

# Evaluation and Impact Assessment of the F-gas Regulation

Fields marked with \* are mandatory.

## Introduction

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Fluorinated gases (F-gases) are strong, man-made greenhouse gases that contribute to global warming. The most relevant F-gases are hydrofluorocarbons (HFCs), as well as perfluorocarbons (PFCs) and sulphur hexafluoride (SF6). Since 1990, EU emissions of F-gases almost doubled until 2014, after which they started to decline due to EU legislation. They are used in various applications (e.g. refrigeration, air-conditioning, insulation foams), but also in some industrial processes and electrical transmission (SF6). The current F-gas Regulation ([Regulation \(EU\) No 517/2014](#)) applies since 2015 and aims at reducing EU F-gas emissions by two-thirds by 2030, compared to 2010 levels.

The F-gas Regulation preceded the passing of both the Paris Climate Agreement and the Kigali Amendment to the Montreal Protocol on substances that deplete the ozone layer, where Parties agreed to limit progressively the production and consumption of HFCs. More recently, the EU Commission adopted the European Green Deal Communication and proposed a European Climate Law establishing the framework for achieving the objective of climate neutrality by 2050, including increasing the ambition of 2030 climate targets. Ambitious action to avoid emissions of high global warming potential (GWP) greenhouse gases such as F-gases is key to reaching these objectives.

The inception impact assessment on the F-gas Regulation can be found [here](#).

*The purpose of this open public consultation (OPC) is to determine public opinion on the performance of the existing F-gas Regulation to date and on the choice and potential impacts of future policy options. As the evaluation of the current Regulation will be conducted back-to-back with the impact assessment of the Commission proposal for revising the rules, this consultation will cover both.*

*This questionnaire is split into three parts: general awareness of F-gas (policy) (Part 1), general views on the F-gas Regulation (Part 2) and specialised views on the choice and impacts of the envisaged policy options (Part 3).*

## About you

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### \* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish

- Dutch
- English
- Estonian
- Finnish
- French
- Gaelic
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

\* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

\* First name

Isabel

\* Surname

PROAÑO

\* Email (this won't be published)

isabel.proano@efanet.org

\* Organisation name

*255 character(s) maximum*

European Federation of Allergy and Airways Diseases Patients' Associations

\* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

Transparency register number

*255 character(s) maximum*

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

28473847513-94

\* Country of origin

Please add your country of origin, or that of your organisation.

- |                                      |  |                                     |  |
|--------------------------------------|--|-------------------------------------|--|
| <input type="radio"/> Afghanistan    | <input type="radio"/> Djibouti           | <input type="radio"/> Libya         | <input type="radio"/> Saint Martin                     |
| <input type="radio"/> Åland Islands  | <input type="radio"/> Dominica           | <input type="radio"/> Liechtenstein | <input type="radio"/> Saint Pierre and Miquelon        |
| <input type="radio"/> Albania        | <input type="radio"/> Dominican Republic | <input type="radio"/> Lithuania     | <input type="radio"/> Saint Vincent and the Grenadines |
| <input type="radio"/> Algeria        | <input type="radio"/> Ecuador            | <input type="radio"/> Luxembourg    | <input type="radio"/> Samoa                            |
| <input type="radio"/> American Samoa | <input type="radio"/> Egypt              | <input type="radio"/> Macau         | <input type="radio"/> San Marino                       |

- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland

- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
  
- Burkina Faso
- Burundi
  
- Cambodia
  
- Cameroon
  
- Canada
- Cape Verde
- Cayman Islands
  
- Central African Republic
- Chad
- Chile
- China
  
- Christmas Island
- Clipperton
  
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
  
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
  
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
  
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
  
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States

- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

**\* Publication privacy settings**

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

**Anonymous**

Only your type of respondent, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.

**Public**

Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

I agree with the [personal data protection provisions](#)

## Part 1 - Awareness of F-gases

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*Part 1 seeks to explore your general awareness of F-gas policy*

### 1. Are you informed about:

	Very well informed	Reasonably well informed	Poorly informed	Not informed
Different types of F-gases, their sources, uses and emissions	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Impact of F-gases on climate change	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
EU F-gas policies	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
International F-gas policies	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
General international and EU climate policies (Paris Agreement, European Green Deal)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

### 2. Are you familiar with:

	Very familiar	Somewhat familiar	Not very familiar	Not familiar
Containment of F-gases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Training and certification for F-gas personnel	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Restrictions related to use of F-gases and equipment	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Quota system for F-gases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Company reporting and verification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

## Part 2 - General views on the F-gas Regulation

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*Part 2 seeks to gather general views as regards the performance of the F-gas Regulation and the need for any changes*

### 3. What impact has the F-gas Regulation had with respect to its objectives?

	Very positive	Positive	Neutral	Negative	Very negative	Cannot say
Contribute towards meeting the EU's climate targets	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Facilitate the agreement to phase down HFCs under the Montreal Protocol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Discourage the use of F-gases with high GWP in the EU	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Promote the use of alternative substances or technologies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Prevent leakage and ensure proper end-of-life treatment of equipment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Stimulate innovation and develop green technologies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

4. To what extent does the F-gas Regulation contribute to recent related EU or international objectives?

	Contributes strongly	Some contribution	Neutral	Adverse contribution	Cannot say
European Green Deal	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Montreal Protocol (Kigali Amendment)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paris Climate Agreement	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. To what extent has the F-gas Regulation been coherent with other EU and international legislation?

	Fully coherent	Somewhat coherent	Not coherent	Cannot say
Montreal Protocol (Kigali Amendment)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paris Climate Agreement	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mobile Air Conditioning (MAC) Directive	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Ozone Regulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Ecodesign Directive	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
WEEE Directive and other waste legislation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Customs legislation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Please elaborate:

*1000 character(s) maximum*



The exemption for MDIs for pharmaceutical ingredients included in the 2014 EU F-Gases Regulation is coherent with the 85% reduction by 2047 introduced by the 2016 Kigali amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer, and exemption for essential medical use therein.

## 6. Does the F-gas Regulation cover all relevant sectors and sub-sectors using F-gases?

- Yes  
 No  
 Don't know

### Please elaborate:

*1000 character(s) maximum*

Given that the 2014 EU F-Gases regulation established an exemption for products for medical use, it did not foresee any preparatory and/or obligatory action to scale-down MDI containing HFCs at the European or national levels. Taking into account the extended use of F-Gases in life-saving medication for airways diseases such as asthma (affecting 30 million children and adults under 45 years of age in Europe) and chronic obstructive pulmonary disease (COPD) (estimated to affect 10% of the European population), the EU Regulation should further address the health requirements to reduce MDI use in Europe, addressing issues such as:

- clinical guidelines application at international, European and national levels
  - healthcare settings for MDI use and administration
  - patients' rights, needs and treatment choices
  - personalised medicine and alternative medicine development and affordability,
- all necessary aspects to scale-down the use of MDI to the strictly necessary circumstances.

## 7. To what extent have the Regulation's requirements been effective regarding its objectives (see question 3 above)?

	Very effective	Effective	Not very effective	Ineffective	Cannot say
Containment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Recovery and producer responsibilities schemes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Training and certification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Labelling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Restrictions on use and equipment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
HFC quota system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Reporting and verification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Collection of emissions data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

**Please elaborate:**

*1000 character(s) maximum*

Patients and end users are not informed about their inhalers propellants' contribution to climate change through labelling, neither systematically on recycling.

**8. Have the following factors presented important challenges for implementing the F-gas Regulation?**

Please rate from 1 (= no challenge) to 5 (=very serious challenge)

	1	2	3	4	5	Cannot say
Lack of technical solutions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Lack of information and awareness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
General economic situation	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F-gas policies in non-EU countries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Unjustified barriers in safety standards and codes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Lack of training on F-gas alternatives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Illegal imports	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Misuse of quota system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
High number of new market players	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
COVID-19 pandemic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

**Other challenges:**

*1000 character(s) maximum*

The EU F-Gases Regulation has not contributed to inform people about the implications of their treatment. Most asthma and COPD patients do not know what an F-Gas is, and consequently ignore their inhaler contains an HFC that contributes to climate change. We base this on EFA's 2019 evidence-based survey on asthma and COPD care. 1 in 3 asthma and COPD patients do not feel involved in decisions regarding their treatment. Less than half have a written management plan and, even worse, COPD (33%) and asthma (20%) patients indicate have "never heard about" written management plans, which are basic tools recommended in clinical management guidelines. Many patients are not empowered to play full part in their care, as well as the environmental impact of their treatments. Informing about environmental impact must come with the information on what the solutions are. There are also economic issues regarding the cost of different treatment options have across Member States.

**9. Have the following measures been effective in preventing illegal activities?**

	Very effective	Effective	Not very effective	Ineffective	Cannot say
Inspections	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Penalties	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Customs control	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Market surveillance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Reporting and verification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Please elaborate:

*1000 character(s) maximum*

10. Has the F-gas Regulation been flexible enough to respond to:

	Yes	No	Cannot say
Delays in technological developments and/or market disruptions	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
New or emerging issues	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

11. In what way has the F-gas Regulation impacted:

	Very positively	Positively	Neutral	Negatively	Very negatively	Cannot say
EU competitiveness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Trade with third countries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Better stewardship of F-gases by equipment operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
F-gas policies by other countries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
EU credibility in this area	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

12. Has the COVID-19 crisis negatively impacted any F-gas sectors?

- yes
- no

Please elaborate:

*1000 character(s) maximum*

During the COVID-19 pandemic, clinicians are proposing patients changes in their inhaler treatment to substitute aerosol because of the higher risk of COVID-19 contamination when the asthma or COPD medicine is nebulised. [Acute asthma management during SARS-CoV2-pandemic 2020, World Allergy Organisation Journal, May 2020: <https://pubmed.ncbi.nlm.nih.gov/32411315/>] These medicines have also been used for COVID-19 patients in their breathing issues.

13. Have the costs of the following measures been justified to achieve the objectives (see question 3)?

Please rate from 1 (benefits significantly outweigh the costs) to 5 (Costs significantly outweigh the benefits)

	1	2	3	4	5	Cannot say
Containment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Training and certification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Recovery and producer responsibilities schemes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Labelling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Restrictions on use and equipment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
HFC quota system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Reporting and verification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Collecting emissions data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
National enforcement actions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

14. How costly have the following measures been for business?

Rate from 1 (marginal costs) to 5 (very high costs)

	1	2	3	4	5	Cannot say
Containment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Training and certification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Recovery and producer responsibility schemes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Labelling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Restrictions on use and equipment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
HFC quota system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Reporting and verification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
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## 16. Is the F-gas Regulation

Rate from 1 (fully agree) to 5 (absolutely not)

	1	2	3	4	5	Cannot say
..clear?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
..consistent?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate:

*1000 character(s) maximum*

## 17. The F-gas Regulation has

Rate from 1 (fully agree) to 5 (absolutely not)

	1	2	3	4	5	Cannot say
..levelled the playing field across the EU	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
..increased the level of policy ambition across the EU	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
..improved consistency of relevant safety standards and codes across the EU	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

18. Do you consider that the F-gas Regulation may lead to an increased accumulation of persistent chemicals in the environment?

- Yes
- No
- Cannot say

## 19. Any other comments

*5000 character(s) maximum*

Please include any further information useful for this evaluation and impact assessment. In particular, please provide public references to relevant studies, position papers, and case studies or upload relevant documents.

In our evidence based survey on asthma and COPD care, asthma patients reported that their asthma is most commonly treated with inhaled corticosteroids (72%) and use emergency relief (62%) medication.

Active Patients Access Care report, 2019 European Federation of Allergies and Airways Diseases Patients' Associations (EFA): [https://www.efanet.org/images/ShowLeadership/Report-Showleadership\\_FINAL.pdf](https://www.efanet.org/images/ShowLeadership/Report-Showleadership_FINAL.pdf)

These results confirm the persistent reliance and overuse of emergency relief (in part MDI). Worryingly, patients are treating asthma symptoms instead of inflammation and end up to the emergency room at least once a year.

Hospitalisations occur even more often among COPD patients. Despite treatment and frequent follow-up consultations, one in three COPD patients are admitted to the emergency room every year. This situation dramatically increases with severity: over half of patients with severe COPD rely on emergency services at least once a year.

On the future steps towards phasing down F-Gases, we call on the European Union to ensure that the access to the care that people with asthma and COPD need is not compromised, as that would be against their health, and impact their social and fundamental rights.

TO QUESTION 10: pMDIs can be considered as irreplaceable medical technologies because of their dual nature of active compounds and medical devices. Alternatives might differ from current treatments, not to mention the patient education that is needed to develop good inhaler techniques, all aspects having implications for the patient.

The F-Gas regulation has been consistent in extending the phase down framework for pharmaceutical ingredients to allow necessary research and innovation processes within the healthcare sector. According to 2015 data drug development in the respiratory field exceeds 12 years on average. We hope the next generation of inhalers will innovate to treat asthma and COPD more effectively, and in a sustainable way for the planet.

TO QUESTION 22: At EFA we believe and call for a strong EU action on access to information, prevention and care. EU action fights inequalities across Member States and sets information, safety and security standards for health-related products. The role of the European Medicines Agency is crucial on the authorisation of medicines and information about them. EU Member States have the competency to shape the use of medicines in their territory, through prescription schemes (target groups) or reimbursement policies. From our perspective, any decision on the availability of a medicine should be in line with EMA and, in the case of F-gas containing MDI, be accompanied by EU recommendations on how to scale them down putting health concerns at the heart.

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## Part 3 - Specialised views on policy options

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*Part 3 seeks to gather specialised views on the existing regulatory provisions and considered changes to the existing rules. It requires detailed technical knowledge of the F-gas Regulation.*

### Information for stakeholders:

The following policy options are under consideration:

1. Seeking alignment with the Montreal Protocol
  - Add new phase-down steps beyond 2030
  - Remove some exemptions and thresholds not foreseen by the Montreal Protocol
  - Make separate HFC production phase-down
  - Add flexibility to align with future Montreal Protocol decisions
2. Raising ambition in line with European Green Deal
  - Increase HFC phase-down ambition
  - Prohibit the use of F-gases where feasible
3. Improve implementation and enforcement
  - Training on non-F-gas alternatives
  - Detailed rules for customs and surveillance authorities, and facilitating the use of the EU Single Window environment for customs
  - Strengthen obligations of economic operators to prevent illegal trade
  - Limit the market players to legitimate participants
  - More comprehensive monitoring

### 20. Do you agree that the following review objectives are relevant:

Rate from 1 (fully agree) to 5 (strongly disagree)

	1	2	3	4	5	Cannot say
Ensure EU long-term compliance with Montreal Protocol	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Raise ambition in light of the Green Deal and technological progress	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve implementation and enforcement	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

21. Do you see any other main objective for the revision, keeping in mind that a large number of changes may delay the negotiations and thus prevent quickly fixing urgent implementation issues? Please elaborate:

*1000 character(s) maximum*

Within the 3rd objective on Improving implementation and enforcement, the F-Gases could also introduce clearer and strengthened rules on information to the public (i.e. on-pack labelling, updated patient information leaflet, online portal) for those F-Gases containing products that remain in the market and/or that are produced in EU Member States or by EU Member States companies and commercialised in third countries, and potential foreseen transition to new technologies replacing the old.

22. Do you think the original objectives of the F-gas Regulation (see question 3) and the proposed policy options (see information above) could be better achieved at EU Member State level?



- Yes
- No
- Cannot say

**Information for stakeholders:** The [EU Single Window Environment for Customs](#) involves establishing automatic links between the F-gas Portal and the IT systems of the Member States' customs authorities via a central system supported by the Commission. This will facilitate the customs clearance process by enabling automatic checks of data in customs declarations with data in the F-gas Portal. Further, it would allow for quantity management of F-gases imported in the Union and help to prevent illegal imports.

### 23. How important are the following measures for improving implementation and enforcement?

Rate from 1 (very important) to 5 (not important)

	1	2	3	4	5	Cannot say
Training of technicians on F-gas alternatives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Strengthen the role of customs and facilitate the link with the EU Single Window Environment for customs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Strengthen obligations of economic operators to prevent illegal trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Limit the market players to legitimate participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
More comprehensive monitoring	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Minimum requirements for penalties at Member State level	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

### Any other relevant measure for improving enforcement, please specify:

*1000 character(s) maximum*

- Integrate the human and patient health aspects including impact and policy scenario assessments, to phase down F-Gases, so that there are no unintended negative impacts on health;
- Work with patient organisations, and with primary and secondary healthcare professionals and producers to understand the health needs of patients with asthma and COPD. Consider adherence to treatment and the psychological aspects, including fear due to change;
- Inform citizens and patients how they can contribute to a healthy environment without compromising their care and treatment; Patient and healthcare professional organisations are partners to reduce the environmental impact of our medications through health literacy, inhaler techniques and simple information;
- Encourage health authorities and professionals to invest in the implementation of asthma and COPD disease management guidelines, such as GINA and ERS-ATS so that every patient has a self-management plan.

### 24. To what extent will the following policy options reduce emissions?

Rate from 1 (large savings) to 5 (no benefit)

	1	2	3	4	5	Cannot say
Increase HFC phase-down ambition in line with technological development	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prohibit the use of HFCs in applications where they are no longer needed	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prohibit the use of other F-gases (i.e. SF6, PFCs,..) in applications where these gases are no longer needed	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

25. To what extent will the following policy options impact administrative costs?

	Reduce significantly	Reduce	No impact	Increase	Increase significantly	Cannot say
Add new HFC phase-down steps beyond 2030	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Remove some exemptions and thresholds not foreseen by the Montreal Protocol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Make separate HFC production phase-down	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Add flexibility to align with future Montreal Protocol decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Increase HFC phase-down ambition	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Prohibit the use of F-gases in products or equipment, where these gases are no longer needed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Technicians training on non-F-gas alternatives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Detailed rules for customs and surveillance authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Strengthen obligations of economic operators to prevent illegal trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Limit the market players to legitimate participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
More comprehensive monitoring	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

26. Where you expect administrative costs to be significant, please quantify them (EUR or person hours) per relevant option:

*1000 character(s) maximum*

As possible cost is to address those patients or situations that will need to remain in F-Gas containing MDI because they do not have an alternative.

27. To what extent will the following policy options impact operational costs?

	Reduce significantly	Reduce	No impact	Increase	Increase significantly	Cannot say
Add new HFC phase-down steps beyond 2030	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Remove some exemptions and thresholds not foreseen by the Montreal Protocol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Make separate HFC production phase-down	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Add flexibility to align with future Montreal Protocol decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Increase HFC phase-down ambition	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Prohibit the use of F-gases in products or equipment, where these gases are no longer needed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Technicians training on non-F-gas alternatives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Detailed rules for customs and surveillance authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Strengthen obligations of economic operators to prevent illegal trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Limit the market players to legitimate participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
More comprehensive monitoring	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

28. Where you expect operational costs to be significant, please quantify them (EUR or person hours) per relevant option:

1000 character(s) maximum

For EFA, if the medical exemption for f-Gases for medical use is removed while there is no proved working alternative for asthma and COPD patients in need of their life-saving medicine, there will be an unquantifiable health burden. Switching chronic disease medicines without warranties might lead some to uncontrolled asthma and worse symptom control in COPD, incurring then in preventable emergency hospitalisations and long-term rehabilitation, or death. The EU has long ago adopted recommendations on personalised medicine, not only referring to the availability of innovative solutions (which are often the most expensive) but also to the accessibility of therapies that work for the individual to be able to offer the right treatment to the right patient. For some, the best available treatment today remains HFC containing MDIs.

29. Do you expect any of the policy options to impact on:

	Significant effect	Slight effect	No effect	Cannot say
EU competitiveness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Trade with non-EU countries	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Employment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Consumer prices	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
R&D and innovation	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Internal market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Specific regions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Non-EU stakeholders and international relations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
SMEs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Public health and safety	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Where significant, please describe effect for the relevant option:

1000 character(s) maximum

**TRADE** – Often, the only medication available in third countries to treat asthma and COPD containing HFCs. We encourage the EC to connect with the World Health Organisation to estimate how potential changes in the EU F-Gases Regulation might impact health care and treatments in third countries, especially the poorest populations in terms of access to basic medication for asthma and COPD.

**CONSUMER PRICES** – Conduct quantitative and qualitative research on the impact on patients when changing treatment, including economic aspects such as accessibility.

**R&D** - Promote and stimulate the development of green smart inhalers that are recyclable.

## Contact

[Contact Form](#)