commercial refrigeration)	9	Y
Condensing units (Commercial refrigeration)	8	Y
Centralised systems (Commercial refrigeration)	8	Y
Domestic refrigeration	5	Y
Fire protection	5	Y
Propellants (non-MDI)	6	Y
Foam blowing agent (open cell)	3	N
Foam blowing agent (closed cell)	20	Y
Foam products	4	N
Solvents	2	N
Cover Gas for magnesium casting	0	N
Metered Dose Inhalers (MDIs)	4	N
Skin coolers used in beauty shops	1	N
Other	1	N
Total	41	--

Most respondents are present in more than one product category, and hence the total number of respondents is lower than the sum of respondents across categories, meaning that the product scope of each of the companies participating in the consultation usually spans multiple compatible F-gas applications (e.g., refrigeration, air conditioning and heat pumps). Therefore, a disaggregation of business figures by category is not exact; for example, turnover by product category refers to turnover from companies reporting in each of the product categories, and many of the companies are counted more than once, across all categories where they are manufacturers. Similarly for other business figures, like employment and costs.

Besides the issue for the disaggregation of business figures, numbers provided for the sample as a whole do not present double counting problems and impacts of each RMO presented in Section 4.2.8.1 can be considered independent across product categories.

Baseline scenario projections and trends are considered for the following seven business indicators (shown below in Table 2-8 along with their current (2019) aggregate levels as reported by survey participants).

Table 2-8 Current (2019) values for each of the variables of analysis, estimated from information provided by the sample of surveyed F-gas downstream users.

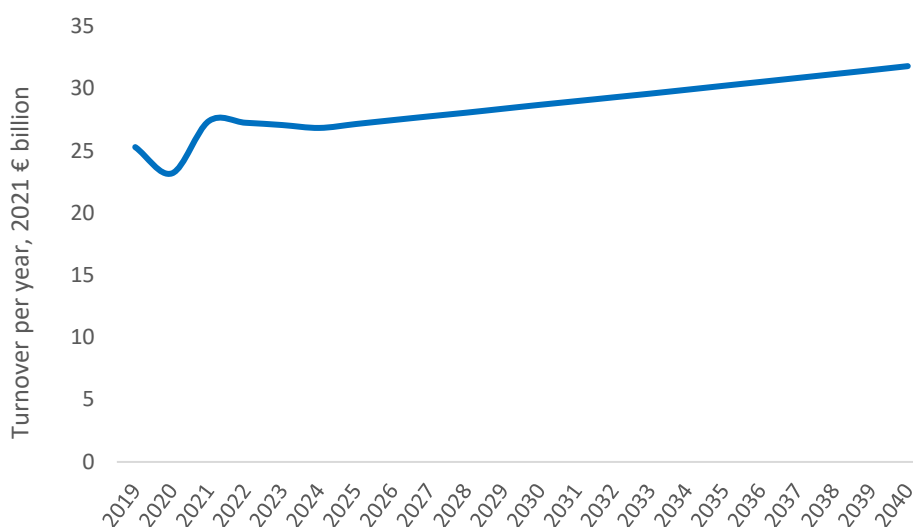
Business indicators	2019 value (2021 €)
Turnover	€25,300 million
Gross Value Added	€4,000 million
Intermediate consumption and operating expenditure	€21,200 million
Capital expenditure	€600 million
Research and development	>€100 million
Regulatory burden	€1,100 million
Employment	59,500 FTE jobs

All baseline growth rates are estimated based on publicly available data of the production volume at the level of each of the application sectors in the EU (see Figure 2-13), and then applied to the figures reported by industry respondents in consultation.

I. Turnover of sample of EEA F-gas Downstream Users

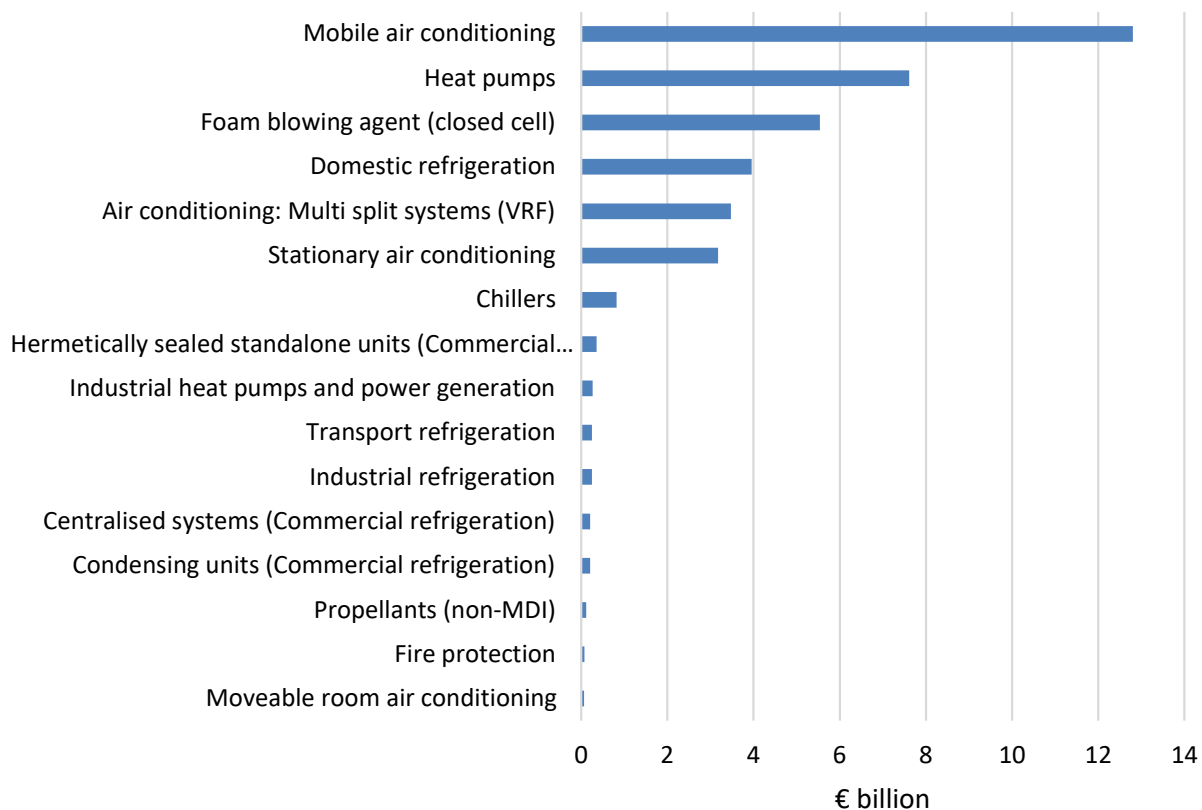
The projections of growth presented in Figure 2-13 were applied to the total turnover of the sample of EEA F-gas downstream users, and result in a CAGR of 1.0% over the next two decades, as depicted in Figure 2-14 below. The projections amount to a cumulative growth of approximately 26% over this period. As shown in the figure below, a consistent upward trend is expected from 2024. Prior to this, there was a short decrease from 2019 – 2020 before a subsequent rise in 2021 when the recovery from the Covid-19 recession begins.

Figure 2-14 Total turnover of the sample of EEA F-gas downstream users. Source: Ricardo estimation based on consultation with downstream users.



The following Figure 2-15 provides an idea of how this turnover represents the different application categories; it shows the turnover provided by companies that manufacture in each of the applications, and it therefore represents duplicated information in cases in which companies are present in more than one application sector.

Figure 2-15 Annual turnover from 2019 by companies manufacturing in each of the F-gas downstream use product categories.

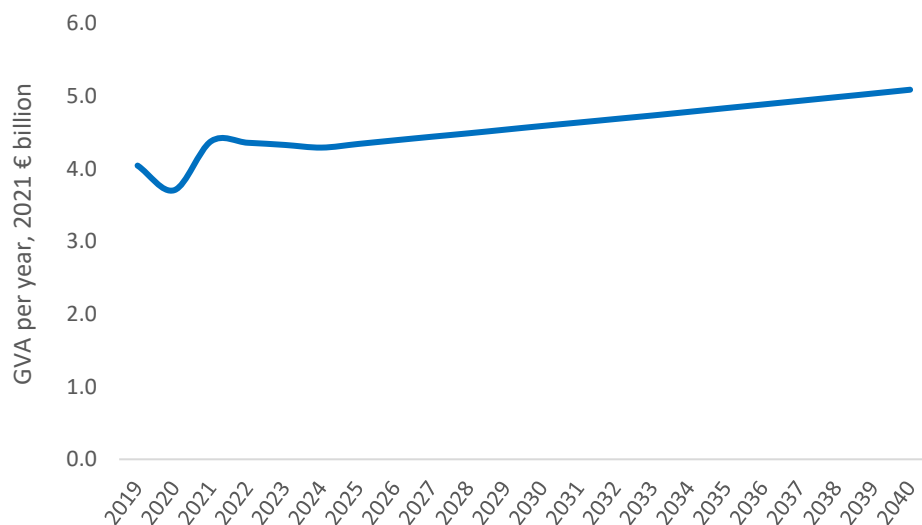


The most prominent categories, as represented by participation in consultation activities for this RMOA, are those related to RACHP, and to foam blowing agent in closed cell, reflecting the fact that they are also the economically largest industries in the EU, from the group of sectors under assessment. It is worth noting that, due to the inability to perfectly differentiate among industries due to limitations in data collection, the turnover value of companies that manufacture in, e.g., Foam blowing agent (closed cell) may also include revenue from their activity as manufacturers of other products.

II. Gross Value Added of the sample of EEA F-gas Downstream Users

The GVA of the sample of downstream users of F-gases in the scope of this Study amounted to approximately €4.0 billion in 2019, equivalent to approximately 16% of turnover. The total GVA of F-gas downstream users is expected to grow at a CAGR of approximately 1.1% over the next two decades, as depicted in Figure 2-16.

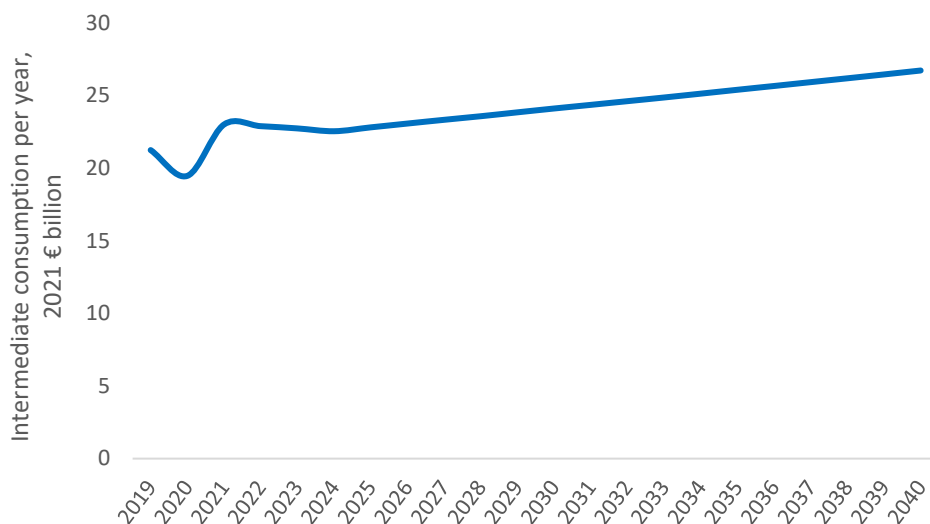
Figure 2-16 Total GVA of the sample of EEA F-gas downstream users. Source: Ricardo estimation based on consultation with downstream users.



III. Intermediate consumption and operating expenditure of the sample of EEA F-gas Downstream Users

The operating expenditure of downstream users of F-gases within the scope of this Study refers to the value of costs incurred by the industry to maintain operations. The total operating expenditure of the downstream users is expected to grow at a CAGR of approximately 1.1% over the next two decades, as depicted in Figure 2-17, just in line with turnover growth. The aggregate value of operating expenditure across sectors is based on the responses provided by downstream users of F-gases within the EEA.

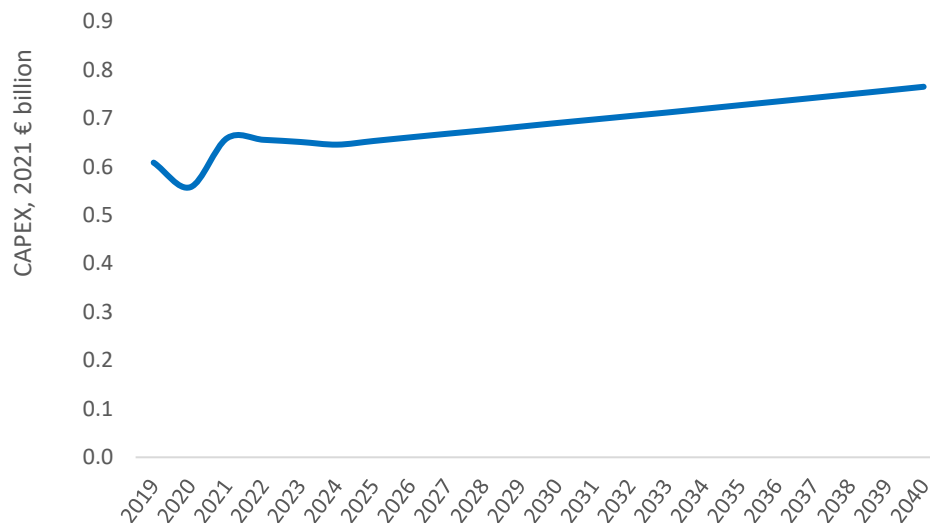
Figure 2-17 Total OPEX of the sample of EEA F-gas downstream users. Source: Ricardo estimation based on consultation with downstream users.



IV. Capital expenditure of the sample of EEA F-gas Downstream Users

Between 2022 and 2040, the expected growth in capital expenditure is estimated to be just in line with turnover growth. This estimate is based on the responses provided by downstream users of F-gases within the EEA. The projections to 2040 are shown in Figure 2-18.

Figure 2-18 Total CAPEX of the sample of EEA F-gas downstream users. Source: Ricardo estimation based on consultation with downstream users.

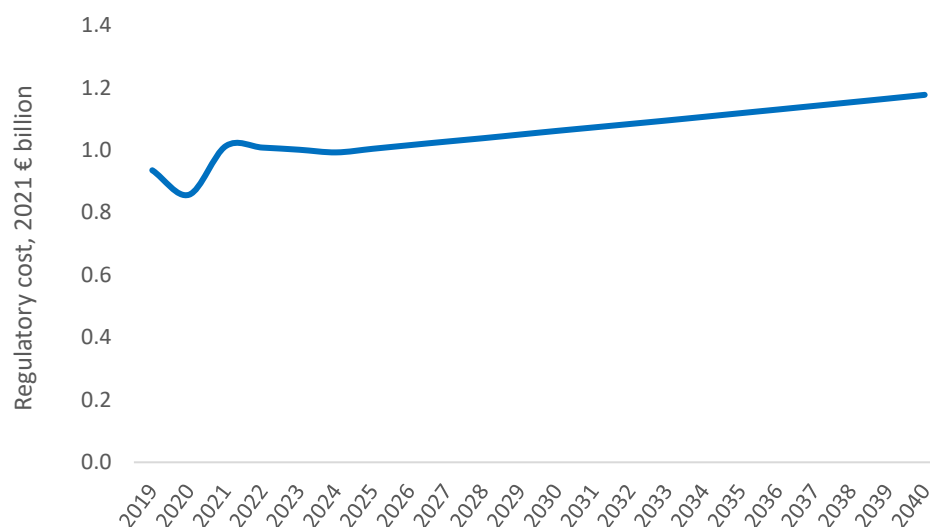


As a part of overall investments made by companies, future R&D and innovation trends will depend upon the recovery from the global pandemic crisis and general economic growth. R&D expenditure of F-gas downstream users is expected to grow in line with the growth of capital investment. Responses provided by downstream users of F-gases within the EEA are too scarce to provide an accurate and anonymous picture.

V. Regulatory burden of the sample of EEA F-gas Downstream Users

Regulatory burden estimates capture the administrative costs generated by EU legislation, which includes the cost of the submission of information for registration dossiers, the issue of permits, certification, and information for product users (e.g., labels), and possibly other sector-specific costs. Based on the survey responses by F-gas downstream users, regulatory costs represent on average 3.7% of the sampled companies' turnover. As displayed in Figure 2-19, the regulatory cost for downstream users is expected to grow at a CAGR of 1.0%, in line with turnover growth.

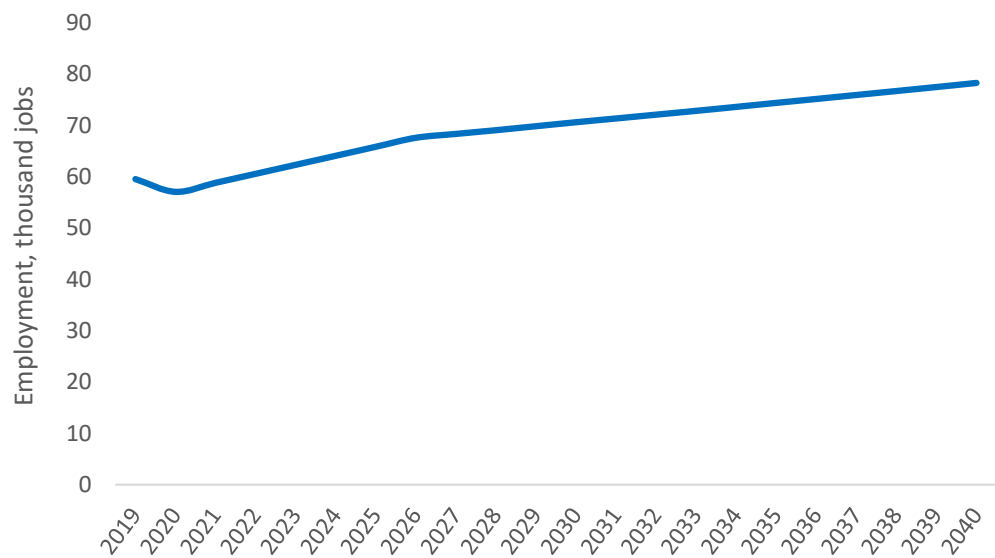
Figure 2-19 Total Regulatory Cost of the sample of EEA F-gas downstream users. Source: Ricardo estimation based on consultation with downstream users.



VI. Employment of the sample of EEA F-gas Downstream Users

As the production volume of F-gas downstream users continues to expand in the future (see Figure 2-13), this is likely to be complemented by an increase in labour demand. There is typically a high correlation between economic output and employment, and this can be expected over the upcoming two decades with both economic indicators projected to increase. As shown in Figure 2-20, employment in F-gas downstream user industries is expected to grow at a CAGR of approximately 0.6% and with a cumulative growth of approximately 11% over this period. This aggregate value of employment across sectors is based on the responses provided by downstream users of F-gases within the EEA.

Figure 2-20 Total Employment levels of the EEA F-gas downstream users. Source: Ricardo estimation based on consultation with downstream users.



3. ALTERNATIVES ASSESSMENT

3.1 INTRODUCTION

The purpose of this section is to conduct a thorough assessment of alternatives to evaluate the options available for replacing F-gases, in order to make informed decision-making. The assessment evaluates each identified alternative based on a range of criteria, including risk to human and environmental health, technical feasibility, economic feasibility, performance, and life-cycle aspects. The assessment doesn't aim to identify the "best" alternatives, but rather present a list of potential alternatives that warrant consideration when seeking to phase out F-gases of concern, such as those meeting the PFAS definition, those with high GWPs, and those that have hazardous breakdown products.

3.2 SCOPING AND PROBLEM FORMULATION

The first step of an alternatives assessment is the scoping phase, which involves determining the goals, principles, and decision rules that will guide the assessment. This is an important step as an assessment of alternatives is not based purely on technical, economic, and hazard considerations. Decisions can also be driven by organisational values and regulatory context, so the goals, principles, and decision rules should be explicitly stated to give transparency on how these influenced the resolution of trade-offs and the conclusions and recommendations of the assessment. Thorough documentation also allows the outcomes of the assessment to be looked at critically and compared to the outcomes of any subsequent assessments²⁰⁶.

The goal of the assessment was to identify less hazardous and technically and economically feasible alternatives to the F-gases in scope, to aid in the identification of the most suitable RMO. This goal reflects the background and motivation for conducting the study and the methodology is consistent with that of many alternatives assessment frameworks, such as those developed by BizNGO²⁰⁷, Interstate Chemicals Clearinghouse²⁰⁸, ECHA²⁰⁹, the National Research Council²¹⁰.

The Commons Principles for Alternatives Assessment were selected for use in this study. These were developed by the Lowell Center for Sustainable Production, the Massachusetts Toxics Use Reduction Institute, the Environmental Defense Fund, and the BizNGO Working Group, with the intention of guiding a process for well informed decision making that supports successful phase out of hazardous products, phase in of safer substitutes, and elimination of hazardous chemicals, where possible²¹¹.

Table 3-1 The Commons Principles for Alternatives Assessment

Principle	Description
Reduce Hazard	Reduce the hazard by replacing a chemical of concern with a less hazardous alternative. This approach provides an effective means to reduce risk associated with a product or process
Minimise Exposure	Assessment of use patterns and exposure pathways to limit exposure to alternatives that may also present risks.
Use Best Available Information	Obtain access to and use information that assists in distinguishing between possible choices. Before selecting the preferred option(s), the product and

²⁰⁶ National Research Council (2014) A Framework to Guide Selection of Chemical Alternatives – Chapter 4, Scoping, Problem Formulation, and Identifying Alternatives. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK253966/>

²⁰⁷ BizNGO (2013) The Commons Principles for Alternatives Assessment – Addressing Chemicals of Concern to Human Health or the Environment. Available at: https://www.bizngo.org/static/ee_images/uploads/resources/commons_principles_AA_2013_10_14.pdf

²⁰⁸ Interstate Chemicals Clearinghouse (2017) Alternatives Assessment Guide – Version 1.1. Available at: http://theic2.org/article/download-pdf/file_name/IC2_AA_Guide_Version_1.1.pdf

²⁰⁹ ECHA (2021) Guidance on the preparation of an application for authorisation. Available at: https://echa.europa.eu/documents/10162/13643/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7

²¹⁰ Ibid 206

²¹¹ BizNGO (2013) The Commons Principles for Alternatives Assessment – Addressing Chemicals of Concern to Human Health or the Environment. Available at: https://www.bizngo.org/static/ee_images/uploads/resources/commons_principles_AA_2013_10_14.pdf

Principle	Description
	process(es) are characterised sufficiently to avoid choosing alternatives that may result in unintended adverse consequences.
Disclosure and Transparency	Requires disclosure across the supply chain regarding key chemical and technical information. Engage stakeholders throughout the assessment process to promote transparency in regard to the alternatives assessment methodologies employed, the data used to characterise alternatives, assumptions made and the decision-making rules applied.
Resolve Trade-offs	Use information about the product's life cycle to better understand potential benefits, impacts, and mitigation options associated with different alternatives. When substitution options do not provide a clearly preferable solution, organizational goals and values to determine appropriate weighting of decision criteria should be considered and acceptable trade-offs identified.

The decision rules of the assessment build on the goal and principles detailed above, which were developed based on a review of decision rules in alternatives assessment frameworks and expert judgement of the study team. These included rules to help streamline the assessment by reducing the number of alternatives that were evaluated in detail, determine how missing data would be handled, and the priorities when considering trade-offs across different aspects of the assessment (see Section A2 in Appendix A).

This step also involves the formulation of the problem, including characterisation of the chemical(s) of concern, which consisted of a description of the technical function performed by the chemicals of concern and their applications. Knowledge of the technical function is important for identifying potential alternatives and understanding the risk from use of the chemicals of concern.

The list of F-gas functions and applications was obtained (see Table 3-2) from literature and expert judgement preceding the socio-economic analysis of the value of F-gases²¹².

Table 3-2 F-gas functions and applications

F-Gas Function	F-Gas Application
Refrigerant Gas	Mobile Air Conditioning
	Industrial Refrigeration
	Transport Refrigeration
	Domestic Refrigeration
	Commercial Refrigeration - Hermetically Sealed Standalone Units
	Commercial Refrigeration – Condensing Units
	Commercial Refrigeration – Centralised Systems
	Moveable Room Air Conditioning
	Stationary Air Conditioning: Single Split Systems

²¹² See Socio-Economic Analysis of the Value of F-Gases – Draft Final Report.

F-Gas Function	F-Gas Application
	Stationary Air Conditioning: Multi Split Systems
	Chillers
	Heat Pumps
	Industrial Heat Pumps & Power Generation
Foam Blowing Agent	Foam Insulation – Refrigeration
	Foam Insulation - Construction
Cover Gas	Magnesium Die Casting
Propellant	Metered Dose Inhalers (MDIs)
	Technical Aerosols (i.e. Dusters, Cleaners, Pesticides)
	Consumer Aerosols (i.e. Personal Care Products, Spray Paint, Food Dispensing Products, Propellants, Household Aerosols)
Solvent	Metal Degreasing; Precision Cleaning in Optics and Electronics
Fire Suppressant	Clean Agent Fire Suppression Systems

3.3 IDENTIFYING ALTERNATIVES

3.3.1 Methodology

The next step in the assessment was to identify potential chemical, material, and design alternatives, based on the requirements established during the scoping and problem formulation. A list of alternatives to be evaluated was obtained through the desk-based research and consultation with industrial stakeholders.

An initial screening was undertaken to remove any potential alternatives that clearly were not suitable, based on whether they were present on any regulatory lists restricting or banning the use of listed chemicals.

Results

Following the literature review and consultation with industry, potential alternatives were identified for each of the applications in scope. The full list of identified potential chemical and non-chemical alternatives for each application is provided in Section A3.2 in Appendix A. The highest number of potential alternatives were identified for the F-gases used as refrigerants and foam blowing agents, while very few alternatives were identified for F-gases used in MDIs and clean agent fire suppression systems, which suggests they are areas warranting further research efforts.

Several decision rules are set out (see Section A2 of Appendix A) to help streamline the assessment by reducing the number of alternatives that were evaluated in detail. One of these rules was the exclusion of chemicals with certain hazard characteristics or environmental concerns, including high GWP. The decision rule for exclusion of HFCs with a GWP above 150 uses the GWP values of AR6. HFC-152a met this exclusion criteria because of its GWP of 164 (according to AR6). Therefore, its inclusion in the detailed assessment would contradict the decision rules. However, HFC-152a would be a viable alternative for certain applications within the scope of this study should AR4 GWP values be used, and on which the current F-gas Regulation is based, as the AR4 GWP value is 124 and is therefore not subject to any use restrictions under the Regulation. Under such an exclusion criterion, it would constitute an alternative for certain applications including MDIs.

None of the identified chemical alternatives were excluded from further analysis based on their regulatory status.

3.4 RISK ASSESSMENT

The risk assessment involves two components, a hazard assessment and an exposure assessment. By combining information on the hazards of each alternative with their estimated exposure, its risk to human health and the environment from their use can be determined.

3.4.1 Hazard Assessment – Methodology

The goal of the hazard assessment is to identify safer chemicals and to avoid regrettable substitution, which is where the chemical of concern is replaced with a chemical that is also unsuitable because of hazard concerns for human health and/or the environment.

The starting point for the hazard assessment was collecting information on the endpoints listed in Table A-5 in Appendix A. The primary source of this information was ECHA's Classification and Labelling Inventory (CLI) database²¹³. Following the use of the CLI, the OECD's eChemPortal²¹⁴ and the U.S. National Institute of Health's Hazardous Substances Database²¹⁵ (HSDB) and Chem ID Plus²¹⁶ databases were used to fill any remaining data gaps.

To investigate hazards not currently included under GHS and recently introduced to EU CLP (i.e. endocrine disruption (human health and the environment); persistent, bioaccumulative, toxic (PBT); very persistent, very bioaccumulative (vPvB); persistent, mobile, toxic (PMT)), a number of authoritative and non-authoritative lists were used (see Section A4.1 in Appendix A).

The column model approach was selected for the hazard assessment because it allows a quick comparison of alternatives and relies on information that is easily accessible. This method was designed by the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA)²¹⁷ as a tool for German companies to identify potential alternative substances and meet the requirement under the German Hazardous Substances Ordinance to replace hazardous substances with those with lower health risks.

Under this approach, alternatives are assigned into one of five hazard levels (very low hazard, low hazard, medium hazard, high hazard, very high hazard), based on their human health and environmental hazard classifications. These levels were assigned a numerical score from 1 (very low hazard) to 5 (very high hazard) to allow the output to be integrating into the final comparative assessment (see A-20 in Appendix A).

The hazard assessment acted as an early screening exercise to eliminate alternatives from further consideration if they exhibited certain hazard endpoints that are subject to current or future regulatory action. This included alternatives meeting any of the criteria for classification as a Substance of Very High Concern (SVHC)²¹⁸: A hazard assessment was also performed for each of the F-gases in scope of the study. This allowed the hazard score for each alternative to be compared against the chemical for which it was a substitute, and enabled alternatives with hazards of greater severity to be identified.

3.4.2 Hazard Assessment – Results

Table A-6 in Appendix A shows the human health and environmental hazards level of each of the F-gases in scope. The primary concern surrounding F-gases in their degradation products and their GWP, while the majority F-gases themselves have low toxicity.

Due to the low levels of human and environmental hazard of the F-gases within in scope, the majority of the identified alternatives were of equal or higher hazard. This was expected as hazards to human health and the environment were not the motivation for performing this alternatives assessment. Table A-7 in Appendix A compares the human health and environmental hazard levels of each identified alternative to the F-gases for which they are potential alternatives.

Several of the alternatives listed in Table A-3 are considered PFAS and are listed on the US EPA's Master List of PFAS Substance²¹⁹. This includes [product name], [product name]), HFE-7000, HFE-7100, HFE-7200, and

²¹³ See: <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>

²¹⁴ See: <https://www.echemportal.org/echemportal/>

²¹⁵ See: <https://pubchem.ncbi.nlm.nih.gov/source/11933>

²¹⁶ See: <https://pubchem.ncbi.nlm.nih.gov/source/ChemIDplus>

²¹⁷ IFA (2020) The GHS Column Model as an aid to selecting substitute substances. Available at: <https://www.dguv.de/ifa/praxishilfen/hazardous-substances/ghs-spaltenmodell-zur-substitutionspruefung/index.jsp>

²¹⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20221217>

²¹⁹ US EPA (2023) Master List of PFAS Substances. Available at: <https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster>

HFE-347pcf2. Despite the human and environmental health impacts associated with PFAS and the global regulatory pressure surrounding this group of substances, these alternatives were considered in this analysis because under the baseline scenario and certain RMOs, their use would be possible. Derogations have also been proposed for some applications in the PFAS Annex XV report²²⁰.

There were also several alternative F-gases identified through the consultation. These include HFC-32, HFC-152a, [product name], and [product name]. Based on their GWP values, HFC-32 and HFC-152a were excluded from further analysis. This is because they have much greater GWP than the HFOs in scope of this study, and one of the primary reasons for further regulating F-gas use. Therefore, F-gases with a high GWP cannot be considered potential alternatives. [product name] and [product name] have GWPs less than 150 (see Section A4.3.1), which were considered to be low as they meet for criteria for allowed use under the revised F-gas Regulation.

3.4.3 Exposure Assessment - Methodology

The objective of the exposure assessment is to determine whether the predicted exposure of an alternative is equivalent or greater than that of the chemicals of concern, which is key to understanding the overall safety of alternatives. This assessment sought to determine the potential for reduced or greater exposure based on the inherent physicochemical properties of the alternatives, levels of expected exposure, the routes of human exposure (dermal, oral, inhalation), and the environmental compartments (i.e. air, water, and soil/sediment) into which the chemicals will partition.

3.4.3.1 Potential for Exposure

The assessment considered the environmental, occupational, and public health exposure potentials. The potential for exposure was estimated as being either much lower than, lower than, equal to, greater than, or much greater than the exposure potential of the chemical of concern for three human exposure routes (dermal, oral, inhalation) and three environmental compartments (air, water, soil/sediment). The human exposure assessment was based on a comparison of chemical state and volatility of the alternative and chemical of concern, while the environmental assessment was based on a comparison of chemical state, volatility, water solubility, and Henry's law constant. The scores for the three human and three environmental exposure routes were averaged to produce a single score, thus, three scores were calculated for environmental, occupational, and public health. These were assigned a numerical value from 1 (much lower potential exposure) to 5 (much greater potential exposure), which were averaged to produce an overall numerical exposure score.

3.4.3.2 Likelihood of Exposure

To account for the effect of physical and administrative controls for reducing exposure, such as operational controls and risk management measures, the likelihood for exposure was assessed, based on the manufacturing process, use patterns, and end-of-life processes of the specific applications. This was also scored from 1 to 5, with 1 denoting very low likelihood of exposure and 5 denoting very high likelihood of exposure (see Table 3-3). An explanation for the scores presented in Table 3-3 are provided in Appendix A.

Table 3-3 Likelihood of exposure for each f-gas application in scope

Application	Likelihood of Human Exposure	Consumer	Occupational	Likelihood of Environmental Exposure	Exposure to air	Exposure to water	Exposure to soil/sediment
Refrigerant	1	Y	Y	2	Y	N	N
Blowing Agent	1	Y	Y	2	Y	N	N
Cover Gas	4	N	Y	5	Y	N	N
MDIs	2	Y	N	5	Y	N	N
Propellant	4	Y	Y	5	Y	N	N

²²⁰ ECHA (2023) Annex XV Restriction: Report Proposal for a Restriction - Per- and polyfluoroalkyl substances (PFASs). Available at: <https://echa.europa.eu/documents/10162/1c480180-ec9-1bdd-1eb8-0f3f8e7c0c49>

Application	Likelihood of Human Exposure	Consumer	Occupational	Likelihood of Environmental Exposure	Exposure to air	Exposure to water	Exposure to soil/sediment
Fire Suppressant	1	N	Y	5	Y	N	N
Solvent	3	N	Y	5	Y	Y	Y

3.4.3.3 Combined Exposure Score

The scores for the potential and likelihood of exposure were then multiplied together in a matrix to assign an overall exposure score from 1 to 5, based on the combined score (see Table 3-4).

Table 3-4 Exposure matrix

Potential for exposure	Likelihood of Exposure					
		Very Low (1)	Low (2)	Medium (3)	High (4)	Very High (5)
	Much lower (1)	1	2	3	4	5
	Lower (2)	2	4	6	8	10
	Equal (3)	3	6	9	12	15
	Greater (4)	4	8	12	16	20
	Much greater (5)	5	10	15	20	25

1-5 (dark green) = Very low exposure; 6-10 (light green) = Low exposure; 11-15 (yellow) = Medium exposure; 16-20 (orange) = High exposure; 21+ (red) = Very high exposure

3.4.4 Risk Assessment - Methodology

The output of the hazard assessment and exposure assessment were combined together to generate a risk level from 1 to 5, with 1 denoting very low risk and 5 denoting very high risk. This was done by multiplying the hazard score, which ranged from 1 to 5, with the exposure score, which also ranged from 1 to 5. This generated a possible score from 1 to 25. A banding approach was then taken, as highlighted in the table below.

Table 3-5 Banding for determining risk score for human health and the environment

Sum of hazard score multiplied by exposure score	HH and ENV Risk Score
1 – 5	1 (Very low risk)
6 – 10	2 (Low risk)
11 – 15	3 (Moderate risk)
16 – 20	4 (High risk)
21 - 25	5 (Very high risk)

3.4.5 Risk Assessment – Results

The F-gases included within the scope of this study all had very low human health and environmental hazards, except for HCFO-1233zd(E), which had low human health hazard and moderate environmental hazard. Consequently, all F-gases represented a very low risk to human health and all except HFCO-1234zd(E) represented a very low risk to environmental health, which had a low risk. A summary of the risks to human

health and the environment from the identified alternatives within each application is provided in Appendix A, along with a table of the risk scores for each alternative.

3.5 TECHNICAL FEASIBILITY ASSESSMENT

3.5.1 Methodology

The objective of the technical assessment is to determine the technical feasibility of alternatives per use and whether there are additional factors that would lead to an alternative being infeasible. The criteria that were used for determining if an alternative is technically feasible or not included technical readiness, availability, and changes to equipment and facilities. Further information is provided in Appendix A.

There is some uncertainty with the output of the technical assessment, as the information obtained through desk research contradicted the consultation responses from stakeholders on the technical readiness of alternatives for some applications. Where appropriate, this information was used to refine the findings from the desk research.

3.5.2 Results

Refrigerant

Although a high number of non-chemical alternatives were identified for refrigerants, the majority of them had low levels of technical readiness, such as thermoacoustic, thermoelastic, ejector heat pump, and membrane heat pump. However, many non-fluorinated refrigerants are commercially available and widely used, such as carbon dioxide, propane, isobutane, and ammonia. However, it should be noted that alternatives are not technically feasible for all refrigeration, air conditioning, and heating applications. Table A 18 and Table A 19 detail the specific uses for each potential alternative.

Hydrocarbon refrigerants, such as propane and isobutane, present human health risks as they are highly flammable and classed as A3 refrigerants. In some RACHP applications, their charge size is limited. For example, in domestic refrigeration the limit is 150g, while the upper charge limit for commercial refrigeration ranges from 500g to 1.5 kg depending on standards²²¹. This means that they cannot be used in large systems, so would not be feasible for use in industrial refrigeration and large commercial refrigeration and air conditioning units. For example, the typical charge limit of commercial condensing units and centralised refrigeration systems are typically 1-10 kg and 20-200 kg respectively²²². Other standards may also limit the use of natural refrigerants in certain applications, such as EU standard EN 12102-1²²³, which sets requirements for noise levels of heat pumps.

The occupancy and size of the room are also factors that need to be considered when using hydrocarbon refrigerants, which can act as barriers to their adoption²²⁴. Ammonia also presents a risk due to its toxicity, which means that its use may not be feasible in certain applications and locations and new facilities will require additional safety precautions²²⁵.

Foam Blowing Agent

The majority of alternatives to F-gas foam blowing agents were commercially available but many require significant changes to manufacturing systems and processes, may have inferior insulation properties, or are highly flammable, which may pose a barrier to use. Aerogel is a high performing alternative insulation material, which is commercially available. However, because the technology is relatively new, there may be concerns related to sufficient manufacturing capacity to produce the material in large enough quantities to allow for wide-scale use. Aerogel also comes in the form of insulation boards and therefore cannot be used in the same applications as spray foams, such as door and window frames, uneven surfaces, and filling. Flammable

²²¹ AREA (2019) Introduction to Refrigeration Standard EN 378. Available at: https://area-eur.be/sites/default/files/2019-07/AREA%20Introduction%20to%20EN%20378%20-%20for%20Publication_0.pdf

²²² UNEP (2015) FACT SHEET 4 Commercial Refrigeration. Available at: https://ozone.unep.org/sites/ozone/files/Meeting_Documents/HFCs/FS_4_Commercial_Refrigeration_Oct_2015.pdf

²²³ See: <https://standardsdevelopment.bsigroup.com/projects/2021-00706#/section>

²²⁴ International Institute of Refrigeration (2022) Hydrocarbon refrigerants. Available at: <https://iifir.org/en/encyclopedia-of-refrigeration/hydrocarbon-refrigerants>

²²⁵ Refcom (2016) Safe management of ammonia refrigeration systems. Available at: https://www.refcom.org.uk/media/1160/ammonia-guide-smars-2016_copy-0023_stephen-crocker.pdf

blowing agents may not be feasible in certain applications, such as spray and cast foams where the foams are applied on site, because of the stricter safety requirements that must be met²²⁶. Flammable blowing agents are therefore not considered acceptable for spray foam applications.

Cover Gas

There were data gaps surrounding the technical readiness of some alternative cover gases, but [product name] and sulphur dioxide are both commercially available for use in cover gas systems. There was also a lack of information on the level of changes required to existing HFC-based cover gas systems to accommodate the identified alternatives, but where the data was available it indicates that either significant or moderate changes are required.

An inert gas system (i.e. argon / nitrogen) is one of the alternatives identified, which may not be suitable for all installations as it requires a higher number of cylinders than F-gas systems. This means the system has a larger footprint and the floor may require reinforcement²²⁷.

MDI

Of the three non-chemical alternatives (i.e. dry powder inhalers (DPIs), soft mist inhalers (SMIs), and nebulisers) identified to replace HFCs in MDIs, all were commercially available but require changes to both manufacturing process and use. It is also important to note that **the alternatives are not suitable for all patients**. DPIs require a deep and forceful inhalation and there are groups of patients that struggle to generate sufficient inspiratory flows to get adequate delivery from a DPI, such as COPD patients, young children, and very old people²²⁸. A systematic literature review found that 90% of patients do not use their DPI correctly²²⁹. SMIs require some assembly, although evidence suggests this is problematic for only a small number of patients²³⁰.

Propellant

All of the chemical alternatives are commercially available (water, carbon dioxide, nitrous oxide, nitrogen, isobutane, butane, propane, and di-methyl ether). However, because of the flammability of some of these alternatives, some changes are required to manufacturing process, such as measures to provide additional ventilation and airflow, as well as the installation of gassing rooms, storage tanks, and piping²³¹. There were also data gaps around the changes needed for the other alternatives, so all were scored as category 2.

It's important to note that the alternatives are not suitable for all propellant applications. For example, carbon dioxide is not compatible with all solutions, such as water-based formulas where it forms carbonic acids that attacks metal cans. It's high vapour pressure also means it can only be used in with solvents that have good Oswald coefficients. Aerosols for which carbon dioxide can be used include insect repellents, degreasers, speciality cleaners, and de-icers²³².

Nitrogen has very low solubility in liquids which means that it only produces a liquid stream, which can be converted to a coarse spray by fitting the propellant's valve with a mechanical breakup actuator. This means that nitrogen is unsuitable for aerosols requiring a fine spray²³³.

Clean Agent Fire Suppressant

Three of the chemical alternatives (carbon dioxide, inert gas (argon/nitrogen) and [product name]) are commercially available and are expected to require some change to the gas delivery system. Information obtained during the desk research indicates that all three use different delivery systems to F-gases and would

²²⁶ Proklima International (2009) Natural Foam Blowing Agents. Available at: <https://www.ctc-n.org/sites/www.ctc-n.org/files/resources/giz2009-en-natural-foam-blowing-agents.pdf>

²²⁷ 3M (2020) Fire suppression systems. The total cost of ownership. Available at: <https://multimedia.3m.com/mws/media/1430143O/fire-suppression-systems-total-cost-ownership-best-practice-guide.pdf>

²²⁸ Pritchard, J. N. (2020). The climate is changing for metered-dose inhalers and action is needed. Drug Design, Development and Therapy, 3043-3055.

²²⁹ Lavorini, F., Magnan, A., Dubus, J. C., Voshaar, T., Corbetta, L., Broeders, M., ... & Crompton, G. K. (2008). Effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD. Respiratory medicine, 102(4), 593-604.

²³⁰ Anderson, P. (2006). Use of Respimat® soft Mist™ inhaler in COPD patients. International journal of chronic obstructive pulmonary disease, 1(3), 251-259.

²³¹ UNEP (2005) Technical Guide for the Safe Handling of Hydrocarbon Propellants. Available at: <https://wedocs.unep.org/handle/20.500.11822/32963>

²³² Southern Aerosol Technology Association (2013) Propellants and Solvents Strategies for the 21st Century. Available at: <https://dokumen.tips/documents/propellants-and-solvents-southern-aerosol-pointspring-13-pdfspring-13.html?page=1>

²³³ Diversified CPC (2021) An Introduction to Aerosol Propellants. Available at: <https://diversifiedcpc.com/wp-content/uploads/2021/12/Introduction-to-Aerosol-Propellants.pdf>

therefore require large process changes²³⁴. Overall, these alternatives were all placed in category 2. The other identified alternative is water, which requires a sprinkler system. A complete product re-design would require significant manufacturing changes, so this scores as category 3. Water-based systems are also only technically feasible in certain environments. For example, they can't be used in electrical installations or in facilities that store chemical products that oxidise in the presence of water.

Solvent

All of the chemical and non-chemical alternatives are commercially available. This includes several hydrofluoroethers (HFE), [product name], and [product name] which do not require any changes to manufacturing process and systems so these score in category 1. Other possible alternatives include heptane and hexane, which would require some manufacturing changes due to their flammability, so score in category 2. All three of the non-chemical alternatives would require significant changes to manufacturing process and use, so scored as category 3.

3.6 PERFORMANCE ASSESSMENT

3.6.1 Methodology

The aim of the performance assessment is to determine whether the performance requirements of the application and function in question can be adequately met by an alternative. Performance was assessed on a 5-point scale, as shown in the table below. The criteria used for determining a performance score is detailed in Appendix A.

Table 3-6 Scoring criteria for performance assessment

Scoring Criteria	Score
Significantly better performance	1 point
Better performance	2 points
Equivalent performance	3 points
Worse performance	4 points
Significantly worse performance	5 points

3.6.2 Results

Few alternatives offered better performance than F-gases, and those that did are limited to certain applications. Examples include ammonia in large industrial refrigeration and chillers where it delivers more efficient cooling because of its high latent heat, high specific heat capacity, high thermal conductivity and low viscosity; and propane and isobutane in domestic refrigeration, which offer better energy efficiency²³⁵. Other higher performing alternatives include boron trifluoride as a cover gas for magnesium die casting, which offers a high level of protection²³⁶. The only alternative that offers significantly better performance than F-gases, is aerogel insulation which has a thermal conductivity as low as 0.010 W/mK and high space efficiency²³⁷, but is limited to specialist applications. A breakdown of the performance of alternatives by application group is provided in Section A6.2

²³⁴ 3M (2020) Fire suppression systems. The total cost of ownership. Available at: <https://multimedia.3m.com/mws/media/14301430/fire-suppression-systems-total-cost-ownership-best-practice-guide.pdf>

²³⁵ Rasti, Mehdi, SeyedFoad Aghamiri, and Mohammad-Sadegh Hatamipour. "Energy efficiency enhancement of a domestic refrigerator using R436A and R600a as alternative refrigerants to R134a." International Journal of Thermal Sciences 74 (2013): 86-94.

²³⁶ US EPA (2016) A Replacement for SF6: The MagShield System. Available at: https://www.epa.gov/sites/default/files/2016-02/documents/conf00_schultz_paper.pdf

²³⁷ Jelle et al. (2015) Aerogel Insulation for Building Applications. Available at: <https://onlinelibrary.wiley.com/doi/10.1002/9783527670819.ch45>

3.7 ECONOMIC FEASIBILITY ASSESSMENT

3.7.1 Methodology

The overall economic feasibility score was based on a consideration of the cost of the alternative, capital expenditure (CAPEX) (i.e. system cost, investment in new manufacturing equipment etc), and operating expenditure (OPEX) (i.e. cost of using the alternative) in comparison to the chemical of concern. The economic feasibility of each alternative was assessed on a 5-point scale, as shown in the table below.

Table 3-7 Scoring criteria for economic feasibility assessment

Scoring Criteria	Score
Significantly cheaper than chemical of concern	1 point
Cheaper than chemical of concern	2 points
Equivalent cost to chemical of concern	3 points
More expensive than chemical of concern	4 points
Significantly more expensive than chemical of concern	5 points

3.7.2 Results

RACHP

The cost of natural refrigerants in the majority of applications was considered to have an equal cost to F-gas refrigerants. However, there were many data gaps on the cost of new systems using alternatives and their operating costs compared to F-gas systems, meaning a neutral weighting was applied to many applications. For example, there was a lack of information on the cost of CO₂ based systems for each of its applications. The only alternative presenting with greater cost-effectiveness over F-gases was the use of ammonia in industrial refrigeration systems as its high latent heat, specific heat capacity, thermal conductivity, and low viscosity make it a highly efficient coolant²³⁸. This can lead to cost savings in large direct expansion systems²³⁹.

There was a lack of economic data on the majority of non-chemical alternatives, as most have not reached technical maturity and are not used commercially.

Blowing Agent

The majority of blowing agents were judged to have a higher cost than using F-gases. While hydrocarbons are typically cheaper than synthetic blowing agents, the additional safety measures required because of their flammability is likely to increase the processing costs. Information received during the consultation also indicated an increase in CAPEX. This means that isobutane, butane, isopentane, pentane, cyclopentane, and di-methyl ether scored a 4 in the economic feasibility assessment.

Methylal was the only chemical alternative that had an equivalent cost (score of 3), with evidence from a UNDP report citing a cost similar to F-gases²⁴⁰. Carbon dioxide also had a score of 3, but this was due to a lack of information on the cost of manufacturing foam while using it as a blowing agent. Water can be used as a sole blowing agent, and due to its cheap cost and non-hazardous nature it scored a 2. However, it should be noted that the thermal performance of water is lower than F-gases²⁴¹ so would not be as cost-effective for end users.

Of the non-chemical alternatives that are available, aerogel and foamed glass were both considered to be significantly more expensive alternatives. Foamed glass has a cost roughly two and half times more than PU

²³⁸ Star Refrigeration (n.d.) Carbon Dioxide for Industrial Refrigeration Applications. Available at: <https://www.star-ref.co.uk/smart-thinking/carbon-dioxide-for-industrial-refrigeration-applications/>

²³⁹ SKM Enviros (2013) Possible Bans for New RAC Equipment - A review of the technical and economic impact of potential bans on the use HFCs for new equipment in RAC market sectors. Available at: https://climate.ec.europa.eu/system/files/2016-11/refrigeration_air_conditioning_en.pdf

²⁴⁰ UNDP (2012) Methylal as Blowing Agent in the Manufacture of Polyurethane Foam Systems. Available at: https://www.undp.org/sites/g/files/zskgke326/files/publications/Methylal_WEB.pdf

²⁴¹ Huntsman (2011) Polyurethanes - Blowing agent options for insulation foam after HCFC phase out. Available at: https://huntsman-pimcore.equisolve-dev.com/Documents/PU_Insulation_Blowing_agents.pdf

foam²⁴², while aerogel insulation is only produced by a few manufacturers and has historically had high production costs, which has restricted its use to specialised applications. However, production costs are expected to fall with the advent of mass production, but aerogel is still significantly more expensive than F-gas-based foam insulation and it is not expected to fall sufficiently to enable it to be used very widely. The majority of the other non-chemical alternatives either scored a 3 or 4, with only straw bales having a cheaper cost.

Cover Gas

Sulfuryl fluoride and sulphur dioxide were judged to have a higher cost than F-gases because of their much higher system costs²⁴³. Boron trifluoride also has a higher cost because systems using the gas require moderate equipment and process upgrades and when boron trifluoride is purchased as a manufactured compressed gas, it is very costly (US EPA, 2016). The remaining chemical alternatives were considered to have an equivalent cost, although largely because of data gaps surrounding the capital expenditure and operating expenditure involved in transitioning to them.

MDIs

All of the alternatives to MDIs present an increase in cost. A recent analysis (Pritchard, 2020) showed that in every country, the cost of DPIs is greater per dose than the cost of MDIs, sometimes by nearly 600%. In recent years the average sale price difference between MDIs and DPIs has narrowed slightly and this is expected to narrow further as the reduction in non-medical uses of HFC propellants is likely to give rise to a 5-fold increase in their cost for MDI uses²⁴⁴. Soft-mist inhalers are also often more costly than other inhalers²⁴⁵, which could affect their uptake²⁴⁶. The cost of giving therapy using nebulisers has been cited as being around 20% more than MDIs²⁴⁷.

Propellant

The majority of alternative propellants were judged to have a higher cost than using F-gases. While hydrocarbons are typically cheaper than synthetic blowing agents, the additional safety measures required because of their flammability is likely to increase the processing costs. There were many data gaps regarding the capital and operating expenditure required to transition to alternative propellants, meaning that a neutral weighting was applied, which skewed the assessment scores of some alternatives towards representing an equivalent cost. This was true of the non-chemical alternatives, such as bag-in-can systems, finger pumps, roll-on liquids, squeeze bottles etc. Nitrogen and air were the only two alternatives considered to be cheaper than F-gas propellants, because of the low cost of these substances.

Fire Suppressant

There were many data gaps on the capital and operating expenditure of involved with systems using alternative fire suppressants. Therefore, a neutral weighting was applied, and they received a score of 3.

Solvent

None of the chemical alternatives represented an improvement in cost-effectiveness over F-gases. Hexane and heptane scored 4 (more expensive) as, although hydrocarbons are typically cheaper than F-gases, the additional safety measures required because of their flammability is likely to increase the processing costs. The HFE solvents were also considered to present a higher cost because they are significantly more expensive than traditional F-gas solvents and have a higher operating cost²⁴⁸. [product name] also scored 4 due to its higher unit cost, while the remaining solvents scored 3 due to a neutral weighting being applied because of the lack of data on their economic feasibility.

²⁴² Building Green (n.d.) Foamglas – My New Favorite Insulation Material. Available at: <https://www.buildinggreen.com/blog/foamglas---my-new-favorite-insulation-material#:~:text=The%20typical%20cost%20of%20Foamglas.about%20%240.40%20per%20board%2Dfoot>.

²⁴³ European Commission (2009) Service contract to assess the feasibility of options to reduce emissions of SF6 from the EU non-ferrous metal industry and analyse their potential impacts. Available at: <https://www.oekorecherche.de/sites/default/files/publikationen/sf6-nf-metal.pdf>

²⁴⁴ Pritchard, J. N. (2020). The climate is changing for metered-dose inhalers and action is needed. *Drug Design, Development and Therapy*, 3043-3055.

²⁴⁵ DeWeerd, S. (2020). THE INHALER MAKEOVER. *Nature*, 581(7807), S14-S17.

²⁴⁶ Anderson, P. (2006). Use of Respimat® soft Mist™ inhaler in COPD patients. *International journal of chronic obstructive pulmonary disease*, 1(3), 251-259.

²⁴⁷ Pritchard, J. N. (2020). The climate is changing for metered-dose inhalers and action is needed. *Drug Design, Development and Therapy*, 3043-3055.

²⁴⁸ Kehren, J. (n.d.) A Comparison of Hydrofluoroether and Other Alternative Solvent Cleaning Systems. Available at: http://www.solvents.net.au/index.htm_files/71IPA%20Engineered%20Fluid.pdf

Off the three non-chemical alternatives, PurgoSpray and plasma cleaning scored 4 because they represent alternative technologies that would require significant process changes to adapt to. There was a lack of data on the use of supercritical fluids so they scored a 3 in the assessment.

3.8 LIFECYCLE ASSESSMENT

A full quantitative life-cycle assessment (LCA) was outside of the scope of this Study and lifecycle aspects were not used as inputs into deriving the list of acceptable alternatives presented in Tables A-18 and A-19. However, a qualitative discussion of life-cycle aspects of each alternative was performed, which considers the differences in material and energy flows, greenhouse gas emissions, lifespan, and recyclability rates between the chemical of concern and the alternative (see Table A-21). Such an analysis can identify where there is a significant difference in these areas and highlight the need for additional quantitative information and analysis to support decision-making. In some cases, a qualitative exercise can provide sufficient detail to make a decision, such that a quantitative analysis would not provide any additional value.

3.9 COMPARATIVE ASSESSMENT

3.9.1 Methodology

The objective of the comparative assessment is to integrate the outputs of the five assessments to identify the most potential alternatives. These were:

- Assessment of risk to human health
- Assessment of risk to the environment
- Technical feasibility assessment
- Performance assessment
- Economic feasibility assessment

Each of the five assessments were scored on a 1 – 5 scale, with 1 representing the most desirable alternatives and five representing the least desirable alternatives. Therefore, each alternative was scored from 5 – 25 in the final comparative assessment, with 5 representing the most desirable alternatives and 25 representing the least desirable alternatives.

Separate comparative assessments were made for the chemical and material and design alternatives. This is because the non-chemical alternatives do not present human health or environmental hazards from their chemical properties, thus precluding a direct comparison between chemical and non-chemical alternatives. Therefore, because only three assessments were made for the material and design alternatives, they were scored from 3 – 15 in the final comparative assessment, with 3 representing the most desirable alternatives and 15 representing the least desirable alternatives.

The output of this task was a ranked list of potential alternatives based on a set of cut-off criteria for each assessment (which are explained in greater detail in Appendix A), along with the rationale for their selection.

3.9.2 Results

The table below represents an overview of all the potential alternatives, grouped by application.

Table 3-8 Potential chemical alternatives by application

Application	Alternative	Suitable Uses
RACHP	Ammonia	Industrial Refrigeration Transport Refrigeration Chillers
	Carbon dioxide	Mobile Air Conditioning Transport Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Commercial Refrigeration (Condensing Units)

Application	Alternative	Suitable Uses
	Isobutane	Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Movable Room Air Conditioning Heat Pumps
	Propane	Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Movable Room Air Conditioning Heat Pumps
	Propylene	Industrial Refrigeration Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units)
Foam Insulation	Di-methyl ether	Building Insulation (excluding spray foam)
	Cyclopentane	Building Insulation (excluding spray foam) Refrigeration Insulation
Magnesium Cover Gas	Carbon dioxide	N/A
Aerosols	Butane/ isobutane	Any aerosol that can use a high flammability propellant; limited by the solubility and compatibility of butane or isobutane with the aerosol formulation and product VOC limits
	Propane	Any aerosol that can use a high flammability propellant; limited by the solubility and compatibility of propane with the aerosol formulation and product VOC limits
	Di-methyl ether	Any aerosol that can use a high flammability propellant; limited by the solubility and compatibility of DME with the aerosol formulation and product VOC limits
	Nitrous oxide	Some technical and consumer aerosols (e.g. dusters) and food products (e.g. cream; cheese) Rocket propellant; limited by the solubility and compatibility of nitrous oxide with the aerosol formulation and product VOC limits
	Carbon dioxide	Some technical and consumer aerosols (e.g. dusters)
	Nitrogen	Some technical and consumer aerosols (e.g. dusters)
Fire Suppressant	[product name]	N/A
Solvent	[product name]	N/A
	MPHE	N/A
	HFE-347pcf2	N/A
	[product name]	N/A
	HFE-7100	N/A
	HFE-7000	N/A
	HFE-7200	N/A

Table 3-9 Potential non-chemical alternatives by application

Application	Alternative	Suitable Uses
RACHP	Brayton Heat Pump	Mobile Air Conditioning
	Ground-Coupled Solid Desiccant Air Conditioner	Industrial Refrigeration Stationary Air Conditioning (Multi-Split Systems)
MDIs	Dry Power Inhalers	Asthma treatment (excluding COPD patients, elderly and very young patients)
Aerosols	Bag-in-can/piston-can systems	Most aerosols

Rather than presenting a ranking of the best alternatives, we have presented a list of potential alternatives. This is because the 'best' alternative will likely depend on a number of factors that are specific to each company. As discussed in the section below, there are a number of uncertainties surrounding the assessment outcome, due to the lack of available data. Therefore, further research may reveal that alternatives deemed to be unacceptable in this assessment are in fact acceptable, and vice-versa. It should also be noted that the AoA was performed as a complimentary exercise to support the assessment of RMOs and was not performed to the same standards required of an AoA for an application for authorisation (AfA). This means that the final list of potential alternatives is not exhaustive.

A summary of the technical, performance, economic, and life-cycle elements that need to be considered when using each potential alternative is provided in Appendix A.

3.10 UNCERTAINTY ANALYSIS

There were several limitations within the individual assessments, which lead to some uncertainty with the final recommendation of potential alternatives. These are as follows:

Exposure assessment

The method chosen for the exposure assessment was based on physicochemical properties and a consideration of likely exposure. Within the assessment of the likelihood of exposure, information on the risk management measures and operational conditions used within each sector to reduce exposure was not considered, as this data was unavailable to the Study team. An accurate assessment of the potential exposure also requires greater information on exposure scenarios than was available.

As risk management measures and operational controls were not considered, these uncertainties are expected to have overestimated exposure. However, because few alternatives were excluded from the analysis based on risk level, these are not expected to have had a large impact on the final output.

Technical feasibility

The technical feasibility assessment focussed on technical readiness and whether any changes were required during production/manufacture or the use phase. Industry standards can also play a key part in how feasible an alternative is within a specific application or geography. However, due to the scope of the project, it was not possible to perform a comprehensive mapping exercise to identify all the relevant standards. This is because standards can be specific to Member States and to sub-applications within the applications in scope of this Study. For each application there can be multiple sub-applications, for example heat pumps consists of air-to-air heat pumps, air-to-water heat pumps, water-to-water heat pumps etc, while building insulation consists of phenolic foams, low pressure spray foam, high pressure spray foam etc. Capturing this complexity was beyond the scope of this study. However, reference has been made to any identified standards in Section 3.5 and A5, and the acceptability of alternatives has been presented at a high level.

The information obtained through desk research was not able to confirm the stakeholder response regarding the technical readiness of alternatives for certain applications. This highlighted that while an alternative may be commercially available for use in an application, there may be a significant amount of testing that is required by end-users to determine whether the performance can align with industry standards. The switch to

alternatives also cannot happen immediately, as time is required by industry to adapt their production facilities and product portfolios.

An example is the use of carbon dioxide in mobile air conditioning. Information obtained from the literature review highlights that some automotive manufacturers already use carbon dioxide within air conditioning systems in their cars. However, respondents to the consultation indicated that the timeframe needed to use CO₂ would be 3-10 years.

This uncertainty was addressed by refining the findings based on appropriate information, and due to the weight of evidence collected through the desk research, this is expected to have had little impact on the certainty of the final output of the assessment. Any data gaps in the technical feasibility assessment are highlighted in Section A9.2

Economic feasibility

The consultation with industry provided limited evidence regarding the changes in capital expenditure (CAPEX) and operational expenditure (OPEX) associated with the use of alternatives. Additionally, there was a lack of published quantitative information on the economic feasibility of both alternatives and the chemicals of concern, resulting in data gaps. This meant the cost of replacing equipment necessary to manufacture and use alternatives could not be taken into account for many alternatives and a neutral weighting was applied. This was particularly true for emerging technologies and material/design alternatives.

The cost of each alternative substance played a significant role in determining their economic feasibility. However, it's important to note that prices can be volatile and subject to change based on market conditions. Therefore, the current cost comparison may not hold true in the future. Due to the limited evidence and dynamic nature of alternative costs, there is a high level of uncertainty surrounding the economic assessment's output. Due to economies of scale, as more downstream users switch to alternatives, their price would be expected to fall. However, the cost of using alternatives could also increase, due to limitations surrounding the location and availability of raw materials and energy prices. These have a large influence on economic feasibility and is a challenge currently for the EU. The data gaps in the economic feasibility assessment are highlighted in Section A9.2

Performance assessment

The performance assessment is considered optional in many analysis of alternatives frameworks, especially when the assessing entity is not a manufacturer or downstream user. Detailed information on performance standards and acceptable tolerances is necessary for a thorough evaluation. However, data gaps remained even after consulting industry and conducting desk research. Therefore, certain alternatives that are presented as acceptable in this analysis might not be able to be used in certain sectors and applications. An example is the use of flammable refrigerants, as there are standards controlling the charge amount, which means that cannot be used in large RACHP systems.

Uncertainty also exists regarding the performance of many emerging technologies and whether modifications can be made to meet the requirements of the chemicals of concern. The data gaps in the performance assessment are highlighted in Section A9.2

The information obtained through desk research was not able to confirm the stakeholder response regarding the performance of alternatives for certain applications. Additionally, direct comparisons between alternatives and the chemicals of concern were not always possible due to a lack of available evidence. This leads to uncertainty in the final output of the performance assessment.

Overall, these findings emphasise the challenges posed by limited evidence, data gaps, volatility of costs, uncertainty in assessments, and the need for more comprehensive information when evaluating alternatives.

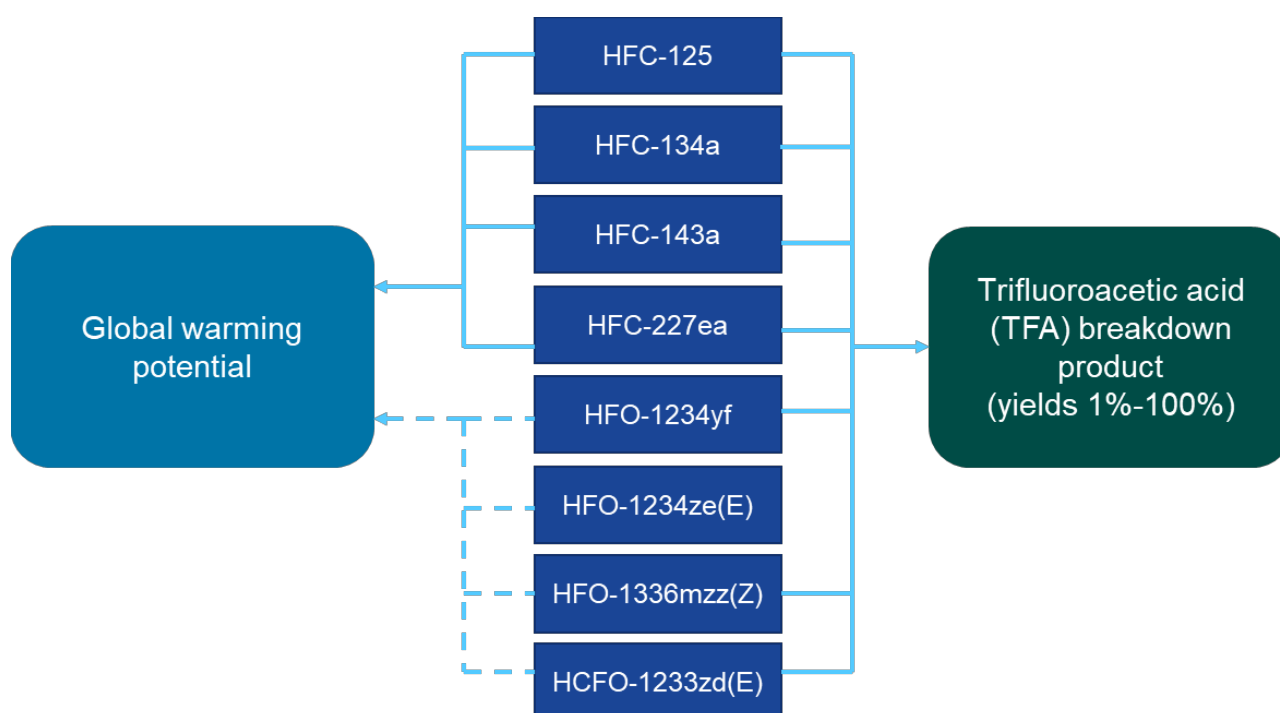
4. REGULATORY MANAGEMENT OPTIONS

F-gases are already a highly regulated group of substances, with legislation targeting their manufacture, use and end-of-life. Although F-gases tend not to exhibit hazards to human health or the environment, beyond their global warming potential (GWP) there remains areas that could be addressed to ensure that the impact of F-gases throughout their lifecycle is reduced to a minimum. The high GWP of certain F-gases and the degradation product TFA, which, although available evidence suggests no health concern at the measured concentrations and is not harmful to ecosystems, are areas which can be addressed further through regulatory management option analysis. The proposed REACH restriction of PFAS has further highlighted regulatory actions that may have serious consequences for F-gases and so, acknowledging the ongoing concerns and regulatory proposals, EFCTC have sought to identify potential regulatory management options that could be efficient and proportionate in addressing these concerns.

4.1 IDENTIFICATION OF RMOS

As mentioned above there are two areas that the potential RMOs aim to address – GWP and the TFA degradation product of the F-gases within scope. As can be seen in Figure 4-1, a number of the F-gases in scope have the potential to degrade into TFA in the environment and so RMOs are needed to address this. Four out of the eight F-gases in scope have GWP greater than 1000, whilst those linked with a dashed line have GWP of less than 5. As can be seen from the alternatives assessment (Section 3), a number of the alternative refrigerants to F-gases also have GWP of less than 5. This suggests that there is a more immediate need to address the manufacture, use and end-of-life management of those F-gases with higher GWP.

Figure 4-1 Focus Areas



The above focus areas require consideration of a variety of RMOs, each of which will have their own strengths and weaknesses. Some will be able to target both the GWP and degradation products of the F-gases in scope, whilst others will only be able to focus on one concern. It should be noted that the RMOs have been developed based on a regulatory baseline at the time of writing. This means that the proposed REACH restriction of PFAS and the amendments to the F-gas Regulation are not in place and so are RMOs in their own right. A systematic review has been carried out to identify a longlist of potential RMOs. This review considered:

- How the RMO addresses the concerns i.e. does it address the GWP/ degradation products of the F-gases directly or indirectly
- Whether the RMO operates in isolation or does it work in combination with other RMOs

- The uses and lifecycle stages that the RMO addresses
- The target of the RMO i.e. human health or the environmental compartment.

The systematic review provides the criteria for screening of the RMOs, evidencing the conclusion of their relevance in addressing the concerns. A qualitative scoring framework has been used to allow clear comparisons (see Table 4-1).

Table 4-1 Qualitative scoring framework for RMO screening

Screening result	Description
1	Not relevant – does not address the concern or is not applicable to F-gases in scope
2	Potential relevance – may be applicable to certain uses or F-gases, or address one of the two concerns
3	Highly relevant – Addressing a large number of uses and F-gases, and addresses both concerns

Table 4-2 presents the preliminary results of the screening of potential RMOs that could be relevant to address the concerns highlighted above, including those RMOs which have been carried forward for further assessment. A summary table is provided in Appendix C.

Table 4-2 RMO screening results

RMO	Screening Result	Carried forward for assessment
No action required	1 Action is required as within certain applications the GWP of refrigerants used requires lowering. The degradation management	No
Substance evaluation under REACH	2 The following substances have not undergone substance evaluation: HFC-125, HFC-134a, HFC-143a, HFC-227ea, HFO-1234ze, HFO-1336mzz, HCFO-1223zd. Concerns related to exposure of environment, high (aggregated) tonnage, wide dispersive use may require addressing.	Yes
REACH restriction – proposed restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS)	2 The REACH restriction proposal for PFAS seeks to address persistence. F-gases are not persistent but some F-gases degrade to their TFA which has been identified as persistent.	Yes
SVHC identification and candidate listing under REACH	2 SVHC identification would not address the concerns on its own, combined with REACH Authorisation for the purpose of this assessment	Yes
REACH Authorisation	In order to address the degradation product TFA, authorisation may allow for the continued use of certain applications whilst prohibiting others.	
Harmonised classification and labelling (CLH) under CLP	1 F-gases do not require additional harmonised classification for physical, human health or environmental endpoints based on their intrinsic properties	No

RMO	Screening Result		Carried forward for assessment
Regulatory proposal for amendment of F-gas Regulation	3	The proposed amendment of the F-gas Regulation targets the use, containment and emissions of F-gases .	Yes
Environmental quality standards (EQS) under Water Framework Directive	1	Water is not a key environmental compartment of concern for emissions of F-gases, although the amendment for Total PFAS may include TFA.	No
Occupational exposure limits (OELs) under CAD	1	F-gases to do not exhibit the hazard properties that would require an OEL	No
End-of life and waste requirements under other EU legislation	1	End-of-life is addressed in the F-gas Regulation, WEEE Directive and End-of-life vehicles Directive	No
Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	2	Additional requirements for monitoring of refrigerant losses may support other regulatory efforts to reduce emissions of F-gases and subsequent GWP and TFA production	Yes
Substitution (industry initiative)	3	use of non-fluorinated (e.g. CO ₂ , hydrocarbons, NH ₃) may tackle both the GWP and production of TFA.	Yes

Although “no action” could be a potential RMO for certain non-F-gas substances within certain applications, this assessment has found that for all the F-gases in scope further action is potentially required to address their GWP/ degradation products. Some of the RMOs carried forward for assessment are already regulatory proposals, for example the regulatory proposal to amend Directive (EU) 2019/1937 and repeal the current F-gas Regulation (EU No 517/2014) is already undergoing triologue negotiation, and the proposal for a REACH restriction of PFAS was published on 7th February 2023 and, at the time of writing, is undergoing public consultation on the restriction proposal. Although these RMOs are tabled for discussion, they are still of relevance to this assessment as the final decisions are yet to be made.

Although the proposed REACH restriction for PFAS would cover the manufacture, placing on the market and use of F-gases, the final decision has not been reached and so investigation of alternative options such as REACH Authorisation are valid. It would be unlikely that both REACH restriction and authorisation would be used to target a substance(s) as this could be considered double regulation and so this assessment considers them in isolation. Therefore the assessment of the RMO for REACH authorisation assumes that the proposed REACH restriction of PFAS does not enter into force covering F-gas applications. As such, this RMOA allows for comparative assessment of each of the potential RMOs which could address the concerns.

The output of the preliminary screening proposes the following RMOs for further analysis:

1. Substance evaluation under REACH
2. REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS
3. REACH authorisation
4. Regulatory proposal for amendment of F-gas Regulation
5. Refrigerant Management Plan under the Food, Drink and Milk Industries BREF
6. Substitution (industry initiative)

The following sub-sections shall describe these RMOs in more detail.

4.1.1 RMO 1: Substance evaluation

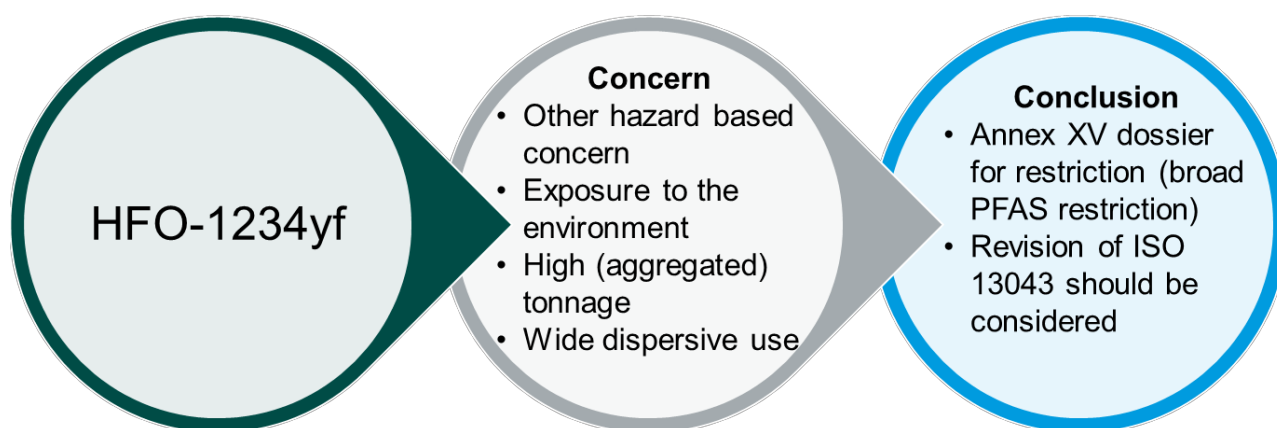
The purpose of substance evaluation under REACH is to gather further evidence to identify whether a substance may cause harm to human health or the environment. Substances are prioritised for evaluation and added to the CoRAP for further evaluation by Member States. Substance evaluation is only carried out for

substances which are registered under REACH. Each of the F-gases within scope of this Study are REACH registered and HFO-1234yf has already undergone substance evaluation.

The evaluating Member State competent authority (eMSCA) has 12 months from publication of the CoRAP to evaluate the need for further information in order to clarify the identified concern. The initial concern may be accompanied by further concerns identified during the evaluation. All registration dossiers of relevance to the substance are assessed to provide aggregated tonnages and combined exposure concerns. Following this evaluation the eMSCA may prepare a draft decision that requests further information from the registrants. Such information is usually more exhaustive than the standard information requirements (Annex VII-X) for the tonnage band of concern, for example, higher tier hazard information or monitoring data may be requested. The eMSCA may also conclude that no further information is required and will then prepare a conclusion document which either notes that the concern is not valid, or the concern is confirmed and a proposal for further regulatory action is put forward. The Member State Committee assess whether the draft decision requires amendment and there must be unanimous agreement by the Member States. The adopted decision is legally binding. Where additional information is requested a follow-up assessment of the data submitted is carried out to determine whether the concern has been clarified. If the eMSCA finds that the concern is confirmed, further regulatory action may be proposed, such as risk management measures, Candidate Listing, harmonised classification or occupational exposure limits.²⁴⁹

Figure 4-2 provides an overview of the concerns identified for HFO-1234yf and the conclusions of the substance evaluation.

Figure 4-2 Substance evaluation conclusion for HFO-1234yf²⁵⁰



Under this RMO it is assumed that other F-gases in scope of this Study are added to the CoRAP based on potential for similar concerns as HFO-1234yf:

- HFC-125
- HFC-134a
- HFC-143a
- HFC-227ea
- HFO-1234ze(E)
- HFO-1336mzz(Z)
- HCFO-1233zd(E).

²⁴⁹ ECHA (no date) Evaluation Process. Available at: <https://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure/phase-1#phase1-5>

²⁵⁰ BAUA (2021) Substance evaluation conclusion as required by REACH Article 48 for polyhaloalkaene. Available at: <https://echa.europa.eu/documents/10162/a794e3ad-c358-b7f8-bc74-268bfea135e7>

4.1.2 RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

The purpose of a REACH restriction is to protect human health and the environment from any unacceptable risk posed by chemicals in the EU. Restrictions can vary, limiting or banning the manufacture, placing on the market and use of a substance, or introducing additional conditions such as technical measures or labelling. Restrictions may apply to a substance on its own, in a mixture or in an article and are not limited by the need for a substance to be registered under REACH.²⁵¹

The proposed restriction on the manufacture, placing on the market and use of PFAS aims to address the risks to human health and the environment posed by their use, notably the persistence of PFAS (or their degradation products). Certain PFAS will also have other (eco)toxicological concerns such as bioaccumulation, mobility or human health effects. The definition of PFAS²⁵² is aligned with that of the OECD and encompasses more than 10,000 substances.

The restriction proposal considers two different restriction options:

- RO1 – a full ban with an 18-month transition period
- RO2 – a ban with use-specific (mostly) time-limited derogations.

Under this RMO, it is RO2 that is the restriction scenario taken forward for assessment as this is the proposed restriction following the outcome of the dossier submitters assessment. It is of relevance to each of the F-gases in scope of this Study. This RMO establishes that PFAS shall not be manufactured, used or placed on the market as substances on their own or in another substance as a constituent, a mixture or an article in concentrations of or above:

- i. *“25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)”*
- ii. *250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification)”*
- iii. *50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.”²⁵³*

This RMO also allows for (potential) time-limited derogations of specific uses as outlined in Table 4-3. There is also a derogation for refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives that is not subject to a time limitation.

Table 4-3 Derogations and potential derogations listed in RO2 of the proposed restriction on the manufacture, placing on the market and use of PFAS²⁵⁴

Within 6.5 years of entry into force	Within 13.5 years of entry into force
• refrigerants in low temperature refrigeration below -50 °C • refrigerants in mobile air conditioning-systems in combustion engine vehicles with mechanical compressors • refrigerants in transport refrigeration other than in marine applications	• refrigerants in laboratory test and measurement equipment and refrigerants in refrigerated centrifuges; • maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist; • propellants for technical aerosols for applications where non-flammability and

²⁵¹ ECHA (no date) Restriction. Available at: <https://echa.europa.eu/regulations/reach/restriction>

²⁵² Any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the proposed restriction: CF₃-X or X-CF₂-X', where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R''', and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-).

²⁵³ BAuA, RIVM, KEMI, Norwegian Environment Agency, Danish EPA (2023) Annex XV Restriction Report. Proposal for a Restriction of per- and polyfluoroalkyl substances (PFAS). Available at: <https://echa.europa.eu/documents/10162/1c480180-ec9-1bdd-1eb8-0f3f8e7c0c49>

²⁵⁴ Ibid Footnote 253253.

Within 6.5 years of entry into force	Within 13.5 years of entry into force
foam blowing agents in expanded foam sprayed on site for building insulation (potential derogation)	- high technical performance of spray quality are required (potential derogation); - use as refrigerants and for mobile air conditioning in vehicles in military applications (potential derogation); - clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health; - cleaning fluids for use in oxygen-enriched environments.

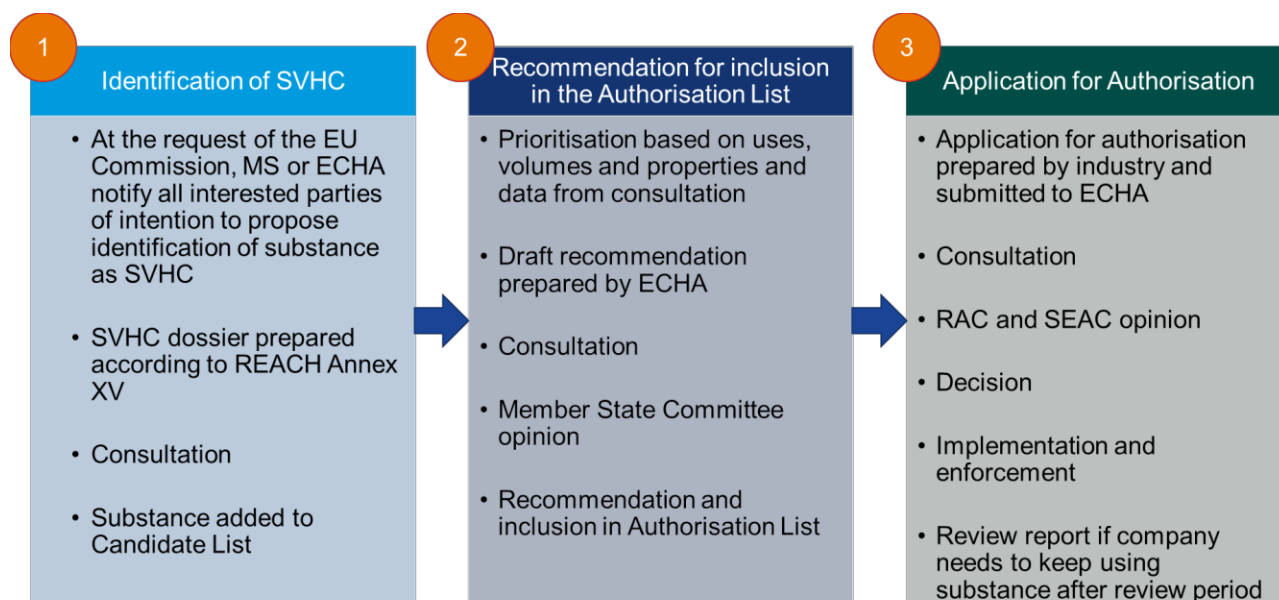
This RMO also has administrative requirements, in that manufacturers and importers of the F-gases in scope or articles containing the F-gases in scope, as well as formulators of mixtures containing the F-gases in scope who make use of any of the derogations must provide by 31 March of each calendar year (following entry into force + 18 months) a report to ECHA which contains:

- the derogation that the intended use belongs to;
- the identity and quantity of the substances placed on the market in the previous year.

4.1.3 RMO 3: REACH Authorisation

REACH authorisation is a legislative process that seeks to ensure that the risks related to SVHCs are controlled throughout their lifecycle, whilst promoting the substitution of SVHCs with chemical (lower hazard profile) and non-chemical (new technologies and processes) alternatives. Authorisation occurs in three phases (see Figure 4-3) and involves the European Commission, Member States (MS), ECHA and industry.²⁵⁵

Figure 4-3 REACH Authorisation steps²⁵⁶



Once a substance has been added to the Candidate List and subsequently included in the Authorisation List (REACH Annex XIV), it is the responsibility of companies that wish to continue to use the substance after the sunset date to prepare and submit an application for authorisation. These applications can be submitted by manufacturers, importers, and downstream users for their own use or uses for which they intend to place the

²⁵⁵ ECHA (no date) Authorisation Process. Available at: <https://echa.europa.eu/authorisation-process>

²⁵⁶ Ibid Footnote 255.

substance on the market for. Applications for authorisation can be submitted for one or several uses, or one or a group of substances.²⁵⁷

As authorisation requires SVHC identification and Candidate Listing, these RMOs have been combined for this assessment. The REACH authorisation RMO is assumed to only be of relevance should the final REACH restriction of PFAS exempt F-gases from its scope. Authorisation of F-gases would not be required should the PFAS restriction enter into force as it is currently written. Therefore, analysis of this RMO is considered to be an alternative, rather than complementary, option. This RMO applies to all F-gases in scope of this Study.

4.1.4 RMO 4: Regulatory proposal for amendment of F-gas Regulation

The F-gas Regulation ((EC) No. 517/2014)²⁵⁸ is the main mechanism through which the EU complies with the Kigali Amendment to the Montreal Protocol. The F-gas Regulation includes several measures to reduce the emissions of fluorinated greenhouse gases, most notably the phase-down of use of HFCs and restrictions/prohibitions, which hand-in-hand seek to reduce the use of high-GWP F-gases. The phase-down established in the F-gas Regulation defines maximum potential CO₂-e quantity of a subset of F-gases that can be placed on the market every year until 2030. This places a strong incentive to switch to F-gases with lower GWP and to non-HFC alternatives, like H(C)FOs. The Regulation also has measures concerning: leakage checks and control, technician certification, F-Gas reporting and end-of-life treatment, including recovery and destruction.

The EU has recently conducted an evaluation of the existing F-gas Regulation (EU No 517/2014)²⁵⁹. This evaluation found that it has been mostly effective and has achieved low-cost emissions abatement. That said, since the 2014 F-gas Regulation was adopted, there have been developments at the international level which mean the existing Regulation is no longer fully fit for purpose. In addition, the F-gas Regulation has not successfully addressed some high emitting sectors, such as crucial medical applications linked with high emissions. Stakeholder feedback to the evaluation (provided through survey responses) noted medical applications such as anaesthetic gases/medical cabinets, as a key gap in coverage of the Regulation. Table 47 of the Evaluation also lists medical applications as a use of F-gases not addressed by specific provisions in the Regulation. This view was also evident in the Impact Assessment of the Regulation²⁶⁰ which notes feedback from NGOs stating there should be stricter requirements for certain sectors currently exempted, such as medical applications.

Further to this, the illegal trade of F-gases, which has been a prevalent issue over the implementation period, has not been sufficiently addressed through the current Regulation. In that context, the European Commission has recently published a proposal to amend legislation on F-Gases (Directive (EU) 2019/1937²⁶¹ and the F-gas Regulation). This regulatory proposal has entered trialogue negotiations between the EU Commission, the European Parliament and the Council.

The regulatory proposal seeks to align the F-gas Regulation with the objectives of the EU Green Deal, European Climate Law and the EU international obligations on HFCs under the Kigali Amendment to the Montreal Protocol, and to strengthen the implementation and enforcement of issues identified related to illegal trade, training on F-gas alternatives and the functioning of the quota system²⁶². Two of the key changes proposed are the extension of containment measures to Annex II substances (H(C)FOs) and additional sectors and subsectors e.g. transport refrigeration. There are also proposals to remove phase-down exemptions for F-gases used as propellants for MDIs, introducing a specific quota for the sector; a more ambitious quota phase-down for HFCs in RACHP applications; and a phase-down concerning the production of HFCs in the EU. A summary of key changes to the current F-gas Regulation are provided in Table 4-4. To note, this list is not exhaustive of all changes proposed.

²⁵⁷ Ibid Footnote 255.

²⁵⁸ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 Text with EEA relevance. Accessible under: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0517>

²⁵⁹ Öko-Recherche, 2022. Support contract for an Evaluation and Impact assessment for amending Regulation (EU) No 517/2014 on fluorinated greenhouse gases, CLIMA.A2/ETU/2019/0016, Evaluation Final Report. European Commission: DG Clima. Available from: https://ec.europa.eu/clima/system/files/2022-04/f-gas_evaluation_report_en.pdf.

²⁶⁰ Commission Staff Working Document Impact Assessment Report Accompanying The Document Proposal For A Regulation Of The European Parliament And Of The Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014

²⁶¹ Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law. Accessible under: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32019L1937>

²⁶² Council of European Union (2023) Interinstitutional File 2022/0099(COD) Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 – mandate for negotiations with the European Parliament.

Table 4-4 Key amendments to the current F-gas Regulation outlined in the regulatory proposal.

Article/ Annex	Amendment	Scope
Article 5 and Article 6 Leak checks and leak detection systems	New requirement for operators of the following mobile equipment that contains 5 tonnes of CO₂ equivalent or more of fluorinated greenhouse gases listed in Annex I or 1 kilogram or more of fluorinated greenhouse gases listed in Annex II to check equipment for leaks: a) refrigeration units of refrigerated trucks and trailers; b) refrigeration units of refrigerated light-duty vehicles, vans, intermodal containers including reefers and train wagons; c) air-conditioning equipment and heat pumps in trucks, vans, busses, non-road mobile machinery used in agriculture, farming, mining and construction operations, tractors, trains, metros, trams, and aircraft. Operators of these three types of equipment containing fluorinated greenhouse gases listed in Annex I in quantities of 500 tonnes of CO₂ equivalent or more shall ensure that the equipment is provided with a leakage detection system which alerts the operator or the service personnel of any leakage, as far as the system is housed or operated in a machinery room. The leakage detection systems shall be checked as regularly as the installed equipment.	All F-gases in scope
	The requirement to check for leaks in equipment containing F-gases in Annex II has been added. The following schedule is provided for leak testing: - Affects HFC-1234yf, HFC-1234ze, HFC-1336mzz, and HCFC-1233zd. a) equipment that contains less than 10 kilograms of fluorinated greenhouse gases listed in Annex II, Section I: at least every 12 months; or where a leakage detection system is installed, at least every 24 months b) equipment that contains between 10 kilograms or more, but less than 100 kilograms of fluorinated greenhouse gases listed in Annex II, Section I: at least every six months or, where a leakage detection system is installed, at least every 12 months c) equipment that contains more than 100 kilograms or more of fluorinated greenhouse gases listed in Annex II, Section I1: at least every three months or, where a leakage detection system is	HFC-1234yf HFC-1234ze HFC-1336mzz HCFC-1233zd

Article/ Annex	Amendment	Scope
	installed, at least every six months. A leakage system which alerts the operator or a service company of any leakage for this equipment is compulsory.	
Article 8 Recovery and destruction	New requirement for operators of the following equipment containing F-gases to ensure that the recovery of those gases is carried out by natural persons that hold the relevant certificates provided for in Article 10, so and that those gases are recycled, reclaimed or destroyed: a) the cooling circuits of refrigeration units of refrigerated trucks and trailers; b) the cooling circuits of refrigeration units of refrigerated light-duty vehicles, vans, intermodal containers including reefers and train wagons; c) the cooling circuits of air-conditioning and heat pumps in trucks, vans, busses, non-road mobile machinery used in agriculture, farming, mining and construction operations, trains, metros, trams and aircraft.	All F-gases in scope
	From 1 January 2024, building owners and contractors must also ensure that during renovation, refurbishing or demolition activities implying the removal of foam panels or foams in laminated boards installed in cavities or built-up structures that contain foams with fluorinated greenhouse gases listed in Annex I and in Annex II, Section 1, the emissions are avoided to the extent possible by handling the foams or the gases contained therein in a way that ensures for the destruction of the gases contained therein. The recovery of the gases contained in the foams shall be carried out by appropriately qualified natural persons.	All F-gases in scope
Article 11 and Annex IV Prohibitions	Stationary refrigeration equipment that contains, or whose functioning relies upon, except equipment intended for applications designed to cool products to temperatures below – 50 °C a) other fluorinated greenhouse gases with GWP of 2 500 or more, from 1 January 2024	HFC-125 HFC-134a HFC-143a
	A ban on plug-in room and other self-contained air-conditioning and heat pumps (including all heat pumps in monobloc construction) with a maximum rated capacity of 50kW that contain F-gases with GWP of 150 or more, except when required to meet safety requirements, from 1 January 2026. (When safety requirements would not allow using fluorinated greenhouse gases with GWP of 150 or less, the GWP limit would be 750)	

Article/ Annex	Amendment	Scope
	A ban on all other self-contained AC and heat pump equipment operating on F-gas with a GWP greater than 150, except when required to meet safety requirements, from 1 January 2030. (When safety requirements would not allow using fluorinated greenhouse gases with GWP of 150 or less, the GWP limit would be 750)	
	A ban on single-split AC units and split heat pumps using less than 3kg of HFCs with a GWP of 750 or more from 1 January 2025	
	A ban on air-to-water split AC or split heat pump systems with a rated capacity of up to and including 12 kW, containing or functioning reliant on HFCs with a GWP of 150 or more (except when required to meet safety requirements) from 1 January 2026	
	A ban on air-to-air split AC or split heat pump systems with a capacity of up to and including 12kW and containing or functioning reliant on HFCs with GWP of 150 or more (except when required to meet safety requirements) from 1 January 2029	
	A ban on split AC or split heat pump systems with capacities of more than 12kW, containing or functioning reliant on HFCs with GWP over 750 (except when required to meet safety requirements) from 1 January 2029	
	A ban on split AC or split heat pump systems over 12kW, operating on HFCs with a GWP over 150 (except when required to meet safety requirements) from 1 January 2033	
Annex VII	Amendment made to the maximum amount of HFCs allowed to be placed on the Union market in a given year: 2024-2026 – 24 874 410 2027-2029 – 20 677 379	HFC-125 HFC-134a HFC-143a HFC-227ea

The applicability of the conditions for this RMO vary by F-gas with amendments to leakage check, recovery and destruction requirements applying to both the HFCs and H(C)FOs in scope of this study, and the restrictions, control of use, production, quota and phase-down requirements applying to HFCs only. It should be noted that the regulatory proposal seeks to ensure that the phase-down of HFCs is taken into account by other legislative proposals, such as the proposed REACH restriction of PFAS, but these two regulatory changes remain independent of each other.

4.1.5 RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

Industrial production processes are a significant contributor to environmental pollution from the emissions of wastewater discharge, air pollutants and waste. The Industrial Emissions Directive (2010/75/EU)²⁶³ (IED) is the main regulatory instrument for managing pollutant emissions from industrial installations in the EU. The IED is an integrated approach which requires permits related to the entire environmental performance of an installation (use of raw materials, emissions to air, water, land, generation of waste, energy efficiency, accident

²⁶³ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast). Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0075-20110106>

prevention, noise and site closures). Best available technique (BAT) reference documents (BREFs) are the point of reference for setting permit conditions under Chapter II of the IED. It is the responsibility of Member State competent authorities to ensure that emissions from installations do not exceed the emission levels associated with BAT, under normal operating conditions, although flexibility is allowed in specific cases where assessment shows that achieving the BAT emission levels would lead to disproportionately higher costs than benefits.²⁶⁴

The original BAT recommendations for the Food, Drink and Milk Industries was adopted by the EU Commission in 2006 and, following a review which commenced in 2013, was updated in 2019. The BREF includes an overview for use of refrigerants without ozone depleting potential and with low global warming potential and suggests the use of alternatives such as CO₂, NH₃ and water. It is noted that HFCs are frequently used in applications that require temperatures below -10°C.²⁶⁵ This RMO proposes the use of a Refrigerant Management Plan under the Food, Drink and Milk Industries BREF. It is acknowledged that this RMO covers only a small part of the industrial use of F-gases and so a management plan would be a complementary RMO and would work together with the current F-gas Regulation (or the regulatory proposal for amendment of the F-gas Regulation) and would include the following conditions:

- monitoring of the energy consumption of the refrigeration system;
- operational measures such as inspection and maintenance of equipment, closing of doors when possible;
- equipment operation by experienced staff;
- monitoring of refrigerant losses.

This RMO would apply to HFCs and H(C)FOs but, due to the phase-down under the F-gas Regulation, is likely to be of greater relevance to the H(C)FOs in the future.

4.1.6 RMO 6: Substitution (industry initiative)

This RMO is not a legal requirement but a voluntary industry initiative to respond to concerns regarding the environmental impacts related to the manufacture and use of the F-gases in scope, via industry led substitution efforts.

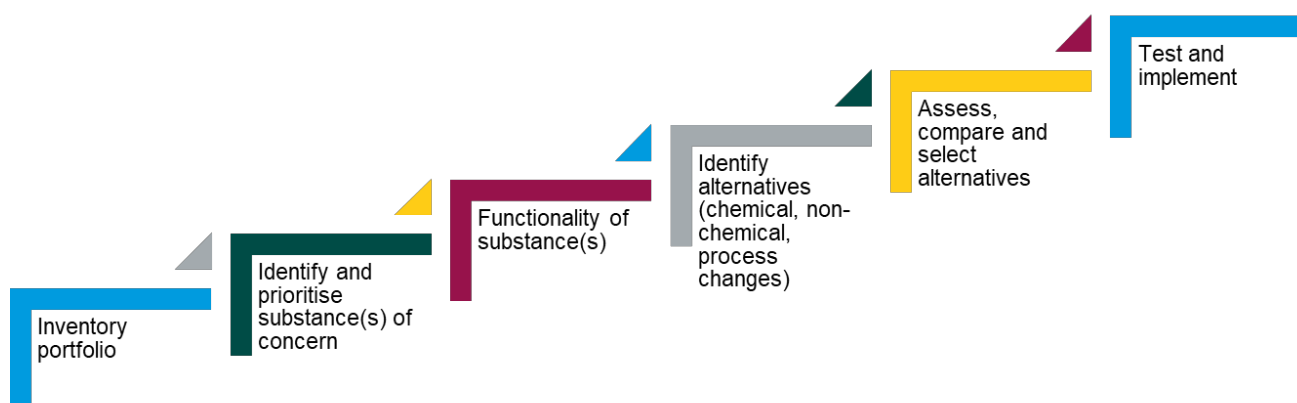
Substitution is the replacement of hazardous substances in products or processes with less hazardous or non-hazardous substances, or the use of non-chemical alternatives, materials, new techniques or processes²⁶⁶. Substitution can be initiated at any level of the supply chain and this will depend on the substitution drivers. The drivers behind substitution can vary but manufacturers of the substance of concern or downstream users may decide that they no longer wish to manufacture/ use the substance for a number of reasons, such as: concerns for market demand, regulatory pressure, raw material feedstocks, efficiencies of processes, public perception, improving the environmental footprint, providing better functionality, or cost implications. Substitution tends to follow sequential steps, as outlined in Figure 4-4.

²⁶⁴ European Commission (no date) DG Environment: Industrial Emissions Directive. Available at: https://environment.ec.europa.eu/topics/industrial-emissions-and-safety/industrial-emissions-directive_en

²⁶⁵ Germán Giner Santonja, Panagiotis Karlis, Kristine Raunkjær Stubdrup, Thomas Brinkmann, Serge Roudier; Best Available Techniques (BAT) Reference Document for the Food, Drink and Milk Industries; EUR 29978 EN; doi:10.2760/243911.

²⁶⁶ KEMI (no date) Substitution of hazardous substances. Available at: <https://www.kemi.se/en/guidance-for-companies/substitution-of-hazardous-substances#:~:text=Substitution%20means%20eliminating%20or%20replacing%20hazardous%20chemicals%20in%20products%20or.new%20techniques%20or%20other%20processes.>

Figure 4-4 Substitution steps



Depending on the use of the substance, substitution can be relatively quick or a long-term investment. When moving to a non-PFAS refrigerant, it can take more than 10 years of development, including material, component and equipment testing. For certain applications, manufacturers or downstream users may already have an alternative substance that they can use as a substitute. This substance may be a drop-in alternative which is already on the market or could be brought to the market quickly. Drop-in substitution comes with the risk of regrettable substitution and so may not always be the most suitable option. Other options may be substitution with alternatives that are already on the market and have the same technical function but may require changes to the production process or adaptation of existing systems. For example, there is already a shift from use of the HFCs in scope of this Study to the lower GWP H(C)FOs, in certain applications, or shifts from the use of F-gases to CO₂, NH₃ and hydrocarbons which require different operating conditions in their downstream uses e.g. redesign of refrigeration systems to allow for higher operating pressures. There may also be non-chemical alternatives such as differing technologies that can perform the ultimate function of the product containing the substance of concern. In other cases, there is need for longer term innovation, seeking to develop new (non)chemical alternatives.

This RMO requires industry to identify the areas of concern within their sector, and their drivers for substitution to select the investment needed (monetary and resource) to substitute the F-gases in scope of this Study with suitable alternatives that have been assessed not only for their functionality and regulatory status but also for the toxicity and environmental properties. For the F-gases in scope of this assessment, likely drivers may be the proposed REACH restriction of PFAS or the regulatory proposal to amend the F-gas Regulation, both of which create regulatory pressure to move towards the use of alternatives. This RMO takes effect before these regulatory requirements enter into force and substitution becomes a mandatory response to restrictions on manufacture and use.

4.2 ASSESSMENT OF RMOS

This section presents an overview of the assessment of the RMOs carried forward in this Study. Four criteria are considered: effectiveness, practicability, regulatory consistency and wider socio-economic impacts. Each of these criteria are then broken down further into key metrics for assessment.

A qualitative scoring framework has been used to provide a methodology for comparison of the RMOs with regard to their overall proportionality (outcome of the assessment of the 4 criteria above). The qualitative framework is provided in Table 4-5.

Table 4-5 Qualitative scoring framework for assessment of RMOs

Score	Description of impact direction and magnitude
-3	High negative impact on the factor is expected from the implementation of the RMO
-2	Medium negative impact on the factor is expected from the implementation of the RMO
-1	Low negative impact on the factor is expected from the implementation of the RMO

Score	Description of impact direction and magnitude
0	Neutral or unknown impact on the factor is expected from the implementation of the RMO
1	Low positive impact on the factor is expected from the implementation of the RMO
2	Medium positive impact on the factor is expected from the implementation of the RMO
3	High positive impact on the factor is expected from the implementation of the RMO

4.2.1 Effectiveness – Risk reduction

For the selected RMOs, it is required to assess the effectiveness of the RMOs for risk reduction to the environment for GWP and for the formation of the TFA degradation product. Each of the RMOs have varying levels of risk reduction depending on the applications and sectors targeted by the RMO. It is also worth noting that where the RMO would result in alternatives being used, that these alternatives both have a positive impact on GWP and the persistent degradation product risk reduction and also do not result in other potential environmental impacts which would affect the effectiveness of the RMO (such as formation of other hazardous degradation products with a higher or equal to hazard than TFA, increased carbon dioxide emissions, decrease in energy efficiency or other environmental hazards).

RMO1: Substance evaluation

As outlined in Section 4.1.1, substance evaluation is an RMO which could lead to further data generation for assessing the risk level. The ability of this RMO to reduce the risk would be dependent on the outcome of the substance evaluation and also the risk(s) identified. HFO-1234yf has undergone substance evaluation, in which the potential need for follow-up regulatory action, restriction based on the properties and other EU-wide measures were identified for further action. For HFC-125, HFC-134a, HFC-143a, HFC-227e, HFO-1234ze and HFCFO-1233zd, potential actions for reducing the risk would be dependent on those identified during the substance evaluation.

Thus, this RMO (score of 0 for risk reduction) would not directly address the risk from GWP and TFA but would allow data generation to support risk assessment and would identify potential actions that could be used for risk reduction.

RMO2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

This RMO, as described in section 4.1.2 would have implications for all the F-gases in scope of this study. This RMO would have the ability to reduce the risk for GWP and TFA formation in the environment sourced in the emission of the 8 F-gases in scope. For 2020 in the EEA, it has been estimated that annual emissions from the applications of fluorinated gases have been 38,806 tonnes/year from F-gases related to emissions related to stock and 1,686 tonnes/year from emissions from tonnages which were new to the market in 2020.²⁶⁷

Under RO1 (full ban), it is estimated that this would result in a 95% decrease in emissions from the applications of F-gases.²⁶⁸ For RO2 (preferred restriction option) this would result in estimated additional 111,705 tonnes of emissions of F-gases from industrial refrigeration applications for a 5-year derogation compared to the full ban restriction option (RO1). However, even though RO2 would result in additional emissions over the short term compared with RO1 (thus, with a lower ability to reduce the risk), this RO will lead to a shift towards alternatives within the derogation period. As outlined in Section 3, alternatives are available for applications of F-gases that would reduce the risk compared to the use of F-gases, however their feasibility is dependent on the alternative and application. For example, for RACHP applications, alternatives that would reduce the risk for GWP and TFA formation include natural refrigerants (such as ammonia). For some applications (RACHP, MDIs and aerosols), non-chemical alternatives are possible which would further reduce the risk (see Section A4.5). However, it is worth noting that some of the potential alternatives to F-gases may have a higher hazard (thus, also a higher risk) to the environment and human health from their use (other than GWP) and their degradation products, as highlighted in Section A4.2.

²⁶⁷ ECHA (2023) Annex XV Restriction: Report Proposal for a Restriction - Per- and polyfluoroalkyl substances (PFASs). Available at: <https://echa.europa.eu/documents/10162/1c480180-ec9-1bdd-1eb8-0f3f8e7c0c49>

²⁶⁸ BAuA, RIVM, KEMI, Norwegian Environment Agency, Danish EPA (2023) Annex XV Restriction Report. Proposal for a Restriction of per- and polyfluoroalkyl substances (PFAS). Available at: <https://echa.europa.eu/documents/10162/1c480180-ec9-1bdd-1eb8-0f3f8e7c0c49>

The proposed REACH restriction (RO2) is expected to have an impact on the ability to reduce the risk (score of 3). The proposed derogation period for the applications of F-gases will result in a shift to alternatives which would be expected to reduce the risk from GWP and the formation of TFA. However, the positive impact of the proposed REACH restriction could be impacted should the alternatives have other environmental impacts.

RMO3: REACH Authorisation

REACH authorisation requires the risk to be minimised and adequately controlled.²⁶⁹ This RMO would only be considered for reducing the risk if the F-gases in scope are not included as part of RMO 2. Authorisation has the ability to reduce the risk by requiring the use of improved operating conditions and risk management measures, which would reduce emissions to the environment, as well as any measures identified in the application for authorisation.

The replacement of substances of concern with alternatives with lower risks is also an objective of authorisation, with 65% of substitution activities being performed as an outcome of the inclusion of substances on the Authorisation list.²⁷⁰ The use of REACH authorisation for reducing risk has been demonstrated in the case of octyl- and nonylphenols. It has been estimated that emissions of octyl- and nonylphenols to the environment are projected to reduce by 90% (from 10 tonnes to 0.7 tonnes per year) over the next decade.²⁷¹ This reduction is primarily driven by the implementation of alternatives.

Authorisation of the F-gases in scope could result in potential increased measures for further reducing emissions to the environment dependent on the outcome of the authorisation application process and also drive the replacement of F-gases with alternatives. However, as discussed for RMO 2, these alternatives would also need to be considered for other potential environmental impacts aside from GWP and the formation of TFA. This would have a positive impact on reducing risk. However, authorisation tends to be a substance-led approach (with some use of grouping) and at the present time none of the F-gases in scope are listed as SVHCs so the reduction of risk is likely to only be felt further into the future. For risk reduction, this RMO has a score of 1.

RMO4: Regulatory proposal for amendment of F-gas Regulation

This RMO concerns the proposed amendments to the F-gas Regulation. The aim of the F-gas Regulation is to reduce the emissions of F-gases to protect the environment and the regulatory proposal for the amendment of the F-gas Regulation will increase the scope by the inclusion of additional sectors and also towards the substances in Annex 2. Reducing the manufacture and uses of F-gases would have a positive impact on the ability to reduce risk as this would decrease potential emissions of the F-gases in scope.

Within the regulatory proposal for the amendment of the F-gas Regulation, it is proposed to reduce the quotas for F-gases which can be placed on the Union Market (in CO₂ equivalent) from 42,875,410 for 2004-2026 to 4,200,133 from 2048 onwards using a stepwise approach to this date. It can be assumed that as the quotas are decreased, there would be a corresponding reduction of risk to the environment. Within this RMO, there would also be a risk reduction from the requirements for operators to perform leak checks for mobile equipment (includes refrigeration units and air-conditioning) that contains 5 tonnes of CO₂-e or more of fluorinated greenhouse gases listed in Annex I or 1 kilogram or more of fluorinated greenhouse gases. The proposed amendment also includes the prevention of emissions for the F-gases listed in Annexes 1 and 2 for the production, storage, transport, manufacturing of F-gases, and equipment containing F-gases. The use of leakage detection systems is also proposed to be extended from equipment that contains F-gases in quantities of 500 tonnes of CO₂ equivalent or more to equipment that contains less than 50 tonnes of CO₂ equivalent. There are also new requirements for the recovery and destruction of F-gases (HFCs, H(C)FOs) and amended prohibition of some uses of the HFCs in scope. Thus, the reduced use of the HFCs in scope, along with the additional control measures, could be assumed to lead to a reduction of risk (risk reduction score of 2).

Reducing the quotas of the HFCs in scope that can be placed on the market is likely to result in a shift to alternatives and the market share of these alternatives would increase over time. This would include an

²⁶⁹ ECHA (2017): Applications for authorisation under REACH. Available at: https://echa.europa.eu/documents/10162/17229/factsheet_applications_authorisation_en.pdf#:~:text=Authorisation%20is%20one%20of%20the%20REACH%20processes%20for.List%20%28i.e.%20Annex%20XIV%20of%20the%20REACH%20Regulation%29

²⁷⁰ ECHA (2021): Socio-economic impacts of REACH authorisations. A meta-analysis of the state of play of applications for authorisation. Available at: https://echa.europa.eu/documents/10162/13637/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3ce0f072918e4#:~:text=Thanks%20to%20the%20conditions%20set,tonnes%20per%20year%20in%202032

²⁷¹ Ibid 270.

increasing shift to lower GWP alternatives, such as H(C)FOs which would also have emission reduction measures (i.e. leakage checks, leak detections, reporting requirements and recovery) and also the use of non-fluorinated refrigerants for RACHP applications, which could have a further positive impact on the reduction of risk.

RMO5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

This RMO is an administrative measure and would only reduce the risk for the food, drink and milk industries in which a leakage rate of 8% has been estimated for industrial HFC refrigeration systems in this BREF.²⁷² To note, the BREF itself does not include specific leakage reduction measures, it does require additional monitoring.

Within this BREF, alternative refrigerants with lower GWPs are included (such as ammonia, carbon dioxide and water) are discussed. To note, although not explicitly mentioned, the use of low GWP H(C)FOs would also be in accordance with the BREF. This RMO would serve as a reminder to installations that they must not only reduce the use of high GWP refrigerants but control the emissions of low GWP alternatives. This RMO would have a potential positive impact (risk reduction score of 1) for the sector as emissions to the environment would be reduced.

RMO 6: Substitution (industry initiative)

This RMO would be expected to have a positive impact for reducing the risks to the environment (risk reduction score of 2). This RMO would be dependent on the risk, regulatory requirements, technical and economic feasibility of the alternative(s) for each use (please see Section 3). The possible alternatives for F-gases also vary from a high substitution potential to a low substitution potential depending on the use. However, the impact of this RMO is also dependent on the alternative not having higher potential hazards than the HFCs which they are replacing.

4.2.2 Effectiveness – Measurability and monitorability

For the selected RMOs, it is required to assess the measurability and monitorability for their potential impacts. Measurability involves assessing if it is possible to evaluate or quantify the efficacy of the RMO and if this can be achieved. Monitorability involves assessing if the RMO can be monitored to evaluate the effectiveness of the RMO in reducing the risk. For monitorability, there are already monitoring requirements in place through the F-gas Regulation which can be used for monitoring the effectiveness of these RMOs

RMO1: Substance evaluation

The measurability and monitorability of this RMO would be dependent on the outcome of the substance evaluation. As this is the case, it is not possible to assess the potential impacts for measurability and monitorability.

RMO2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

The effectiveness of this RMO is possible to be measured. The requirements of this RMO includes time periods for derogations for the applications of F-gases proposed. The effectiveness of the RMO could be measured by quantifying the uses of the F-gases in scope, such as volume placed on the market, by regularly updating the baseline values provided in the ECHA Annex XV restriction proposal for PFAS. However, there are already monitoring requirements under the F-gas Regulation which would still occur. The market share of the alternatives could also be used for monitoring, as their market share would be expected to increase over time. This monitoring could however be complex as substances could be allowed for some uses and not others and reporting could also be complex for the different actors in the supply chain. Lack of supply chain communication and visibility could impact the monitorability of this RMO.

The monitoring of this RMO would be performed under the reporting requirements of the F-gas Regulation.

RMO3: REACH Authorisation

The effectiveness of the RMO can be measured in a similar manner to RMO2. Emissions to the environment could be calculated by using tonnages as a proxy and the uptake of alternatives used for measuring the

²⁷² Germán Giner Santonja, Panagiotis Karlis, Kristine Raunkjær Stubdrup, Thomas Brinkmann, Serge Roudier; Best Available Techniques (BAT) Reference Document for the Food, Drink and Milk Industries; EUR 29978 EN; doi:10.2760/243911.

efficiency, such as the case for octyl- and nonylphenols where alternative substances are being taken up through authorisation.²⁷³

Monitorability of this RMO could be performed in the same manner as RMO2 with monitoring continuing under the F-gas Regulation. However, as part of the REACH authorisation process, specific monitoring arrangements may be put in place.

RMO4: Regulatory proposal for amendment of F-gas Regulation

There are requirements already in place for measuring and monitorability in the F-gas Regulation, with adjustments made in this RMO. Under the F-gas Regulation reporting mechanisms already exist for producers, importers, exporters, feedstock users, destruction and reclamation facilities. Monitoring data is required to be submitted to the United Nations Framework Convention on Climate Change (UNFCCC) in the form of an annual greenhouse gas inventory which covers both emissions and removals of direct greenhouse gases.²⁷⁴ This monitoring has indicated that, for F-gases in the EU, there has been a downward trend in the supply of F-gases in the EU since the introduction of the 2014 F-gas Regulation.²⁷⁵

RMO5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

This RMO already includes measuring and monitoring recommendations in the BREF. Measuring can be performed with suggestions in the BREF including performing direct measurements, calculations and recording at frequent appropriate points, whilst another suggestion could be performing leakage measurements that complement those under the F-gas Regulation.²⁷⁶ Integrated monitoring systems could be used to monitor energy consumption from implementing the refrigeration management plan. The monitoring of this RMO would continue to occur under the requirements of the F-gas Regulation.

RMO6: Substitution (industry initiative)

The measurability of this RMO could be measured in a similar manner to RMOs 2 and 3. The monitoring of this RMO would continue to occur under the requirements of the F-gas Regulation.

4.2.2.1 Conclusions on Effectiveness of RMOs

As can be seen from the summaries above, the effectiveness of the RMOs vary. Table 4-6 presents an overview of the qualitative scoring for the effectiveness of the RMOs within this assessment.

Table 4-6 Qualitative Scoring of RMOs for Effectiveness

RMO	Risk reduction	Measurability/ Monitorability	Total
RMO1: Substance evaluation	0	0	0
RMO2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS	3	2/3, average 2.5	8
RMO 3: REACH Authorisation	1	2/3, average 2.5	6
RMO 4: Regulatory proposal for amendment of F-gas Regulation	2	2/3, average 2.5	7

²⁷³ ECHA (2021): Socio-economic impacts of REACH authorisations. A meta-analysis of the state of play of applications for authorisation. Available at: https://echa.europa.eu/documents/10162/13637/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3-ce0f072918e4#:~:text=Thanks%20to%20the%20conditions%20set,tonnes%20per%20year%20in%202032

²⁷⁴ United Nations Climate Change (undated): Reporting requirements. Available at: <https://unfccc.int/process-and-meetings/transparency-and-reporting/reporting-and-review-under-the-convention/greenhouse-gas-inventories-annex-i-parties/reporting-requirements>

²⁷⁵ Council of European Union (2023) Interinstitutional File 2022/0099(COD) Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 – mandate for negotiations with the European Parliament.

²⁷⁶ European Commission (2023): Final Draft of the Revised BREF document- Reference Document on Best Available Techniques in the Slaughterhouses and Animal By-product Industries. Available at: <https://eippcb.jrc.ec.europa.eu/reference/slaughterhouses-and-animals-products-industries>

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	1	2	5
RMO 6: Substitution (industry initiative)	2	2/1, average 1.5	5

4.2.3 Practicability – Ease of implementation by industry and regulators

The ease of implementation of an RMO by both industry and regulators needs to be considered so that the necessary action required for implementation of an RMO can be identified and undertaken.

RMO1: Substance evaluation

For this RMO, it is likely that most of the relevant actors will be aware of their responsibilities and obligations for substance evaluation, which includes review by the eMSCA and potentially data generation by industry. Approximately 4% of substances have been selected for evaluation, according to the REACH Review²⁷⁷. Therefore, there is a high likelihood that most actors will be familiar with their responsibilities and obligations. Implementation by regulators may pose a greater challenge, as a review of substance evaluation under REACH found that for 74% of substances for which a concern has been demonstrated, no regulatory follow-up has yet been initiated to control the risks²⁷⁸. This highlights the lengthy process of regulatory action and a potential lack of resource, which has been reported previously due to the many open cases and follow-up evaluations²⁷⁹.

RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

In this RMO, and as stated by the restriction Dossier submitters, some speciality applications could be adversely impacted where there are no feasible chemical and/or non-chemical alternatives²⁸⁰. This could result in issues for low temperature refrigeration applications, although a derogation for these applications is included within the proposed restriction. According to the analysis of the survey to F-gas downstream users, even more applications could be subject to these difficulties, such as foam blowing agents, as alternatives of any type are not always available, as reported by respondents (see Section 4.2.8.1 for an overview of the scope of substitution under this RMO).

RMO 3: REACH Authorisation

Under RMO 3 (REACH authorisation), similar issues as those expected under RMO 2 could be encountered for alternatives which are not yet feasible to be implemented, such as the speciality applications listed in the proposed PFAS restriction for which derogations have been proposed²⁸¹. For both RMOs under REACH, there are also skill requirements to be considered, as a skills shortage in the use of natural refrigerants has been highlighted, which are potential alternatives²⁸².

²⁷⁷ European Commission (2018) Commission Staff Working Document accompanying the COM (2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements - Conclusions and Actions. Available at: <https://ec.europa.eu/docsroom/documents/28202>

²⁷⁸ EEB (2019) Chemical Evaluation - Achievements, challenges, and recommendations after a decade of REACH. Available at: <https://eeb.org/wp-content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf>

²⁷⁹ ECHA (2017) Substance Evaluation Workshop 2017 Proceedings 12 October – 13 October 2017. Available at: https://echa.europa.eu/documents/10162/17221/substance_evaluation_workshop_october_2017_proceedings_en.pdf/2d72799c-85a6-86ad-03df-2a2b9ebf0b84

²⁸⁰ ECHA (2023) Annex XV Restriction Report: Per- and polyfluoroalkyl substances (PFASs). Available at: <https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>

²⁸¹ Ibid: <https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>

²⁸² EEB (2022). Revised F-Gas Regulation lags behind market evolution, NGOs warn. Available at: <https://eeb.org/revised-f-gas-regulation-lags-behind-market-evolution-ngos-warn/>

RMO 4: Regulatory proposal for amendment of F-gas Regulation

The actions required for implementation under RMO 4 should be known to the relevant actors. Under this RMO, there are already requirements for manufacturers to comply with the provisions of the F-gas Regulation. This RMO would be technically feasible for certain applications that are not subject to specific prohibitions under the Regulation, as using a phase-down approach would allow alternatives to be developed and brought to market. Under the F-gas Regulation, the phase-down is implemented through quotas and in recent years industry has not used the full quota allocation²⁸³, which indicates that RMO 4 may be implementable by industry. The prohibitions are also based on GWP, meaning that low GWP F-gases would still be viable alternatives, such as H(C)FOs.

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

The actions required under RMO 5 are not expected to significantly add to the administrative burden on industry. The requirement to keep records of leak checks is already included in the F-gas Regulation, so it is assumed that there is general awareness and systems already in place. The requirement to monitor refrigerant losses and energy consumption is assumed not to place an undue burden on industry as monitoring equipment is available for these purposes and used routinely to meet requirements under the F-gas Regulation. Within the existing BREF, there are already recommendations for improving the environmental performance of industrial cooling systems by preventing leaks and improving energy²⁸⁴.

RMO 6: Substitution (industry initiative)

In relation to RMO 6 (substitution), an industry initiative would be implementable as, for the majority of uses, our analysis has shown that chemical and material alternatives exist. It is noted that these alternatives would be required investment to e.g. design systems. There is also evidence that certain sector groups are already proactively pushing for a transition to non-fluorinated refrigerants. One example is heat pumps, where it is claimed the use of natural refrigerants, such as hydrocarbons and carbon dioxide, is being slowed by conservative regulation (i.e. continued use of HFCs allowed under the F-gas Regulation for applications where alternatives are available) and a lack of training, rather than the availability of acceptable alternatives²⁸⁵. Manufacturers of heating and cooling equipment are also already in the process of adapting their product portfolios to accommodate non-fluorinated refrigerants, such as ammonia, carbon dioxide, and hydrocarbons²⁸⁶. It should be noted that a large number of F-gas applications are subject to codes and standards, which require testing to demonstrate compliance. This adds to the timeline for implementation.

It is envisaged that this RMO would be implemented through setting time dependant substitution targets, such as those used in the US EPA's PFOA Stewardship Program, which invited manufacturers to commit to achieving a 95% percent reduction in the use of PFOA by 2010, compared to 2000 levels²⁸⁷.

4.2.4 Practicability – Enforcement

For the selected RMOs, it is required to assess the feasibility of enforcement for the relevant actors.

RMO1: Substance evaluation

For RMO 1 (substance evaluation under REACH), feasibility of enforcement is high as there is a historically high level of compliance with substance evaluations, with all evaluations between 2013-2016 being addressed within the legal timeframe²⁸⁸.

RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

²⁸³ Defra (2022) F gas regulation in Great Britain – Assessment Report. Available at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1126230/F_gas_regulation_in_Great_Britain.pdf

²⁸⁴ European Commission (2019). Best Available Techniques (BAT) Reference Document for the Food, Drink and Milk Industries – Section 2.3.4.5.

Available at: <https://eippcb.jrc.ec.europa.eu/reference/food-drink-and-milk-industries>

²⁸⁵ Ibid footnote 282.

²⁸⁶ Dnafooss (n.d.). Accelerate refrigerant transition and turn down climate impact. Available at: <https://assets.danfooss.com/documents/209637/AD135486444159en-001202.pdf>

²⁸⁷ US EPA (2023) Fact Sheet: 2010/2015 PFOA Stewardship Program. Available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program>

²⁸⁸ European Commission (2018) Commission Staff Working Document accompanying the COM (2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements - Conclusions and Actions. Available at: <https://ec.europa.eu/docsroom/documents/28202>

Enforcement of RMO 2 is expected to have a negative impact, due to the additional reporting requirements for actors using F-gases under the derogations, and the additional resources that are likely to be required by Member States in order to enforce such a large restriction. Under option 2 of the restriction proposal, reporting requirements are proposed for all derogations which will help in collecting data in these sectors, monitor developments and changes and enforce the restriction. Techniques are also available for enforcement such as analytical methods which can be used for measurements²⁸⁹. The overall rate of non-compliance for restrictions is 17%, although it is assumed that the enforcement levels are improving from the number of trained inspectors²⁹⁰. As some survey respondents point out, a critical element of enforceability are illicit imports, which remain one of the most difficult points of non-compliance to control (with the same issues for enforcement as in RMO 4). It should be acknowledged that the proposed REACH restriction of PFAS has a considerably larger scope than other restrictions and so enforcement could be more difficult due to the breadth of applications and substances, lack of standardised analytical techniques and possible lack of trained enforcement staff.

RMO 3: REACH Authorisation

The enforceability of RMO 3 (REACH authorisation) could be similar to that of the RMO 2, with potentially a similar impact. In addition to the enforcement options for using analytical methods for detecting concentrations of the HFCs in scope, there is the possibility of extra burden for authorities. Part of the enforcement process involves assessing conditions of use at each site, which present efficiency issues and put a strain on the resources of ECHA and the Commission if a high number of applications are received²⁹¹.

RMO 4: Regulatory proposal for amendment of F-gas Regulation

Enforcement of RMO 4 (proposed amendment to the F-gas Regulation) would be expected to have a neutral impact as there are existing requirements already in place for the annual reporting of F-gases listed in Annexes I or II of the Regulation, which are used for monitoring purposes. However, issues have been highlighted with the enforcement of the F-gas Regulation. Illegal imports of HFCs are estimated to account for 20-30% of HFCs sold in the EU²⁹², however the number of Member States carrying out seizures and the amount of HFCs seized has increased year-on-year since from 2018-2020²⁹³. This indicates that whilst illegal imports are a concern, enforcement of the F-gas Regulation is improving.

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

In relation to RMO 5 (Refrigerant Management Plan under Food, Drink and Milk Industries BREF), there are enforcement requirements in place. Operators are required to report on compliance with the BREF permit conditions specified by authorities. However, enforcement could be an issue as it is reported that the number of installations without a permit (estimated that 87% of installations have a permit on average) is greater than the number of enforcement actions²⁹⁴. This indicates that additional resources may be needed to enforce this RMO, although as it is complementary to the requirements of the F-gas Regulation, efficiencies may be built in.

RMO 6: Substitution (industry initiative)

For RMO 6, enforcement by authorities is not envisaged as it is a voluntary initiative. The use of annual progress reports was an approach taken under other industry initiatives, such as the US EPA's PFOA Stewardship Program²⁹⁵ and would not place a significant burden on participating companies. As a result, this RMO is expected to have a neutral impact on enforcement.

²⁸⁹ ECHA (2023) Annex XV Restriction Report - Appendix E4. <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>

²⁹⁰ European Commission (2021) REACH and CLP enforcement. Available at: <https://op.europa.eu/en/publication-detail/-/publication/199c348e-00e9-11ec-8f47-01aa75ed71a1>

²⁹¹ ECHA (2021) Report on the operation of REACH and CLP 2021. Available at: https://echa.europa.eu/documents/10162/17226/operation_reach_clp_2021_en.pdf/

²⁹² EIA (2021) Europe's Most Chilling Crime The illegal trade in HFC refrigerant gases. Available at: <https://eia-international.org/wp-content/uploads/EIA-Report-Europes-most-chilling-crime-Spreads.pdf>

²⁹³ EIA (2021) Europe's Most Chilling Crime The illegal trade in HFC refrigerant gases. Available at: <https://eia-international.org/wp-content/uploads/EIA-Report-Europes-most-chilling-crime-Spreads.pdf>

²⁹⁴ European Commission (2021) IED IA Final Report. Available at: <https://circabc.europa.eu/ui/group/06f33a94-9829-4eee-b187-21bb783a0fbf/library/e54637dc-b95c-48ac-8e82-2c987d4c32f8/details>

²⁹⁵ US EPA (2023) Fact Sheet: 2010/2015 PFOA Stewardship Program. Available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program>

4.2.5 Practicability – Manageability

This section considers whether actors will be capable of managing the progress of the RMO in terms of ensuring its effectiveness, complexity of the supply chains impacts, and the proportionality of the administrative burden for actors and authorities.

RMO1: Substance evaluation

Substance evaluation is deemed to have a high level of management because it involves data generation, which is a core requirement for REACH Registration, so the majority of actors will be familiar with the processes involved. There would be a financial cost placed on Member State authorities, and it is estimated that the cost per substance evaluation is €50,000²⁹⁶, which is lower than the costs for a REACH restriction or authorisation.

RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

A restriction under REACH (RMO 2) would involve additional requirements for manageability. The F-gas supply chain complexity is unknown as this would require mapping of the whole supply chain, which was not possible in this study, although stakeholders have indicated that the F-gas supply chain is complex due to the number of applications. Under this RMO, reporting requirements are proposed for derogations for manufacturers and formulators with a management plan required for manufacturers, importers and downstream users, which could be used to verify the progress of the restriction. These requirements would place an administrative burden on the relevant actor, which could be large where actors are subject to multiple derogations. There would be a large financial burden from the cost of R&D efforts and adapting processes to transition to alternatives (see Section 4.2.8.1, which contains a comparison of the cost burden on manufacturers and downstream users of the different RMOs). However, this is also considered to be manageable as our analysis has shown potential alternatives are available for the majority of applications (see Section 3). A question remains open regarding how derogations for certain uses will translate to allowances for F-gas manufacturers and importers, which might negatively impact manageability of this RMO.

RMO 3: REACH Authorisation

For RMO 3, there would be an additional administrative burden on actors wanting to submit applications for authorisation. The burden on SMEs is greater as there is a lack of expertise around preparing applications of sufficient quality²⁹⁷. Regarding the overall burden, the information requirements between authorisation and restriction are similar across the different actors²⁹⁸. However, it is worth noting for authorisation, many industry actors consider that the burden of the authorisation process is disproportionate to the benefits of authorisation, with potential additional burden on SMEs²⁹⁹. Regardless, it is assumed that companies shall apply for authorisation where the benefits outweigh the economic costs (see Section 0).

RMO 4: Regulatory proposal for amendment of F-gas Regulation

Actions related to RMO 4 are expected to result in an increase in administrative burden to actors. However, the proposed revisions to the F-gas Regulation are cost-effective with some marginal emission abatement costs for the relevant sectors³⁰⁰.

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

The manageability of RMO 5 is assumed to be manageable as the RMO is targeting one sector. It is assumed that companies would need to reapply for permits to demonstrate compliance with the new requirements and cost requirements may be low (€0.01m/year to €0.8m/year for operators and €0.02m/year to €0.5m/year for authorities)³⁰¹. Industry may already have systems in place for monitoring and leakage detection from compliance from the F-gas Regulation.

²⁹⁶ ECHA (2015) MB/16/2015 FINAL 17.6.2015. Available at: https://echa.europa.eu/documents/10162/17212/echa_procurement_plan_2015_en.pdf/384102e3-17b0-4a2c-b0d1-3bd0ef952228?t=1437580917055

²⁹⁷ Okopol et al. (2018) Reach Beyond 2018 – Restriction and Authorisation as Regulatory Alternatives: Summary. Available at: https://www.bmwk.de/Redaktion/EN/Downloads/Studien/summary-reach-after-2018.pdf?__blob=publicationFile&v=3

²⁹⁸ Okopol et al. (2018) Reach Beyond 2018 – Restriction and Authorisation as Regulatory Alternatives: Summary. Available at: https://www.bmwk.de/Redaktion/EN/Downloads/Studien/summary-reach-after-2018.pdf?__blob=publicationFile&v=3

²⁹⁹ Okopol et al. (2018) Reach Beyond 2018 – Restriction and Authorisation as Regulatory Alternatives: Summary. Available at: https://www.bmwk.de/Redaktion/EN/Downloads/Studien/summary-reach-after-2018.pdf?__blob=publicationFile&v=3

³⁰⁰ Okopol et al. (2022). Support contract for an Evaluation and Impact assessment for amending Regulation (EU) No 517/2014 on fluorinated greenhouse gases. Available at: https://climate.ec.europa.eu/system/files/2022-04/f-gas_evaluation_report_en.pdf

³⁰¹ Ibid: https://climate.ec.europa.eu/system/files/2022-04/f-gas_evaluation_report_en.pdf

RMO 6: Substitution (industry initiative)

Under RMO 6, there would be the expectation that industry would undertake all technically feasible measures to eliminate F-gases from their portfolios and equipment within a certain timeframe. However, this can place a large financial burden on companies, particularly SMEs. The benefit of a voluntary initiative is that it would allow industry flexibility in addressing challenges in the sector, as there is no legal basis for meeting substitution targets. This would help make the RMO more manageable for SMEs.

4.2.6 Practicability - Implementation timeline*RMO1: Substance evaluation*

A review of the substance evaluation procedure under REACH (RMO 1) found that 64% of the substances under evaluation initially lacked the information to demonstrate the safety of the chemicals marketed in Europe. Evidence gathering to produce information was needed from industry before the concerns could be clarified, extending the evaluation procedure to an average estimated 7 - 9 years. Following this, the development of risk management measures such as restriction or authorisation begins, which may take another 5-7 years until implementation. This means that it may take 12 to 16 years to regulate chemicals that are declared of concern³⁰².

RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

Under RMO 2, the implementation would be decided by the authorities, however it is expected that this could be implemented by 2026 or 2027, already including an 18-month transition period³⁰³, with derogations of 5 to 12 years where applicable.

RMO 3: REACH Authorisation

The implementation timeline for RMO 3 would potentially depend on the authorities, however it is expected that it would mirror the 18-month transition period proposed under Restriction Option 1 (full ban) of the proposed PFAS restriction. As highlighted in the proposed PFAS restriction³⁰⁴, as well as in the survey to F-gas downstream users (see Section 4.2.8.1), there are some problematic uses, for which acceptable alternatives are not currently available. Therefore, not all the required technology for a full ban under Authorisation is available, and it is likely that applications for authorisation will need to be made.

Authorisation is a lengthy process that involves first listing a substance or substance group under the Candidate List. The second stage is recommendation for inclusion in the Authorisation List, which typically takes 18 months³⁰⁵. Given that the PFAS substance group is not currently on the Candidate List, the implementation of this RMO is likely to be at least 24 months away. Consultations on proposals for inclusion on the Candidate list meet twice per year, meaning that listing typically has a minimum frame of 6 months³⁰⁶.

The timeline for reviewing applications for authorisation is approximately 18 months from submission of the application to a decision on whether to grant or refuse the authorisation. This includes around 12 months for the RAC and SEA to prepare their final opinions on the application, and a further 6 months for the European Commission to prepare a draft decision and vote in the REACH Committee and the subsequent adoption procedure³⁰⁷. It should be noted that there is some uncertainty in the implementation timeline regarding RMO3 as if a large number of applications for authorisation are received, this may extend the time needed to process them due to a lack of resources within the regulatory authorities.

RMO 4: Regulatory proposal for amendment of F-gas Regulation

RMO 4 would require no additional technology requirements as the annual reporting and quota system for selected applications are already in place and it is expected this could be implemented within a timeframe of

³⁰² EEB (2019) Chemical Evaluation - Achievements, challenges, and recommendations after a decade of REACH. Available at: <https://eeb.org/wp-content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf>

³⁰³ ECHA (2023) Annex XV Restriction Report. Available at: <https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>

³⁰⁴ ECHA (2023) Annex XV Restriction Report. Available at: <https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>

³⁰⁵ ECHA (2023) Authorisation process – Phase II: Recommendation for Inclusion in the Authorisation List. Available at: <https://echa.europa.eu/phase-2-recommendation-for-inclusion-in-the-authorisation-list>

³⁰⁶ ECHA (2023) Authorisation Process – Phase I: Substances of Very High Concern (SVHC). Available at: <https://echa.europa.eu/phase-1-substances-of-very-high-concern>

³⁰⁷ ECHA (2023) Authorisation process – Phase III: Application for Authorisation. Available at: <https://echa.europa.eu/phase-3-application-for-authorisation#phase3-2>

12-24 months, with the European Commission, Parliament, and Council reportedly aiming for an entry into force date of January 2024³⁰⁸. However, the risk reduction would occur over a longer timeframe given the phase-down nature of the Regulation. Under the European Commission's proposed amendment to the Regulation, reductions in the maximum quantity of tonnes of CO₂ equivalent occur every three years up to 2048. Timelines for prohibitions based on GWP for specific applications are proposed to enter into force between 2025 – 2033.

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

RMO 5, likewise is expected to have a timeframe of 12-24 months for implementation due to its high level of technical feasibility and that monitoring systems are expected to be in place in the food, drink and milk sector.

RMO 6: Substitution (industry initiative)

There is no information available for the time required for implementation of RMO 6, however it is assumed this could be within a timeframe of 12-24 months, as the main requirement for implementation is developing a framework for monitoring progress of the initiative. Regarding the timelines to bringing new products to market, respondents to the industry consultation indicated timelines for substitution of between 1 – 10 years, suggesting that there will be a wide variation between companies and uses or applications.

4.2.6.1 Conclusions on Practicability of RMOs

As can be seen from the summaries above, the practicability of the RMOs vary. Table 4-8 Table 4-7 presents an overview of the qualitative scoring for the practicability of the RMOs within this assessment.

Table 4-7 Qualitative Scoring of RMOs for Practicability

RMO	Ease of implementation by industry and regulators	Enforcement	Manageability	Implementation timeline	Total
RMO1: Substance evaluation	0	0	0	-3	-3
RMO2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS	-1	-1	-3	-2	-7
RMO 3: REACH Authorisation	-1	-1	-2	-2	-6
RMO 4: Regulatory proposal for amendment of F-gas Regulation	0	0	-1	-1	-2
RMO 5: Refrigerant Management Plan under the	1	-1	-1	2	1

³⁰⁸ R744 (2023) Let the Trilogue Begin: European Institutions Begin Negotiating Final Shape of Next EU F-gas Regulation. Available at: <https://r744.com/let-the-trilogue-begin-european-institutions-begin-negotiating-final-shape-of-next-eu-f-gas-regulation/>

RMO	Ease of implementation by industry and regulators	Enforcement	Manageability	Implementation timeline	Total
Food, Drink and Milk Industries BREF					
RMO 6: Substitution (industry initiative)	0	0	0	-1	-1

4.2.7 Consistency – Regulatory consistency across EU – Existing regulations, initiatives, objectives

The assessment of regulatory consistency is two-fold: 1) consistency with EU legislation, 2) consistency with other EU policy objectives. Any RMO that puts F-gases under regulatory scrutiny for their global warming potential or the presence of the degradation product TFA can be considered to be overwhelmingly consistent with wider EU legislation, policy objectives and initiatives. The majority of the RMOs considered in this assessment have potential to support actions under the EU Green Deal, in particular:

- EU Climate Law
- 2030 Climate Target Plan
- REPowerEU (heat pumps)
- Chemicals Strategy for Sustainability (links to PFAS via the TFA concern³⁰⁹).

This sub-section presents a summary of the assessment of regulatory consistency of the RMOs carried forward in this Study.

4.2.7.1 RMO1: Substance evaluation

As outlined in Section 4.1.1, substance evaluation is a RMO which calls for closer examination of the substance of concern, with potential for data generation to provide authorities with the information required to decide upon further regulatory action. Any additional data generated may be able to feed into wider EU legislation, regulatory actions, or policy objectives and support the identification of actions that could contribute to the aims of the EU Green Deal. Substance evaluation has been carried out for HFO-1234yf on the grounds of:

- Other hazard-based concern
- Exposure of environment
- High (aggregated) tonnage
- Wide dispersive use.

Of the F-gases potentially in scope for this RMO, according to their registration dossiers, all could be considered to be of potentially similar level of concern for: hazardous degradation products (TFA), wide dispersive uses and environmental exposure. HFC-125, HFC-134a, HFC-143a, HFC-227e, HFO-1234ze(E) and HFCFO-1233zd(E) are all registered to be placed on the market within the tonnage band >1000-<10,000 tonnes, which suggests high aggregated tonnage. Consumer exposure concerns may also apply to all F-gases in scope except from HFO-1336mzz(Z).

The substance evaluation for HFO-1234yf raised concerns for mutagenicity but harmonised classification was not found to be warranted for any endpoints. Additional human health hazard concerns for the F-gases within scope of this RMO are unknown and would likely only emerge as a result of substance evaluation, although, based on the outcome of the assessment for HFO-1234yf, human health hazards are unlikely to be of concern.

³⁰⁹ "Some substances contain only a single –CF₃ group attached to carbon, and because of their structure they are potential precursors to trifluoroacetic acid (TFA). To this subgroup belong, amongst others, some fluorinated gases... Fluorinated gases fulfilling the scope definition form the largest contribution by production volume to this subgroup." Ibid footnote 253

4.2.7.2 RMO2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

Section 4.1.2 notes that the F-gases in scope of this Study fall within the scope of the proposed REACH restriction of PFAS due to their chemical structure and the persistency of the degradation product TFA. The use of a REACH restriction to target groups of chemicals is becoming more common but the use of this process must follow the current rules laid out in Article 68 of REACH. This means that the dossier submitter, ECHA committees and the Commission must establish that the manufacture, placing on the market or use of a substance "poses a risk to human health or the environment that is not adequately controlled and needs to be addressed" (emphasis added). For F-gases, human health hazards are not of concern and the environmental impact of the manufacture, use and end-of-life of F-gases is controlled by other legislation. At present the TFA degradation product is not directly regulated as a result of F-gas use, although leakage detection, recovery and destruction targets under the F-gas Regulation, WEEE Directive and End-of-Life Vehicles Directive seek to indirectly address the environmental risks.

As outlined in Section 4.1.2, the concern related to TFA is its persistence in the environment. Article 68 requires the demonstration of unacceptable risk, in the form of a risk assessment. Risk assessment is carried out on the basis of hazard and exposure. In the case of TFA, which is a persistent substance, considering that persistence, as persistence is not yet recognised as a hazard under EU law (CLP Regulation) there are concerns that the hazard part of the risk assessment is not correctly justified.³¹⁰

Other legal concerns have been highlighted relating to:

- A lack of listing of the chemical substances that are subject to the restriction, instead using a structural definition, which may be considered contrary to Article 68(1) and the principle of legal certainty.
- "de facto" application of the Precautionary Principle without respect of the requirements for its application set out by the Court of Justice of the EU and the European Commission.
- Disproportionate societal costs.
- Lack of enforceability which may be considered a breach of the principle of legal certainty.³¹¹

The proposed REACH restriction is consistent with the wider EU objectives with regards to PFAS, most notably: the ban of all PFAS as a group in fire-fighting foams as well as in other uses; and allowing their use only where they are essential for society. It may, however, have an impact on the availability of heat pumps in the long term, which is not consistent with the REPowerEU initiative. The time limited derogations for selected uses also appear to extend beyond those outlined in the prohibitions of the F-gas Regulation (Annex III). This could be complementary in practice, but raises concerns with regard to legal certainty for rules governing the placing on the market.

4.2.7.3 RMO 3: REACH Authorisation

This RMO is considered to be an alternative to RMO 2 as there is no need for authorisation of F-gases where a REACH restriction of PFAS exists that includes F-gases within its scope. To note, F-gases do not have the hazards of concern for SVHC listing (CMR, PBT, vPvB) and TFA only meets the criteria for persistence.

The use of REACH Authorisation could be considered as coherent with the CSS objective to ban PFAS in other uses. This ban would be in the form of a REACH authorisation rather than a group restriction of PFAS. It possible that RMO 3 could also be coherent with ensuring critical products remain on the market, as uses would only be authorised where risk and socio-economic assessment have deemed continued use necessary. REACH authorisation also has the ability to stimulate innovation, a wider EU objective, as industry is given an early warning signal that they need to remove their product from the market in the future, relocating EU production for exported products to non-EU countries, and, through the use of sunset dates, time is given to allow for innovation and the bringing to the market of alternatives.

³¹⁰ Steptoe (2023) Proposal for EU Restrictions for PFAS: The Beginning of a Long and Complex Process (Part 1). Available at: <https://www.steptoe.com/en/news-publications/proposal-for-eu-restrictions-for-pfas.html>

³¹¹ Mayer Brown (2023) EU Proposed Restriction on PFAS. Available at: <https://www.mayerbrown.com/en/perspectives-events/publications/2023/02/eu-proposed-restriction-on-pfas>

4.2.7.4 RMO 4: Regulatory proposal for amendment of F-gas Regulation

RMO 4 can be considered an amendment of existing legislation, whereby the principles of the original legal act remain in place but the requirements are updated in line with scientific and technological progress and wider international and EU climate actions. The regulatory proposal seeks to target the reduction in use of HFCs more ambitiously and brings HFOs into consideration via requirements for containment, including recovery etc. This seeks to ensure that the EU maintains its responsibilities with regard the Kigali Amendment of the Montreal Protocol, but also addresses areas of strategic importance, such as ensuring access to refrigerants that are required to meet the goals of the REPowerEU initiative, and those which contribute to wider climate targets. With regard to REPowerEU, the amendment notes that *"In order to avoid that the HFCs quotas phase down creates disruptions in the Union's heat pump market to an extent which may endanger the attainment of the heat pumps deployment target under the REPowerEU Plan, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annex VII in order to allow the placing on the market of an additional amount of HFCs for a certain period of time."* It is noted that although the amendment aims to ensure deployment of heat pumps, concerns remain regarding the process for releasing additional quota and the inclusion of a maximum value, which could result in supply chain and business planning complications for industry, leading to market shortages³¹². RMO 4 also maintains coherence with other EU legislation, such as Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products, Directive (EU) 2018/2002 on energy efficiency, and the MAC Directive.

The regulatory proposal under RMO 4 also tries to ensure consistency with wider objectives linked to the CSS, by including consideration of ongoing work on PFAS. The amendment text states that *"It is of great importance that the Commission takes the phasing out of HFCs into account in its upcoming legislative proposals, such as in the revision of Regulation EC/1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (the 'REACH Regulation') regarding the phase out of per- and polyfluoroalkyl substances (PFAS)...In order to ensure coherence with Union policy and a high level of protection of health and the environment, and given the availability of non-toxic alternatives, this Regulation should not encourage substitution of HFCs with fluorinated greenhouse gases that are also PFAS, whose production produces PFAS or otherwise decomposes into PFAS. If the prohibitions in Annex IV allow for the placing on the market and export of products and equipment containing PFAS, it is important that Member States work with the industry to direct investments into alternatives. This will also prevent stranded assets, should the revision of the REACH Regulation introduce PFAS bans. Immediately after the adoption of the revised REACH Regulation, the Commission should assess the coherence between this Regulation and that Regulation."*³¹³

4.2.7.5 RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

The Food, Drink and Milk Industries BREF is used to promote best practice and support the rules of legislation that regulates the use of substances. As such, the use of F-gases as refrigerants in this industry is regulated primarily by the F-gas Regulation, with support from the relevant BREFs. As noted in Section 4.1.5, an updated BREF was published in 2019 and the rules of the F-gas Regulation were taken into account. There is a push within the BREF to use alternatives to HFCs but H(C)FOs are not specifically mentioned. This may be due to their considerably lower GWP, which is in line with certain other natural alternatives. As the BREF mentions the use of water, CO₂ and NH₃ in an effort to avoid the use of harmful substances, RMO 5 is considered to bring the current BREF into coherence with the updated Slaughterhouses BREF, that has considered the use of F-gases as refrigerants in depth. The requirement for monitoring of refrigerant losses, via the Refrigerant Management Plan, would align with the Slaughterhouse BREF and also the requirements of the F-gas Regulation.

Under the current F-gas Regulation there are leak check requirements for a number of HFCs within refrigeration applications. These are to be updated in the regulatory proposal for amendment of the F-gas Regulation, and should this enter into force, the requirements for H(C)FOs could be complemented by a Refrigerant Management Plan under RMO 5.

³¹² Joint Industry Statement (2023) F-gas Mandate Lacks Sufficient Precision. Available at: <https://epeglobal.org/wp-content/uploads/2023/04/Joint-industry-statement-following-COREPER-6-April-2023-FINAL.pdf>

³¹³ European Parliament (2023) Texts Adopted: P9_TA(2023)0092. Fluorinated gases regulation. Amendments adopted by the European Parliament on 30 March 2023 on the proposal for a regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (COM(2022)0150 – C9-0142/2022 – 2022/0099(COD))

4.2.7.6 RMO 6: Substitution (industry initiative)

Industry led substitution has a number of drivers (see Section 4.1.6) and in some cases may be a proactive response to political or public pressure, or a response to scientific and technological advances. There are a number of pieces of legislation that seek to reduce exposure to/emissions of hazardous substances which rely on the substitution efforts of industry to maintain the market. Current Regulation that directly addresses the use of F-gases and requires substitution efforts are:

- F-gas Regulation
- MAC Directive.

The progressive substitution of SVHCs is also one of the aims of REACH authorisation. In January 2018 ECHA published their substitution strategy which aims to support "*informed and meaningful substitution of chemicals of concern in the EU and to boost availability and adoption of safer alternative substances and technologies*".³¹⁴ The strategy is related to REACH, CLP and the Biocidal Products Regulation ((EU) No. 528/2012) but the scope of the PFAS restriction brings F-gases under this remit.

Substitution contributes to many of EU objectives not least the EU Green Deal, Circular Economy, non-toxic environment, CSS, safe and sustainable by design.

4.2.7.7 Conclusions on Regulatory Consistency of RMOs

As can be seen from the summaries above, the regulatory consistency of the RMOs vary. Table 4-8 presents an overview of the qualitative scoring for the regulatory consistency of the RMOs within this assessment.

Table 4-8 Qualitative Scoring of RMOs for Regulatory Consistency

RMO	Consistency with EU legislation	Consistency with other EU policy objectives	Total
RMO1: Substance evaluation	3	2	5
RMO2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS	0	2	2
RMO 3: REACH Authorisation	1	2	3
RMO 4: Regulatory proposal for amendment of F-gas Regulation	3	3	6
RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	1	1	2
RMO 6: Substitution (industry initiative)	3	3	6

4.2.8 Other impacts

In this section, wider socio-economic impacts of each RMO are assessed. Those include quantitative and/or qualitative assessments of:

- Economic impacts: how each RMO affects businesses, both on the side of F-gas manufacture and import, and F-gas downstream users in the EEA. Specifically, their turnover sales value, the viability of their production, feasibility of alternatives, administrative burden and other costs incurred as a result of each RMO, impacts on their employment, and consideration of knock-on implications when feasible.
- Human health impacts: how each RMO impacts on human health. This is based on the acceptable alternatives identified in the analysis of alternatives and how the risks of these alternatives compare with the F-gases used for impacts to human health.

³¹⁴ ECHA (2018) Strategy to promote substitution to safer chemicals through innovation.

- c) Environmental impacts: how each RMO impacts on the health of the environment. This is based on the acceptable alternatives identified in the analysis of alternatives and how the risks of these alternatives compare with the F-gases used for impacts to the environment.

4.2.8.1 Economic impacts – Supply chain disruption, SME impacts, R&D and innovation

RMO 1: Substance evaluation

In determining the economic impact of RMO1 it is first important to note refrigerant HFO-1234yf has already undergone evaluation, and therefore the impact will only apply to manufacturers of the other seven F-gases.

Based on the findings of the 2018 Reach Review³¹⁵ a range of expected economic impacts associated with substance evaluation have been estimated for both industry operators and Member State Competent Authorities. For Member State Competent Authorities, it has been noted that this activity can be both time and resource intensive. The substance evaluation is estimated to take over 2 years, with an additional 13 months required to include the relevant substance on evaluation list. It has also been noted that external support may be provided to the Member State Competent Authorities to help compensate these costs. ECHA have previously provided a proportion of the fees collected from industry applications to Member State Competent Authorities to help provide some support. Six Member State Competent Authorities provided feedback on their own costs to perform this activity. The annual budgets for competent authorities range from € 35,000 (Portugal) to € 480,000 (Sweden)³¹⁶.

Annex 4 of the Reach Review provided specific estimates on the expected costs linked to substance evaluation and dossier evaluation. Although costs for the latter are separate to those associated with substance evaluation, the compilation of the dossier with supporting information is a key step in the overall process, and as such the costs are commonly grouped. The review found that, on average, approximately 86 FTE per year were required for ECHA staff to support the substance evaluation and a further 7 FTE to support in decision making (work of Committees and support to Committee work) over the 2014 – 2016 period. For Member State Competent Authorities these costs were 42 and 44 FTE respectively, and for the European Commission 7 and 9 FTE (over this period). The costs were based on the expectation that approximately 99 substances would be evaluated annually.

Annex 6 of the review has separately noted that the European Commission has estimated the total cost per evaluation decision to be approximately € 60,000 (based on time required). This is based on information related to the dossier evaluation activity. However, additional costs linked to dossier evaluation include an annual 59 FTE for ECHA staff³¹⁷. The Commission review³¹⁸ has also estimated costs according to specific substance evaluations, although the Commission review has noted that it is challenging to accurately determine the time requirements for Member State Competent Authorities to complete an assessment. It has been estimated in the Commission review that the co-ordination processes require 13 FTE from ECHA.

Impacts of this RMO on the activities of companies are limited to an increase in costs: on the one hand, the administrative burden of submitting information for substance registrants (F-gas manufacturers/ importers), and on the other hand, possibly conducting and paying for studies that collect evidence independently. This does not lead to portfolio losses and given the configuration of the market, with mostly large to medium sized companies manufacturing and importing F-gases, no particular imbalances in impacts to SMEs would be expected.

³¹⁵ Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions, European Commission, 2018. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A116%3AFIN>

³¹⁶ Commission Staff Working Document Accompanying the Document Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the Operation of REACH and review of certain elements: Conclusions and Actions, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD%3A2018%3A58%3AFIN>

³¹⁷ Commission Staff Working Document Accompanying the Document Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the Operation of REACH and review of certain elements: Conclusions and Actions: Annex 4

³¹⁸ Commission Staff Working Document Accompanying the Document Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the Operation of REACH and review of certain elements: Conclusions and Actions; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD%3A2018%3A58%3AFIN>

RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS

Consultation activities were conducted by Ricardo³¹⁹ with both F-gas manufacturers and importers, and F-gas downstream users in order to gather evidence and understanding on what the impacts from a restriction on the manufacture, placing on the market and use of PFAS that would include F-gases in its scope could be.

Direct impacts for F-gas manufacturers and importers are estimated based on a survey to 8 participants that represented more than 90% of the F-gas supply in the EEA. These direct impacts were estimated to be a permanent reduction of 84% of the turnover value associated to the eight F-gases in scope under RO1³²⁰. If all time-limited derogations intended to be submitted were granted, this impact would lower to 21% of their turnover value. This means that, when allowed time and resource (i.e., delaying turnover losses), companies expect to attain higher levels of substitution that translate into a permanent loss that is just one quarter of the loss that would be expected with an immediate restriction of all substances in scope.

These impacts already account for the scope of substitution, reformulation and other innovation that F-gas manufacturers and importers consider feasible. In order to carry out said substitution, reformulation and innovation, it is estimated that manufacturers and importers would have to incur additional costs: 3.4% increase in capital expenditure per unit of revenue (annualised €25 million per year), and 7.7% increase in operating expenditure per unit of revenue (annualised €150 million per year). Associated with the portfolio loss, it is estimated that the F-gas industry involved in the 8 F-gases in scope would lose 250 FTE employees overall, gradually from the entry into force of the restriction. Under RO2, this would happen later in time, depending on derogation timelines, and it is expected that workers and employers would anticipate this impact and mitigate it by seeking relocation to other positions.

Another survey targeted 41 F-gas downstream users from 23 different application sectors. Evidence collected from this survey highlights how the loss of market for F-gases would propagate through the value chain, and to what extent different industries rely on F-gases. In this context, it is useful to look first at what percentage of their sales portfolio is reliant on F-gases (i.e., the 'affected portfolio'), meaning that upon restriction, it would be either substituted or lost (abstracting from time-limited derogations).

Table 4-9 Affected portfolio as a percentage of total turnover and loss after substitution, reformulation and other innovation strategies. Source: Ricardo treatment of information gathered via survey.

Application name	Affected portfolio	RO1: Turnover loss after substitution, reformulation and innovation
Mobile air conditioning	98%	44%
Moveable room air conditioning	28%	13%
Stationary air conditioning	_1	_1
Air conditioning: Multi split systems (VRF)	16%	5%
Chillers	61%	19%
Heat pumps	19%	5%
Industrial heat pumps and power generation	63%	8%
Industrial refrigeration	35%	33%
Transport refrigeration	29%	24%
Hermetically sealed standalone units (Commercial refrigeration)	72%	20%

³¹⁹ Online surveys shared with relevant stakeholders

³²⁰ RO2 was not explicitly considered in the consultation exercise as the proposal was published after launch of the consultation.

Application name	Affected portfolio	RO1: Turnover loss after substitution, reformulation and innovation
Condensing units (Commercial refrigeration)	43%	35%
Centralised systems (Commercial refrigeration)	43%	35%
Domestic refrigeration	11%	4%
Fire protection	5%	1%
Propellants (non-MDI)	25%	8%
Foam blowing agent (open cell)	- ¹	- ¹
Foam blowing agent (closed cell)	66%	36%
Foam products	- ¹	- ¹
Solvents	- ¹	- ¹
Cover Gas for magnesium casting	- ¹	- ¹
Metered Dose Inhalers (MDIs)	- ¹	- ¹
Skin coolers used in beauty shops	- ¹	- ¹
Other [To specify]	- ¹	- ¹

¹: Empty cells cannot be reported due to too low response numbers to maintain anonymity and confidentiality.

All of these portfolio losses after substitution and other forms of innovation (i.e., the last column in Table 4-9 above) jointly account to around 20% loss and €5.3 billion in annualised terms for the surveyed companies. If these impacts were to be generalised for the whole sectors that this sample of downstream user applications represents (i.e., our surveyed sample is found to account for 72% of the joint market value of all applications), they could reach up to €7.4 billion losses. In terms of employment, this has been estimated to potentially imply the loss of 28,000 FTE employees across all application sectors in the long run (or around 21% of baseline employment projections for 2040 in the surveyed downstream user application sectors).

In order to attain the mitigation (i.e., the last column in Table 4-9), of the potential impact that could imply losing the whole 'Affected portfolio' (i.e., the first column in Table 4-9), companies need to invest in developing and/or buying alternatives. Costs associated to these investments, based on information provided in consultation, have been estimated to involve 3.7% additional capital investment (annualised €30 million for the surveyed sample), and 2.0% additional operating expenditure (annualised €300 million) for downstream users.

Given the substantial burden to innovate and invest in new systems that lies on F-gas downstream users, SMEs could be most impacted among all firms. For any company, lacking the financial capacity to incur in the costs of investing in the necessary changes could mean a risk of being forced out of the market upon a restriction in the form of RO1, and this risk would be expected to be larger for SMEs. Under RO2, allowing time for the whole industry to innovate and substitute also allows SMEs more time to be prepared for the changes and to take advantage of innovation occurring elsewhere in the industry. This is only true if the derogation timelines are sufficiently long for the sector to innovate and transition. An early indication of whether a 6.5-year derogation or 13.5 year derogation would be necessary are the expected levels of substitution and innovation reported at present (i.e., the difference between the percentages in the first and in the second column of Table 4-9): larger levels of substitutability indicate that alternatives are known and that a shorter timeline could work; lower levels indicate the need of more time to develop alternatives.

There are also enforcement costs that need to be considered for authorities, for example it is estimated that enforcement authorities would incur annual administrative enforcement costs of €55,000 per year for each of the sectors for which a restriction is proposed³²¹. However, it is also noted that the approach to determine this cost has reflected the broad scope of the restriction and diverse potential impacts across multiple sectors. As

³²¹ ECHA (2023) Annex XV Restriction Report. <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>

a consequence, it is acknowledged that the annual cost of €55,000 may represent an over-estimate. Further to this, enforcement costs would be expected to reduce over time as familiarisation with restriction requirements becomes more common and compliance levels increase.

RMO 3: REACH Authorisation

REACH Authorisation is considered to be an alternative, rather than a complementary, option to a restriction that includes all F-gases in scope (RMO 2), as in a full restriction situation, authorisation is not an option. REACH Authorisation acts as a restriction of the substances in scope, where manufacturers need to apply for authorisation to continue placing each of the F-gases on the market if there are no viable alternatives. Applications are costly and their success is not guaranteed. Therefore, costs linked to REACH Authorisation will only be relevant if the final REACH restriction of PFAS exempt F-gases from its scope. If the currently proposed PFAS restriction is implemented, then authorisation of F-gases will not be required. Therefore, analysis of this RMO is considered to be an alternative, rather than complementary, option to a restriction that includes F-gases in its scope.

The requirement for REACH authorisation will result in an economic cost to both industry and Member State competent authorities. Authorisations are requested by and granted to specific uses in a given industry and for a given substance. Therefore, the extent to which applications for authorisation will be required, and therefore total cost, is expected to be dependent upon the availability of substitutes. Applications for authorisation are expected to be high in environments where substitution availability is low and the product is important to society, and conversely, a reduced number of applications are expected if banned refrigerants can be readily substituted.

One of the sources of additional cost of this RMO for industry is linked to the fees charged for authorisation. A desk-based review of case study examples has revealed that the ECHA application fee for non-SMEs can cost a minimum of €53,300 excluding potential additional third-party fees³²². However, there is evidence of examples of reduced fees for certain applications³²³.

In addition, time and resources are needed for the preparation of the application, as well as potential external costs incurred, such as consultancy fees, to support the application, which are likely to be higher than ECHA fees. The cost per application is expected to vary; including fees paid to ECHA and the administrative cost of preparing, submitting and defending the application dossier. ECHA have estimated this to be approximately €120,000 in 2016 – representing a reduction from €230,000 in 2013 for first time applicants. However, it has been noted that these estimates exclude some of the costs linked to administrative burden, such as time taken to prepare the applications for authorisation or the costs of complying with certain requirements set by the authorisations. The latter set of costs can be higher depending on the complexity of the application, which will determine the costs of consultancy support.

A further cost, which has not been quantified, is linked to the uncertainty concerning future legislative requirements of substances used by industry, the conditions set out in granted authorisations and the impact upon authorisation processes. This will impact, for example, future investment in R&D, adaptation of production process or the implementation of any substitutes. Since applying for authorisation is costly and its outcome uncertain, they are a dominant option only if no viable alternatives are available. As a result, substitution, reformulation and other innovation costs from RMO 2 are expected to happen to a similar degree under this RMO 3, as that is the scope of potential substitution that is known or expected at present by companies.

The impact is expected to be most significant for SMEs as they are less likely to have a financial buffer to absorb the additional costs linked to REACH authorisation.

RMO 4: Regulatory proposal for amendment of F-gas Regulation

RMO 4 is an alternative to RMO 2 (restriction) that can only happen if the REACH restriction of PFAS excludes F-gases from its scope. Based on consultation of F-gas industry stakeholders, two business projections were developed: one baseline projection under the current F-gas Regulation and the HFC phase-down in force, and

³²² Tim Becker, Chief EU Compliance Officer, REACHLaw Ltd, REACH, 2015, How it works from a space sector perspective, https://indico.esa.int/event/81/attachments/2607/3021/150422_REACH_intro_-_REACHLaw_FINAL.pdf

³²³ Chemical Watch, 2021, Simplified EU authorisation for substances in legacy spare parts begins this month, <https://chemicalwatch.com/275465/simplified-eu-authorisation-for-substances-in-legacy-spare-parts-begins-this-month>

another business projection under the proposed amendment for the F-gas Regulation with a more stringent and extended phase-down. These two scenarios were developed using, in addition to each F-gas phase-down profile:

- tonnes placed on the market for each F-gas from the EEA F-gas Reports 2019-2022,
- tonnes placed on the market for each F-gas as reported by survey participants in 2019 – based on this, the survey to F-gas manufacturers and importers was found to cover 93% of the EEA F-gas market for the F-gases in scope,
- turnover from the sales of each of the F-gases in scope as reported by survey participants in 2019.

The RMO 4 Scenario takes into account that the placing on the market of phased down HFCs can be at least partially substituted by placing on the market of H(C)FOs. Although it is challenging to specifically quantify the extent to which H(C)FOs replace HFCs, there is significant market evidence to highlight this scenario. The 2022 impact assessment of the F-Gas Regulation³²⁴ has noted this, stating that the reduced use of highly warming HFCs is resulting in an increased use and emissions of the climate-friendly H(C)FOs, and more specifically there substituted use in RAC equipment such as in-car air conditioning units.

Resulting from the comparison of the RMO4 Scenario with the baseline Scenario, a joint net permanent loss of 5% turnover value for manufacturers and importers of the 8 F-gases in scope was estimated (€135 million annualised loss in the EEA from 2024 to 2050, as compared with baseline projections). This impact already takes into account potential innovation that would be expected to happen in the future, according to reported levels of substitution by survey respondents. This would be accompanied by proportional losses in employment in the long run, although the predictability of this scenario, with a phase-down profile up to 2050, is expected to allow for some early mitigation by workers themselves by seeking relocation to other positions. This loss would happen gradually over the phase-down schedule.

No significant additional costs (either one off or recurring) from switching towards lower GWP H(C)FOs, when feasible, are expected from RMO 4, and no significant impacts or additional costs are estimated for downstream users from switching towards lower GWP H(C)FOs, when feasible, in comparison to the baseline under the current F-gas Regulation. For SMEs, no additional impacts with respect to the baseline under the current F-gas Regulation, assuming H(C)FOs alternatives to phased down HFCs are available. If the H(C)FO supply cannot make up for phased down HFC demand, costs could increase.

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

This RMO is complementary to the F-gas Regulation (or to its amendment).

Evidence has shown that there are potential economic benefits associated with the implementation of the Refrigerant Management Plan as it is expected to result in energy savings. It is reported that an energy saving of 20% typically has under a 2-year investment payback period³²⁵.

However, although there are expected to be economic costs associated with the implementation and operation of the Refrigerant Management Plan, a desk-based review of relevant literature sources did not identify any reliable monetary estimates. It can be assumed that efficiencies exist, as there are already similar reporting requirements under the F-gas Regulation.

RMO 6: Substitution (industry initiative)

It is assumed that there will not be net costs associated with voluntary action taken by industry stakeholders as they are expected to act rationally and be profit-driven. This will result in action only being taken if there will be a net benefit to doing so, which includes situations in which there is a risk of greater costs realising if substitution does not take place (i.e., profit maximising behaviour includes cost minimisation).

The expected costs of substitution have been estimated based on data collected through the stakeholder survey. The analysis of the feedback provided by F-gas manufacture and import stakeholders calculated a 3.4% increase in capital expenditure per unit of turnover (annualised €25 million per year) and 7.7% increase

³²⁴ European Commission, 2022, Commission staff working document impact assessment report accompanying the document proposal for a regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 https://climate.ec.europa.eu/system/files/2022-04/f-gases_impact_assessment_en.pdf

³²⁵ Slaughterhouses and Animal By-Products Industries: BREF Document, European Commission, 2005. Available at: <https://eippcb.jrc.ec.europa.eu/reference/slaughterhouses-and-animals-products-industries>

in operating expenditure per unit of turnover (annualised €150 million per year) under RMO 2, while it was estimated to involve 3.7% additional capital investment (annualised €30 million for the surveyed sample), and 2.0% additional operating expenditure (annualised €300 million) for downstream users in the case of a total restriction in the terms proposed. As noted, this action will only be undertaken if it will result in a net saving (including risk mitigation, i.e., saving on uncertain costs), and therefore, this may not result in additional costs relative to the baseline, although regulatory requirements are only expected to increase already in the baseline. Companies which choose not to innovate (and transition to a substitute) could potentially face future opportunity costs and may only be able to supply to less profitable market segments.

Together, these voluntary actions are not considered to be different from the baseline scenario in which companies react to the F-gas phase-down imposed by the F-gas Regulation.

Summary of economic impacts of RMOs

Table 4-10 below summarises the conclusions from the Socio-Economic Assessment of each of the RMOs and provides a final score to each of them.

Table 4-10 Socio-economic assessment and scoring of RMOs.

RMO	Direct market loss after mitigation through Innovation	Additional costs	Supply chain disruption	SME impacts	Score
RMO 1: Substance evaluation	No direct market losses.	Costs to perform this activity for Member State competent authorities, range. The annual budgets for substance evaluation are between € 35,000 (Portugal) to € 480,000 (Sweden)³²⁶ based on Member State feedback. The European Commission has estimated the cost per evaluation decision to be approximately € 60,000 (based on time required) which would total €420,000 across the seven substances. Administrative burden of submitting information, including	No supply chain disruption directly resulting from this RMO. Transitory increase in costs for registrants due to admin burden dilutes over time via prices.	No relevant differences expected due to the configuration of the market of F-gas manufacturers/importers (mostly large and a few medium-sized companies).	-1

³²⁶ Commission Staff Working Document Accompanying the Document Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the Operation of REACH and review of certain elements: Conclusions and Actions, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD%3A2018%3A58%3AFIN>

RMO	Direct market loss after mitigation through Innovation	Additional costs	Supply chain disruption	SME impacts	Score
		additional testing, for substance registrants (F-gas manufacturers/ importers).			
RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS	RO1: 84% turnover loss for F-gas manufacturers / importers (annualised €2.2 billion per year in the EEA). 250 FTE reduction in F-gas industry (lower bound - up to 850 FTE if companies cannot continue their operations). RO2: 21% turnover loss if all time-limited derogations are granted. If some are not granted, this loss will range between 21% and 84%.	3.4% increase in capital expenditure per unit of turnover (annualised €25 million per year). 7.7% increase in operating expenditure per unit of turnover (annualised €150 million per year).	Downstream user (DU) impacts on F-gas application sectors losing between 4% and 35%, on average, of the production portfolio after substitution and innovation, depending on the application sector (central estimate €5.3 billion based on sample representing €25.3 billion, and up to €7.4 when scaling to the whole value of downstream using sectors). Knock-on impacts further down the value chain.	Most of the F-gas manufacturers or producers are large companies, with only two among the surveyed that are medium-sized. 41% of the respondents in the surveyed DU sample are SMEs. Impact estimated to be harder to mitigate for SMEs due to needed investments and lower buffer for manoeuvre.	-3
RMO 3: REACH Authorisation	Based on reported substitution and innovation, some applications with low scope for substitution would be in a position to apply for REACH Authorisation. Additionally, companies may apply for authorisation	The cost per application is expected to vary, and typically include fees paid to ECHA and administrative burden incurred by applicants: preparing, submitting and defending the application dossier, and consultancy fees; higher cost the more complex the application is.	Costs of applications estimated €120,000 per use and per applicant (~1% increase in operating expenditure) (downstream users). Costs of alternatives from RMO 2 apply for application sectors with a significant scope	SMEs with no buffer to incur the cost of applying for authorisation could be forced out of business. Conclusions on the feasibility to invest in alternatives as in RMO 2.	-2

RMO	Direct market loss after mitigation through Innovation	Additional costs	Supply chain disruption	SME impacts	Score
	where they need a limited period to bring a product to the market, e.g., those which require changes to operating conditions. Loss will be smaller than (some authorisations granted) or equal to (no authorisation granted) RMO 2, RO1.	Total costs per application are estimated to be €120,000 on average.	for substitution and innovation (see Table 4-9) so they do not apply for REACH Authorisation.		
RMO 4: Regulatory proposal for amendment of F-gas Regulation	Not significant impact of 5% turnover loss for F-gas manufacturers / importers (annualised €135 million per year in the EEA).	Proportional reductions in capital and operating expenditure. No significant additional costs from switching towards lower GWP H(C)FOs when feasible.	No significant impacts or additional costs are estimated for DUs from switching towards lower GWP H(C)FOs when feasible in comparison to baseline under current F-gas Regulation.	None additional to baseline under current F-gas Regulation. If H(C)FO supply cannot make up for HFC demand, costs could increase.	0
RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	None for F-gas manufacturers.	None for F-gas manufacturers.	Significant energy savings (up to 20%) with investments paying back in two years (positive net benefits over a period of 20 years). ³²⁷	SMEs with no buffer to incur the cost of implementing the monitoring measures could be forced out of business.	3
RMO 6: Substitution (industry initiative)	No direct losses when substitution not feasible under this RMO.	3.4% increase in capital expenditure per unit of turnover (annualised €25 million per year).	No direct losses when substitution not feasible under this RMO, only investment costs	Possibly some opportunity costs for companies that do not innovate. Market will likely be	0

³²⁷ Integrated Pollution Prevention and Control Reference Document on Best Available Techniques in the Slaughterhouses and Animal By-products Industries May 2005, <https://eippcb.jrc.ec.europa.eu/reference/slaughterhouses-and-animals-products-industries>

RMO	Direct market loss after mitigation through Innovation	Additional costs	Supply chain disruption	SME impacts	Score
		7.7% increase in operating expenditure per unit of turnover (annualised €150 million per year).	of substitution. If industry voluntarily innovates, at least some profitability is assumed.	segmented in different niches.	

4.2.8.2 Human health impacts – Higher level of protection (workers, consumers etc), other health impacts

In the following two sections, the human health impacts and environmental impacts that can be expected under each RMO are discussed. The expected impacts are based on the list of potential alternatives identified in the analysis of alternatives (see Section 3.9.2) and the risk to human health and the environment that these substances pose compared to the F-gases currently used. The table below illustrates the list of potential alternatives under each RMO as there is some variation between the RMOs due to the different concerns and applications they target. The green ticks indicate where use is allowed, the orange ticks indicate where the use is allowed but is time limited, and the red crosses indicate where use is not allowed.

Table 4-11 Potential alternatives per RMO

Application	Alternative	RMO 1	RMO 2	RMO 3	RMO 4	RMO 5	RMO 6
RACHP	Ammonia	✓	✓	✓	✓	✓	✓
	Carbon dioxide	✓	✓	✓	✓	✓	✓
	Isobutane	✓	✓	✓	✓	✓	✓
	Propane	✓	✓	✓	✓	✓	✓
	Propylene	✓	✓	✓	✓	✓	✓
Foam Insulation	Di-methyl ether	✓	✓	✓	✓	✓	✓
	Cyclopentane	✓	✓	✓	✓	✓	✓
Magnesium Cover Gas	Carbon dioxide	✓	✓	✓	✓	✓	✓
Propellant	Butane	✓	✓	✓	✓	✓	✓
	Propane	✓	✓	✓	✓	✓	✓
	Di-methyl ether	✓	✓	✓	✓	✓	✓
	Nitrous oxide	✓	✓	✓	✓	✓	✓
	Carbon dioxide	✓	✓	✓	✓	✓	✓
	Nitrogen	✓	✓	✓	✓	✓	✓

Application	Alternative	RMO 1	RMO 2	RMO 3	RMO 4	RMO 5	RMO 6
Fire suppressant	[product name]	✓	✗	✓	✓	✓	✓
Solvent	[product name]	✓	✓	✓	✓	✓	✓
	MPHE	✓	✓	✓	✓	✓	✓
	HFE-347pcf2	✓	✗	✓	✓	✓	✓
	[product name]	✓	✗	✓	✓	✓	✓
	HFE-7100	✓	✗	✓	✓	✓	✓
	HFE-7000	✓	✗	✓	✓	✓	✓
	HFE-7200	✓	✗	✓	✓	✓	✓

RMO 1: Substance Evaluation

There will be no reduction in exposure or a switch to alternatives required under RMO 1 so there will be no impact on human health for workers and consumers.

RMO 2: REACH Restriction

RMO 2 refers to the second restriction option outlined in the proposed PFAS restriction, which foresees a ban on the use of F-gases, with derogations for applications for which acceptable alternatives are not currently available.

HFC-125 and HFC-227ea potentially pose a human health risk as a result of thermal decomposition, which releases hydrogen fluoride³²⁸; hydrogen fluoride is a highly toxic (H300: Fatal if swallowed, H310: Fatal in contact with skin, H330: Fatal if inhaled) and corrosive (H314: Causes severe skin burns and eye damage) gas. Though, the release of hydrogen fluoride is only likely to occur during high heat exposure applications such as fire suppression. Therefore, with the exception of HFC-125 and HFC-227ea fire suppression applications, the impact to human health by replacing these substances with an alternative that does not provide a toxic decomposition product, is likely to be negligible.

Any impact on human health under this RMO will therefore come from the choice of alternatives for the different F-gas applications.

RACHP

The main alternatives for RACHP applications are carbon dioxide, ammonia, and hydrocarbons. CO₂ is a suitable alternative in mobile air conditioning and industrial and commercial refrigeration. Carbon dioxide is not classified as being hazardous to human health under the CLP Regulation and occurs naturally in the air at concentrations of approximately 400ppm where it is non-toxic. However, at higher concentrations (e.g. >5,000ppm) it can cause increased rate of breathing, depression of the central nervous system and asphyxiation³²⁹. The operating pressure of carbon dioxide is much higher than many other F-gas refrigerants, with a pressure ten times greater than that of HFC-134a required. Pressurised CO₂ presents a potential health hazard from blast effects such as explosions. However, due to the higher operating pressure, smaller volumes of piping and components are used (approximately 80-90% for some components compared to HFC-134a) and thus the stored explosion energy in a CO₂ system may not be much different compared to an HFC-134a system³³⁰. When used in industrial and commercial refrigeration, the systems are typically enclosed so the

³²⁸ Ting Wang, Ying-jie Hu, Pin Zhang, Ren-ming Pan (2016). Study on thermal decomposition properties and its decomposition mechanism of pentafluoroethane (HFC-125) fire extinguishing agent. *Journal of Fluorine Chemistry*. 190, pp.48-55, Available at: <https://www.sciencedirect.com/science/article/abs/pii/S0022113916302457>

³²⁹ Sawalha, S., 2008. Safety of CO₂ in Large Refrigeration Systems, Sweden: Royal Institute of Technology.

³³⁰ Neská et al., 2010. CO₂ - A Refrigerant From The Past With Prospects Of Being One Of The Main Refrigerants In The Future, Trondheim: SINTEF Energy Research.

probability of human exposure is low. Therefore, it can be concluded that there is minimal risk to human health from use of carbon dioxide over an F-gas system.

In the case of ammonia as an alternative, it presents a number of human health hazards. Exposure to ammonia can result in burning or irritation of the eyes and throat, as ammonia bonds with moisture on the body to form ammonia hydroxide. More serious hazards of ammonia at high concentrations include severe burns to skin and eyes, blindness, respiratory damage, and death³³¹. Furthermore, ammonia can form highly flammable hydrogen gas during thermal decomposition. Ammonia emissions contribute to fine particulate matter (PM_{2.5}) pollution through the chemical formation of particulate ammonium sulphate and ammonium nitrate, which are responsible for tens of thousands of deaths annually³³². 80% of ammonia produced is used in agriculture³³³ and nearly 90% of global ammonia emissions come from agricultural sources³³⁴. Whereas less than 2% of ammonia produced globally is currently used for refrigeration³³⁵. Emissions from its adoption as an alternative refrigerant are expected to be small in comparison, considering that ammonia is only suited to certain RACHP applications, namely industrial refrigeration and chillers, although this has not been quantified. Ammonia is also hazardous when released in large quantities, but because of its irritating odour, people are unlikely to voluntarily stay near concentrations that pose a threat to human health. While ammonia isn't innately flammable, when exposed to high temperatures it can decompose into hydrogen gas, which is highly flammable. However, outside of normal operating temperatures and controls, hydrogen gas as a result of the thermal degradation of ammonia is unlikely to pose a serious risk.

Due to ammonia's toxic and flammable breakdown properties, the use of ammonia as an alternative refrigerant is expected to pose some degree of risk to human health (e.g. through accidental release or leakage)..

Hydrocarbons are suitable alternatives in domestic and commercial refrigeration, chillers, movable air conditioning, and heat pumps. Propane, isobutane, and propylene are all considered to have low toxicity to humans and are not classified for any human health hazards. They are however highly flammable, posing an additional risk to human health over F-gases. Some hydrocarbons are toxic to human health. For example, according to the REACH registration dossier, pentane is classified as Asp. Tox. 1 (may be fatal if swallowed and enters airways) and STOT SE 3 (may cause drowsiness or dizziness)³³⁶. As a volatile material, the respiratory system is the primary target of pentane exposure, as pentane can disperse in ambient conditions³³⁷. Human exposure studies have revealed that pentane can cause respiratory arrest, seizure, haemorrhage, polyneuropathies, dizziness, narcosis, anorexia, depression, and confusion³³⁸. Chronic exposure of pentane has been found to result in anoxia.

Under the second restriction option outlined in the proposed PFAS restriction, an indefinite derogation is given to refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives. This exists to ensure that HVACR equipment is available where non-PFAS alternatives are restricted at the national level according to standards and building codes due to properties like e.g. flammability. The IEC 60335-2-89 standard raised the charge limit in commercial refrigerating appliances from 150g to 300g for the class of most flammable refrigerants (A3), to which propane, isobutane, propylene, and pentane belong³³⁹. There is uncertainty regarding when this standard will be adopted and enforced via national legislation. This will vary from country to country and could take up to five years³⁴⁰. Standard EN 378:2016 also sets charge limits for A3 refrigerants unless all refrigerant-containing parts are in a machinery room or open air with authorised access. Because of the stringent safety standards surrounding the use of flammable refrigerants, the likelihood of human exposure to these substances is expected to be low and the ability to use such alternatives if limited to certain applications.

³³¹ ECHA. Ammonia, anhydrous REACH Dossier. Available at: <https://echa.europa.eu/brief-profile/-/briefprofile/100.028.760>

³³² Ma, R., Li, K., Guo, Y. et al. Mitigation potential of global ammonia emissions and related health impacts in the trade network. *Nat Commun* 12, 6308 (2021). <https://doi.org/10.1038/s41467-021-25854-3>

³³³ Ashrae (2010) Ammonia as a refrigerant. Available at: https://www.epa.gov/sites/default/files/documents/ASHRAE_PD_Ammonia_Refrigerant_2010_1.pdf

³³⁴ Ma, R., Li, K., Guo, Y. et al. Mitigation potential of global ammonia emissions and related health impacts in the trade network. *Nat Commun* 12, 6308 (2021). <https://doi.org/10.1038/s41467-021-25854-3>

³³⁵ Ibid 333

³³⁶ ECHA (2023) Pentane. ECHA REACH dossier. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15177/2/1>

³³⁷ Kim, J.K., et al. (2012). Subchronic Inhalation Toxicity Study of n-pentane in Rats. *Saf Health Work.* 3(3), pp. 224-34. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3443698/>

³³⁸ Ibid

³³⁹ Colbourne, D., Suen, K. O., Li, T. X., Vince, I., & Vonsild, A. (2020). General framework for revising class A3 refrigerant charge limits—a discussion. *International Journal of Refrigeration*, 117, 209-217.

³⁴⁰ Danfoss (n.d.) IEC 60335-2-89 flammable refrigerant limit change. Available at: <https://www.danfoss.com/en-gb/about-danfoss/our-businesses/cooling/refrigerants-and-energy-efficiency/refrigerant-faq-iec/>

The derogation for HVACR equipment is also expected to result in a significant proportion HVACR equipment continuing to use F-gases or carbon dioxide where applicable. Therefore, the impact to human health from the use of alternative refrigerants is expected to be low, due to their low hazard and low likelihood of exposure.

Foam Insulation

The potential alternative foam blowing agents for non-spray foam insulation include dimethyl ether (DME) and cyclopentane. To note, flammable blowing agents cannot be used for spray foams due to concerns related to accumulation of flammable vapours. DME has been shown to have a very low acute inhalation toxicity with a 4h LC₅₀ in rats of 164,000 ppm³⁴¹. Past repeated inhalation studies of up to 2 years in rats, also show that DME was not deemed to be carcinogenic and produced minimal toxicity at 25,000 and 10,000 ppm, with a No-Observed-Adverse-Effect Concentration (NOAEC) of 2000 ppm. The primary finding with inhalation exposure during these studies was a reversible central nervous system depression³⁴². However, DME does present some physical hazards to humans as it is classed as being an "Extremely flammable gas" (H220 Flam. Gas 1A) and "Contains gas under pressure; may explode if heated" (H280 Compressed gas)³⁴³.

Cyclopentane which is used as a foam blowing agent in the same way as DME is also considered to be of low toxicity and thus classified as not hazardous to human health in its REACH registration dossier; although much like DME it also presents a physical hazard and is classified as a highly flammable liquid and vapour (Flam. Liq. 2)³⁴².

Despite these hazards, both DME and cyclopentane are expected to pose a minimal risk to human health because of the low likelihood of exposure to foam blowing agents. Foam blowing agents are additives in the manufacture of foam insulation that react during processing to form gas, which is dissipated around the foam³⁴⁴. Therefore, the gas (HFO or non-HFO gas) is contained within the foam and emissions of the blowing agent from closed cell foam are typically less than 2% per year³⁴⁵.

Magnesium Cover Gas

The only potential non-fluorinated alternative for use as a cover gas for magnesium die casting has been found to be carbon dioxide. While carbon dioxide is not toxic at low concentrations, at higher concentrations it can cause increased rate of breathing, depression of the central nervous system and asphyxiation³⁴⁶. Because it is an odourless gas and does not have the benefit of being self-alarming, this presents a considerable risk to human health in areas that are not equipped with CO₂ sensors for any potential releases of concentrations exceeding 5,000 ppm (the Threshold Limit Value that one may be repeatedly exposed for 8 hours per day 40 hours per week without adverse effect)³⁴⁶. Recommended safety measures for die casting include the use of personal protective equipment (PPE), such as respiratory protection³⁴⁷, which would reduce exposure to carbon dioxide. If such safety measures are in place, the human health risk (e.g. for workers) to carbon dioxide is expected to be low.

Aerosols

The potential alternative propellants for aerosols include carbon dioxide, hydrocarbons, nitrogen, nitrous oxide, di-methyl ether, HFC-152a and air. As documented above, the risk to human health from carbon dioxide is low for applications where high concentrations of the substance do not occur. Nitrogen presents a physical hazard from its classification as a pressurised gas under CLP³⁴⁸, but this matches the classification of F-gases currently used as propellants, so there would be no additional risk to human health from the use of nitrogen.

Nitrous oxide is currently limited to use as a propellant in rocketry and aerosols for food products, where exposure is low. Nitrous oxide is classified for STOT SE 3 (H335: Specific target organ toxicity, single

³⁴¹ Workplace Environmental Exposure Level (WEEL) Committee; Occupational Alliance for Risk Science (OARS); Toxicology Excellence for Risk Assessment (TERA) (2022). Dimethyl ether (DME). Toxicol Ind Health. pp.713-716. Available at: <https://pubmed.ncbi.nlm.nih.gov/36190179/>

³⁴² Ibid

³⁴³ ECHA (2023). Di-methyl ether ECHA REACH Dossier. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15974/2/1>

³⁴⁴ Heim, H. P. (2015). Specialized injection molding techniques. William Andrew.

³⁴⁵ EFCTC (n.d.) Insulation Foam Blowing Agent. Available at: <https://www.fluorocarbons.org/applications/insulation-foam-blowing-agent/>

³⁴⁶ Sawalha, S., 2008. Safety of CO₂ in Large Refrigeration Systems, Sweden: Royal Institute of Technology.

³⁴⁷ Zetwerk (2023) Top 5 Safety Measures in Die Casting. Available at: <https://www.zetwerk.com/resources/knowledge-base/die-casting/top-5-safety-measures-in-die-casting/>

³⁴⁸ ECHA (2023) Substance Infocard: Nitrogen. Available at: <https://echa.europa.eu/substance-information/-/substanceinfo/100.028.895>

exposure; Respiratory tract irritation) with documented health impacts from prolonged exposure occurring from the use of the substance as a recreational drug or medical or dental anaesthetic^{349,350}.

Although hydrocarbons, HFC-152a and di-methyl ether present a physical hazard to humans from their flammability, the proposed restriction sets a derogation for propellants for technical aerosols in applications where non-flammability and high technical performance of spray quality are required. Allowing the use of F-gases in these applications would limit the use of flammable propellants to applications where their flammability does not present a safety risk. Use of HFC-152a also offers a potential reduction in product VOC content compared to the use of hydrocarbons and DME.

Solvents

Under the proposed REACH restriction there are several derogations for the use of solvents, but it is not clear whether all solvent applications using F-gases will fall under this scope. Therefore, any PFAS alternatives have been considered unacceptable under this use. As all the identified alternatives meet the PFAS definition our analysis concludes that there are no potential non-fluorinated alternatives. Therefore, the health impacts for solvent applications will be the same as those under the current baseline e.g. no impact.

Fire Suppressant

Under the proposed REACH Restriction there is a derogation for the use as fire suppressants, but it is not clear whether all fire suppression applications using F-gases will fall under this scope. Therefore, any PFAS alternatives have been considered unacceptable under this use. As the only identified alternative meet the PFAS definition our analysis concludes that there are no potential non-fluorinated alternatives. Therefore, the health impacts for fire suppressant applications will be the same as those under the current baseline e.g. no impact.

RMO 3: REACH Authorisation

This RMO, which incorporates an Candidate Listing and addition to the Authorisation List, restricting its use, would result in a very similar outcome to RMO 2 REACH restriction and subsequent derogations. As previously stated in in Section 0, RMO 2 REACH restriction, none of the F-gases in scope are classified as having human health hazards, so similarly, a RMO 3 would have a negligible impact of human health. HFC-125 does pose a human health risk as a result of its thermal decomposition, which releases hydrogen fluoride, though the release of hydrogen fluoride is not expected to occur under normal conditions of use, and so the impact to human health in comparison to an alternative is expected to be negligible.

As it is likely that the only companies that would seek authorisation for continued use would be those that would also seek a derogation under the RMO 2 REACH restriction, for no potential alternatives being available, it can be assumed that the potential health impacts of RMO 3 and RMO 2 and the identified alternatives will be the same and thus a low negative impact.

RMO 4: Regulatory proposal for amendment of F-gas Regulation

For context, under RMO 4 it is expected that HFC-125, HFC-134a, HFC-143a, and HFC227ea would all be restricted where they are not being used in blends that have GWP<150, as the RMO restricts certain applications using F-gases with a GWP greater than 150 and thus these applications would require a switch to alternatives. However, under this RMO F-gases with low GWPs, such as HFO-1234yf could be used as an alternative for selected applications, which have similar toxicological properties to higher GWP F-gases. Therefore, the number of companies switching to non-fluorinated alternatives is expected to be lower than the proportion under RMO 2 REACH restriction of PFAS and RMO 3 REACH authorisation.

³⁴⁹ Oussalah, A., Julien, M., Levy, J., Hajjar, O., Franczak, C., Stephan, C., ... & Guéant, J. L. (2019). Global burden related to nitrous oxide exposure in medical and recreational settings: a systematic review and individual patient data meta-analysis. *Journal of clinical medicine*, 8(4), 551.

³⁵⁰ Shah, K., and Murphy, C. (2019). Nitrous Oxide Toxicity: Case Files of the Carolinas Medical Center Medical Toxicology Fellowship. *J Med Toxicol.* (4), pp.299-303. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6825085/>

HFC-125³⁵¹, HFC-134a³⁵², HFC-143a³⁵³, and HFC227ea³⁵⁴ all do not have any human health classifications under CLP. Therefore, the impact of this RMO to human health will be dependent on the choice of alternatives for each application. However, as outlined above, HFC-125 does pose a human health risk as a result of its thermal decomposition. Though, the release of hydrogen fluoride is not expected to occur under normal conditions of use, and so the impact to human health by replacing HFC-125 with an alternative is likely to be negligible.

RACH

The alternatives for RACH applications are expected to be the same as under RMO 2 REACH restriction, therefore the potential human health impacts have also been determined to be the same, which is minimal or no impact depending on the adopted alternative.

Foam Insulation

The alternatives for foam insulation applications are expected to be the same as under RMO 2 REACH restriction, therefore the potential human health impacts have also been determined to be the same, which are minimal.

Magnesium Cover Gas

The alternatives for magnesium cover gas applications are expected to be the same as under RMO 2 REACH restriction, therefore the potential human health impacts have also been determined to be the same, which are low, due to CO₂ being the only identified alternative which includes potential physical hazards.

Aerosols

The alternatives for aerosol applications are expected to be the same as under RMO 2 REACH restriction, therefore the potential human health impacts have also been determined to be the same, which is low, based on the identified alternatives of CO₂, nitrous oxide, nitrogen, air, hydrocarbons and di-methyl ether.

Fire Suppressant

Our analysis found that there were no potential non-fluorinated alternatives. The only potential fluorinated alternative is [product name] Magnesium Protection Fluid, which is not classified as being hazardous under the CLP Regulation. Therefore, no impacts on human health have been identified.

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

This RMO would not require a switch to alternatives and does not directly set provisions for reducing exposure/emissions. Though, it is expected that more leaks would be prevented and minimised as a result of implementing the best available techniques (BATs) outlined in the RMO. However, as the majority of F-gases in scope are of low toxicity to human health, a reduction in leaks is not expected to have a significant impact on human health.

RMO 6: Substitution (industry initiative)

RMO 6 is expected to have a similar impact to RMO 2, but because the initiative is voluntary, all companies are not expected to participate, due to the lower incentives to phase out F-gas use beyond regulatory requirements. As highlighted in the analysis of the other RMOs, the risk to human health of the potential alternatives is small, because of their low toxicity, the presence of industry standards, occupational exposure limits, and recommended risk management measures. Due to the low toxicity of F-gases, a small negative impact on human health is expected from the transition away from F-gases that would occur under RMO 2 (REACH restriction of PFAS), RMO 3 (REACH authorisation), and RMO 4 (Regulatory proposal for amendment of F-gas Regulation). Under this RMO, the impact to human health is assumed to be lower than for RMOs that require substitution within a shorter timeframe, as there would be more time for industry to select

³⁵¹ HFC-125. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15415>

³⁵² HFC-134a. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15155>

³⁵³ HFC-143a. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15086>

³⁵⁴ HFC-227ea. ECHA REACH dossier. Available at: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/1989>

or develop less harmful alternatives to F-gases (noting that majority of F-gases are already non-hazardous for human health), and during this development the current F-gases may continue to be used.

4.2.8.3 *Environmental impacts – GWP, circularity and waste, other*

RMO 1: Substance Evaluation

No reduction in exposure or switch to alternatives is required under RMO 1 so there will be no impact on environmental health.

RMO 2: REACH Restriction

RMO 2 refers the second restriction option outlined in the proposed PFAS restriction, which foresees a ban on the use of F-gases with derogations for applications for which potential alternatives are not currently available.

Only one of the F-gases in scope is hazardous to the environment, with HCFO-1233zd (102687-65-0) having a reported REACH dossier classification of Aquatic Chronic 3³⁵⁵. However, five of the in scope F-gases degrade fully or partially into Trifluoroacetic acid (TFA). For example, HFO-1234yf has a molar yield of TFA of 100% TFA, where its persistence and mobility within the environment is of concern³⁵⁶. Alternatively, some studies have shown that TFA currently exists within the environment in concentrations not likely to have adverse toxicological consequences³⁵⁷. It should be noted that F-gases are not the only source of TFA, hydrothermal vents have been identified as sources in the oceans, whilst the production of TFA as an industrial chemical, fluoropolymers, and pesticides such as trifluralin are other known anthropogenic sources.³⁵⁸

However, based on the current understanding of TFA, the low toxicity of F-gases, and their high volatility, the baseline of environmental impacts from the current use of F-gases is negligible. Thus, any impact on the environment under this RMO will come from the choice of alternatives. It is important to note that none of the stated alternatives degrade to TFA and therefore may provide a small positive benefit over F-gases in regard to concerns over TFA's environmental persistence and mobility. The degradation products of the alternatives have not been studied in detail and so some may have degradation products which also exhibit persistence or mobility concerns.

RACHP

The main alternatives for use in RACHP applications are carbon dioxide, ammonia, and hydrocarbons.

Carbon dioxide is not known to have any adverse environmental effects, aside from its global warming potential, although it may be considered persistent³⁵⁹. Because of its low GWP, a switch to carbon dioxide would bring significant positive environmental impacts where high GWP F-gases are currently being used.

Of the potential hydrocarbon refrigerants, propane, propylene, and isobutane gas are not classified as being hazardous to the environment and are neither persistent nor bioaccumulative. However, concerns exist related to the environmental fate of propane and the resulting degradation products. The atmospheric degradation of propane (reaction of propane with OH) produces acetone (CAS # 67-64-1) and propionaldehyde (CAS # 123-38-6) in a ratio of 80:20, with minor degradation products including formaldehyde (CAS # 50-00-0) and acetaldehyde (CAS # 75-07-0). Each of these degradation products undergo further atmospheric degradation.³⁶⁰ Acetone undergoes further atmospheric degradation to produce formaldehyde and CO₂ (major degradation products), and acetic acid and methyl glyoxal (minor degradation products).³⁶¹ Formaldehyde is ubiquitous in the environment and comes from natural and anthropogenic sources. It is readily photo-oxidised to form CO₂ and further reacts with OH to form CO₂ and H₂O.³⁶² Propionaldehyde undergoes atmospheric

³⁵⁵ ECHA (2023) Substance Infocard: (1E)-1-chloro-3,3,3-trifluoroprop-1-ene. Available at: <https://echa.europa.eu/substance-information/-/substanceinfo/100.149.148>

³⁵⁶ ECHA (2021). Substance evaluation conclusion for Polyhaloalkene EC No 468-710-7 CAS RN 754-12-1. Available at: <https://www.echa.europa.eu/documents/10162/a794e3ad-c358-b7f8-bc74-268bfea135e7>

³⁵⁷ Neale, R. E., Barnes, P. W., Robson, T. M., Neale, P. J., Williamson, C. E., Zepp, R. G., et al. (2021), "Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: UNEP Environmental Effects Assessment Panel, Update 2020", Photochemical & Photobiological Sciences <https://doi.org/10.1007/s43630-020-00001-x>. See sections 7.8 to 7.11 for Trifluoroacetic acid (TFA). Open access paper.

³⁵⁸ UNEP (2016) Sources, fates, toxicity and risks of trifluoroacetic acid and its salts: relevance to substances regulated under the Montreal and Kyoto Protocols. Available at: <https://ozone.unep.org/sites/default/files/2019-08/TFA2016.pdf>

³⁵⁹ No REACH registration assessment for persistence.

³⁶⁰ Rosado-Reyes, C.M., et. al., Atmospheric oxidation pathways of propane and its by-products: Acetone, acetaldehyde, and propionaldehyde, J. Geophys. Res. Vol. 112, d14310, doi:10.1029/2006JD007566, 2007.

³⁶¹ Ibid footnote 360

³⁶² Zhang, W., et. al., Catalytic Effect of Water, Formic Acid, or Sulfuric Acid on the Reaction of Formaldehyde with OH Radicals, J. Phys. Chem. A 2014, 118, 4797–4807.

degradation to produce CO₂, acetaldehyde and peroxypropionyl nitrate. Acetaldehyde undergoes atmospheric degradation to CO₂, formaldehyde and peroxyacetyl nitrate.³⁶³

Propane is a non-methane volatile organic compound (NMVIC), which contribute to ground level ozone formation. Each of the degradation products of propane listed about are also classified as NMVOCs.

Table 4-12 Photochemical Ozone Creation Potential of Propane and its degradation products³⁶⁴

Substance	Photochemical Ozone Creation Potential (POCP)
Propane	14
Acetone	6
Propionaldehyde	72
Formaldehyde	46
Acetaldehyde	55

Ammonia is one of the main sources of nitrogen pollution which impacts negatively on biodiversity through nitrogen accumulation within habitats³⁶⁵. As nitrogen is a natural fertiliser, common fast growing plant species may adapt to the abundance of nitrogen and out compete more specifically adapted plant species, resulting in a loss of biodiversity. The increased acid depositions from ammonia emissions can have a negative impact on aquatic ecosystems due to 1) the exertion of biochemical oxygen demand on receiving waters (nitrogenous biological oxygen demand or NBOD), which occurs when dissolved oxygen is consumed by bacteria and other microbes which oxidise ammonia into nitrite and nitrate³⁶⁶; and 2) eutrophication which can lead to high plant growth and harmful algal blooms, which consumer oxygen and lead to fish mortality^{367, 368, 369, 370}.

Ammonia itself is toxic to aquatic life, and when dissolved in surface water ammonia exists in two forms, unionised and ionised. The unionised form is of concern because it has greater bioavailability and therefore can readily pass from the water into fish via the gills, often through the process of passive diffusion of ammonia gas in the water³⁷¹. Acute exposure of ammonia to fish may cause loss of equilibrium, hyperexcitability, increased breathing/oxygen uptake, cardiac output, convulsions, coma, and death.

Ammonia is a suitable refrigerant for industrial refrigeration, transport refrigeration, and chillers, which have leakage rates of 7-25%, 15-50%, and 2-15% respectively³⁷². Despite these wide-ranging reference estimates, they demonstrate that refrigerant emissions are not insignificant. Industrial refrigeration facilities have to follow the guidelines laid out in EN 378373, which stipulates that leak detection systems must be in place. Under EU occupational safety and health legislation, indicative occupational exposure limits for ammonia are set at 20ppm over 8 hours and 50ppm over 15 minutes³⁷⁴. Because of these safety measures, the environmental emissions of ammonia will be controlled, and the likelihood of environmental impacts will be reduced.

³⁶³ Ibid footnote 360

³⁶⁴ Derwent, R.G., et. al., Reactivity-based strategies for photochemical ozonecontrol in Europe, Env. Sci. Policy 10 (2007), 445-453.

³⁶⁵ Susan Guthrie et al (2018). The impact of ammonia emissions from agriculture on biodiversity. Available at:

<https://royalsocietypublishing.org/~/media/policy/projects/evidence-synthesis/Ammonia/Ammonia-report.pdf>

³⁶⁶ US EPA (no date) Ammonia. Available at: [https://www.epa.gov/caddisvol2/ammonia#:~:text=Ammonia%20\(NH3\)%20is%20a,\(ammonia%2C%20NH3\)](https://www.epa.gov/caddisvol2/ammonia#:~:text=Ammonia%20(NH3)%20is%20a,(ammonia%2C%20NH3))

³⁶⁷ Ibid footnote 366

³⁶⁸ Viney P. Aneja et al. Ammonia Assessment from Agriculture: U.S. Status and Needs. Journal of Environmental Quality 37, 515-520, <https://doi.org/10.2134/jeq2007.0002in> (2008).

³⁶⁹ Denise Breitburg et al. Declining oxygen in the global ocean and coastal waters. Science 359, eaam7240, <https://doi.org/10.1126/science.aam7240> (2018).

³⁷⁰ Innovation for Cool Earth Forum (ICEF) (2022) Low-carbon Ammonia Roadmap. Available at: https://www.icef.go.jp/pdf/summary/roadmap/icef2022_roadmap_Low-Carbon_Ammonia.pdf

³⁷¹ The Nature Conservancy (2010) .A Literature Review of Effects of Ammonia on Fish. Available at:

<https://www.nature.org/content/dam/tnc/nature/en/documents/literature-review-ammonia.pdf>

³⁷² IPCC (2000) Good Practice Guidelines and Uncertainty Management in National Greenhouse Gas Inventories.

³⁷³ AREA (2019) Introduction to Refrigeration Standard EN 378. Available at: https://area-eur.be/sites/default/files/2019-07/AREA%20Introduction%20to%20EN%20378%20-%20for%20Publication_0.pdf

³⁷⁴ Commission Directive 2000/39/EC. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0039-20180821> "https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0039-20180821"

According to the UNEP, all of the non-F-gas refrigerants listed above have low GWPs ranging from 0 to 10^{375,376} and do not degrade to TFA. Therefore, a switch to these alternatives could have a large positive benefit on climate change, and not contribute to the release of TFA into the environment. It is acknowledged that some of the alternatives, such as propane have atmospheric degradation products of concern, or have environmental impacts such as eutrophication (ammonia).

Foam Insulation

The potential alternative foam blowing agents for foam insulation include dimethyl ether (DME) and cyclopentane. Di-methyl ether (DME) is not classified as being toxic to aquatic life according to its REACH dossier and the substance does not meet the criteria for persistence and bioaccumulation. It is however a VOC.

A literature review on the ecotoxicity of cyclopentane returned few results, however information on predicted ecotoxicity can be found within the substance's REACH dossier. Cyclopentane is stated to be classified under the CLP Regulation as toxic to aquatic life with long lasting effects (aquatic chronic category 2). This classification was determined using the PETROTOX computer model (v4.0)³⁷⁷. Cyclopentane is also a VOC.

As highlighted in Section 3.4.3, the chance of exposure to foam blowing agents is low due to the low leakage rates. On this basis the environmental impacts are not expected to be large, but the use of alternatives presents a higher risk to environmental health than the use of F-gases.

Di-methyl ether and cyclopentane have GWPs of 1 and <25 respectively³⁷⁸. Therefore, a switch to these alternatives would have a large positive benefit for climate change where high GWP F-gases are used.

Magnesium Cover Gas

The only potential non-fluorinated alternative for use as a cover gas for magnesium die casting was found to be carbon dioxide. As detailed above carbon dioxide is not known to have any adverse environmental effects, aside from its global warming potential. Carbon dioxide's GWP of 1 is much lower than some F-gases, such as HFC-134a, so its use is expected to bring significant positive impacts on climate change.

Aerosols

The potential alternative propellants for aerosols include carbon dioxide, hydrocarbons, nitrogen, nitrous oxide, di-methyl ether³⁷⁹, and air. Hydrocarbon alternatives include propane and butane, both of which are not classified for environmental hazards under the CLP Regulation or meet the criteria for persistence of bioaccumulation, but they are VOCs. They also have low GWPs of 0.02 and 0.006 respectively³⁸⁰.

Nitrogen occurs naturally within the earth's atmosphere, making up approximately 78% of the air we breathe³⁸¹. It has a global warming effect 300 times greater than carbon dioxide and remains active in the atmosphere for more than 100 years. It can also cause algal blooms in lakes and waterways³⁸², which themselves emit greenhouse gases, although emissions of nitrogen to water are unlikely to occur when used as a gas.

Nitrous oxide has a 100-year GWP of 273, however it is only a viable alternative in a couple of niche applications, namely as a rocket propellant and a propellant for dispensing certain food products, where it is already used widely, no change in environmental impact is expected from the baseline.

³⁷⁵ UNEP (2021) Climate Change 2021 The Physical Science Basis. Available at:

https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_Full_Report.pdf

³⁷⁶ UNEP (2014) Global Warming Potential (GWP) of Refrigerants: Why are Particular Values Used? Available at:

https://wedocs.unep.org/bitstream/handle/20.500.11822/28246/7789GWPref_EN.pdf

³⁷⁷ Cyclopentane. ECHA REACH dossier. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/14830/6/2/1>

³⁷⁸ US EPA (2016) Transitioning to Low-GWP Alternatives in Domestic Refrigeration. Available at: https://www.epa.gov/sites/default/files/2016-12/documents/transitioning_to_low-gwp_alternatives_in_domestic_refrigeration.pdf

³⁷⁹ Volatile organic compound

³⁸⁰ UNEP (2021) Climate Change 2021 The Physical Science Basis. Available at:

https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_Full_Report.pdf

³⁸¹ NASA (n.d.). 10 interesting things about air. Available at:

<https://climate.nasa.gov/news/2491/10-interesting-things-about-air/#:~:text=It's%20a%20mixture%20of%20different,nitrogen%20and%2021%20percent%20oxygen.>

³⁸² UNEP (2023) Four reasons why the world needs to limit nitrogen pollution. Available at: <https://www.unep.org/news-and-stories/story/four-reasons-why-world-needs-limit-nitrogen-pollution#:~:text=Nitrogen%20is%20a%20key%20contributor%20to%20climate%20change&text=This%20gas%20is%20300%20times,off%2C%20also%20emit%20greenhouse%20gases.>

In summary, the potential alternative propellants are not expected to lead to significant impact on the environment. This is because most have low GWPs and low environmental toxicity.

Solvents

Under the proposed REACH restriction there are several derogations for the use of solvents, but it is not clear whether all solvent applications using F-gases will fall under this scope. Therefore, any PFAS alternatives have been considered unacceptable under this use. As all the identified alternatives meet the PFAS definition our analysis concludes that there are no potential non-fluorinated alternatives. Therefore, the environmental impacts for solvent applications will be the same as those under the current baseline e.g. no impact.

Fire Suppressant

Under the proposed REACH Restriction there is a derogation for the use as fire suppressants, but it is not clear whether all fire suppression applications using F-gases will fall under this scope. Therefore, any PFAS alternatives have been considered unacceptable under this use. As the only identified alternative meet the PFAS definition our analysis concludes that there are no potential non-fluorinated alternatives. Therefore, the environmental impacts for fire suppressant applications will be the same as those under the current baseline e.g. no impact.

RMO 3: REACH Authorisation

HCFO-1233zd is the only F-gases in scope that is classified as having an environmental hazard, with a self-classification of Aquatic Chronic 3 under CLP. However, due to the volatile nature of F-gases, emissions to water are low and therefore the risk of adverse environmental impacts is low as well.

Conversely, the most significant environmental impact will be on climate change and environmental persistence, with the main environmental concerns surrounding F-gases being their GWPs and the release of TFA. Emissions from all F-gas applications are forecast to be 1,942,313 tonnes³⁸³. The reduction in emissions that could be expected under REACH authorisation has not been quantified, but it is expected that this would be around 90% or greater, given that authorisation would ban all uses of F-gases unless an application for authorisation is granted for a specific use. Five of the in scope F-gases degrade to TFA of varying percentage yields, from 1% (HFC-125) to 100% (HFO-1234yf) and so reduction in emissions of F-gases will contribute to a reduction in TFA emissions across all applications.

The majority of problematic uses highlighted in the PFAS Annex XV report³⁸³, for which derogations may be granted, have been estimated to contribute a small percentage of emissions to the total F-gas emissions across all applications. Therefore, the reduction in environmental emissions (including TFA) under this RMO is expected to be a large positive impact across all applications, but this depends on the number and nature of the applications for authorisation that are successful.

RMO 4: Regulatory proposal for amendment of F-gas Regulation

The quota phase-down of an amendment of the F-gas Regulation will require applications using F-gases with a GWP greater than 150 to switch to alternatives. This would mean that high GWP refrigerants that typically contain large proportions of HFC-125, HFC-134a, HFC-143a, and HFC227ea would all be restricted, and likely replaced with alternatives that have low GWPs or refrigerants that contain low proportions of higher GWP substances, with some no longer produced. Depending on the low GWP refrigerant composition and the refrigerant it is replacing, there will be a change in the yield of TFA, and where this is lower it could potentially produce a modest positive environmental impact in the context of reduced emissions of TFA. Additionally, a reduction in the global warming potential of the refrigerant sector as a result of the use of alternatives could be seen as a positive environmental impact as a result of this RMO. The aforementioned high GWP HFC refrigerants could likely be replaced with alternatives such as ammonia, CO₂, hydrocarbons, and the H(C)FOs, that have GWPs closer to zero.

HFO-1234yf has been identified as an alternative, due to its GWP <1, however it presents a potential environmental concern linked to its molar yield of TFA. Within the atmosphere HFO-1234yf has a molar yield of 100% trifluoroacetic acid (TFA), and when in the atmosphere TFA rapidly partitions and precipitates onto land and primarily ends up in waterbodies. Although the current consensus is that TFA has a negligible impact

³⁸³ ECHA (2023). Annex XV restriction report proposal for a restriction substance name(s): Per- and polyfluoroalkyl substances (PFASs). Available at: <https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea>

on the environment, a number of knowledge gaps remain³⁸⁴. Nevertheless, through a substance evaluation of HFO-1234yf, ECHA deemed that emissions to the environment of sources of TFA should be minimised based on the persistency and mobility of TFA³⁸⁵.

RACHP

The alternatives for RACHP applications are expected to be the same as under RMO 2 REACH restriction of PFAS, therefore the potential environmental impacts have also been determined to be the same, which is a large positive impact for the majority of identified alternatives. Ammonia presents a possible negative impact to biodiversity and aquatic life.

Foam Insulation

The alternatives for foam insulation applications are expected to be the same as under RMO 2 REACH restriction of PFAS, therefore the potential environmental impacts have also been determined to be the same, which is a large positive impact.

Magnesium Cover Gas

The alternatives for magnesium cover gas applications are expected to be the same as under RMO 2 REACH restriction of PFAS, therefore the potential environmental impacts have also been determined to be the same, which are significant positive impacts for climate change.

Aerosols

The alternatives for aerosol applications are expected to be the same as under RMO 2 REACH restriction of PFAS, therefore the potential environmental impacts have also been determined to be the same, which are no significant impacts.

Fire Suppressant

The alternatives for fire suppressant applications are expected to be the same as under RMO 2 REACH restriction of PFAS, therefore the potential environmental impacts have also been determined to be the same.

RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF

This RMO would not require a switch to alternatives and does not directly set provisions for reducing exposure/emissions. However, as a result of implementing the best available techniques (BATs) outlined in the RMO, it is expected that more leaks would be prevented and minimised. Therefore, a reduction in overall F-gas emissions from the food, drink, and milk sectors can be expected. The food and drink sector is a large GHG emitter. In 2015, emissions accounted for 18 Gt CO₂-e, which represents 34% of global GHG emissions. F-gases emissions make up 2% of the sector's total emissions³⁸⁶. Therefore, even a modest decrease in environmental emissions from the sector could lead to a positive impact for the climate.

RMO 6: Substitution (industry initiative)

Under RMO 6, a lower reduction in environmental emissions of F-gases is expected as under a voluntary initiative, there may be less financial incentive to phase-down use of F-gases to the same extent as that demanded under RMO 2 (REACH restriction of PFAS) and RMO 3 (REACH authorisation). As the majority of potential alternatives have significantly lower GWPs than the F-gases within scope, a lower positive impact on climate change is expected. Additionally, as none of the alternatives produce TFA, there will be a modest environmental benefit in regard to reducing TFA emissions, which are a substance of some concern.

However, it should be noted that there is some uncertainty with this assumption, as previous industry initiatives, such as the US EPA's PFOA Stewardship Program, have been highly effective at eliminating the use of

³⁸⁴ RPA (2017). Study on environmental and health effects of HFO refrigerants (Publication number: M-917 2017). Available at: <https://www.miljodirektoratet.no/globalassets/publikasjoner/m917/m917.pdf>

³⁸⁵ ECHA (2021). Substance evaluation conclusion for Polyhaloalkene EC No 468-710-7 CAS RN 754-12-1. Available at: <https://www.echa.europa.eu/documents/10162/a794e3ad-c358-b7f8-bc74-268bfea135e7>

³⁸⁶ Crippa, M., Solazzo, E., Guizzardi, D., Monforti-Ferrario, F., Tubiello, F. N., & Leip, A. J. N. F. (2021). Food systems are responsible for a third of global anthropogenic GHG emissions. *Nature Food*, 2(3), 198-209.

chemical of concern. If this is the case, the same positive environmental impact as that under RMO 2 and RMO 3 can be expected.

4.2.8.4 Conclusions on the wider socio-economic impacts of RMOs

As can be seen from the summaries above, the wider socio-economic and environmental impacts of the RMOs vary. Table 4-8 presents an overview of the qualitative scoring for the socio-economic impacts of the RMOs within this assessment.

Table 4-13 Qualitative Scoring of RMOs for Broader impacts

RMO	Economic impacts	Human health	Environmental impacts	Total
RMO1: Substance evaluation	-1	0	0	-1
RMO2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS	-3	-1	2	-2
RMO 3: REACH Authorisation	-2	-1	2	-1
RMO 4: Regulatory proposal for amendment of F-gas Regulation	0	-1	1.5	-0.5
RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	3	0	1	3
RMO 6: Substitution (industry initiative)	0	1	2	3

4.2.9 Overall score

In order to identify the most appropriate RMO or combination of RMOs for further consideration there is a need to compare the assessments of effectiveness, practicability, consistency and socio-economic impact. A qualitative scoring method has been used throughout the assessment to allow for comparison of each metric (see Section 4.2).

As the level of importance varies in relation to the overall proportionality of an RMO, weightings have been applied to each metric. The weighting indicates the significance of each metric in the overall assessment of proportionality and the same weighting is applied to each metric irrespective of the RMO. The weightings take into account the general objectives of EU regulatory action, which is to ensure a high level of protection of human health and the environment, whilst enhancing competitiveness. As such, the ability to reduce risk and the broader economic impacts have been given a weighting of 2 (RMO score x2 = twice the value of the baseline), with e.g. consistency weighted neutrally (RMO score x1 = equal to the baseline). Metrics for measurability/ monitorability, implementation and enforcement are considered to be more important than the baseline but of lower relevance than others and so have been given a weighting of 1.25 (RMO score x1.25). Column 3 provides an overview of the weightings that have been applied to the qualitative assessment of overall proportionality in Table 4-14.

Table 4-14 Weightings for Qualitative Assessment

Criteria	Metric	Weight	Criteria contribution
Effectiveness	Ability to reduce risk	2	24%
	Measurability/ Monitorability	1.25	

Criteria	Metric	Weight	Criteria contribution
Practicability	Implementable	1.25	33%
	Enforceable	1.25	
	Manageable	1	
	Time to implementation	1	
Regulatory consistency	Consistency with EU legislation	1	15%
	Consistency with other EU policy objectives	1	
Broader socio-economic impacts	Economic	2	29%
	Human Health	1	
	Environmental	1	

The qualitative assessment of overall proportionality in the table below provides the final ranking for RMOs.

Table 4-15 Qualitative Assessment of Overall Proportionality (weighted score)

RMO	Overall effectiveness	Overall practicability	Overall consistency	Overall economic impact	Overall human health impact	Overall environmental impact	Overall proportionality	Final ranking
RMO 1: Substance evaluation	0	-3	5	-2	0	0	0	Not ranked
RMO 2: REACH restriction – proposed restriction on the manufacture, placing on the market and use of PFAS	9.125	-7.5	2	-6	-1	-2	-5.4	5
RMO 3: REACH Authorisation	5.125	-6.5	3	-4	-1	-1	-4.4	4
RMO 4: Regulatory proposal for amendment of F-gas Regulation	7.125	-.2	6	0	-1	-0.5	9.6	3
RMO 5: Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	4.5	1	2	6	0	3	16.5	1
RMO 6: Substitution (industry initiative)	5.875	-1	6	0	1	3	14.9	2

4.3 SELECTION OF RMOS

Each RMO has been assessed based on the current legal framework and state of play, including regulatory pressures, uses, availability of alternatives and broader initiatives. Although some of the F-gases have more specialist applications than others, each of them is key to the functioning of society at this time. As such, the RMOs have been compared based on their applicability to the substances in scope, as well as their basis within the current legal framework. The RMOs do not apply uniformly to all substances in scope and so certain RMOs are of greater relevance to selected F-gases than others. Some RMOs would require significant investments to meet their aims, and this has been balanced against the wider benefits to society. As such, the comparison of RMOs has considered whether there are RMOs that could bring about an acceptable level of risk reduction, without compromising on wider societal needs or placing an undue burden on industry and regulators.

The combined use of RMO4 and RMO 5 would address emissions of F-gases across all applications and would enforce a reduction in production and use over time. The combination of these RMOs would also ensure best practice monitoring to further measure and subsequently control emissions of F-gases. RMO 6 is a voluntary industry initiative which has significant potential to reduce the risks of F-gases, should there be a strong industry push for substitution. Although it is reliant on industry efforts, there are a number of drivers which are already pushing industry into R&D activities. Where the combination of RMO 4 and 5 add increased regulatory pressure to reduce the use of F-gases, RMO 6 could be utilised by industry to mitigate the costs associated with the legally enforced restriction on use. By substituting early, companies could see first mover advantage. As such, it is recommended that these RMOs are grouped together for further consideration.

RMO 1 is a data gathering exercise and so scored neutrally for the vast majority of criteria. This has resulted in a low score for proportionality but that does not mean that it should be excluded. RMO 1 has the benefit of providing key information to conclude on the need for further regulatory action and so, where a concern is identified, the use of substance evaluation could feed data into any further evaluation of regulatory management options.

From the assessment of RMOs and the final weighted scores it would appear that the inclusion of F-gases within the proposed REACH restriction of PFAS is not proportionate. It is strongly effective at reducing the risk to the environment from the TFA degradation product, although the most recent review (UNEP 2023) concludes that current and projected (to 2100) concentrations of TFA in the oceans provide a very large margin of exposure (thousand-fold) when compared to thresholds of toxicity and risks to the environment and human health are de minimis, and, although not the aim, would also reduce the risk to global warming, however, significant concerns remain with regard to costs vs the benefits. There may potentially be significant impacts with regards to the practicability of RMO 2, in particular the ability for Member States and the Commission to enforce a restriction when there are a such a large number of substances and uses within its scope (F-gas and non-F-gas PFAS). The derogation timelines given in the preferred option for REACH restriction are, in some cases, ambitious and where there is a need to bring new products to the market or make significant investments in changing the articles that function using F-gases, there could be a significant economic impact which would not be balanced by the benefits.

Although RMO 2 is, at face value, coherent with wider EU legislation and the use of REACH restriction, concerns remain around the legal basis for such a large restriction, which are of relevance to the inclusion of F-gases. The use of RMO 2 also has potential to compromise wider EU objectives, including competitiveness and the goals and initiatives set by the EU Green Deal, such as the REPowerEU initiative. Although RMO 3 REACH authorisation also does not score favourably for overall proportionality, it may be somewhat less burdensome as it can allow for continued use of key F-gas applications whilst ensuring there is a switch to alternatives over time. This RMO would work in combination with other EU legislation targeting F-gases but would not be an option should the REACH restriction of PFAS continue to include F-gases within its scope, as this would be double regulation and would lead to legal uncertainty for companies.

Although certain RMOs clearly score higher than others in their overall proportionality, they would not work to address the concerns of this RMOA in isolation. When concluding on the most appropriate RMO there is a need to consider whether there should in fact be a package of RMOs which would work in a complementary way to address the concerns identified in this RMOA. The aim is to reduce the risk in the most appropriate and proportionate way and the analysis has shown that it may be of greater benefit to combine certain RMOs than to select one.

4.4 UNCERTAINTIES

As with all ex-ante assessments, there are inherent uncertainties in the analysis. Within this Study uncertainties such as the quality of data, the high level of complexity for how these RMOs may affect the EU F-gas sector, and the use of expert judgement in qualitative assessment may have had an influence on the evaluation of the RMOs.

It is noted that the data available has limitations. There is limited historical evidence of relevance for certain RMOs, given that RMOs, such as the proposed PFAS restriction, go over and above any other policies implemented in the EU and internationally. It has been, therefore, necessary to rely on consulting businesses to gather evidence as to the potential actions they may take in response to the RMOs and the associated costs and benefits, as pertinent. The data gathered through the consultation exercises is limited by the sample of respondents and their understanding and assessment of how the policies considered may affect their operations. The sample comprises a disproportionate number of large firms which may not accurately reflect the experiences and potential impacts on SMEs. Also, the response rate for certain downstream sectors is not entirely representative and so the study team have quantitatively analysed the impacts on the sample and not the entire sector. Data availability has also led to uncertainties in the alternatives assessment (see Section 3.10) as the study team did not have access to high quality data for all alternatives under each of the assessment parameters and so assumptions have had to be made in the exposure, performance and economic feasibility assessments.

The RMOs under consideration will affect the EU F-gas sector in multiple and complex ways. This study has limitations by design, in that it is focussed on the F-gas sector (manufacturers and downstream users) and does not consider impacts up the supply chain or impacts on consumers in detail. The key metrics for assessment have been considered via direct and indirect impacts on the F-gas sector (and broader society where relevant). How businesses may respond will vary, and will be dependent on the wider policy context as none of these RMOs work in entire isolation due to the wider EU regulatory landscape. Businesses may choose to discontinue, reformulate or substitute the use and manufacture of certain products as a result of increased costs and these considerations have been made depending on the drivers of impact for each RMO.

The use of a qualitative framework for evaluation relies upon data availability and expert judgement. A great deal of the data obtained in the evaluation of RMOs was from publicly available literature, and so inference was made as to the applicability of the historical evidence to the proposed RMOs. The application of expert judgment means that unconscious bias cannot be excluded. In an effort to reduce such bias, the assessment of the RMOs has been checked and iterated by multiple technical experts within the Study team. As such, the scores assigned to each of the criteria should not be taken as absolute, but an indication of the direction of positive vs negative impact. As this is a qualitative exercise, quantification has not been carried out for all metrics, only those where data was sufficient e.g. economic impacts.

5. CONCLUSIONS

The intention to submit a proposal for a REACH restriction on the manufacture, placing on the market and use of PFAS was identified by EFCTC as being potentially significantly impactful for the F-gas sector. These impacts provide justification for this RMOA, in order to identify whether or not there are potentially more proportional regulatory management options that could address the concerns.

This RMOA identified two main concerns that require attention, the global warming potential of F-gases and the generation of the persistent degradation product, TFA. Following a review of publicly available data and a consultation of manufacturers, importers and downstream users of F-gases it has been confirmed that F-gases are currently essential for meeting multiple societal needs. This includes, but is not limited to, the production, distribution and storage of food; industrial processes; building safety, delivery of medicinal products, and meeting climate goals through energy efficiency.

It has been found that chemical and non-chemical alternatives exist for a number of F-gas applications but that there are limited to no drop-in alternatives for existing systems, which may result in significant costs associated with their use (e.g. higher operating costs due to their performance inefficiencies), including the need to entirely change systems which currently operate on F-gases and require e.g. higher operating pressures when using alternatives. Some of the potential alternatives are also hazardous, be that physical, human health or environmental, whilst others have concerns related to their breakdown products.

A Regulatory Management Option Analysis has been performed to identify proportional regulatory management options that seek to address the concerns related the manufacture, use and end-of-life treatment of F-gases. This assessment should identify the best option, or combination of options, that shall ensure a high-level of protection to human health and the environment, whilst maintaining EU competitiveness and the functioning of society. There are already regulatory requirements for the reduction in use of F-gases and the move to alternatives, forming the baseline regulatory context, and this was taken into consideration when identifying and assessing the potential RMOs.

The analysis has concluded that there is no single RMO that would effectively address the concerns related to the lifecycle of F-gases. As such, it is suggested that a combination of measures could be the most proportionate way forward:

- RMO 4 – Regulatory proposal for amendment of F-gas Regulation
- RMO 5 – Refrigerant Management Plan under the Food, Drink and Milk Industries BREF
- RMO 6 – Substitution (industry initiative)

RMO 1 – substance evaluation, is considered to be a separate but complimentary RMO which could produce valuable evidence for further regulatory management considerations, should a concern be identified under REACH. In order to address concerns related to GWP and the TFA degradation product, the analysis suggests a combination of RMO 4, 5 and 6 would be the most proportionate option. RMO 4 is the overarching measure that would address the production, use and end-of-life treatment of the F-gases in scope. It further strengthens the current F-gas Regulation and so seeks to bring about greater control and reduction in emissions of F-gases, whilst ensuring that key initiatives, such as REPowerEU, are not compromised. It is noted that further amendments could be made to the F-gas Regulation to enhance the current proposal, although this is outside of the scope of this assessment. RMO 5 is a complimentary measure, in that it supports the actions under the proposed amendment to the F-gas Regulation, increasing regulatory pressure to reduce emissions and move to lower GWP refrigerants. The combination of the three RMOs may see a move to non-fluorinated refrigerants within a timeline that is feasible for industry and as such, may not place undue burden on industry or regulators, although it should be acknowledged that the supply of alternative refrigerants is unlikely to be able to demand and so further R&D would be needed. RMO 6 relies on industry efforts to substitute F-gases for alternatives. As noted in the assessment, there are a number of drivers for substitution and regulatory pressure is only going to increase. Should industry invest in R&D to find alternatives and make the switch early enough, there may be a first mover advantage and potential mitigation of the costs associated with innovation. By combining RMO 6 with RMO 4 and 5, it may be possible for the reduction in manufacture and use of F-gases to be reduced faster than is legally required under the F-gas Regulation phase-down. It must be noted that substitution should not be rushed as this increases the chances of regrettable substitution, but that increased investment early on could be beneficial overall.

RMO 2 – REACH restriction of PFAS, has been found to be effective at reducing risk yet concerns remain regarding the practicability of enforcement, implementation, and consistency which reflects in the lower overall score for proportionality. When combined with the economic impacts, this raises questions over the potential overall negative impacts from its implementation. RMO 3 – REACH authorisation, is marginally more proportional but neither have been identified as appropriate regulatory management options to address the concerns.

As F-gases are so key to the functioning of society at present, it is recommended that further evaluation is carried out to assess the proportionality of the REACH restriction proposal to ensure that an undue burden is not placed on industry, regulators or wider society.

Appendices

APPENDIX A ANALYSIS OF ALTERNATIVES

A1 INTRODUCTION

The purpose of this section is to conduct a thorough assessment of alternatives to evaluate the options available for replacing F-gases, in order to make informed decision-making. The assessment evaluates each identified alternative based on a range of criteria, including risk to human and environmental health, technical feasibility, economic feasibility, performance, and life-cycle aspects. The assessment doesn't aim to identify the "best" alternatives, but rather present a list of potential alternatives that warrant consideration by companies seeking to phase out F-gases.

A2 SCOPING AND PROBLEM FORMULATION

The first step of an alternatives assessment is the scoping phase, which involves determining the goals, principles, and decision rules that will guide the assessment. This is an important step as an assessment of alternatives is not based purely on technical, economic, and hazard considerations. Decisions can also be driven by organisational values and regulatory context, so the goals, principles, and decision rules should be explicitly stated to give transparency on how these influenced the resolution of trade-offs and the conclusions and recommendations of the assessment. Thorough documentation also allows the outcomes of the assessment to be looked at critically and compared to the outcomes of any subsequent assessments³⁸⁷.

The goal of the assessment was to identify less hazardous and technically and economically feasible alternatives to the F-gases in scope, to aid in the identification of the most suitable RMO. This goal reflects the background and motivation for conducting the study and is consistent with that of many alternatives assessment frameworks, such as those developed by BizNGO³⁸⁸, Interstate Chemicals Clearinghouse³⁸⁹, ECHA³⁹⁰, the National Research Council³⁹¹.

There are several possible frameworks available to guide and assessment of alternatives, which vary in their methodology, scope, and complexity. Whilst some are designed to facilitate a quick assessment, others are designed to allow a detailed and exhaustive analysis requiring extensive data collection. An example is ECHA's guidance for performing an analysis of alternatives, within the context of an application for authorisation. As the assessment involved a high-level analysis, the methodology was not explicitly based on ECHA's guidance, and instead various other frameworks, such as those mentioned above, were consulted.

The Commons Principles for Alternatives Assessment were selected for use in this study. These were developed by the Lowell Center for Sustainable Production, the Massachusetts Toxics Use Reduction Institute, the Environmental Defense Fund, and the BizNGO Working Group, with the intention of guiding a process for well informed decision making that supports successful phase out of hazardous products, phase in of safer substitutes, and elimination of hazardous chemicals, where possible³⁹².

Table A 1 The Commons Principles for Alternatives Assessment

Principle	Description
Reduce Hazard	Reduce the hazard by replacing a chemical of concern with a less hazardous alternative. This approach provides an effective means to reduce risk associated with a product or process

³⁸⁷ National Research Council (2014) A Framework to Guide Selection of Chemical Alternatives – Chapter 4, Scoping, Problem Formulation, and Identifying Alternatives. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK253966/>

³⁸⁸ BizNGO (2013) The Commons Principles for Alternatives Assessment – Addressing Chemicals of Concern to Human Health or the Environment. Available at: https://www.bizngo.org/static/ee_images/uploads/resources/commons_principles_AA_2013_10_14.pdf

³⁸⁹ Interstate Chemicals Clearinghouse (2017) Alternatives Assessment Guide – Version 1.1. Available at: http://theic2.org/article/download-pdf/file_name/IC2_AA_Guide_Version_1.1.pdf

³⁹⁰ ECHA (2021) Guidance on the preparation of an application for authorisation. Available at: https://echa.europa.eu/documents/10162/13643/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7

³⁹¹ Ibid footnote 387

³⁹² BizNGO (2013) The Commons Principles for Alternatives Assessment – Addressing Chemicals of Concern to Human Health or the Environment. Available at: https://www.bizngo.org/static/ee_images/uploads/resources/commons_principles_AA_2013_10_14.pdf

Principle	Description
Minimise Exposure	Assessment of use patterns and exposure pathways to limit exposure to alternatives that may also present risks.
Use Best Available Information	Obtain access to and use information that assists in distinguishing between possible choices. Before selecting the preferred option(s), the product and process(es) are characterised sufficiently to avoid choosing alternatives that may result in unintended adverse consequences.
Disclosure and Transparency	Requires disclosure across the supply chain regarding key chemical and technical information. Engage stakeholders throughout the assessment process to promote transparency in regard to the alternatives assessment methodologies employed, the data used to characterise alternatives, assumptions made and the decision-making rules applied.
Resolve Trade-offs	Use information about the product's life cycle to better understand potential benefits, impacts, and mitigation options associated with different alternatives. When substitution options do not provide a clearly preferable solution, organizational goals and values to determine appropriate weighting of decision criteria should be considered and acceptable trade-offs identified.

The decision rules of the assessment build on the goal and principles detailed above, which were developed based on a review of decision rules in alternatives assessment frameworks and expert judgement of the study team. These included rules to help streamline the assessment by reducing the number of alternatives that were evaluated in detail, such as alternatives with hazard classifications subject to existing and future regulatory controls and substances that present a risk to vulnerable populations. The decision rules also determined how missing data would be handled and the priorities when considering trade-offs across different aspects of the assessment. The decisions rules were as follows:

- Avoid chemicals with certain inherent hazard characteristics (i.e. high GWP (>150 according to AR6), hazard classifications meeting SVHC criteria, substances considered most harmful under the Chemicals Strategy for Sustainability (CSS))
- Avoid alternatives that might impact vulnerable populations, such as children and pregnant women.
- Neutral weighting of alternatives where there are critical data gaps
- Avoid options that do not meet the specific performance criteria
- Negatively weight alternatives that are not widely available.

This step also involves the formulation of the problem, including characterisation of the chemical(s) of concern, which consisted of a description of the technical function performed by the chemicals of concern and their applications. Knowledge of the technical function allows an understanding of how and why the chemical of concern is used³⁹³. This is important for understanding the potential hazards and exposure, as well as whether non-chemical (i.e. material) alternatives, such as process or product redesign can be considered. A focus on function can also highlight whether the chemical of concern's use is necessary for achieving product

³⁹³ National Research Council (2014) A Framework to Guide Selection of Chemical Alternatives – Chapter 4, Scoping, Problem Formulation, and Identifying Alternatives. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK253966/>

performance. If it's not necessary, it might be possible to remove the chemical of concern without substituting it for an alternative.

Another advantage of considering both technical function and application/intended use, and distinguishing between the two, is that it helps to identify appropriate alternatives. For example, whilst a flammable substance fulfilling the same function as the alternative could be considered acceptable at first glance, if the application demands stringent safety standards, then it would be deemed unacceptable.

The list of F-gas functions and applications was obtained (see Table A-2 from literature and expert judgement preceding the socio-economic analysis of the value of F-gases³⁹⁴).

Table A 2 F-gas functions and applications

F-Gas Function	F-Gas Application
Refrigerant Gas	Mobile Air Conditioning
	Industrial Refrigeration
	Transport Refrigeration
	Domestic Refrigeration
	Commercial Refrigeration - Hermetically Sealed Standalone Units
	Commercial Refrigeration – Condensing Units
	Commercial Refrigeration – Centralised Systems
	Moveable Room Air Conditioning
	Stationary Air Conditioning: Single Split Systems
	Stationary Air Conditioning: Multi Split Systems
	Chillers
	Heat Pumps
	Industrial Heat Pumps & Power Generation
Foam Blowing Agent	Foam Insulation – Refrigeration
	Foam Insulation - Construction
Cover Gas	Magnesium Die Casting
Propellant	Metered Dose Inhalers (MDIs)
	Technical Aerosols (i.e. Dusters, Cleaners, Pesticides)
	Consumer Aerosols (i.e. Personal Care Products, Spray Paint, Food Dispensing Products, Propellants, Household Aerosols)
Solvent	Metal Degreasing in Optics and Electronics
Fire Suppressant	Clean Agent Fire Suppression Systems

³⁹⁴ See Socio-Economic Analysis of the Value of F-Gases – Draft Final Report.

A3 IDENTIFYING ALTERNATIVES

A3.1 METHODOLOGY

The next step in the assessment was to identify potential chemical, material, and design alternatives, based on the requirements established during the scoping and problem formulation. A list of alternatives to be evaluated was obtained through the desk-based research and consultation with industrial stakeholders. The alternatives were separated into two categories: 1) chemical alternatives, where the function performed by the F-gas is being replaced with a different chemical substance; 2) non-chemical alternatives, where the function performed by the F-gas is being replaced with a different technology or product whose function does not rely on a particular chemical substance.

An initial screening was undertaken to remove any potential alternatives that clearly were not suitable. This involved excluding any alternatives that were included on regulatory lists either restricting or prohibiting a substance's use. This included:

- REACH Annex XIV – Authorisation List
- REACH Annex XVII Restrictions
- EU POPs Regulation – Annex I & Annex II
- Stockholm Convention – Annex A & Annex B

A3.2 RESULTS

Following the literature review and consultation with industry, potential alternatives were identified for each of the applications in scope. The full list of identified potential chemical alternatives to the substances of concern (see Section 1.2) for each application is provided in Table A 3, which includes all possible alternatives identified in the literature review and stakeholder consultation. The highest number of alternatives were identified for the F-gases used as refrigerants and foam blowing agents, while very few alternatives were identified for F-gases used in MDIs and fire suppression systems, which suggests they are areas warranting further research efforts.

Several decision rules are set out (see Appendix Section A2) to help streamline the assessment by reducing the number of alternatives that were evaluated in detail. One of these rules was the exclusion of chemicals with certain hazard characteristics or environmental concerns, including high GWP. The decision rule for exclusion of HFCs with a GWP above 150 uses the GWP values of AR6. HFC-152a met this exclusion criteria because of its GWP of 164 (according to AR6). Therefore, its inclusion in the detailed assessment would contradict the decision rules. However, HFC-152a would be a viable alternative for certain applications within the scope of this study should AR4 GWP values be used, and on which the current F-gas Regulation is based, as the AR4 GWP value is 124 and is therefore not subject to any use restrictions under the Regulation. Under such an exclusion criterion, it would constitute an alternative for certain applications including MDIs.

Table A 3 Chemical alternatives identified for the F-gases in scope through literature review and stakeholder consultation.

Alternative	Refrigerant	Blowing Agent	Cover Gas	MDI	Aerosols	Fire Suppressant	Solvent
[product name]							
Air							
Ammonia							
Argon							
Boron trifluoride							
Butane							
Carbon dioxide							
Cyclopentane							
Di-methyl ether							
Heptane							
Hexane							
HFC-152a							
HFC-32							
HFE-347pcf2							
HFE-7000							

Alternative	Refrigerant	Blowing Agent	Cover Gas	MDI	Aerosols	Fire Suppressant	Solvent
HFE-7100							
HFE-7200							
Isobutane							
Isopentane							
Methoxytridecafluoroheptene (MPHE)							
Methyl formate							
Methylal							
Nitrogen							
Nitrous oxide							
[product name]/1230							
[product name]							
Pentane							
Propane							
Propylene							
[product name]							
Sulfur dioxide							
Sulfuryl fluoride							
Water							

None of the identified chemical alternatives were excluded from further analysis based on their regulatory status. In addition, a large number of material and design (non-chemical) alternatives were identified, primarily through literature review (see Table A 4).

Table A 4 Material and design alternatives to the F-gases in scope identified through literature review and stakeholder consultation.

Alternative	RACHP	Blowing Agent	Cover Gas	MDI	Aerosols	Fire Suppressant	Solvent
Absorption Heat Pump							
Adsorption Heat Pump							
Brayton Heat Pump							
Duplex-Stirling Heat Pump							
Ejector Heat Pump							
Evaporative Cooling							
Evaporative Liquid Desiccant Air Conditioner							
Ground-Coupled Solid Desiccant Air Conditioner							
Magnetocaloric							
Membrane Heat Pump							
Standalone Liquid Desiccant Air Conditioner							
Standalone Solid Desiccant Air Conditioner							
Thermoacoustic							
Thermoelastic							
Thermoelectric							
Thermotunneling							
Vuilleumier Heat Pump							
Aerogel							
Cellulose							
Cork							
Cotton							
Expanded clay							
Fibreglass							
Flax							
Foam concrete							
Foamed glass							
GEOLYTH							

Alternative	RACHP	Blowing Agent	Cover Gas	MDI	Aerosols	Fire Suppressant	Solvent
Hemp							
Mineral fibres							
Perlite							
Reeds							
Sheep's wool							
Straw bales							
Vermiculite							
Wood fibres							
Dry Powder Inhalers							
Nebuliser							
Soft-mist inhaler							
Bag-in-can/piston-can systems							
Finger pumps							
Non-spray products							
Powders							
Roll-on liquids / sticks							
Squeeze bottles							
Plasma cleaning							
PurgoSpray							
Supercritical fluids							

A4 RISK ASSESSMENT

The risk assessment involves two components, a hazard assessment and an exposure assessment. The goal of the hazard assessment is to identify safer chemicals and to avoid regrettable substitution, which is where the chemical of concern is replaced with a chemical that is also unsuitable because of hazard concerns for human health and/or the environment. This is a key step in the analysis of alternatives and involves an assessment of human health hazards, environmental hazards, and physical hazards. This allows the types of adverse effects that can potentially be caused by exposure to an alternative and characterises the quality of evidence available on a substance's physicochemical properties. The goal of the exposure assessment is to determine whether the predicted exposure of an alternative is equivalent or greater than that of the chemicals of concern, which is key to understanding the overall safety of alternatives. By combining information on the hazards of each alternative with their estimated exposure, its risk to human health and the environment from their use can be determined.

A4.1 HAZARD ASSESSMENT – METHODOLOGY

Information on the endpoints listed in Table A 5 were collected for each identified alternative and included in the hazard assessment.

Table A 5 Hazard endpoints included in the hazard assessment.

Hazard Category	Hazard Endpoint
Human Health Toxicity	Acute toxicity
	Repeated dose/specific target organ toxicity
	Eye/skin corrosion/irritation
	Skin sensitization
	Neurotoxicity
	Chronic Toxicity/Repeated Dose Toxicity
	Carcinogenicity
	Mutagenicity/Genotoxicity
	Reproductive Toxicity
	Developmental Toxicity

Hazard Category	Hazard Endpoint
	Endocrine Activity Respiratory Sensitization
Ecotoxicity	Aquatic toxicity Other ecotoxicity (avian, bees, terrestrial, etc.)
Environmental fate/transport	Persistence Bioaccumulation Mobility
Physical/Safety Hazards	Corrosivity Flammability Reactivity Explosivity Oxidizing properties Pyrophoric properties

The primary information source for obtaining information on hazard classifications was ECHA's Classification and Labelling Inventory (CLI) database³⁹⁵. Following the use of the CLI, the OECD's eChemPortal³⁹⁶ and the U.S. National Institute of Health's Hazardous Substances Database (HSDB)³⁹⁷ and Chem ID Plus³⁹⁸ databases were used to fill any remaining data gaps.

To investigate hazards not currently included under GHS and recently introduced to EU CLP (i.e. endocrine disruption, persistence, mobility, and bioaccumulation), the following authoritative and non-authoritative lists were also utilised:

- European Union Priority List of Suspected Endocrine Disruptors³⁹⁹
- ECHA's PBT assessment list⁴⁰⁰
- ECHA's list of PBT/vPvB assessments under the previous EU chemicals legislation⁴⁰¹
- US EPA's Priority PBTs⁴⁰²
- Oregon Department of Environmental Quality (OR DEQ) Priority Persistent Pollutants⁴⁰³
- ChemSec SIN List⁴⁰⁴
- UNEP Stockholm Convention – Persistent Organic Pollutants⁴⁰⁵
- TEDX – Potential Endocrine Disruptors⁴⁰⁶

The column model approach was selected for the hazard assessment because it allows a quick comparison of alternatives and relies on information that is easily accessible. This method was designed by the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA)⁴⁰⁷ as a tool for German companies to identify potential alternative substances and meet the requirement under the German Hazardous Substances Ordinance to replace hazardous substances with those with lower health risks.

³⁹⁵ See: <https://echa.europa.eu/information-on-chemicals/cli-inventory-database>

³⁹⁶ See: <https://www.echemportal.org/echemportal/>

³⁹⁷ See: <https://pubchem.ncbi.nlm.nih.gov/source/11933>

³⁹⁸ See: <https://pubchem.ncbi.nlm.nih.gov/source/ChemIDplus>

³⁹⁹ https://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#priority_list

⁴⁰⁰ <https://echa.europa.eu/pbt>

⁴⁰¹ <https://echa.europa.eu/information-on-chemicals/pbt-vpnb-assessments-under-the-previous-eu-chemicals-legislation>

⁴⁰² <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals>

⁴⁰³ <https://pharosproject.net/hazard-lists/54>

⁴⁰⁴ <https://sinlist.chemsec.org/>

⁴⁰⁵ <http://chm.pops.int/TheConvention/ThePOPs/ListingofPOPs/tabid/2509/Default.aspx>

⁴⁰⁶ <https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/search-the-tedx-list>

⁴⁰⁷ IFA (2020) The GHS Column Model as an aid to selecting substitute substances. Available at: <https://www.dguv.de/ifa/praxishilfen/hazardous-substances/ghs-spaltenmodell-zur-substitutionspruefung/index.jsp>

Under this approach, alternatives are assigned into one of five hazard levels (negligible hazard, low hazard, medium hazard, high hazard, very high hazard), based on their hazard classification, for human health and environmental hazard categories. Physical hazards were assessed but a quantitative score was not used in the hazard assessment. This is because of the difficulty in assigning a risk score to a physical hazard classification based on exposure, as, for example, exposure to a highly flammable gas does not necessarily lead to adverse health effects. However, flammability is noted within the technical feasibility and final comparison of alternatives.

These levels were assigned a numerical score from 1 (negligible hazard) to 5 (very high hazard) to allow the output to be integrating into the final comparative assessment (see Section A9).

The hazard assessment acted as an early screening exercise to eliminate alternatives from further consideration if they exhibited certain hazard endpoints that are subject to current or future regulatory action. This included alternatives meeting any of the following criteria for classification as a Substance of Very High Concern (SVHC), as listed under Article 57 of the REACH Regulation⁴⁰⁸:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with Regulation (EC) No 1272/2008 (CLP Regulation)⁴⁰⁹
- Substances which are persistent, bio-accumulative, and toxic (PBT) in accordance with the criteria set out in Annex XIII of the REACH Regulation
- Substances which are very persistent and very bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation
- Substances giving rise to an equivalent level of concern to substances meeting the above criteria, such as substances having, or suspected of having, endocrine disrupting properties, or substances that do not meet the criteria for being a CMR, PBT, or vPvB, but for which there is scientific evidence of probable serious effects to human health or the environment

A hazard assessment was also performed for each of the F-gases in scope of the study. This allowed the hazard score for each alternative to be compared against the chemical for which it was a substitute, and enabled alternatives with hazards of greater severity to be identified. For alternatives with hazards of greater severity, but which do not meet any of the SVHC criteria, the subsequent exposure assessment (see Section A4.3) is important to understand the relevance of these hazards and whether it will contribute to a greater overall risk. Similarly for alternatives with hazards of lower severity, the overall risk may still have been equivalent or greater depending on the outcome of the exposure assessment.

The hazard assessment focused on the hazards of the alternatives themselves and did not extend to any degradation products that may resulting from an alternatives environmental fate. These can sometimes present concerns to human health and the environment and need to be considered when selecting an alternative. Concerns surrounding breakdown products are discussed in Sections 4.2.8.2 and 4.2.8.3 where the human health and environmental impacts of each RMO are assessed.

A4.2 HAZARD ASSESSMENT – RESULTS

The primary concern surrounding F-gases is their GWP, as they typically have low toxicity, with seven of the eight F-gases in scope (HFC-125, HFC-134a, HFC-143a, HFC-227ea, HFO-1234yf, HFO-1234ze, and HFO-1336mzz) having the lowest level of human and environmental hazards (see table below).

Table A 6 Human health and environmental hazard scores for the eight F-gases in scope.

F-Gas	HH Hazards under CLP	HH Hazard Level	ENV Hazards under CLP	ENV Hazard Level
HFC-125	None	1	None	1
HFC-134a	None	1	None	1
HFC-143a	None	1	None	1

⁴⁰⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20221217>

⁴⁰⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20221217>

F-Gas	HH Hazards under CLP	HH Hazard Level	ENV Hazards under CLP	ENV Hazard Level
HFC-227ea	None	1	None	1
HFO-1234yf	None	1	None	1
HFO-1234ze(E)	None	1	None	1
HCFO-1233zd(Z)	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3	2	Aquatic Chronic 3	3
HFO-1336mzz(E)	None	1	None	1

Due to the low levels of human and environmental hazard of the F-gases within in scope, the majority of the identified alternatives were of equal or higher hazard. This was expected as hazards to human health and the environment were not the motivation for performing this alternatives assessment. Consequently, alternatives were not excluded from further analysis at this stage, unless they met the criteria for classification as an SVHC or a PFAS substance. Table A7 compares the human health and environmental hazard levels of each identified alternative to the F-gases for which they are potential alternatives.

Table A 7 Human health and environmental hazard scores of alternatives

Alternative	HH Hazards under CLP	HH Hazard Level	Compared to Chemical of Concern	ENV Hazards under CLP	ENV Hazard Level	Compared to Chemical of Concern
Isobutane	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
Butane	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
Propane	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
Methylal	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
Argon	None	1	Equal Hazard	None	1	Equal Hazard
Water	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
Air	None	1	Equal Hazard	None	1	Equal Hazard
HFE-7000	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
HFE-7100	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
Propylene	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
HFC-32	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
HFC-152a	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
[product name]	None	1	Lower / Equal Hazard	Aquatic Chronic 4	2	Lower / High Hazard
Cyclopentane	None	1	Lower / Equal Hazard	Aquatic Chronic 3	3	Equal / Higher Hazard
[product name]/1230	None	1	Equal Hazard	Aquatic Chronic 3	3	Higher Hazard
MPHE	None	1	Lower / Equal Hazard	None	3	Equal / Higher Hazard

Alternative	HH Hazards under CLP	HH Hazard Level	Compared to Chemical of Concern	ENV Hazards under CLP	ENV Hazard Level	Compared to Chemical of Concern
[product name]	None	1	Lower / Equal Hazard	None	1	Lower / Equal Hazard
Di-methyl ether	None	1	Lower / Equal Hazard	None	5	Higher Hazard
Nitrous oxide	STOT SE 3	2	Higher Hazard	None	1	Equal Hazard
HFE-347pcf2	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3	2	Lower / Equal Hazard	None	1	Lower / Equal Hazard
[product name]	Skin Corr. 3; Eye Dam. 2B STOT SE 3	2	Lower / Equal Hazard	Aquatic Acute 3 Aquatic Chronic 3	3	Equal / Higher Hazard
Isopentane	Asp. Tox. 1 STOT SE 3	2	Lower / Equal Hazard	Aquatic Chronic 2	4	Higher Hazard
Pentane	Asp. Tox. 1 STOT SE 3	2	Lower / Equal Hazard	Aquatic Chronic 2	4	Higher Hazard
Heptane	Skin Irrit. 2 Asp. Tox. 1 STOT SE 3	2	Lower / Equal Hazard	Aquatic Acute 1 Aquatic Chronic 1	5	Higher Hazard
Methyl formate	Eye Irrit. 2 Acute Tox. 4 STOT SE 3	3	Higher Hazard	Aquatic Chronic 2	1	Lower / Equal Hazard
Carbon dioxide	None	3	Higher Hazard	None	1	Lower / Equal Hazard
Nitrogen	None	3	Higher Hazard	None	1	Lower / Equal Hazard
Hexane	Skin Irrit. 2 Asp. Tox. 1 STOT SE 3 STOT RE 2 Repr. 2	3	Higher Hazard	Aquatic Chronic 2	3	Equal / Higher Hazard
HFE-7200	None	3	Higher Hazard	None	3	Equal / Higher Hazard

Alternative	HH Hazards under CLP	HH Hazard Level	Compared to Chemical of Concern	ENV Hazards under CLP	ENV Hazard Level	Compared to Chemical of Concern
Sulphur dioxide	Skin Corr. 1B Acute Tox. 3	4	Higher Hazard	None	1	Equal Hazard
Sulfuryl fluoride	Acute Tox. 3 STOT RE 2	4	Higher Hazard	Aquatic Acute 1	4	Higher Hazard
Ammonia	Skin Corr. 1B Acute Tox. 3	4	Higher Hazard	Aquatic Acute 1	5	Higher Hazard
Boron trifluoride	Skin Corr. 1A Acute Tox. 2	5	Higher Hazard	None	1	Equal Hazard

Several of the alternatives listed in the table above are considered PFAS and are listed on the US EPA's Master List of PFAS Substances⁴¹⁰. This includes [product name] (CAS 756-13-8), [product name] (CAS 297730-93-9), HFE-7000 (CAS 375-03-1), HFE-7100 (CAS 163702-07-6), HFE-7200 (CAS 163702-05-4), and HFE-347pcf2 (CAS 406-78-0). Despite the adverse human and environmental health impacts associated with PFAS and the global regulatory pressure surrounding this group of substances, these alternatives were included in the analysis because under the baseline scenario (i.e. in the absence of an EU-wide PFAS restriction) these substances are allowed to be used.

However, PFAS substances will not be considered acceptable under RMO2 (REACH Restriction), unless they are alternatives for applications for which a derogation is not proposed in the PFAS Annex XV report⁴¹¹. Applications for which these substances are alternatives which have received a potential derogation include fire suppressants and cleaning fluids / solvents. Conversely, PFAS alternative could be considered acceptable under the other RMOs that have been proposed in Section 4.2. Table XX in Section 4.2 illustrates the chemical alternatives deemed to be acceptable under this analysis that could be used under each RMO.

There were also a number of alternative F-gases identified through the consultation. These include HFC-32, HFC-152a, [product name], and [product name], the GWPs of which are shown in the table below.

Table A 8 Alternative F-gases and their GWP values

Alternative	GWP
HFC-32	771 ⁴¹²
HFC-152a	164 ⁴¹³
[product name]	148 ⁴¹⁴
[product name]	< 2.5 ⁴¹⁵

Based on their GWP values, all F-gases except for [product name] and [product name] were excluded from further analysis. This is because they are much greater than the GWPs of the HFOs in scope of this study, and the primary reasons for further regulating F-gas use is the environmental impacts from their GWP. Therefore, F-gases with a high GWP cannot be considered potential alternatives. However, it should be noted that high GWP F-gases can be mixed with low GWP F-gases to produce a blend with a low overall GWP. It may be possible to derive suitable alternatives using this approach, but blends were excluded from the scope of this study due to the large number of possible blends that would need to be considered.

A4.3 EXPOSURE ASSESSMENT – METHODOLOGY

This assessment sought to determine the potential for reduced or greater exposure based on the inherent physicochemical properties of the alternatives, levels of expected exposure, the routes of human exposure (dermal, oral, inhalation), and the environmental compartments (i.e. air, water, and soil/sediment) into which the chemicals will partition. This approach was taken, rather than developing exposure scenarios, as this requires information on risk management measures and controls taken by manufacturers and downstream users to control exposure, which it was not possible to collect as part of the study.

To obtain physicochemical information, an extensive literature review was performed covering the following databases:

⁴¹⁰ US EPA (2023) Master List of PFAS Substances. Available at: <https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster>

⁴¹¹ ECHA (2023) Annex XV Restriction: Report Proposal for a Restriction - Per- and polyfluoroalkyl substances (PFASs). Available at: <https://echa.europa.eu/documents/10162/1c480180-ec9-1bdd-1eb8-0f3f8e7c0c49>

⁴¹² IPCC (2021) AR6 WGI Report. Available at: https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_Chapter_07_Supplementary_Material.pdf

⁴¹³ IPCC (2021) AR6 WGI Report. Available at: https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_Chapter_07_Supplementary_Material.pdf

⁴¹⁴ Honeywell (2023) [product name]: Technical Data Sheet.

⁴¹⁵ Opteon (n.d.) [product name].

- ECHA Registered Substances Database⁴¹⁶
- OECD eChemPortal⁴¹⁷
- Hazardous Substances Data Bank⁴¹⁸
- U.S. EPA Comptox Dashboard⁴¹⁹
- Chem ID Plus⁴²⁰
- Google Scholar

A4.3.1 POTENTIAL FOR EXPOSURE

Methodology

The assessment considered the environmental, occupational, and public health exposure potentials. The potential for exposure was estimated as being either much lower than, lower than, equal to, greater than, or much greater than the exposure potential of the chemical of concern for three human exposure routes (dermal, oral, inhalation) and three environmental compartments (air, water, soil/sediment). The human exposure assessment was based on a comparison of chemical state and volatility of the alternative and chemical of concern, while the environmental assessment was based on a comparison of chemical state, volatility, water solubility, and Henry's law constant. The scores for the three human and three environmental exposure routes were averaged to produce a single score, thus, three scores were calculated for environmental, occupational, and public health. These were assigned a numerical value from 1 (much lower potential exposure) to 5 (much greater potential exposure), which were averaged to produce an overall numerical exposure score.

Table 5-1 Assessment of potential for environmental exposure for ammonia compared to the F-gases in scope

Environmental Compartment	Potential for Exposure Compared to F-Gas	Rationale
Exposure to air	Less than (Score: 2)	Gaseous state and higher VP, but lower Henry's law constant
Exposure water	Greater than (Score: 4)	Gaseous state, higher VP, and lower water solubility (still soluble), but lower Henry's constant
Exposure to soil/sediment	Greater than (Score: 4)	Gaseous state, higher VP, lower water solubility, but lower Henry's law constant
Overall Score	Equal to (Score: 3) *	

* Average of scores for three compartments rounded to nearest integer

Table 5-2 Assessment of potential for human exposure for ammonia compared to the F-gases in scope

Environmental Compartment	Potential for Exposure Compared to F-Gas	Rationale
Inhalation exposure	Much greater than (Score: 5)	Gaseous state and higher VP
Ingestion exposure	Much greater than (Score: 5)	Gaseous state and higher VP

⁴¹⁶ ECHA (2023) Registered substances. Available at: <https://echa.europa.eu/information-on-chemicals/registered-substances>

⁴¹⁷ OECD (2023) eChemPortal. Available at: <https://www.echemportal.org/echemportal/>

⁴¹⁸ US National Library of Medicine (2023) Hazardous Substances Data Bank (HSDB). Available at: <https://pubchem.ncbi.nlm.nih.gov/source/11933>

⁴¹⁹ US EPA (2023) CompTox Chemicals Dashboard. Available at: <https://comptox.epa.gov/dashboard/>

⁴²⁰ US National Library of Medicine (2023) ChemIDplus. Available at: <https://pubchem.ncbi.nlm.nih.gov/source/ChemIDplus>

Environmental Compartment	Potential for Exposure Compared to F-Gas	Rationale
Dermal exposure	Much greater than (Score: 5)	Gaseous state and higher VP. Meets classification for Skin Corrosion Cat. 1B under CLP
Overall Score	Much greater than (Score: 5) *	

*Average of scores for three exposure route rounded to nearest integer

Results

Table 5-3 Results of assessment of potential for exposure for each alternative

Alternative	Air Exposure	Water Exposure	Soil / Sediment Exposure	Average Score	Inhalation Exposure	Ingestion Exposure	Dermal Exposure	Average Score
Isobutane	2	1	4	2	1	1	1	1
Butane	5	1	4	3	5	5	5	5
Propane	5	1	4	3	5	5	5	5
Methylal	1	5	5	4	1	5	5	4
Argon	5	1	1	2	5	5	5	5
Water	1	5	5	4	1	5	5	4
Air	-	-	-	3	5	5	5	5
HFE-7000	-	-	-	3	2	2	2	2
HFE-7100	5	1	5	4	1	1	1	1
Propylene	5	1	4	3	5	5	5	5
[product name]	5	1	5	4	1	1	1	1
Cyclopentane	1	5	5	4	5	1	1	2
[product name]/1230	1	5	5	4	1	5	5	4
MPHE	-	-	-	3	-	-	-	3
[product name]	-	-	-	3	-	-	-	3
Di-methyl ether	4	4	1	3	5	5	5	5
Nitrous oxide	5	4	1	3	5	5	5	5
HFE-347pcf2	-	-	-	3	2	2	2	2
[product name]	1	5	5	4	2	2	2	2
Isopentane	1	4	5	3	1	5	5	4
Pentane	1	5	5	4	5	1	1	2
Heptane	5	1	5	4	1	1	1	1
Methyl formate	1	5	5	4	1	5	5	4
Carbon dioxide	5	4	4	4	5	5	5	5
Nitrogen	5	3	1	3	5	5	5	5
Hexane	5	1	5	4	1	1	1	1
HFE-7200	-	-	-	3	1	1	1	1
Sulphur dioxide	1	1	1	1	1	1	1	1
Sulfuryl fluoride	5	1	1	2	5	5	5	5
Ammonia	2	4	4	3	5	5	5	5
Boron trifluoride	5	1	1	2	5	5	5	5

Alternative	Air Exposure	Water Exposure	Soil / Sediment Exposure	Average Score	Inhalation Exposure	Ingestion Exposure	Dermal Exposure	Average Score
HFO-1234ze(E)	1	1	5	2	1	1	1	1

A4.3.2 LIKELIHOOD OF EXPOSURE

To account for the effect of physical and administrative controls for reducing exposure, such as operational controls and risk management measures, the likelihood for exposure was assessed, based on the manufacturing process, use patterns, and end-of-life processes of the specific applications. This was also scored from 1 to 5, with 1 denoting very low likelihood of exposure and 5 denoting very high likelihood of exposure (see Table A 9). Precise information on the combination of risk management measures used and their efficiency was not available, so these were not considered in this analysis.

Table A 9 Likelihood of exposure for each F-gas application in scope.

Application	Likelihood of Human Exposure	Consumer	Occupational	Likelihood of Environmental Exposure	Exposure to air	Exposure to water	Exposure to soil/sediment
Refrigerant	1	Y	Y	2	Y	N	N
Blowing Agent	1	Y	Y	2	Y	N	N
Cover Gas	4	N	Y	5	Y	N	N
MDIs	2	Y	N	5	Y	N	N
Propellant	4	Y	Y	5	Y	N	N
Fire Suppressant	1	N	Y	5	Y	N	N
Solvent	3	N	Y	5	Y	Y	Y

Refrigeration was considered to have a low likelihood of environmental exposure to the air, based on reported leakage rates of refrigerants, which average around 10%^{421,422}, although this varies from system to system and can be as high as 30%⁴²³. Human inhalation exposure to refrigerants was considered to be lower as not all leaks will result in exposure, due to the gaseous nature and volatility of refrigerants and the enclosed nature of some refrigeration systems.

Information on the leakage rates of low-GWP HFC foam blowing agents and their alternatives is limited⁴²⁴, but are expected to be low, as the thermal conductivity of foam insulation is dependent on low emission rates. Environmental exposure to the air is most likely to occur during end-of-life, when insulation is broken up for recycling, where any remaining foam blowing agent inside the insulation will escape to the atmosphere. Inhalation exposure is also most likely to occur during end-of-life but is expected to be very low due to the volatility of F-gases and small amounts contained in insulation.

⁴²¹ Umweltbundesamt (2009) Comparative Assessment of the Climate Relevance of Supermarket Refrigeration Systems and Equipment. Available at: https://www.epa.gov/sites/default/files/documents/ubastudy_supermarkets.pdf

⁴²² Koronaki, I. P., Cowan, D., Maidment, G., Beerman, K., Schreurs, M., Kaar, K., ... & Cazauran, X. (2012). Refrigerant emissions and leakage prevention across Europe—Results from the RealSkillsEurope project. *Energy*, 45(1), 71-80.

⁴²³ Beshr, M., Aute, V., Sharma, V., Abdelaziz, O., Fricke, B., & Radermacher, R. (2015). A comparative study on the environmental impact of supermarket refrigeration systems using low GWP refrigerants. *International Journal of Refrigeration*, 56, 154-164.

⁴²⁴ Yakushin, V., Cabulis, U., Fridrihsone, V., Kravchenko, S., & Pauliks, R. (2021). Properties of polyurethane foam with fourth-generation blowing agent. *e-Polymers*, 21(1), 763-769.

Magnesium cover gas was considered to have a very high likelihood of environmental exposure, as it has been estimated that 100% of the amount of sulphur hexafluoride used in this application is emitted to the atmosphere⁴²⁵. The emissions of alternative cover gases are therefore expected to be similarly high. There was a lack of evidence on human inhalation exposure to cover gases, but based on the level of environmental emissions, the likelihood was expected to be high.

The likelihood for human inhalation exposure from use in MDIs is low, as the propellant is intended to be exhaled during proper application. Because of this use pattern, the likelihood of direct environmental exposure to the air is very high.

Due to the nature in which propellants are used, the propellant gas is emitted directly to the atmosphere, so the likelihood of environmental exposure was considered to be very high. As propellant are designed to be exhaled, the likelihood of human inhalation exposure is considered to be low.

There is extensive evidence of chemicals used in fire suppression systems making their way into local water bodies and sediment^{426,427}. On this basis, the likelihood of environmental exposure was considered to be very high. The use of personal protective equipment (PPE) is expected to reduce levels of human exposure, but there is also evidence of elevated levels of PFAS in firefighters⁴²⁸, so human exposure was considered to be moderately likely. Oral, dermal, and inhalation exposure have all been reported as possible exposure routes⁴²⁹, while exposure to water and soil/sediment are possible environmental exposure routes⁴³⁰.

Solvents were considered to have a very high likelihood of exposure as the IPCC Good Practice Guidance recommends a default emission factor of 50% of the initial solvent charge per year, while the US EPA assumes 90% of the solvent consumed annually is emitted to the atmosphere⁴³¹. Solvents can also be emitted to air, soil, and water⁴³². Although various risk management measures will reduce the likelihood of human inhalation exposure, this was still considered to be moderate based on the level of environmental emissions.

A4.3.3 COMBINED EXPOSURE SCORE

The scores for the potential and likelihood of exposure were then multiplied together in a matrix to assign an overall exposure score from 1 to 5, based on the combined score (see table below).

Table A 10 Exposure matrix

Potential for exposure	Likelihood of Exposure					
		Very Low (1)	Low (2)	Medium (3)	High (4)	Very High (5)
	Much lower (1)	1	2	3	4	5
	Lower (2)	2	4	6	8	10
	Equal (3)	3	6	9	12	15
	Greater (4)	4	8	12	16	20
	Much greater (5)	5	10	15	20	25

1-5 (dark green) = Very low exposure; 6-10 (light green) = Low exposure; 11-15 (yellow) = Medium exposure; 16-20 (orange) = High exposure; 21+ (red) = Very high exposure

⁴²⁵ Penman, J., Kruger, D., Galbally, I. E., Hiraishi, T., Nyenzi, B., Emmanuel, S., ... & Tanabe, K. (2000). Good practice guidance and uncertainty management in national greenhouse gas inventories.

⁴²⁶ De Vries, P., Slijkerman, D. M., Kwadijk, C. J., Kotterman, M. J., Posthuma, L., De Zwart, D., ... & Foekema, E. M. (2017). The toxic exposure of flamingos to per- and Polyfluoroalkyl substances (PFAS) from firefighting foam applications in Bonaire. *Marine pollution bulletin*, 124(1), 102-111.

⁴²⁷ Xu, Y., Fletcher, T., Pineda, D., Lindh, C. H., Nilsson, C., Glynn, A., ... & Li, Y. (2020). Serum half-lives for short- and long-chain perfluoroalkyl acids after ceasing exposure from drinking water contaminated by firefighting foam. *Environmental health perspectives*, 128(7), 077004.

⁴²⁸ Laitinen, J. A., Koponen, J., Koikkalainen, J., & Kiviranta, H. (2014). Firefighters' exposure to perfluoroalkyl acids and 2-butoxyethanol present in firefighting foams. *Toxicology letters*, 231(2), 227-232.

⁴²⁹ US Fire Administration (2020) The Hidden Dangers in Firefighting Foam. Available at: <https://www.usfa.fema.gov/blog/cb-021120.html>

⁴³⁰ Adams, R., & Simmons, D. (1999). Ecological effects of fire fighting foams and retardants: a summary. *Australian Forestry*, 62(4), 307-314.

⁴³¹ IPCC (2018) IPCC/TEAP Special Report: Safeguarding the Ozone Layer and the Global Climate System - Non-Medical Aerosols, Solvents, and HFC 23. Available at: <https://www.ipcc.ch/site/assets/uploads/2018/03/sroc10-1.pdf>

⁴³² Tobiszewski, M., Namieśnik, J., & Pena-Pereira, F. (2017). Environmental risk-based ranking of solvents using the combination of a multimedia model and multi-criteria decision analysis. *Green Chemistry*, 19(4), 1034-1042.

A4.4 RISK ASSESSMENT – METHODOLOGY

The output of the hazard assessment and exposure assessment were combined together to generate a risk level from 1 to 5, with 1 denoting very low risk and 5 denoting very high risk. This was done by multiplying the health score, which ranged from 1 to 5, with the exposure score, which also ranged from 1 to 5. This generated a possible score from 1 to 25. A banding approach was then taken, as highlighted in the table below.

Table A 11 Risk matrix

HH or ENV Hazard	Exposure Band					
		Very Low Exposure (1)	Low Exposure (2)	Medium Exposure (3)	High Exposure (4)	Very High Exposure (5)
	Very Low Hazard (1)	1	2	3	4	5
	Low Hazard (2)	2	4	6	8	10
	Medium Hazard (3)	3	6	9	12	15
	High Hazard (4)	4	8	12	16	20
	Very High Hazard (5)	5	10	15	20	25

1-5 (dark green) = Very low risk; 6-10 (light green) = Low risk; 11-15 (yellow) = Medium risk; 16-20 (orange) = High risk; 21+ (red) = Very high risk

This meant it could be determined whether alternatives that appeared either acceptable or unacceptable from a hazard perspective were also considered as such based on the potential and likelihood of exposure. For example, alternatives with a hazard score higher than the chemical of concern could be no longer deemed unacceptable if there is very low chance for human or environmental exposure throughout the alternative's life cycle.

A4.5 RISK ASSESSMENT - RESULTS

The F-gases included within the scope of this study all had very low human health and environmental hazards, except for HCFO-1233zd, which had low human health hazard and moderate environmental hazard. Consequently, all F-gases represented a very low risk to human health and all except HFCO-1234zd represented a very low risk to environmental health, which had a low risk.

RACHP

All of the identified alternative refrigerants (see Table A-12) represent a very low risk to human health. This is because of the very low likelihood of human exposure in this application. The likelihood of environmental exposure was considered to be higher but was still classified as low. This resulted in the majority of alternatives also being considered to represent a very low risk to environmental health.

Foam Insulation

All of the identified alternative foam blowing agents (see Table A-12) represent a very low risk to human health. This is primarily because of the very low likelihood of human exposure in this application. The risk to environmental health from the alternatives was either very low or low, which again was primarily due to the likelihood of environmental exposure being considered to be low.

Magnesium Die Casting

Application as a cover gas for magnesium die casting was considered to have a high likelihood of human exposure and a very high likelihood of environmental exposure. However, despite this, most alternatives represented a medium risk to human and environmental health or lower, because they either had low levels

of hazard or low potential for exposure when compared to the chemicals of concern being replaced. The exceptions are boron trifluoride and sulfuryl fluoride, which were classified as having a high risk.

MDIs

There were no identified alternatives for a propellant in MDIs, as HFC-152a was excluded based on its GWP being greater than 150.

Propellant

Application as a propellant in aerosols was considered to have a high likelihood of human exposure and a very high likelihood of environmental exposure. Carbon dioxide and nitrogen had a medium level of human health hazard, which equated to medium risk to human health. All other alternatives had low human health hazards and posed a low or very low risk to human health. All alternatives also posed a very low risk to environmental health because of their level of levels of environmental hazard.

Fire Suppressant

Application as a fire suppressant in firefighting was considered to have a high likelihood of human exposure and a very high likelihood of environmental exposure. However, despite this, most alternatives represented a very low, low, or medium risk to human and environmental health because they either had low levels of hazard or low potential for exposure when compared to the F-gases.

Solvent

Application as a solvent was considered to have a medium likelihood of human exposure, but a very high likelihood of environmental exposure. One alternative, heptane, was classed as having a very high level of environmental hazard, which equated to a high risk to the environment. Hexane and [product name] both had moderate environmental hazards, which equated to a moderate level of environmental risk. All other alternatives had either a very low or low risk to human health and the environment.

The individual risk scores for each alternative are presented in the tables below.

Table A 12 Human health and environmental risk scores for each identified alternative

Application	Alternative	HH Risk	Environment Risk
RACHP	Isobutane	1	1
	Propane	1	1
	Ammonia	1	2
	Carbon dioxide	1	1
	Propylene	1	1
Foam Blowing Agent	Butane	1	1
	Isobutane	1	1
	Di-methyl ether	1	1
	Methyl formate	1	1
	Isopentane	1	2
	Pentane	1	2
	Cyclopentane	1	2
	Methylal	1	1
	Carbon dioxide	1	1
	Water	1	1
Cover Gas	Boron trifluoride	4	2

Application	Alternative	HH Risk	Environment Risk
	Sulphuryl fluoride	4	2
	Sulphur dioxide	1	1
	Carbon dioxide	3	1
	Nitrogen	3	1
	Argon	1	1
	[product name]/1230	1	3
Propellant	Butane	1	1
	Isobutane	1	1
	Propane	1	1
	D-methyl ether	1	1
	Nitrous oxide	2	1
	Carbon dioxide	3	1
	Nitrogen	3	1
	Air	1	1
Fire suppressant	[product name]	1	3
	Carbon dioxide	1	1
	Water	1	1
Solvent	Heptane	2	4
	Hexane	2	3
	[product name]	2	3
	MPHE	1	2
	HFE-347pcf2	2	1
	[product name]	1	2
	HFE-7100	1	1
	HFE-7000	1	1
	HFE-7200	2	2

A5 TECHNICAL FEASIBILITY ASSESSMENT

A5.1 METHODOLOGY

The objective of the technical assessment is to determine the technical feasibility of alternatives per use and whether there are additional factors that would lead to an alternative being infeasible, whilst the objective of the performance assessment is to determine if an alternative can meet the performance requirements of the intended application. The following criteria were used for determining if an alternative is technically feasible or not.

Technical Readiness

Technical readiness was judged against three stages of development listed below, based on evidence collected during the literature review:

- 1) Stage 1: Is there a proven proof concept for the alternative?

- 2) Stage 2: Has the alternative met performance requirements with testing at/near full-size scale?
- 3) Stage 3: Is the alternative commercially available?

Availability

An alternative that may appear to be feasible may not be available in sufficient quantities to be considered a favourable alternative. This could be due to low abundance of the alternative or its feedstocks, concentration of supply in certain geographical regions, competition for supply from other sectors, or because it is cost prohibitive.

Equipment & Facilities

When determining an alternative's feasibility, it's important to consider whether the manufacturing facilities, equipment, and processes for the chemical of concern can be used for the alternative, and if not, to consider the level of adjustment required. If substitution would lead to existing equipment and processes becoming obsolete, the investment in new equipment and processes may come at a large cost to industry and impact on the competitiveness of SMEs. In some cases, the design of production plants may have been based on specific requirements of the chemical of concern, and alterations to the whole plant may be required to accommodate an alternative.

The scoring criteria outlined in the table below was used to calculate an overall technical feasibility score.

Table A 13 Technical feasibility scoring.

Technical Feasibility Aspects	Scoring Criteria	Score
Technical Readiness	Proven proof of concept	1 point
	Successfully tested at full-size scale	2 points
	Commercially available	3 points
Is the Alternative Available in Sufficient Quantities	No (strong availability concerns)	1 point
	Possible availability concerns	2 points
	Yes (no availability concerns)	3 points
Are Changes to Current Manufacturing Processes / Equipment Required?	Significant changes	1 point
	Moderate changes	2 points
	No (i.e. drop-in replacement) / minimal changes	3 points
Are Changes to the Processes / Equipment for Use Required	Significant changes	1 point
	Moderate changes	2 points
	No (i.e. drop-in replacement) / minimal changes	3 points

This meant a maximum possible score of 12 points and a minimum possible score of 4 points. The following scoring bands were then used to convert this to a 5-point scale for use in the final comparative assessment:

- 12 Points = Category 1 (Alternative commercially available and no barriers to use)
- 10-11 Points = Category 2
- 8-9 Points = Category 3
- 6-7 Points = Category 4
- 4-5 Points = Category 5 (Alternative has a low level of technical readiness and/or there are significant barriers to use)

Uncertainties

There is some uncertainty with the output of the technical assessment, as the information obtained through desk research contradicted the consultation responses from stakeholders on the technical readiness of alternatives for some applications. Where appropriate, this information was used to refine the findings from the desk research.

A5.2 RESULTS

Refrigerant

Although a high number of non-chemical alternatives were identified for refrigerants, the majority of them had low levels of technical readiness, such as thermoacoustic, thermoelastic, ejector heat pump, and membrane heat pump. However, many chemical refrigerants are commercially available and widely used, such as carbon dioxide, propane, isobutane, and ammonia. However, it should be noted that alternatives are not technically feasible for all refrigeration, air conditioning, and heating applications. Table A 18 and Table A 19 detail the specific uses for each potential alternative.

Hydrocarbon refrigerants, such as propane and isobutane, present human health risks as they are highly flammable and classed as A3 refrigerants. In some RACHP applications, their charge size is limited. For example, in domestic refrigeration the limit is 150g, while the upper charge limit for commercial refrigeration ranges from 500g to 1.5 kg depending on standards⁴³³. This means that they cannot be used in large systems, so would not be feasible for use in industrial refrigeration and large commercial refrigeration and air conditioning units. For example, the typical charges for commercial condensing units and centralised refrigeration systems are typically 1-10 kg and 20-200 kg respectively⁴³⁴, while chillers for air conditioning has charges of 20-250 kg for a small/medium system and 250-6,000kg for a large system. Other standards may also limit the use of natural refrigerants in certain applications, such as EU standard EN 12102-1⁴³⁵, which sets requirements for noise levels of heat pumps.

The occupancy and size of the room are also factors that need to be considered when using hydrocarbon refrigerants, which can act as barriers to their adoption⁴³⁶. Ammonia also presents a risk due to its toxicity, which means that its use may not be feasible in certain applications and locations and new facilities will require additional safety precautions⁴³⁷.

Foam Blowing Agent

The majority of alternatives to F-gas foam blowing agents were commercially available but many require significant changes to manufacturing systems and processes, which may pose a barrier to use. Aerogel is a high performing alternative insulation material, which is commercially available. However, because the technology is relatively new, there may be concerns related to sufficient manufacturing capacity to produce the material in large enough quantities to allow for wide-scale use. Flammable foam blowing agents may not be feasible in certain applications, such as spray and cast foams where the foams are applied on site, because of the stricter safety requirements that must be met^{438,439}. Flammable foam blowing agents are therefore not considered acceptable for spray foam applications.

Cover Gas

There were data gaps surrounding the technical readiness of some alternative cover gases, but [product name] and sulphur dioxide are both commercially available for use in cover gas systems. There was also a lack of information on the level of changes required to existing HFC-based cover gas systems to accommodate the identified alternatives, but where the data was available it indicates that either significant or moderate changes are required.

⁴³³ AREA (2019) Introduction to Refrigeration Standard EN 378. Available at: https://area-eur.be/sites/default/files/2019-07/AREA%20Introduction%20to%20EN%20378%20-%20for%20Publication_0.pdf

⁴³⁴ UNEP (2015) FACT SHEET 4 Commercial Refrigeration. Available at: https://ozone.unep.org/sites/ozone/files/Meeting_Documents/HFCs/FS_4_Commercial_Refrigeration_Oct_2015.pdf

⁴³⁵ See: <https://standardsdevelopment.bsigroup.com/projects/2021-00706#/section>

⁴³⁶ International Institute of Refrigeration (2022) Hydrocarbon refrigerants. Available at: <https://iifir.org/en/encyclopedia-of-refrigeration/hydrocarbon-refrigerants>

⁴³⁷ Refcom (2016) Safe management of ammonia refrigeration systems. Available at: https://www.refcom.org.uk/media/1160/ammonia-guide-smars-2016_copy-0023_stephen-crocker.pdf

⁴³⁸ Proklima International (2009) Natural Foam Blowing Agents. Available at: <https://www.ctc-n.org/sites/www.ctc-n.org/files/resources/giz2009-en-natural-foam-blowing-agents.pdf>

⁴³⁹ Linde-gas (2015) Fact Sheet 13 – Insulating Foam. Available at: https://www.linde-gas.com/en/images/FS_13_Insulating_Foam_Oct_2015_tcm17-235793.pdf

An inert gas system (i.e. argon / nitrogen) is one of the alternatives identified, which may not be suitable for all installations as it requires a higher number of cylinders than F-gas systems. This means the system has a larger footprint and the floor may require reinforcement⁴⁴⁰.

MDI

Of the three non-chemical alternatives (i.e. dry powder inhalers (DPIs), soft mist inhalers (SMIs), and nebulisers) identified to replace HFCs in MDIs, all were commercially available but require changes to both manufacturing process and use. It is also important to note that **the alternatives are not suitable for all patients**. DPIs require a deep and forceful inhalation and there are groups of patients that struggle to generate sufficient inspiratory flows to get adequate delivery from a DPI, such as COPD patients, young children, and very old people⁴⁴¹. A systematic literature review found that 90% of patients do not use their DPI correctly⁴⁴². SMIs require some assembly, although evidence suggests this is problematic for only a small number of patients⁴⁴³.

Propellant

All of the chemical alternatives are commercially available (water, carbon dioxide, nitrous oxide, nitrogen, isobutane, butane, propane, and di-methyl ether). However, because of the flammability of some of these alternatives, some changes are required to manufacturing process, such as measures to provide additional ventilation and airflow, as well as the installation of gassing rooms, storage tanks, and piping⁴⁴⁴. There were also data gaps around the changes needed for the other alternatives, so all were scored as category 2.

It's important to note that the alternatives are not suitable for all propellant applications. For example, carbon dioxide is not compatible with all solutions, such as water-based formulas where it forms carbonic acids that attacks metal cans. It's high vapour pressure also means it can only be used in with solvents that have good Oswald coefficients. Aerosols for which carbon dioxide can be used include insect repellents, degreasers, speciality cleaners, and de-icers⁴⁴⁵.

Nitrogen has very low solubility in liquids which means that it only produces a liquid stream, which can be converted to a coarse spray by fitting the propellant's valve with a mechanical breakup actuator. This means that nitrogen is unsuitable for aerosols requiring a fine spray⁴⁴⁶.

Fire Suppressant

Three of the chemical alternatives (carbon dioxide, inert gas (argon/nitrogen) and [product name]) are commercially available and are expected to require some change to the gas delivery system. Information obtained during the desk research indicates that all three use different delivery systems to F-gases and would therefore require large process changes⁴⁴⁷. Overall, these alternatives were all placed in category 2. The other identified alternative is water, which requires a sprinkler system. A complete product re-design would require significant manufacturing changes, so this scores as category 3. Water-based systems are also only technically feasible in certain environments. For example, they can't be used in electrical installations or in facilities that store chemical products that oxidise in the presence of water.

Solvent

All of the chemical and non-chemical alternatives are commercially available. This includes several hydrofluoroethers (HFE), [product name], and [product name] which do not require any changes to manufacturing process and systems so these score in category 1. Other possible alternatives include heptane and hexane, which would require some manufacturing changes due to their flammability, so score in category

⁴⁴⁰ 3M (2020) Fire suppression systems. The total cost of ownership. Available at: <https://multimedia.3m.com/mws/media/1430143O/fire-suppression-systems-total-cost-ownership-best-practice-guide.pdf>

⁴⁴¹ Pritchard, J. N. (2020). The climate is changing for metered-dose inhalers and action is needed. *Drug Design, Development and Therapy*, 3043-3055.

⁴⁴² Lavorini, F., Magnan, A., Dubus, J. C., Voshaar, T., Corbetta, L., Broeders, M., ... & Crompton, G. K. (2008). Effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD. *Respiratory medicine*, 102(4), 593-604.

⁴⁴³ Anderson, P. (2006). Use of Respimat® soft Mist™ inhaler in COPD patients. *International journal of chronic obstructive pulmonary disease*, 1(3), 251-259.

⁴⁴⁴ UNEP (2005) Technical Guide for the Safe Handling of Hydrocarbon Propellants. Available at: <https://wedocs.unep.org/handle/20.500.11822/32963>

⁴⁴⁵ Southern Aerosol Technology Association (2013) Propellants and Solvents Strategies for the 21st Century. Available at: <https://dokumen.tips/documents/propellants-and-solvents-southern-aerosol-pointspring-13-pdfspring-13.html?page=1>

⁴⁴⁶ Diversified CPC (2021) An Introduction to Aerosol Propellants. Available at: <https://diversifiedcpc.com/wp-content/uploads/2021/12/Introduction-to-Aerosol-Propellants.pdf>

⁴⁴⁷ 3M (2020) Fire suppression systems. The total cost of ownership. Available at: <https://multimedia.3m.com/mws/media/1430143O/fire-suppression-systems-total-cost-ownership-best-practice-guide.pdf>

2. All three of the non-chemical alternatives would require significant changes to manufacturing process and use, so scored as category 3.

A6 PERFORMANCE ASSESSMENT

A6.1 METHODOLOGY

The aim of the performance assessment is to determine whether the performance requirements of the application and function in question can be adequately met by an alternative. The performance of each alternative was assessed against that of the chemical of concern. Where data allowing this comparison was not readily available, the alternative's performance was assessed against a similar chemical of concern (i.e. other F-gases in scope) or other potential alternatives, such that inferences could be made. Performance was assessed on a 5-point scale, as shown in the table below.

Table A 14 Scoring criteria for performance assessment

Scoring Criteria	Score
Significantly better performance	1 point
Better performance	2 points
Equivalent performance	3 points
Worse performance	4 points
Significantly worse performance	5 points

A performance assessment includes consideration of multiple trade-offs, including efficiency, safety, durability, resource use, and factors specific to the application (see table below). These were considered in combination and an overall performance score was assigned.

Table A 15 Performance criteria specific to each application in scope

Application	Performance Criteria
Refrigeration & heating	Cooling coefficient of performance; Refrigeration capacity
Foam insulation	Thermal conductivity; Mould resistance; Fire resistance; Acoustic insulation
Magnesium cover gas	Amount of metal loss; Quality/purity of magnesium metal; Corrosivity of cover gas
Propellant (metered dose inhalers)	Effectiveness of drug delivery; Ease of use
Propellant (aerosols)	Effectiveness of aerosol delivery; Ease of use
Solvent	Cleaning effectiveness
Fire Suppressant	Speed of fire suppression

A6.2 RESULTS

Refrigerant

Only a small number of alternative refrigerants had an improved performance compared to F-gases and these are only in select RACHP applications. These include ammonia in large industrial refrigeration and chillers where it delivers more efficient cooling because of its high latent heat, high specific heat capacity, high thermal conductivity and low viscosity; propane and isobutane in domestic refrigeration, which offer better energy

efficiency⁴⁴⁸; and propane and isobutane in hot water heat pumps where higher coefficients of performance (COP) are achieved⁴⁴⁹.

Foam Blowing Agent

The only alternative that offers significantly better performance than F-gases, is aerogel insulation which has a thermal conductivity as low as 0.010 W/mK and high space efficiency⁴⁵⁰, and has scored as a 5. However, they have several limitations, including their brittleness, which means that nearly all the commercial products using aerogel are a part of a composite design⁴⁵¹. This means they are limited to specialised application.

Cyclopentane and dimethyl ether were considered to have a similar performance to F-gas foam blowing agents, while the remaining foam blowing agents and material alternatives were judged to have a lower performance.

Cover Gas

Boron trifluoride was the only alternative cover gases able to exceed the performance of F-gases and was given of score of 4 in the performance assessment. Boron trifluoride is equally as protective as sulphur hexafluoride (SF6), which was traditionally the industry standard for melt protection, but has been banned for use in magnesium die-casting under Article 13 of the EU F-Gas Regulation (No. 517/2014)⁴⁵². The gas can be used with a system called MagShield which means there is no odour, fume, or smoke, and no observed system corrosion. Boron trifluoride can also protect for 50% longer than SF6 following a power failure⁴⁵³.

Two alternatives offer a similar performance to F-gases, which are carbon dioxide and [product name]/1230. Pure carbon dioxide and mixtures up to 20 vol.% air/CO2 can protect molten magnesium⁴⁵⁴, while [product name]/1230 can protect pure magnesium or its alloys at melt temperatures from 650°C to 800°C (1170°F to 1450°F) in furnaces and during casting operations⁴⁵⁵.

Sulphur dioxide, nitrogen, and argon were judged to have a worse performance than F-gas cover gases. Sulphur dioxide has several performance disadvantages as in a dilute form it is not able to reduce metal loss during the casting process, so they don't offer the same cost savings as F-gas-based systems. It is also subject to strict OELs and is more difficult to scrub than boron trifluoride^{456,457}. Argon can only protect magnesium to a certain extent and is not very effective at suppressing the evaporation of magnesium from the melt⁴⁵⁸. Nitrogen has a lower performance because it reacts with the melt forming magnesium nitride.

MDI

Soft mist inhalers (SMIs) scored a 2 in the performance assessment as they have a higher performance than MDIs. This is because they achieve higher lung drug deposition and lower oropharyngeal deposition⁴⁵⁹. DPIs also achieve higher lung drug deposition and lower oropharyngeal deposition than MDIs⁴⁶⁰, but lower rates than SMIs. However, because DPIs are not effective for certain patient groups (i.e. COPD patients, young children, and the elderly) this was judged to outweigh the performance benefits, and DPIs subsequently scored a 3 in the performance assessment.

⁴⁴⁸ Rasti, Mehdi, SeyedFoad Aghamiri, and Mohammad-Sadegh Hatamipour. "Energy efficiency enhancement of a domestic refrigerator using R436A and R600a as alternative refrigerants to R134a." *International Journal of Thermal Sciences* 74 (2013): 86-94.

⁴⁴⁹ Nawaz, K., Shen, B., Elatar, A., Baxter, V., & Abdelaziz, O. (2017). R290 (propane) and R600a (isobutane) as natural refrigerants for residential heat pump water heaters. *Applied Thermal Engineering*, 127, 870-883

⁴⁵⁰ Jelle et al. (2015) Aerogel Insulation for Building Applications. Available at: <https://onlinelibrary.wiley.com/doi/10.1002/9783527670819.ch45>

⁴⁵¹ Collins, R (2019) Why isn't the aerogel industry booming? Available at: <https://www.idtechex.com/fr/research-article/why-isnt-the-aerogel-industry-booming/16671>

⁴⁵² See: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0517>

⁴⁵³ US EPA (2016) A Replacement for SF6: The MagShield System. Available at: https://www.epa.gov/sites/default/files/2016-02/documents/conf00_schultz_paper.pdf

⁴⁵⁴ Balart, M. J., Patel, J. B., & Fan, Z. (2016). Melt protection of Mg-Al based alloys. *Metals*, 6(6), 131.

⁴⁵⁵ 3M (2011) 3M™ Novec™ 612 as a Substitute for SF6 in Magnesium Processing:

Experience to Date in Varied Casting Operations. Available at: <https://multimedia.3m.com/mws/media/739948O/3mtm-novectm-612-substitute-for-sf6.pdf>

⁴⁵⁶ Balart, M. J., Patel, J. B., & Fan, Z. (2016). Melt protection of Mg-Al based alloys. *Metals*, 6(6), 131.

⁴⁵⁷ US EPA (2016) Alternatives to SF6 for Magnesium Melt Protection. Available at: https://www.epa.gov/sites/default/files/2016-02/documents/magbrochure_english.pdf

⁴⁵⁸ Hort, N., Wiese, B. Ö. R. N., Dieringa, H., & Kainer, K. U. (2015, September). Magnesium melt protection. In *Materials Science Forum* (Vol. 828, pp. 78-81). Trans Tech Publications Ltd.

⁴⁵⁹ Anderson, P. (2006). Use of Respimat® soft Mist™ inhaler in COPD patients. *International journal of chronic obstructive pulmonary disease*, 1(3), 251-259.

⁴⁶⁰ Anderson, P. (2006). Use of Respimat® soft Mist™ inhaler in COPD patients. *International journal of chronic obstructive pulmonary disease*, 1(3), 251-259.

Nebulisers are effective for people who can't breathe in with sufficient force to use inhalers and are effective in emergencies and when higher doses of treatment are required. However, they also have several performance disadvantages, such as being bulky and inconvenient to transport, slower drug delivery, and requiring regular maintenance⁴⁶¹. On balance, nebulisers were therefore considered to have a lower performance than MDIs and scored a 4 in the performance assessment.

Propellant

The performance of all alternative propellants was scored as a 3 and therefore judged to be equivalent to f-gas propellants. However, these scores were assigned because of the lack of conclusive evidence on the performance of these alternatives compared to F-gas propellants. It should be noted that most alternative propellants are limited in their application. For example, carbon dioxide is not compatible in an aerosol tin with water or traces of water due at least in part to the formation of carbonic acid and resultant reduction in the pH of the system. The acidity of water-carbon dioxide aerosol systems has a corrosive effect on many aerosol containers, and may additionally have a deleterious effect on the active ingredients dissolved or dispersed in the aqueous system or impair their storage stability^{462,463}. Nitrous oxide also only has applications in food dispensers and rocket propulsion.

Fire Suppressant

Only [product name] was able to match the performance of f-gas fire suppressants and scored a 3 in the performance assessment, due to its ability to extinguish a fire very rapidly⁴⁶⁴. Carbon dioxide, inert gas, and water were judged to have a worse performance.

Solvent

Hexane and heptane scored 4 in the performance assessment because of their lower solvency power. All other chemical alternatives scored a 3 and were considered to have an equal performance to f-gas solvents. These all fall into the hydrofluoroether (HFE) chemical group, which are compatible with a large range of materials including most metals, numerous plastics, flex circuits and glues. They offer a solvency performance comparable to HFCs^{465,466,467}.

Uncertainties

Under many analysis of alternatives frameworks, the performance assessment is considered optional as the entity performing the assessment may not be a manufacturer or downstream user, and is therefore not in a position to thoroughly evaluate performance⁴⁶⁸, as detailed information on performance standards and acceptable tolerances is needed. The study team sought to address this data need by consulting industry through an online survey, supplemented by desk research. However, after both gathering exercises were completed, some data gaps remained. This included information on the performance of technologies that have not reached maturity, such as those cited as replacements to conventional vapour compression refrigeration. In these instances, a neutral weighting was applied, as specified in the decision rules. There is also uncertainty of whether modifications to products and processes could be made to address the inferior performance of some alternatives to allow them to meet the performance requirements of the chemical of concern.

Evidence collected through consultation with industry also did not always align with information collected through literature review. Furthermore, direct comparisons between each alternative and the F-gases was also not always possible due to a lack of available evidence. Subsequently, there is some uncertainty in the final output of the performance assessment.

⁴⁶¹ DeWeerd, S. (2020). THE INHALER MAKEOVER. *Nature*, 581(7807), S14-S17.

⁴⁶² Mosil (2021) Aerosol and its Propellant. Available at: <https://www.mosil.com/blog/aerosol-and-its-propellant/>

⁴⁶³ Google Patents (1977) Stable aqueous aerosol system with carbon dioxide propellant. Available at: <https://patents.google.com/patent/US4161458A/en>

⁴⁶⁴ 3M (n.d.) Fire suppression — [product name] Fire Protection Fluid.

⁴⁶⁵ 3M (n.d.) Sustainable HFC alternatives sought as F-Gas Regulation impacts multiple industries across West Europe. Available at: <https://multimedia.3m.com/mws/media/1572594O/j432262-ee-emsd-12-novec-technical-bulletin-fluorinated-lubricants-pdf.pdf>

⁴⁶⁶ Kehren (n.d.) A Comparison of Hydrofluoroether and Other Alternative Solvent Cleaning System. Available at: <http://www.solvents.net.au/index.htm?files/71IPA%20Engineered%20Fluid.pdf>

⁴⁶⁷ Ecolink (2022) What are Hydrofluoroethers? Available at: https://ecolink.com/info/what-are-hydrofluoroethers/?utm_source=rss&utm_medium=rss&utm_campaign=what-are-hydrofluoroethers

⁴⁶⁸ National Research Council (2014) A Framework to Guide Selection of Chemical Alternatives – Chapter 10, Life Cycle, Performance, and Economic Considerations. Washington (DC): National Academies Press (US). Available at: <https://www.ncbi.nlm.nih.gov/books/NBK253968/>

A7 ECONOMIC FEASIBILITY ASSESSMENT

A7.1 METHODOLOGY

The overall economic feasibility score was based on a consideration of the cost of the alternative, capital expenditure (CAPEX) (i.e. system cost, investment in new manufacturing equipment etc), and operating expenditure (OPEX) (i.e. cost of using the alternative) in comparison to the chemical of concern. Where data allowing this comparison was not readily available, the alternative's performance was assessed against a similar chemical of concern (i.e. other F-gases in scope) or other potential, such that inferences could be made.

The economic feasibility of each alternative was assessed on a 5-point scale, as shown in the table below.

Table A 16 Scoring criteria for economic feasibility assessment.

Scoring Criteria	Score
Significantly cheaper than chemical of concern	1 point
Cheaper than chemical of concern	2 points
Equivalent cost to chemical of concern	3 points
More expensive than chemical of concern	4 points
Significantly more expensive than chemical of concern	5 points

A7.2 RESULTS

RACHP

The cost of natural refrigerants in the majority of applications was considered to have an equal cost to F-gas refrigerants. However, there were many data gaps on the cost of new systems using alternatives and their operating costs compared to F-gas systems, meaning a neutral weighting was applied to many applications. For example, there was a lack of information on the cost of CO₂ based systems for each of its applications. The only alternative presenting with greater cost-effectiveness over F-gases was the use of ammonia in industrial refrigeration systems as its high latent heat, specific heat capacity, thermal conductivity, and low viscosity make it a highly efficient coolant⁴⁶⁹. This can lead to cost savings in large direct expansion systems⁴⁷⁰.

There was a lack of economic data on the majority of non-chemical alternatives, as most have not reached technical maturity and are not used commercially.

Blowing Agent

The majority of blowing agents were judged to have a higher cost than using F-gases. While hydrocarbons are typically cheaper than synthetic blowing agents, the additional safety measures required because of their flammability is likely to increase the processing costs. Information received during the consultation also indicated an increase in CAPEX. This means that isobutane, butane, isopentane, pentane, cyclopentane, and di-methyl ether scored a 4 in the economic feasibility assessment.

Methylal was the only chemical alternative that had an equivalent cost (score of 3), with evidence from a UNDP report citing a cost similar to F-gases⁴⁷¹. Carbon dioxide also had a score of 3, but this was due to a lack of information on the cost of manufacturing foam while using it as a blowing agent. Water can be used as a sole blowing agent, and due to its cheap cost and non-hazardous nature it scored a 2. However, it should be noted that the thermal performance of water is lower than F-gases⁴⁷² so would not be as cost-effective for end users.

⁴⁶⁹ Star Refrigeration (n.d.) Carbon Dioxide for Industrial Refrigeration Applications. Available at: <https://www.star-ref.co.uk/smart-thinking/carbon-dioxide-for-industrial-refrigeration-applications/>

⁴⁷⁰ SKM Enviros (2013) Possible Bans for New RAC Equipment - A review of the technical and economic impact of potential bans on the use HFCs for new equipment in RAC market sectors. Available at: https://climate.ec.europa.eu/system/files/2016-11/refrigeration_air_conditioning_en.pdf

⁴⁷¹ UNDP (2012) Methylal as Blowing Agent in the Manufacture of Polyurethane Foam Systems. Available at: https://www.undp.org/sites/g/files/zskgke326/files/publications/Methylal_WEB.pdf

⁴⁷² Huntsman (2011) Polyurethanes - Blowing agent options for insulation foam after HCFC phase out. Available at: https://huntsman-pimcore.equisolve-dev.com/Documents/PU_Insulation_Blowing_agents.pdf

Of the non-chemical alternatives that are available, aerogel and foamed glass were both considered to be significantly more expensive alternatives. Foamed glass has a cost roughly two and half times more than PU foam⁴⁷³, while aerogel insulation is only produced by a few manufacturers and has historically had high production costs, which has restricted its use to specialised applications. However, production costs are expected to fall with the advent of mass production, but aerogel is still significantly more expensive than F-gas-based foam insulation and it is not expected to fall sufficiently to enable it to be used very widely. The majority of the other non-chemical alternatives either scored a 3 or 4, with only straw bales having a cheaper cost.

Cover Gas

Sulfuryl fluoride and sulphur dioxide were judged to have a higher cost than F-gases because of their much higher system costs⁴⁷⁴. Boron trifluoride also has a higher cost because systems using the gas require moderate equipment and process upgrades and when boron trifluoride is purchased as a manufactured compressed gas, it is very costly (US EPA, 2016). The remaining chemical alternatives were considered to have an equivalent cost, although largely because of data gaps surrounding the capital expenditure and operating expenditure involved in transitioning to them.

MDIs

All of the alternatives to MDIs present an increase in cost. A recent analysis (Pritchard, 2020) showed that in every country, the cost of DPIs is greater per dose than the cost of MDIs, sometimes by nearly 600%. In recent years the average sale price difference between MDIs and DPIs has narrowed slightly, and this is expected to narrow further as the reduction in non-medical uses of HFC propellants is likely to give rise to a 5-fold increase in their cost for MDI uses⁴⁷⁵. Soft-mist inhalers are also often more costly than other inhalers⁴⁷⁶, which could affect their uptake⁴⁷⁷. The cost of giving therapy using nebulisers has been cited as being around 20% more than MDIs⁴⁷⁸.

Propellant

The majority of alternative propellants were judged to have a higher cost than using F-gases. While hydrocarbons are typically cheaper than synthetic blowing agents, the additional safety measures required because of their flammability is likely to increase the processing costs. There were many data gaps regarding the capital and operating expenditure required to transition to alternative propellants, meaning that a neutral weighting was applied, which skewed the assessment scores of some alternatives towards representing an equivalent cost. This was true of the non-chemical alternatives, such as bag-in-can systems, finger pumps, roll-on liquids, squeeze bottles etc. Nitrogen and air were the only two alternatives considered to be cheaper than F-gas propellants, because of the low cost of these substances.

Fire Suppressant

There were many data gaps on the capital and operating expenditure of involved with systems using alternative fire suppressants. Therefore, a neutral weighting was applied, and they received a score of 3.

Solvent

None of the chemical alternatives represented an improvement in cost-effectiveness over F-gases. Hexane and heptane scored 4 (more expensive) as, although hydrocarbons are typically cheaper than F-gases, the additional safety measures required because of their flammability is likely to increase the processing costs. The HFE solvents were also considered to present a higher cost because they are significantly more expensive than traditional F-gas solvents and have a higher operating cost⁴⁷⁹. [product name] also scored 4 due to its higher unit cost, while the remaining solvents scored 3 due to a neutral weighting being applied because of the lack of data on their economic feasibility.

⁴⁷³ Building Green (n.d.) Foamglas – My New Favorite Insulation Material. Available at: <https://www.buildinggreen.com/blog/foamglas---my-new-favorite-insulation-material#:~:text=The%20typical%20cost%20of%20Foamglas,about%20%240.40%20per%20board%2Dfoot>.

⁴⁷⁴ European Commission (2009) Service contract to assess the feasibility of options to reduce emissions of SF6 from the EU non-ferrous metal industry and analyse their potential impacts. Available at: <https://www.oekorecherche.de/sites/default/files/publikationen/sf6-nf-metal.pdf>

⁴⁷⁵ Pritchard, J. N. (2020). The climate is changing for metered-dose inhalers and action is needed. *Drug Design, Development and Therapy*, 3043-3055.

⁴⁷⁶ DeWeerd, S. (2020). THE INHALER MAKEOVER. *Nature*, 581(7807), S14-S17.

⁴⁷⁷ Anderson, P. (2006). Use of Respimat® soft Mist™ inhaler in COPD patients. *International journal of chronic obstructive pulmonary disease*, 1(3), 251-259.

⁴⁷⁸ Pritchard, J. N. (2020). The climate is changing for metered-dose inhalers and action is needed. *Drug Design, Development and Therapy*, 3043-3055.

⁴⁷⁹ Kehren, J. (n.d.) A Comparison of Hydrofluoroether and Other Alternative Solvent Cleaning Systems. Available at: http://www.solvents.net.au/index.htm_files/71IPA%20Engineered%20Fluid.pdf

Off the three non-chemical alternatives, PurgoSpray and plasma cleaning scored 4 because they represent alternative technologies that would require significant process changes to adapt to. There was a lack of data on the use of supercritical fluids so they scored a 3 in the assessment.

Uncertainties

Limited evidence was provided during the consultation with industry on the changes in CAPEX and OPEX from the use of alternatives. There was also a lack of published quantitative information on the economic feasibility of both alternatives and the chemicals of concern, meaning many data gaps remained following the desk research. This was the case for the majority of material and design alternatives, as many of these are emerging technologies. As specified in the decisions rules, a neutral weighting was applied to these data gaps and an equivalent cost was assumed.

The cost of each alternative substance was one of the main considerations in determining their economic feasibility. However, it should be noted that this can be volatile and changes depending based on current market conditions. Therefore, while the price on an alternative may be significantly cheaper or more expensive currently, this may not be the case in the future.

Due to the limited evidence available to the study team, and the dynamic nature of the cost of alternatives, there is a high level of uncertainty surrounding the output of the economic assessment.

A8 LIFECYCLE ASSESSMENT

A full quantitative life-cycle assessment (LCA) was outside of the scope of this Study and lifecycle aspects were not used as inputs into deriving the list of acceptable alternatives presented in Tables A-18 and A-19. However, a qualitative discussion of life-cycle aspects of each alternative was performed, which considers the differences in material and energy flows, greenhouse gas emissions, lifespan, and recyclability rates between the chemical of concern and the alternative (see Table A-21). Such an analysis can identify where there is a significant difference in these areas and highlight the need for additional quantitative information and analysis to support decision-making. In some cases, a qualitative exercise can provide sufficient detail to make a decision, such that a quantitative analysis would not provide any additional value.

A9 COMPARATIVE ASSESSMENT

A9.1 METHODOLOGY

The objective of the comparative assessment is to integrate the outputs of the five assessments to identify the most potential alternatives. These were:

- Risk to human health
- Risk to the environment
- Technical feasibility assessment
- Performance assessment
- Economic feasibility assessment

Under many frameworks, a life-cycle assessment is an optional component. A full life-cycle assessment was outside of the scope of this Study, which precluded attaching a score for each alternative for this assessment. Therefore, the life-cycle assessment was not used within the comparative assessment of alternatives. However, a qualitative discussion of life-cycle aspects is provided for each alternative considered to be acceptable.

Each of the five assessments were scored on a 1 – 5 scale, with 1 representing the most desirable alternatives and five representing the least desirable alternatives. Therefore, each alternative was scored from 5 – 25 in the final comparative assessment, with 5 representing the most desirable alternatives and 25 representing the least desirable alternatives.

Separate comparative assessments were made for the chemical and material and design alternatives. This is because the non-chemical alternatives do not present human health or environmental hazards from their chemical properties, and the chemicals are either fully enclosed within the equipment, with minimal risk of exposure, or there are no chemical components. This precluded a direct comparison between chemical and

non-chemical alternatives. Therefore, because only three assessments were made for the material and design alternatives, they were scored from 3 – 15 in the final comparative assessment, with 3 representing the most desirable alternatives and 15 representing the least desirable alternatives.

The output of this task was a ranked list of potential alternatives. The cut-off criteria that were applied for a chemical alternative to be considered acceptable, and the rationale for their selection, is outlined in Table A-17

Table A 17 Criteria for determining potential alternatives

Assessment	Cut-off Criteria
Risk to human health	Low or very low risk to human health
Risk to environmental health	Low or very low risk to the environment
Technical feasibility assessment	Category 1 (Alternative commercially available and no barriers to use) or category 2 (Alternative commercially available and moderate changes manufacturing and use, or significant changes to either manufacturing or use and must be commercially available)
Performance assessment	Category 1 (Significantly better performance), Category 2 (Better performance) & Category 3 (Equivalent performance)
Economic feasibility assessment	Category 1 (Significantly cheaper), Category 2 (Cheaper), Category 3 (Equivalent cost) & Category 4 (More expensive)

The goal of the assessment was to identify less hazardous alternatives. Given the low inherent hazards of F-gases, the risk they pose to human health and the environment from their hazards is very low, with their global warming potential (GWP) being the primary concern. Therefore, despite the goal of the assessment, excluding alternatives with a greater risk to human health and the environment than each F-gas would eliminate some alternatives which could potentially address the primary environmental concern relating to the GWP of F-gases. Because of this, a pragmatic approach was chosen and the criteria for considering alternatives acceptable was having either a low or very low risk to both human health and the environment.

For alternatives to be considered technically feasible they must be readily available and there must not be significant barriers in their manufacture and use. Therefore, only category 1 and 2 alternatives were considered, which encompassed alternatives that were commercially available and requiring moderate changes to both manufacturing and use, or alternatives that were commercially available and requiring significant changes to either manufacture or use.

Performance is a key aspect in determining how viable an alternative is and therefore an alternative was only considered acceptable if it was able to meet an equivalent or improved level of performance. It should be noted that improvements in performance may be possible with optimisation of product and system design, so alternatives excluded on the basis of performance could be considered acceptable with further R&D.

Only alternatives presenting a significant increase in cost were not considered acceptable (i.e. category 5 in the economic feasibility assessment). This conservative threshold was chosen partly due to the uncertainty in the outcome of the economic assessment and partly because economies of scale can lower the future cost of an alternative.

A9.2 RESULTS

The table below represents an overview of all the potential alternatives, grouped by application. The suitable uses presented in the table are broad use categories that cover numerous types of products, systems, and installations. As discussed through the report, the suitable uses have been presented at a high level, meaning the alternatives may not be suitable for use in all products, systems, and installations falling within the use category. A more detailed analysis of the potential of alternatives was out of scope of this study.

Table A 18 Potential chemical alternatives by application

Application	Alternative	Suitable Uses
RACHP	Ammonia	Industrial Refrigeration Transport Refrigeration Chillers (excluding those in populous areas)
	Carbon dioxide	Mobile Air Conditioning Transport Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Commercial Refrigeration (Condensing Units)
	Isobutane	Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Movable Room Air Conditioning Heat Pumps
	Propane	Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Movable Room Air Conditioning Heat Pumps
	Propylene	Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units)
Foam Insulation	Di-methyl ether	Building Insulation (excluding spray foam)
	Cyclopentane	Building Insulation (excluding spray foam) Refrigeration Insulation
Magnesium Cover Gas	Carbon dioxide	Melt protection
Aerosols	Butane/ isobutane	Any aerosol that can use a high flammability propellant; limited by the solubility and compatibility of butane or isobutane with the aerosol formulation and product VOC limits
	Propane	Any aerosol that can use a high flammability propellant; limited by the solubility and compatibility of propane with the aerosol formulation and product VOC limits
	Di-methyl ether	Any aerosol that can use a high flammability propellant; limited by the solubility and compatibility of DME with the aerosol formulation and product VOC limits
	Nitrous oxide	Some technical and consumer aerosols (e.g. dusters) and food products (e.g. cream; cheese) Rocket propellant
	Carbon dioxide	Insect repellents, degreasers, speciality cleaners, and de-icers
	Nitrogen	Some technical and consumer aerosols (e.g. dusters); Course spray aerosols
Fire Suppressant	[product name]	N/A
Solvent	[product name]	N/A
	MPHE	N/A
	HFE-347pcf2	N/A
	[product name]	N/A
	HFE-7100	N/A

Application	Alternative	Suitable Uses
	HFE-7000	N/A
	HFE-7200	N/A

Table A 19 Potential non-chemical alternatives by application

Application	Alternative	Suitable Uses
RACHP	Brayton Heat Pump	Mobile Air Conditioning
		Industrial Refrigeration
	Ground-Coupled Solid Desiccant Air Conditioner	Stationary Air Conditioning (Multi-Split Systems)
MDIs	Dry Power Inhalers	Asthma treatment (excluding COPD patients, elderly and very young patients)
Aerosols	Bag-in-can/piston-can systems	Most aerosols

The scores for each assessment for all of the identified alternatives is presented in Table A-20 below.

Rather than presenting a ranking of the best alternatives, we have presented a list of potential alternatives. This is because the 'best' alternative will likely depend on a number of factors that are specific to each company. A summary of the technical, performance, economic, and life-cycle elements that need to be considered when using each potential alternative is provided in the Table A-21 below. The red highlighting denotes where there were complete or partial data gaps influencing the score provided for either the hazard, exposure, technical feasibility, performance, or economic feasibility assessment.

Table A 20 Assessment scores for each identified chemical alternative.

Application	Alternative	HH Risk Score	ENV Risk Score	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
Mobile Air Conditioning	Carbon dioxide	1	1	2	3	3	10	Y
Industrial Refrigeration	Ammonia	1	2	2	3	2	10	Y
	Carbon dioxide	1	1	1	4	3	10	N
	Propylene	1	1	1	3	3	9	Y
Transport Refrigeration	Ammonia	1	2	2	3	2	10	Y
	Carbon dioxide	1	1	1	3	3	9	Y
Domestic Refrigeration	Isobutane	1	1	2	2	3	9	Y
	Propane	1	1	2	2	3	9	Y
	Propylene	1	1	2	3	3	10	Y
Comm. Refrigeration - Hermetic	Isobutane	1	1	2	2	3	9	Y
	Propane	1	1	2	2	3	9	Y
	Carbon dioxide	1	1	2	2	3	9	Y
	Propylene	1	1	2	2	3	9	Y
Comm. Refrigeration - Condensing	Carbon dioxide	1	1	2	3	3	10	Y
Comm. Refrigeration - Centralised	Carbon dioxide	1	1	1	4	3	10	N
	Isobutane	1	1	1	3	3	9	Y

Application	Alternative	HH Risk Score	ENV Risk Score	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
Moveable Room AC	Propane	1	1	1	3	3	9	Y
Chillers	Ammonia	1	2	1	2	2	8	Y
Heat Pumps	Isobutane	1	1	1	3	3	9	Y
	Propane	1	1	1	3	3	9	Y
Foam Insulation Refrigeration	Butane	1	1	2	4	4	12	N
	Pentane	1	2	1	4	4	12	N
	Cyclopentane	1	2	1	3	4	11	Y
	Isopentane	1	2	1	4	4	12	N
	Methyl formate	1	1	1	4	4	11	N
	Methylal	1	1	2	4	3	11	N
	Carbon dioxide	1	1	2	4	3	11	N
Foam Insulation Construction	Isobutane	1	1	1	4	4	11	N
	Butane	1	1	2	4	4	12	N
	Di-methyl ether	1	1	1	3	4	10	Y
	Methyl formate	1	1	1	4	4	11	N
	Isopentane	1	2	1	4	4	12	N
	Pentane	1	2	1	4	4	12	N
	Cyclopentane	1	2	1	3	4	11	Y
	Methylal	1	1	2	4	3	11	N
	Carbon dioxide	1	1	2	4	3	11	N
	Water	1	1	1	5	2	10	N
	Boron trifluoride	4	2	2	2	4	14	N

Application	Alternative	HH Risk Score	ENV Risk Score	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
Cover Gas for Magnesium Die Casting	Sulfuryl fluoride	4	2	2	3	4	15	N
	Sulphur dioxide	1	1	2	4	4	12	N
	Nitrogen	3	1	2	4	3	13	N
	Carbon dioxide	3	1	2	3	3	12	Y
	Argon	1	1	2	4	3	11	N
	[product name]/1230	1	3	1	3	3	11	N
Propellant	Isobutane	1	1	2	4	4	12	N
	Butane	1	1	2	3	4	11	Y
	Propane	1	1	2	3	4	11	Y
	Di-methyl ether	1	1	2	3	4	11	Y
	Nitrous oxide	2	1	1	3	3	10	Y
	Carbon dioxide	3	1	1	3	3	11	Y
	Nitrogen	3	1	1	3	2	10	Y
	Air	1	1	1	4	1	8	N
Fire suppressant	Inert gas	2	1	2	4	3	11	N
	Carbon dioxide	2	1	2	4	3	12	N
	[product name]	1	3	2	3	3	12	Y
	Water	1	1	2	5	3	12	N
Solvent	[product name]	2	3	1	3	4	13	Y
	MPHE	1	2	2	3	3	11	Y
	HFE-347pcf2	2	1	1	3	3	10	Y
	[product name]	1	2	1	3	3	10	Y

Application	Alternative	HH Risk Score	ENV Risk Score	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
	HFE-7100	1	1	1	3	4	10	Y
	HFE-7000	1	1	1	3	4	10	Y
	HFE-7200	2	2	1	3	4	10	Y
	Heptane	2	4	2	4	4	16	N
	Hexane	2	3	2	4	4	15	N

Table A-21 Assessment scores for each identified non-chemical alternative.

Application	Alternative	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
Mobile Air Conditioning	Brayton Heat Pump	2	2	3	7	Y
	Thermoelastic	4	3	3	10	N
Industrial Refrigeration	Brayton Heat Pump	2	2	3	7	Y
	Duplex-Stirling Heat Pump	3	3	3	9	N
	Thermoacoustic	3	3	4	10	N
Transport Refrigeration	Thermoelastic	4	3	3	10	N
Domestic Refrigeration	Magnetocaloric	4	3	3	10	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
	Thermoelectric	2	4	4	10	N
Comm. Refrigeration - Hermetic	Brayton Heat Pump	2	5	3	10	N
	Duplex-Stirling Heat Pump	2	5	3	10	N

Application	Alternative	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
	Magnetocaloric	3	3	3	9	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
Comm. Refrigeration - Condensing	Brayton Heat Pump	2	5	3	10	N
	Duplex-Stirling Heat Pump	2	5	3	10	N
	Magnetocaloric	3	3	3	9	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
Comm. Refrigeration - Centralised	Brayton Heat Pump	2	5	3	10	N
	Duplex-Stirling Heat Pump	2	5	3	10	N
	Magnetocaloric	3	3	3	9	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
Moveable Room AC	Absorption Heat Pump	3	3	5	11	N
	Adsorption Heat Pump	3	3	3	9	N
	Brayton Heat Pump	2	5	3	10	N
	Duplex-Stirling Heat Pump	4	3	3	10	N
	Ejector Heat Pump	4	3	3	10	N
	Evaporative Cooling	2	5	3	10	N

Application	Alternative	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
	Evaporative Desiccant Conditioner Liquid Air	4	3	4	11	N
	Ground-Coupled Desiccant Conditioner Solid Air	4	3	4	11	N
	Magnetocaloric	4	3	3	10	N
	Membrane Heat Pump	4	3	3	10	N
	Standalone Desiccant Conditioner Liquid Air	3	3	5	11	N
	Standalone Desiccant Conditioner Solid Air	1	5	5	11	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
	Thermoelectric	4	3	4	11	N
	Thermotunneling	4	3	4	11	N
	Vuilleumier Heat Pump	4	3	3	10	N
Heat Pumps	Absorption Heat Pump	3	3	5	11	N
	Adsorption Heat Pump	3	3	3	9	N
	Brayton Heat Pump	4	3	3	10	N
	Duplex-Stirling Heat Pump	3	3	3	9	N
	Ejector Heat Pump	4	3	3	10	N

Application	Alternative	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
	Magnetocaloric	4	3	3	10	N
	Membrane Heat Pump	4	3	3	10	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
	Thermoelectric	3	3	4	10	N
	Thermotunneling	4	3	3	11	N
	Vuilleumier Heat Pump	4	3	3	10	N
Stationary AC: Single split systems	Absorption Heat Pump	3	3	5	11	N
	Adsorption Heat Pump	3	3	3	9	N
	Brayton Heat Pump	2	5	3	10	N
	Duplex-Stirling Heat Pump	4	5	3	12	N
	Ejector Heat Pump	4	3	3	10	N
	Evaporative Desiccant Conditioner Liquid Air	4	3	4	11	N
	Ground-Coupled Desiccant Conditioner Solid Air	3	3	4	10	N
	Magnetocaloric	4	3	3	10	N
	Membrane Heat Pump	4	3	3	10	N
	Standalone Desiccant Conditioner Liquid Air	3	5	5	13	N

Application	Alternative	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
	Standalone Desiccant Conditioner Solid Air	2	5	5	12	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
	Thermoelectric	4	3	4	11	N
	Thermotunneling	4	3	4	11	N
	Vuilleumier Heat Pump	3	3	3	9	N
AC: Multi split systems (VRF)	Absorption Heat Pump	3	3	5	11	N
	Adsorption Heat Pump	3	3	3	9	N
	Brayton Heat Pump	2	5	3	10	N
	Duplex-Stirling Heat Pump	4	5	3	12	N
	Ejector Heat Pump	3	3	3	9	N
	Evaporative Desiccant Conditioner Liquid Air	3	3	4	10	N
	Ground-Coupled Desiccant Conditioner Solid Air	2	3	4	9	Y
	Magnetocaloric	4	3	3	10	N
	Membrane Heat Pump	4	3	3	10	N
	Standalone Desiccant Conditioner Liquid Air	2	5	5	12	N

Application	Alternative	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
	Standalone Desiccant Conditioner Solid Air	1	5	5	11	N
	Thermoacoustic	4	3	4	11	N
	Thermoelastic	4	3	3	10	N
	Thermoelectric	4	3	4	11	N
	Thermotunneling	4	3	4	11	N
	Vuilleumier Heat Pump	3	3	3	9	N
Foam Insulation Construction -	Cellulose	2	4	4	10	N
	Cork	2	4	4	10	N
	Cotton	2	4	3	9	N
	Expanded clay	2	5	3	11	N
	Fibreglass	2	4	3	9	N
	Flax	2	4	4	10	N
	Foam concrete	3	4	3	10	N
	Foamed glass	3	4	5	12	N
	Mineral fibres	2	4	3	9	N
	Perlite	3	4	3	10	N
	Reeds	3	5	3	11	N
	Sheep's wool	2	4	4	10	N
	Straw bales	3	4	2	9	N
	Vermiculite	2	4	4	10	N
	Wood fibres	2	4	4	10	N

Application	Alternative	Technical Assessment	Performance Assessment	Economic Assessment	Total Score	Acceptable
Foam Insulation - Refrigeration	Aerogel	2	1	5	8	N
	Hemp	2	4	4	10	N
	GEOLYTH	3	4	3	10	N
Metered Dose Inhalers	Aerogel	2	1	5	8	N
	Hemp	2	4	4	10	N
	Dry Powder Inhalers	2	3	4	9	Y
Propellant	Nebuliser	4	4	4	12	N
	Soft-mist inhaler	3	2	4	9	N
	Bag-in-can/piston-can systems	2	2	4	8	Y
	Finger pumps	3	3	3	9	N
	Non-spray products	3	3	3	9	N
	Powders	2	3	3	8	Y
Solvent	Roll-on liquids / sticks	3	4	3	10	N
	Squeeze bottles	3	3	3	9	N
	PurgoSpray	3	3	4	10	N
Solvent	Plasma cleaning	3	2	4	9	N
	Supercritical fluids	3	3	3	9	N

Table A 21 Summary of technical, performance, economic, and lifecycle considerations of each potential alternative.

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
RACH	Ammonia	Industrial Refrigeration Transport Refrigeration Chillers	Exposure to ammonia can result in burning or irritation of the eyes and throat, as ammonia bonds with moisture on the body to form ammonia hydroxide. More serious hazards of ammonia at high concentrations include severe burns to skin and eyes, blindness, respiratory damage, and death ⁴⁸⁰ . Furthermore, ammonia can form highly flammable hydrogen gas during thermal decomposition. Ammonia emissions also contribute to fine particulate matter (PM _{2.5}) pollution through the chemical formation of particulate ammonium sulphate and ammonium nitrate, which are responsible for tens of thousands of deaths annually ⁴⁸¹ .	Ammonia is one of the main sources of nitrogen pollution which impacts negatively on biodiversity through nitrogen accumulation within habitats ⁴⁸² . As nitrogen is a natural fertiliser, common fast growing plant species may adapt to the abundance of nitrogen and out compete more specifically adapted plant species, resulting in a loss of biodiversity. Ammonia itself is toxic to aquatic life, and when dissolved in surface water ammonia exists in two forms, unionised and ionised. The unionised form is of concern because it has greater bioavailability and therefore can readily pass from the water into fish via the gills, often through the process of passive diffusion of ammonia gas in the water ⁴⁸³ . Acute exposure of ammonia to fish may cause loss of equilibrium, hyperexcitability, increased breathing/oxygen uptake, cardiac output, convulsions, coma, and death.	Ammonia is currently the preferred refrigerant for low and medium temperature systems.	Ammonia delivers highly efficient cooling because of its high latent heat, high specific heat capacity, high thermal conductivity, and low viscosity. The use of ammonia is not always suitable, for example in populous residential areas, due to its hazardous properties.	The use of ammonia is not always suitable for smaller systems where the cost of equipment and safety compliance can be prohibitive. This means it is only cost-effective for large systems.	Current commercial production of ammonia involves processes that consume large amounts of fossil fuels. Producing ammonia via renewable or nuclear energy reduce the GWP, but this is dependent on either the availability of large-scale renewable energy resources and the socio-political acceptability of nuclear power.
	Carbon dioxide	Mobile Air Conditioning Transport Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units)	Carbon dioxide is not classified as being hazardous to human health under the CLP Regulation and occurs naturally in the air at concentrations of approximately 400ppm where it is non-toxic. However, at higher concentrations (e.g. >5,000ppm) it can cause increased rate of breathing, depression of the central	Carbon dioxide is not known to have any adverse environmental effects, aside from its global warming potential.	Carbon dioxide is commonly used in supermarket refrigeration systems and has been used in marine transportation. Use in land transportation may be deemed unsuitable because of strict transport fire regulation. Medium industrial refrigeration systems are similar in size to	The energy efficiency of CO ₂ systems is comparable to systems using other refrigerants, particularly in cool climates. CO ₂ systems have a lower performance in warm climate.	Carbon dioxide is cheaper than f-gas refrigerants, given that it is a by-product of industrial processes. Installation of CO ₂ systems are also cited as being cheaper than HFC-based systems. However, because CO ₂ systems operate	From a lifecycle perspective, CO ₂ is considered to more environmentally advantageous because of its low GWP. The use of ejector expansion in CO ₂ systems can also result in reduced energy use. However, CO ₂ is a derivative from fossil fuel processing so emissions

⁴⁸⁰ ECHA. Ammonia, anhydrous REACH Dossier. Available at: <https://echa.europa.eu/brief-profile/-/briefprofile/100.028.760>⁴⁸¹ Ma, R., Li, K., Guo, Y. *et al.* Mitigation potential of global ammonia emissions and related health impacts in the trade network. *Nat Commun* 12, 6308 (2021). <https://doi.org/10.1038/s41467-021-25854-3>⁴⁸² Susan Guthrie *et al* (2018). The impact of ammonia emissions from agriculture on biodiversity. Available at: <https://royalsocietypublishing.org/~media/policy/projects/evidence-synthesis/Ammonia/Ammonia-report.pdf>⁴⁸³ The Nature Conservancy (2010) .A Literature Review of Effects of Ammonia on Fish. Available at: <https://www.nature.org/content/dam/tnc/nature/en/documents/literature-review-ammonia.pdf>

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
			nervous system and asphyxiation ⁴⁸⁴ .		supermarket systems so there is the potential for the technology to transfer over to industrial refrigeration. Carbon dioxide operates at higher temperatures and needs special components and safety features built into the refrigeration system. Therefore, it is not possible to use CO2 in existing HFC-based refrigeration systems.		at a higher pressure, require special components and greater safety controls are needed, which lead to a higher initial system cost.	from fossil fuel extraction must be taken into account. Carbon dioxide can be recycled to deliver emissions reductions. Some CO2 recycling pathways have reached market parity today, while the costs of remaining pathways are high (Columbia Climate School, 2021).
	Isobutane	Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Commercial Refrigeration (Centralised Systems) Mobile Air Conditioning Movable Room Air Conditioning Chillers Heat Pumps	Isobutane is considered to have low toxicity to humans and is not classified for any human health hazards. However, it is highly flammable, posing an additional risk to human health over F-gases.	Isobutane gas is not classified as being hazardous to the environment and isn't persistent nor bioaccumulative so does not pose a risk to environmental health.	Isobutane is used in nearly all domestic refrigerators and freezers. Isobutane and blends of isobutane and propane are available for use in air conditioners and heat pumps. Due to their flammability, hydrocarbons can only be used safely in small air-conditioning systems where their charge is low. When hydrocarbons are used, safety precautions must be taken. Because of the additional safety measures required, they cannot be retrofitted to existing HFC systems.	Studies have shown the performance of isobutane is comparable HFC-134a in heat pumps, air conditioning, and refrigeration, when used as a sole refrigerant or in combination with propane.	Isobutane is often less expensive than F-gases and requires less total refrigerant charge. Systems using isobutane as a refrigerant can be more cost-effective to operate as isobutane has a higher refrigeration capacity and a high coefficient of performance. However, the production costs are most expensive due to the need to additional safety measures.	Isobutane is derived from fossil fuels, so the emissions associated with oil and natural gas extraction must be taken into account.
	Propane	Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Commercial Refrigeration (Centralised Systems) Mobile Air Conditioning	Propane is considered to have low toxicity to humans and is not classified for any human health hazards. However, it is highly flammable, posing an additional risk to human health over F-gases.	Propane gas is not classified as being hazardous to the environment and isn't persistent nor bioaccumulative so does not pose a risk to environmental health.	Propane is used in domestic and commercial refrigeration systems. Propane and blends of propane and propane are available for use in air conditioners and heat pumps. Due to their flammability, hydrocarbons can only be used safely in small air-conditioning systems and chillers where their charge is low. When	Studies have shown the performance of propane is comparable HFC-134a in heat pumps, air conditioning, and refrigeration, when used as a sole refrigerant or in combination with isobutane.	Propane is often less expensive than F-gases and requires less total refrigerant charge. Systems using propane as a refrigerant can be more cost-effective to operate under most conditions as propane has a higher refrigeration capacity and a high coefficient of performance. However, the production costs are	Propane is derived from fossil fuels, so the emissions associated with oil and natural gas extraction must be taken into account. Propane systems may last longer than HFC system because they have fewer moving parts, although there is no conclusive evidence to suggest they have greater longevity.

⁴⁸⁴ Sawalha, S., 2008. Safety of CO2 in Large Refrigeration Systems, Sweden: Royal Institute of Technology.

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
		Movable Room Air Conditioning Chillers Heat Pumps			hydrocarbons are used, safety precautions must be taken. Because of the additional safety measures required, they cannot be retrofitted to existing HFC systems.		most expensive due to the need to additional safety measures.	
	Propylene	Industrial Refrigeration Domestic Refrigeration Commercial Refrigeration (Hermetically Sealed Standalone Units) Commercial Refrigeration (Centralised Systems) Movable Room Air Conditioning Stationary Air Conditioning (Single-Split Systems) Stationary Air Conditioning (Multi-Split Systems) Chillers	Propylene is considered to have low toxicity to humans and is not classified for any human health hazards. However, it is highly flammable, posing an additional risk to human health over F-gases.	Propylene gas is not classified as being hazardous to the environment and isn't persistent nor bioaccumulative so does not pose a risk to environmental health.	Due to their flammability, hydrocarbons can only be used safely in small air-conditioning systems and chillers where their charge is low. When hydrocarbons are used, safety precautions must be taken. Because of the additional safety measures required, they cannot be retrofitted to existing HFC systems.	Propylene has excellent thermodynamic properties leading to high energy efficiency. A direct comparison to HFC refrigerants was not available.	The cost of hydrocarbons is typically cheaper than HFCs. However, the production costs are most expensive due to the need to additional safety measures.	Propane is derived from fossil fuels, so the emissions associated with oil and natural gas extraction must be taken into account.
	Brayton Heat Pump	Mobile Air Conditioning	No human health risk.	No environmental health risk.	Brayton heat pumps are commonly used in mobile air conditioning in aircraft and trains due to their high reliability and low maintenance requirements. The technology has limited potential for building space conditioning due to its low coefficient of performance (COP) (Ashrae, 2014).	Higher reliability and lower maintenance than vapour compression systems. Heating and cooling coefficients of performance (COP) are below conventional vapour compression systems, so this technology has limited potential for building space conditioning.	No cost data available.	No lifecycle concerns identified.
Foam Insulation	Di-methyl ether	Building Insulation	DME has been shown to have a very low acute inhalation toxicity with a 4h LC ₅₀ in rats of 164,000 ppm ⁴⁸⁵ . Past repeated inhalation studies of up to 2 years in rats, also show that	Di-methyl ether (DME) is not classified as being toxic to aquatic life according to its REACH dossier and the substance does not meet the criteria for persistence and bioaccumulation. Therefore,	Dimethyl ether has long been used as a blowing agent for plastic products.	Limited data on performance	The cost of DME is generally lower than many other commonly used refrigerants. It is typically less expensive than	No evidence found relating to the lifecycle of DME in foam insulation. Studies focusing on the use of DME as a fuel have reported that the largest

⁴⁸⁵ Workplace Environmental Exposure Level (WEEL) Committee; Occupational Alliance for Risk Science (OARS); Toxicology Excellence for Risk Assessment (TERA) (2022). Dimethyl ether (DME). Toxicol Ind Health. pp.713-716. Available at: <https://pubmed.ncbi.nlm.nih.gov/36190179/>

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
			DME was not deemed to be carcinogenic and produced minimal toxicity at 25,000 and 10,000 ppm, with a No-Observed-Adverse-Effect Concentration (NOAEC) of 2000 ppm. The primary finding with inhalation exposure during these studies was a reversible central nervous system depression ⁴⁸⁶ . However, DME does present some physical hazards to humans as it is classed as being an "Extremely flammable gas" (H220 Flam. Gas 1A) and "Contains gas under pressure; may explode if heated" (H280 Compressed gas) ⁴⁸⁷ .	its not consider to pose a risk to environmental health.			hydrofluorocarbons (HFCs) such as R-134a,	environmental impact during its lifecycle was related to the production stage. The production method of DME has a big impact on its environment footprint, as it can be produced from fossils fuels, such as natural gas and coal. DME can also be produced from renewable methods, such as CO2 hydrogenation (Demirel & Matzen, 2016).
	Cyclopentane	Building Insulation Refrigeration Insulation	Cyclopentane is not classified for any health hazards in its in its REACH registration dossier; although it presents a physical hazard and is classified as a highly flammable liquid and vapour (Flam. Liq. 2) ³⁴² .	A literature review on the ecotoxicity of cyclopentane returned few results, however information on predicted ecotoxicity can be found within the substance's REACH dossier. Cyclopentane is stated to be classified under the CLP Regulation as toxic to aquatic life with long lasting effects (aquatic chronic category 2). This classification was determined using the PETROTOX computer model (v4.0) ⁴⁸⁸ .	Cyclopentane is flammable and may only be suitable for use in certain cases, when local storage regulations are not too stringent and a non-flammable blowing agent is needed.	Cyclopentane is able to produce low thermal conductivity foams of 11-13 mW/m.K, which make it suitable for use in both building and refrigeration foam insulation. Appliances using hydrocarbon blown foam can achieve the highest A+ energy efficiency category under the EU's standards ⁴⁸⁹	The cost of hydrocarbons is typically cheaper than HFCs, but they increase the operating cost because they have a lower insulating performance. The cost of necessary safety measures and infrastructure during manufacture can make cyclopentane an uneconomical choice of blowing agent for SMEs ⁵⁰² UNEP estimates the cost of a typical cyclopentane technology set up of \$375,000 - \$445,000.	Cyclopentane is typically produced from petroleum refining or cracking of natural gas, so the emissions associated with oil and natural gas extraction must be taken into account.
Metered Dose Inhalers	Dry Power Inhalers	N/A	No risk to human health.	No risk to environmental health.	Can be used to deliver most drugs. DPIs may not be suitable for some patient groups	Simple to use for those with cognitive impairments and suitable for those who have difficulty with	Drug costs would rise if MDIs were replaced with DPIs. A recent analysis (Pritchard, 2020) showed that in	DPIs can be recycled and contain 1kg of CO2 vs 20kg for an MDI. While DPIs have been found to bring significant benefits

⁴⁸⁶ Ibid⁴⁸⁷ ECHA (2023). Di-methyl ether ECHA REACH Dossier. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15974/2/1>⁴⁸⁸ Cyclopentane. ECHA REACH dossier. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/14830/6/2/1>⁴⁸⁹ IPCC (2007) Climate Change 2007: Working Group I: The Physical Science Basis. Available at: https://archive.ipcc.ch/publications_and_data/ar4/wg1/en/ch2s2-10-2.html

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
					because they require a deep and forceful inhalation and there are groups of patients that struggle to generate sufficient inspiratory flows to get adequate delivery from a DPI, such as COPD patients, young children, and very old people.	coordination. However, there are groups of patients who struggle to generate sufficient inspiratory flows to get adequate delivery from a DPI. DPIs are also not suitable for use in hot or humid climates.	every country, the cost of DPIs is greater per dose than the cost of MDIs, sometimes by nearly 600%. However, in recent years the average sale price difference between MDIs and DPIs has narrowed slightly. It's also projected that the reduction in non-medical uses of HFC propellants is likely to give rise to a 5-fold increase in their cost for MDI uses and is likely to hit the Western world in 2025.	to climate change impacts (i.e. GWP and ozone depletion), they have been found to perform worse in many other environmental impacts, such as marine eutrophication and fossil depletion ⁴⁹⁰ .
Magnesium Cover Gas	Carbon dioxide	N/A	Carbon dioxide is not classified as being hazardous to human health under the CLP Regulation and occurs naturally in the air at concentrations of approximately 400ppm where it is non-toxic. However, at higher concentrations (e.g. >5,000ppm) it can cause increased rate of breathing, depression of the central nervous system and asphyxiation ⁴⁹¹ . The use of solid CO2 has also been cited to generate toxic carbon monoxide ⁴⁹²	Carbon dioxide is not known to have any adverse environmental effects, aside from its global warming potential.	Carbon dioxide is commercially available and no technical barriers were identified.	Pure CO2 and mixtures up to 20 vol.% air/CO2 can protect molten magnesium ⁴⁹²	Carbon dioxide is cheaper than F-gases, given that it is a by-product of industrial processes.	From a lifecycle perspective, CO2 is considered to more environmentally advantageous because of its low GWP. The use of ejector expansion in CO2 systems can also result in reduced energy use. However, CO2 is a derivative from fossil fuel processing so emissions from fossil fuel extraction must be taken into account. Carbon dioxide can be recycled to deliver emissions reductions. Some CO2 recycling pathways have reached market parity today, while the costs of remaining pathways are high (Columbia Climate School, 2021).
Aerosols	Butane	Any aerosol that can use a high	Butane is not classified for any human health hazards. However it is highly flammable, posing an	Butane is not classified for environmental hazards under the CLP Regulation and doesn't meet the criteria for	Hydrocarbons can be selected to provide a range of pressure characteristics (by using	No information available comparing performance to F-gases.	The cost of hydrocarbons is typically cheaper than HFCs, making them	Butane is derived from fossil fuels, so the emissions associated with oil and natural gas

⁴⁹⁰ Jeswani, H. K., & Azapagic, A. (2019). Life cycle environmental impacts of inhalers. *Journal of Cleaner Production*, 237, 117733.

⁴⁹¹ Sawalha, S., 2008. Safety of CO2 in Large Refrigeration Systems, Sweden: Royal Institute of Technology.

⁴⁹² Balart, M. J., Patel, J. B., & Fan, Z. (2016). Melt protection of Mg-Al based alloys. *Metals*, 6(6), 131.

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
		flammability propellant	additional risk to human health over F-gases.	persistence of bioaccumulation. It also has a low GWP of 0.006 ⁴⁹³ . It therefore poses a very low risk to environmental health.	different blends of propane and butane). This means that they can be used in all weather/climate conditions. Hydrocarbons are extremely flammable so can only be used where flammability isn't a concern. A significant proportion of consumer aerosols have used hydrocarbons and dimethyl ether (DME) since the 1980s (e.g. personal products such as hair sprays). Most one component foam (OCF) aerosols are now formulated with hydrocarbons or DME. The aerosols have been reengineered to minimise the safety risk and safety instructions alert users on how to avoid ignition ⁴⁹⁷ .		most cost-effective propellants.	extraction must be taken into account.
	Propane	Any aerosol that can use a high flammability propellant	Propane is considered to have low toxicity to humans and are not classified for any human health hazards. They are however highly flammable, posing an additional risk to human health over F-gases.	Propane gas is not classified as being hazardous to the environment and isn't persistent nor bioaccumulative so does not pose a risk to environmental health.	Hydrocarbons can be selected to provide a range of pressure characteristics (by using different blends of propane and butane). This means that they can be used in all weather/climate conditions. Hydrocarbons are extremely flammable so can only be used where flammability isn't a concern. Hydrocarbons are extremely flammable so can only be used where flammability isn't a concern. A significant proportion of consumer aerosols have used hydrocarbons and dimethyl ether (DME) since the 1980s (e.g.	No information available comparing performance to F-gases.	The cost of hydrocarbons is typically cheaper than HFCs, making them most cost-effective propellants.	Propane is derived from fossil fuels, so the emissions associated with oil and natural gas extraction must be taken into account.

⁴⁹³ UNEP (2021) Climate Change 2021 The Physical Science Basis. Available at: https://www.ipcc.ch/report/ar6/wg1/downloads/report/IPCC_AR6_WGI_Full_Report.pdf

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
					personal products such as hair sprays). Most one component foam (OCF) aerosols are now formulated with hydrocarbons or DME. The aerosols have been reengineered to minimise the safety risk and safety instructions alert users on how to avoid ignition ⁴⁹⁷			
	Di-methyl ether	Any aerosol that can use a high flammability propellant	DME has been shown to have a very low acute inhalation toxicity with a 4h LC ₅₀ in rats of 164,000 ppm ⁴⁹⁴ . Past repeated inhalation studies of up to 2 years in rats, also show that DME was not deemed to be carcinogenic and produced minimal toxicity at 25,000 and 10,000 ppm, with a No-Observed-Adverse-Effect Concentration (NOAEC) of 2000 ppm. The primary finding with inhalation exposure during these studies was a reversible central nervous system depression ⁴⁹⁵ . However, DME does present some physical hazards to humans as it is classed as being an "Extremely flammable gas" (H220 Flam. Gas 1A) and "Contains gas under pressure; may explode if heated" (H280 Compressed gas) ⁴⁹⁶ .	Di-methyl ether (DME) is not classified as being toxic to aquatic life according to its REACH dossier and the substance does not meet the criteria for persistence and bioaccumulation. Therefore, its not consider to pose a risk to environmental health.	A significant proportion of consumer aerosols have used hydrocarbons and dimethyl ether (DME) since the 1980s (e.g. personal products such as hair sprays). Most one component foam (OCF) aerosols are now formulated with hydrocarbons or DME. The aerosols have been reengineered to minimise the safety risk and safety instructions alert users on how to avoid ignition ⁴⁹⁷	No information available comparing performance to F-gases.	The cost of DME is typically cheaper than HFCs, making it a most cost-effective propellant.	No evidence found relating to the lifecycle of DME as a propellant. Studies focusing on the use of DME as a fuel have reported that the largest environmental impact during its lifecycle was related to the production stage. The production method of DME has a big impact on its environment footprint, as it can be produced from fossils fuels, such as natural gas and coal. DME can also be produced from renewable methods, such as CO ₂ hydrogenation (Demirel & Matzen, 2016).
	Nitrous oxide	Some technical and consumer aerosols (e.g. dusters) and food products (e.g. cream; cheese)	Nitrous oxide is classified for STOT SE 3 (H335: Specific target organ toxicity, single exposure; Respiratory tract irritation) with documented health impacts from prolonged exposure occurring from the use of the	Nitrous oxide has a 100-year GWP of 273 so has the potential to contribute significantly to climate change.	Generally made by heating ammonium nitrate, with by-products nitrogen dioxide (poisonous red gas) ammonia (poisonous), chloride (green-yellow, poisonous), carbon	No information available comparing performance to F-gases.	No information available comparing cost to F-gases.	Nitrous oxide has a 100-year GWP of 298 ⁵⁰² . Nitrous oxide is also an ozone depleting substance ⁵⁰³ and is a precursor to the formation

⁴⁹⁴ Workplace Environmental Exposure Level (WEEL) Committee; Occupational Alliance for Risk Science (OARS); Toxicology Excellence for Risk Assessment (TERA) (2022). Dimethyl ether (DME). Toxicol Ind Health. pp.713-716. Available at: <https://pubmed.ncbi.nlm.nih.gov/36190179/>

⁴⁹⁵ Ibid

⁴⁹⁶ ECHA (2023). Di-methyl ether ECHA REACH Dossier. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15974/2/1>

⁴⁹⁷ Gluckman Consulting (2015) <http://www.gluckmanconsulting.com/wp-content/uploads/2015/04/FS-14-Aerosols-final-rev1.pdf>

⁵⁰² IPCC (2007) Climate Change 2007: Working Group I: The Physical Science Basis. Available at: https://archive.ipcc.ch/publications_and_data/ar4/wg1/en/ch2s2-10-2.html

⁵⁰³ Ravishankara, A. R., Daniel, J. S., & Portmann, R. W. (2009). Nitrous oxide (N₂O): the dominant ozone-depleting substance emitted in the 21st century. science, 326(5949), 123-125.

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
		Rocket propellant	substance as a recreational drug or medical or dental anaesthetic ^{498,499} .		monoxide (poisonous), nitrogen, carbon dioxide, water ⁵⁰⁰ Severe accidents have happened before at facilities producing nitrous oxide from ammonium nitrate. In addition, nitrous oxide gas in elevated concentrations can cause health effects in operators which should be prevented. Careful attention needs to be paid to the equipment used and the operating procedures ⁵⁰¹			of ground-level ozone, a component of smog ⁵⁰⁴
	Carbon dioxide	Some technical and consumer aerosols (e.g. dusters)	Carbon dioxide is not classified as being hazardous to human health under the CLP Regulation and occurs naturally in the air at concentrations of approximately 400ppm where it is non-toxic. However, at higher concentrations (e.g. >5,000ppm) it can cause increased rate of breathing, depression of the central nervous system and asphyxiation ⁵⁰⁵ .	Carbon dioxide is not known to have any adverse environmental effects, aside from its global warming potential.	CO2 has long been used as a propellant in some technical and consumer applications (e.g., dusters).	Tec Industries have patented a technology that uses carbon dioxide as a propellant. When it used at a maximum of 3% in spray cans, CO2 can last 3 times longer than other propellants. ⁵⁰⁶	Carbon dioxide is cheaper than f-gas refrigerants, given that it is a by-product of industrial processes.	CO2 is a derivative from fossil fuel processing so emissions from fossil fuel extraction must be taken into account. Carbon dioxide can be recycled to deliver emissions reductions. Some CO2 recycling pathways have reached market parity today, while the costs of remaining pathways are high (Columbia Climate School, 2021).
	Nitrogen	Some technical and consumer aerosols (e.g. dusters)	Nitrogen is not classified under CLP for human health hazards but it presents a physical hazard from its classification as a pressurised gas under CLP ⁵⁰⁷ .	Nitrogen occurs naturally within the earth's atmosphere, making up approximately 78% of the air we breathe ⁵⁰⁸ . It has a global warming effect 300 times greater than carbon dioxide and remains active in the atmosphere for more than	Nitrogen has long been used as a propellant in some technical and consumer applications (e.g., dusters). Nitrogen can be used with in bag on valve (BOV) products, piston can aerosol products and, more	A benefit of nitrogen use as a propellant in aerosols is that it doesn't burn as it is not organic. However, tilting the can over the horizontal level can	Nitrogen is cheaper than HFCs due to its abundance in the atmosphere and because it is relatively easy and cost-effective to extract nitrogen from the atmosphere using	A 2010 study conducted by the European Industrial Gas Institute (EIGA) which was re-validated in 2019, found that the production of nitrogen at a typical air separation plant requires

⁴⁹⁸ Oussalah, A., Julien, M., Levy, J., Hajjar, O., Franczak, C., Stephan, C., ... & Guéant, J. L. (2019). Global burden related to nitrous oxide exposure in medical and recreational settings: a systematic review and individual patient data meta-analysis. *Journal of clinical medicine*, 8(4), 551.

⁴⁹⁹ Shah, K., and Murphy, C. (2019). Nitrous Oxide Toxicity: Case Files of the Carolinas Medical Center Medical Toxicology Fellowship. *J Med Toxicol.* (4), pp.299-303. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6825085/>

⁵⁰⁰ University of Utah (n.d.) Nitrous Oxide – Physical Characteristics. Available at: https://library.med.utah.edu/kw/derm/pages/ni01_2.htm

⁵⁰¹ EIGA (2010) Indirect CO2 emissions compensation: Benchmark proposal for Air Separation Plants. Available at: <https://puritygas.ca/wp-content/uploads/2021/12/EIGA-PP33.pdf>

⁵⁰⁴ Brind'Amour & Lee (2022) Laughing Gas Is No Joke: The Forgotten Greenhouse Gas. Available at: <https://www.eesi.org/articles/view/laughing-gas-is-no-joke-the-forgotten-greenhouse-gas>

⁵⁰⁵ Sawalha, S., 2008. Safety of CO2 in Large Refrigeration Systems, Sweden: Royal Institute of Technology.

⁵⁰⁶ PURMate (n.d.) Aerosol with CO2 As A Propellant. Available at: <https://www.purmate.com/en/aerosol-with-co2-as-a-propellant/>

⁵⁰⁷ ECHA (2023) Substance Infocard: Nitrogen. Available at: <https://echa.europa.eu/substance-information/-/substanceinfo/100.028.895>

⁵⁰⁸ NASA (n.d.). 10 interesting things about air. Available at:

<https://climate.nasa.gov/news/2491/10-interesting-things-about-air/#:~:text=It's%20a%20mixture%20of%20different,nitrogen%20and%2021%20percent%20oxygen.>

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
				100 years. It can also cause algal blooms in lakes and waterways ⁵⁰⁹ , which themselves emit greenhouse gases, although emissions of nitrogen to water are unlikely to occur when used as a gas.	recently, in the original general aerosol ⁵¹⁰	reduce spraying performance ⁵¹⁰	air separation technologies. Nitrogen gas is widely used in various industries, such as food processing, electronics, pharmaceuticals, and metal fabrication. Due to its extensive use and high demand, nitrogen gas production is well-established, and economies of scale are achieved, leading to lower production costs.	549 kWh per tonne of liquid nitrogen ⁵⁰¹ Nitrogen released to the atmosphere does not pose any environmental concerns.
	Bag-in-can/piston-can systems	Most aerosols	No human health risk.	No environmental health risk.	Not suitable for products that need to be shaken before use (e.g. paint and powder products) or substances that have little gas propellants such as shaving cream, mousse and foaming products ⁵¹²	Advantages include: • Can be used with container in any convenient position; • About 98% of the contents can be dispensed • No risk of product contamination by metals • Allows for a controlled spray • Contents can be kept moisture free Disadvantages include: • Some designs can leak • The bag reduces space for contents ⁵¹¹	Bag-in-can systems have a high cost than conventional aerosols ^{511 512}	Bag-in-can system use more materials because of the laminated bag inside, which is made from four layers of plastic. A bigger can is also required for the same quantity of contents because of the space the bag occupies. However, bag-in-can systems can be close to 100% of the contents out of the can, so there is minimal waste ⁵¹²
Fire Suppressant	[product name]	N/A	[product name] is not classified as being hazardous under the CLP Regulation so does not pose a risk to human health.	[product name] has moderate toxicity as it is classified as Aquatic Chronic 3 under CLP.	The greater reactivity of [product name] means that it is best to upgrade components of the cover gas delivery system as needed rather than to use [product name] fluid as a simple drop-in replacement agent	Extinguishes fire much more quickly than CO ₂ or inert gas - 40 seconds compared to 150 seconds. It also requires 5 times fewer cylinders than CO ₂ , meaning a lower system footprint. Provides a high safety margin with	Requires 5 times fewer cylinders than CO ₂ , meaning a lower system cost. A lower concentration is needed than HFC227ea ⁵¹³ .	[product name] has a short atmospheric lifetime of 5 days resulting in a GWP of 1. It can also reportedly be disposed of at an industrial waste facility or incinerated through a waste facility, but the environmental

⁵⁰⁹ UNEP (2023) Four reasons why the world needs to limit nitrogen pollution. Available at: <https://www.unep.org/news-and-stories/story/four-reasons-why-world-needs-limit-nitrogen-pollution#:~:text=Nitrogen%20is%20a%20key%20contributor%20to%20climate%20change&text=This%20gas%20is%20300%20times,off%2C%20also%20emit%20greenhouse%20gases.>

⁵¹⁰ Dawsom (2020) 8 Advantages to Use Nitrogen (N₂) as Aerosol Propellant Gas. Available at: <https://www.dawsom.com/8-advantages-to-use-nitrogenn2-as-aerosol-propellant-gas/>

⁵¹¹ US EPA (1989) Aerosol Industry Success in Reducing CFC Propellant Usage. Available at: <https://nepis.epa.gov/Exe/ZyPDF.cgi/P1010UDW.PDF?Dockey=P1010UDW.PDF>

⁵¹² Signature Filling Company (2019). How Bag on Valve Is Changing the Aerosol Industry. Available at: <https://signaturefillingcompany.com/bag-on-valve-changing-aerosol-industry/>

⁵¹³ Fire Suppression (n.d.) How much does a fire suppression system cost. Available at: <https://www.firesuppression.co.uk/price-for-fire-suppression-systems.aspx>

Application	Alternative	Suitable Uses	Human Health Considerations	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Cycle Considerations
						a 4.2% use concentration and a 10% NOAEL level.		consequences are not known.
Solvent	[product name]; [product name]; HFE-7000; HFE-7100; HFE-7200; HFE-347pcf2	Cleaning of electronics, metals, and plastics	[product name], [product name], HFE-7000, HFE-7100, and HFE-7200, are all not classified for any human health hazards under CLP and would therefore not present a risk to human health. [product name] has a self-classification of Eye Irr. 2B (H320 Causes eye irritation) and STOT SE 3 (H336 May cause drowsiness or dizziness) ⁵¹⁴ and therefore presents a greater risk to human health than the currently used F-gases. HFE-347pcf2 is classified under CLP for Irrit. 2 (H315); Eye Irrit. 2 (H319); STOT SE 3 (H335) ⁵¹⁵ . The US EPA state that higher concentrations may produce heart irregularities, central nervous system depression, narcosis, unconsciousness, respiratory failure, and death. The EPA also indicate that that HFE-347pcf2 is toxic by inhalation, and mortality was observed at high concentrations of 2000 ppm and above ⁵¹⁶ .	HFE-7000, HFE-7100, and HFE-347pcf2 all have GWP values greater than 300 ^{517,518,519} . They are not classified under the CLP Regulation for environmental hazards, so their use is not expected to have a negative impact on the environment other than from their GWP. HFE-7200 has the lowest GWP of the Novec fluids (GWP = 55) is primarily made of ethoxy-nonafluorobutane, which is a mixture of two isomers, both of which are classified as Aquatic Chronic 4 under the CLP Regulation ⁵²⁰ .	HFEs are commercially available and do not pose any technical barriers to use.	HFEs are a credible solution across multiple applications. Compatible with a large range of materials including most metals, numerous plastics, flex circuits and glues. They offer a performance comparable to CFCs ⁵²¹	There was a lack of data on the CAPEX and OPEX costs of using HFEs as solvents. However, the cost of HFEs in generally higher than F-gases. HFEs are more cost effective than several non-fluorinated alternatives because they are non-flammable, which means that HFE safety systems do not require additional safety equipment ⁵²²	The cost of ownership of a solvent cleaning process is greatly impacted by the solvent losses during operation. HFEs have exceptionally low diffusive and drag-out losses compared to most solvents used in vapour degreasing equipment. Diffusive and drag-out losses have a dramatic impact on the operating cost of a cleaning operation ⁵²² .
	MPHE	Oil and grease removal, precision cleaning, vapour decreasing,	MPHE is not classified for human health under the CLP Regulation. However, short-term, high dose inhalation exposure to MPHE has been shown to produce central	MPHE is not classified to environmental hazards under CLP and has a low GWP.	MPHE is commercially available.	Reported to have superior cleaning performance with best solvency power in its class. No data available	No cost data available	No lifecycle concerns identified.

⁵¹⁴ Chemours (2023). SAFETY DATA SHEET [product name] Specialty Fluid. Available at: <https://www.3eonline.com/ImageServer/ImageViewer.aspx?id=XlQc3bGTJQ4mTiUZpsRR7XnRxGqToCKWFLW1ORILW7fU3Hk2qTLSCMF8tg1qN62Nx3UfVLI1a9nqwEO4SRtmly5zFJKZ1LquRRWUkwlaRIY7taVLxIRT0Gt0MYqPkGbh>

⁵¹⁵ ECHA Substance Infocard 1,1,2,2-tetrafluoro-1-(2,2,2-trifluoroethoxy)ethane. Available at: <https://echa.europa.eu/substanceinformation/-/substanceinfo/100.113.045>

⁵¹⁶ US EPA (2015). Air Quality: Revision to the Regulatory (Definition of Volatile Organic Compounds – Exclusion of 1,1,2,2-Tetrafluoro-1-(2,2,2-trifluoroethoxy) ethane (HFE-347pcf2). Available at: https://www.epa.gov/sites/default/files/2016-07/documents/hfe-347pcf2_direct_final.pdf

⁵¹⁷ 3M (n.d.) 3M™ Novec™ 7000 Engineered Fluid: Technical Data Sheet. Available at: <https://multimedia.3m.com/mws/media/121372O/3m-novec-7000-engineered-fluid-tds.pdf>

⁵¹⁸ 3M (n.d.) 3M™ Novec™ 7100 Engineered Fluid: Technical Data Sheet. Available at: <https://multimedia.3m.com/mws/media/199818O/3m-novec-7100-engineered-fluid.pdf>

⁵¹⁹ Greenhouse Gas Protocol (2016) Global Warming Potential Values. Available at: https://ghgprotocol.org/sites/default/files/ghgp/Global-Warming-Potential-Values%20%28Feb%2016%202016%29_1.pdf

⁵²⁰ Sigma Aldrich (2023) Ethoxynonafluorobutane: Safety Data Sheet. Available at: <https://www.sigmaaldrich.com/GB/en/sds/aldrich/592781>

⁵²¹ Kehren (n.d.) A Comparison of Hydrofluoroether and Other Alternative Solvent Cleaning Systems. Available at: http://www.solvents.net.au/index.htm_files/71IPA%20Engineered%20Fluid.pdf

Application	Alternative	Suitable Uses	Human Considerations	Health	Environmental Considerations	Technical Considerations	Performance Considerations	Economic Considerations	Life Considerations	Cycle
		high solvency defluxing, cold cleaning, silicone removal	nervous system depression in rats ⁵²³ .				on direct comparison with F-gases ⁵²⁴			

⁵²³ Methoxytridecafluoroheptene isomers (MPHE) (2021). Toxicology and Industrial Health. 37(8), pp.451-457. Available at: <https://journals.sagepub.com/doi/full/10.1177/07482337211020698>

⁵²⁴ Opteon (n.d.) [product name] Speciality Fluid.

A10 UNCERTAINTY ANALYSIS

There were several limitations within the individual assessments, which lead to some uncertainty with the final recommendation of potential alternatives. These are as follows:

Exposure assessment

The method chosen for the exposure assessment was based on physicochemical properties and a consideration of likely exposure. Within the assessment of the likelihood of exposure, information on the risk management measures and operational conditions used within each sector to reduce exposure was not considered, as this data was unavailable to the Study team. An accurate assessment of the potential exposure also requires greater information on exposure scenarios than was available.

As risk management measures and operational controls were not considered, these uncertainties are expected to have overestimated exposure. However, because few alternatives were excluded from the analysis based on risk level, these are not expected to have had a large impact on the final output.

Technical feasibility

The technical feasibility assessment focussed on technical readiness and whether any changes were required during production/manufacture of the use phase. Industry standards can also play a key part in how feasible an alternative is within a specific application or geography. However, due to the resource constraints of the project, it was not possible to perform a comprehensive mapping exercise to identify all the relevant standards. This is because standards can be specific to Member States and to sub applications within the applications in scope of this study. For each application there can be multiple sub applications, as for example the heat pumps application consists of air-to-air heat pumps, air-to-water heat pumps, water-to-water heat pumps etc, while building insulation consists of phenolic foams, low pressure spray foam, high pressure spray foam etc. Due to resource constraints, capturing this complexity was beyond the scope of this study. However, reference has been made to any identified standards in Section 3.5 and A5, and the acceptability of alternatives has been presented at a high level.

The information obtained through desk research was not able to confirm the stakeholder response regarding the technical readiness of alternatives for certain applications. This highlighted that while an alternative may be commercially available for use in an application, there may be a significant amount of testing that is required by end-users to determine whether the performance can align with industry standards. The switch to alternatives also cannot happen immediately, as time is required by industry to adapt their production facilities and product portfolios.

This uncertainty was addressed by refining the findings based on appropriate information, and due to the weight of evidence collected through the desk research, this is expected to have had little impact on the certainty of the final output of the assessment. Any data gaps in the technical feasibility assessment are highlighted in Section A9.2

Economic feasibility

The consultation with industry provided limited evidence regarding the changes in capital expenditure (CAPEX) and operational expenditure (OPEX) associated with the use of alternatives. Additionally, there was a lack of published quantitative information on the economic feasibility of both alternatives and the chemicals of concern, resulting in data gaps. This was particularly true for emerging technologies and material/design alternatives. The cost of each alternative substance played a significant role in determining their economic feasibility. However, it's important to note that prices can be volatile and subject to change based on market conditions. Therefore, the current cost comparison may not hold true in the future. Due to the limited evidence and dynamic nature of alternative costs, there is a high level of uncertainty surrounding the economic assessment's output. The data gaps in the economic feasibility assessment are highlighted in Section A9.2

Performance assessment

The performance assessment is considered optional in many analysis of alternatives frameworks, especially when the assessing entity is not a manufacturer or downstream user. Detailed information on performance standards and acceptable tolerances is necessary for a thorough evaluation. However, data gaps remained even after consulting industry and conducting desk research. Uncertainty exists regarding the performance of emerging technologies and whether modifications can be made to meet the requirements of the chemicals of concern. The data gaps in the performance assessment are highlighted in Section A9.2

Evidence collected through industry consultation also contradicted information from literature review. Additionally, direct comparisons between alternatives and the chemicals of concern were not always possible due to a lack of available evidence. This leads to uncertainty in the final output of the performance assessment.

Overall, these findings emphasise the challenges posed by limited evidence, data gaps, volatility of costs, uncertainty in assessments, and the need for more comprehensive information when evaluating alternatives.

APPENDIX B SOCIO-ECONOMIC ASSESSMENT METHODOLOGY

This annex provides additional details of the methodology employed for the assessment of business impacts and knock-on economic effects that could potentially result from the implementation of the proposed restriction. Three aspects are explored:

- Baseline estimation
- Knock-on effects to the wider economy
- Annualization of impacts

B1 BASELINE ESTIMATION

This study defined and characterised how different business figures of the EEA F-gas manufacturers and importers, and EEA F-gas downstream users, would likely evolve in the absence further regulatory action, drawing from Tool #57, Tool #58, Tool #59, and Tool #60 of the EC's Better Regulation Toolbox⁵²⁵. This includes:

- Defining the **'Do nothing' or baseline scenario**, that is, what the EEA F-gas manufacturers and importers, and EEA F-gas downstream users would look like in the absence of further regulatory action;
- Identifying key economic and sectoral indicators that can be used to characterise the potential evolution of the market of EEA F-gas manufacture and import, and EEA's different F-gas downstream using applications; and
- Quantifying how these indicators would likely evolve over a period of 20 years (2020-2040⁵²⁶).

First, policy experts from the study team defined what the 'Do nothing' scenario would look like in terms of EEA legislation. In particular, the study team experts confirmed the existing legislation and the legislative changes that are already expected for implementation over the period without the need for the EEA to take any further legal action.

From a business perspective, it was assumed that the existing framework with the phase-down established by the F-gas Regulation, would continue broadly as-is over the period, and F-gas manufacturers and importers progressively switching from higher GWP (and subject to the phase-down) F-gases to lower GWP H(C)FOs and blends of HFC/H(C)FOs (not subject to the phase-down).

Secondly, the team established a set of indicators of focus to characterise the baseline of the EEA F-gas manufacturers and importers, the EEA F-gas downstream users, and the EEA economy, which would become the quantitative baseline against which the policy options would be assessed. Table B 1 below outlines the selected indicators, based on their relevance and the evidence available from Eurostat, the EEA and OECD Statistics.

Table B 1 Sectoral indicators selected for baseline characterisation.

Theme	Indicators
Business volume and growth	• Sectoral output, production value or turnover (€ millions), total and by F-gas in scope • Sectoral Gross Value Added (€ millions), approximately capturing the F-gases in scope's contribution to Gross Domestic Product • Gross investment (€ millions) • Operating expenditure (€ millions) • Research and Development expenditure (€ millions)
Regulatory burden	• One-off and recurring regulatory costs (€ millions)

⁵²⁵ European Commission, (2021) Tool #57 Methods to assess costs and benefits, Tool #58 EU Standard Cost Model, Tool #59 Cost estimates and the 'one in, one out' approach, and Tool #60 Baselines. Available from: https://ec.europa.eu/info/sites/default/files/br_toolbox_-_nov_2021_-_chapter_8.pdf

⁵²⁶ A horizon of 30 years, from 2020 to 2050, was estimated for F-gas manufacturers and importers, so as to be able to calculate impacts of RMO 4: Regulatory proposal for amendment of the F-gas Regulation, as this RMO has a timeline for gradual phase-down until 2050.

Theme	Indicators
Employment	Number of jobs supported by the sector (Number of jobs)

Historical evidence and data were collected from multiple, publicly available sources. Table B 2 provides an overview of these sources for each indicator.

Table B 2 List of economic indicators and statistics used in the definition of a baseline and analysis of impacts.

Indicator	Scope	Sources
Turnover	- Geo: EU-27 - Time: 2008-2019 - Other: industrial gases sector, NACE Rev. 2 Code C20.11	Eurostat Structural Business Statistics
Production value	- Geo: EU-27 - Time: 2008-2019 - Other: F-gas downstream using application product categories	Eurostat Prodcom Database
Gross Value added (GVA)	- Geo: EU-27 - Time: 2008-2019 - Other: industrial gases sector, NACE Rev. 2 Code C20.11	Eurostat Structural Business Statistics
Intermediate consumption/ Opex	- Geo: EU-27 - Time: 2008-2019 - Other: industrial gases sector, NACE Rev. 2 Code C20.11	Eurostat Structural Business Statistics
Capital expenditure	- Geo: EU-27 - Time: 2008-2019 - Other: industrial gases sector, NACE Rev. 2 Code C20.11	Eurostat Structural Business Statistics
R&D	- Geo: EU-27 - Time: 2008-2019 - Other: industrial gases sector, NACE Rev. 2 Code C20.11	Cefic Facts and Figures 2021 and Country Reports
Regulatory burden	- Geo: EU-27 - Time: 2008-2019 - Other: industrial gases sector, NACE Rev. 2 Code C20.11	Cefic Facts and Figures 2021 and Country reports
Employment	- Geo: EU-27 - Time: 2008-2019 - Other: industrial gases sector, NACE Rev. 2 Code C20.11	- Eurostat Structural Business Statistics - Eurostat LFSI_EMP_A
GDP	- GDP historic series and baseline projections for EU countries (2020-2040) - GDP deflator historic series and baseline projections for EU countries (2020-2040) - Population historic series and baseline projections for EU countries (2020-2040)	- OECD long-term macroeconomic projections⁵²⁷ - Eurostat NAMA_10 - Eurostat NAIDA_10 - European Commission (2022). Winter 2022 Economic Forecast.

Some data gaps were identified, which rendered the data series incomplete for some of the economic indicators at the EU-27 industrial gases sector level. These gaps were addressed by employing data available

⁵²⁷ OECD (2018), GDP long-term forecast (indicator). doi: 10.1787/d927bc18-en (Accessed on April 2022)

at the sector and country levels for EU-27 and employing trend analysis or other reasonable assumptions to address said gaps.

For those figures for the EEA F-gas manufacturers and importers that are at the level of the EU-27 and/or the industrial gas sector, their percentage annual growth was calculated, and then applied to the figures declared in consultation by F-gas manufacturers and importers, which are estimated to represent their whole sector (i.e., F-gas manufacture and import).

For downstream using application sectors, their sales value at the level of the EEA was the only evidence available that would represent (close to) the whole sector for each of them. Based on the value of turnover provided via consultation by F-gas downstream users, an extrapolation could be done to obtain sector-level values of production value and employment, assuming the share of their industries that did not participate in consultation was well represented by the participant sample.

Once a historical dataset was completed based on the best evidence available and expert input, regression analysis techniques were employed to estimate sectoral turnover over the next two decades (2020-2040). A pooled Ordinary Least Squares model was specified to quantify the historical relationships between sectoral turnover (the dependent variable) and real GDP per capita, population growth and a time trend (the independent variables). This was done for the turnover of F-gas manufacturers and importers, and for the production value of each downstream using application with independent estimations and individual sector-specific parameters. A second layer of evidence of future trajectory was added to the baseline of F-gas manufacture and import by F-gas, whereby the F-gas Regulation phase-down was applied to the volumes of each of the F-gases in scope, in tonnes, using the CO₂-e emission factor to convert from the actual phase-down in the F-gas Regulation (in tCO₂-e) to tonnes. The turnover from phased down HFCs reduces proportionally to the phase-down in tonnes (as transformed from the phase-down profile in tonnes of CO₂-e using GWP factors), while the turnover from H(C)FOs is left to grow freely following past trends from the F-gas industry and including GDP projection trends.

These estimated relationships were coupled with projections of real GDP capita and population by public institutions such as Eurostat and the OECD to produce turnover projections.

All other selected variables were estimated based on their relationship with turnover, as summarised in the Table below.

Table B 3 Baseline projection of the other selected indicators.

Indicator	Method of projection
Output/ production value	Economic output or production value projections are computed as a proportion of turnover, based on the average historic ratio of turnover to economic output/production value from 2008-2019.
Gross Value added (GVA)	GVA projections are developed from the difference between production value and intermediate consumption.
Intermediate consumption/ Opex	Intermediate consumption is estimated based on the average historic ratio of intermediate consumption per unit of production over the period 2008-2019. Opex is assumed to follow similar annual growth as intermediate consumption.
Capital expenditure	Capital expenditure is estimated based on the historical average capex per unit of turnover from 2008-2019.
R&D	R&D expenditure is estimated to follow a similar growth pattern as turnover.
Regulatory burden	Baseline regulatory burden is expected to remain constant as a 3.7% of turnover, based on Technopolis Group, VVA. (2016) and Cefic Facts & Figures reports, for specialty chemicals.
Employment	Number of employees is computed by assuming a relatively constant relationship in employment per unit of production, whilst taking into account employment stickiness observed in the past (i.e., slower downward adjustments, based on historical evidence and the evidence collected through a bespoke survey).

B2 KNOCK-ON EFFECTS TO THE WIDER ECONOMY AND INPUT-OUTPUT METHODOLOGY

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the proposed restriction on the F-gas manufacture and import have been estimated using an Input-Output methodology.

First, GVA measures the contribution that the EEA F-gas manufacture and import makes to the economy. The two methods of measuring GVA used in this analysis are:

- The production approach that estimates the value of the goods and services produced minus the value of inputs into their production (such as raw materials)
- The income approach that determines the incomes earned by businesses and workers in producing these goods and services

Secondly, the total impact of a policy change in the sectoral GVA equals the sum of:

- Direct impact, that is, the immediate effect of a policy change on the sectoral production and, thus, on its value added; and
- Indirect impacts, that is, any impacts on the sector's value chain, which would be reflected in changes to the intermediate demand for inputs to other sectors; and
- Induced impacts, that is, knock-on effects on the broader economy attributed to how the direct and indirect effects may result in changes to the compensation of employees, which would cause further changes in final demand and spending throughout the whole economy.

The direct effects have been estimated by drawing on the survey to F-gas manufacturers and importers and publicly available data.

The Leontief or Input-Output model, and the associated matrices of economic activity and interconnectedness, provides a methodology for estimating the indirect and induced effects, or the knock-on effects on the economy associated with the direct impacts on the F-gas sector, as pertaining to the wider chemicals sector.

This model allows us to estimate the multipliers or factors that represent how one euro spent in one sector results in economic activity throughout the supply chain and/or other sectors, and so on and so forth).

- Type I multipliers capture the direct and indirect effects only (that is, Type I multiplier minus 1 would capture the indirect effects or the economic impacts throughout the supply chain).
- Type II multipliers also capture the induced effects, under the implicit assumption that final consumers do not change their final consumption patterns in response to changes in income (that is, Type II multiplier minus 1 would capture the indirect and induced effects or the impact throughout the supply chain as well as the effects on the wider economy resulting from changes in compensation to employees).

For the production approach, the cumulative Type I and Type II multipliers have been assumed at around 2.8 and 3.4 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

For the income approach, the cumulative Type I and Type II multipliers have been assumed at around 2.1 and 3.1 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

B3 ANNUALIZATION OF TOTAL IMPACTS AND COSTS

Where required, Equivalent Annual Costs or Impacts were calculated for the selected indicators.

First, the Net Present Value (NPV) of any impact or cost over the period 2024-2040 was estimated by summing the projected cost over the period and discounted at a real discount rate of 4% in line with the Commission's Better Regulation Toolbox #64⁵²⁸. The following equation was employed.

⁵²⁸ European Commission, (2021) *TOOL #64. DISCOUNT FACTORS* Available from: https://ec.europa.eu/info/sites/default/files/br_toolbox_-_nov_2021_-_chapter_8.pdf

Equation B 1 $NPV = \sum_{t=0}^n \frac{C_t}{(1+r)^t}$, where n refers to the time period from 2023-2040, C_t refers to the costs or impacts in time period t , and r refers to the real discount rate.

Secondly, the NPV of the cost or impact was multiplied by an annualization factor, pertaining to the period of policy impact, which is 2024-2040. This factor is given by the following equation.

Equation B 2 $AF = r/[1 - (1 + r)^{-n}]$, where r refers to the real discount rate and n refers to the number of periods. Note that this formula and approach were adapted to account for the timetable of policy implementation. No impacts are expected before 2025.

APPENDIX C RMO SCREENING

Table C 1 Summary of RMO longlist screening

RMO	How does the RMO address the risk	Isolation or combination of RMO	Considerations	Uses	F-gases	Lifecycle stage	Substance of concern	Human health/ environmental concern	Environmental compartment
No action required	It does not. Only valid where no concern is justified	N/A	There is sufficient risk management employed and there is no reduction in risk possible so no action is needed	All	All	All	F-gases TFA	All	All
Substance evaluation under REACH	It does not address the risk directly, it allows for the generation of data to assess the level of risk	Combination	Have the substances been evaluated? What were the conclusions of the evaluation?	All	HFC-125 HFC-134a HFC-143a HFC-227ea HFO-1234ze(E) HFO-1336mzz(Z) HCFO-1233zd(E)	All	F-gases	All	N/A
Restriction under REACH	It addresses the risk stemming from the TFA breakdown product by restricting the use of F-gases after a certain period of time. The restriction allows for alternatives to be brought to the market to	Isolation	Is there an immediate risk of harm to human health or the environment? Is the risk to human health or the environment being addressed under other legislation?	All	All	All	F-gases TFA	Env	All

RMO	How does the RMO address the risk	Isolation or combination of RMO	Considerations	Uses	F-gases	Lifecycle stage	Substance of concern	Human health/ environmental concern	Environmental compartment
	mitigate socio-economic impacts (the degree to which is unknown)								
SVHC identification and candidate listing under REACH	It does not address the risk directly but would allow for further regulatory action	Combination	Does the substance meet the criteria of Article 57?	All	All	All	F-gases TFA	Env	All
Authorisation under REACH	It may address the risk stemming from the TFA breakdown product by restricting the use of F-gases after a certain period of time. The authorisation allows for alternatives to be brought to the market to mitigate socio-economic impacts (the degree to which is unknown)	Combination	Are there uses for which alternatives could be brought to the market within a set period of time? Is there an immediate risk of harm to human health or the environment? Is the risk to human health or the environment being addressed under other legislation?	All	All	All	F-gases TFA	Env	All
Harmonised classification and labelling (CLH) under CLP	It does not address the risk directly, it allows for the generation of data to assess the level of risk	Combination	Does the substance meet the classification criteria for human health or environmental end points	All	All	All	F-gases	Env	N/A

RMO	How does the RMO address the risk	Isolation or combination of RMO	Considerations	Uses	F-gases	Lifecycle stage	Substance of concern	Human health/ environmental concern	Environmental compartment
			including PBT, PMT, EDC						
Regulatory proposal for amendment of F-gas Regulation	It addresses the risk stemming from the TFA breakdown product by restricting the use of F-gases over a certain period of time. Addresses GWP as restricting the use and emission of F-gases.	Combination	Are all of the substances and uses included in the phase down?	All	All	All	F-gases TFA	Env GWP	Air
Environmental quality standards (EQS) under Water Framework Directive	It does not directly address the risk, but could reduce the amount of F-gases present which then reduces the amount of TFA	Combination	Is water a compartment of concern?	All	All	All	F-gases TFA	Env	Water
Occupational exposure limits (OELs) under CAD	It does not address the risk as it concerns human exposure which is not a relevant risk for the F-gases	Isolation	Does the substance have human health or physical hazard concerns that require greater protection?	All	N/A	Manufacture Use	F-gases	Human health	N/A
End-of life and waste requirements	It would reduce the risk of emissions of F-gases and	Combination	Do recovery targets already exist?	All	All	EoL	F-gases TFA	Env GWP	All

RMO	How does the RMO address the risk	Isolation or combination of RMO	Considerations	Uses	F-gases	Lifecycle stage	Substance of concern	Human health/ environmental concern	Environmental compartment
under other EU legislation	potential TFA emissions by recovering and either reusing or destroying the F-gases at waste source								
Refrigerant Management Plan under the Food, Drink and Milk Industries BREF	It works with the F-gas Regulation to ensure that installations monitor their losses and uses of HFOs. It is to be used as duplication of requirements to reinforce, not double regulation.	Combination		RACHP	HFO-1234yf HFO-1234ze(E) HCFO-1233zd(E)	Use	F-gases	GWP	All
Substitution (industry initiative)	It would directly reduce the risk from emissions of F-gases over time by reducing their presence on the market	Combination	Availability of alternatives	All	All	Manufacture Use	F-gases	Env GWP	All



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