PUBLISHED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

DSC REF: DSC/01/2024

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Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014. OJ L, 2024/573, 20.2.2024

This Regulation replaces 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 [link]; Protocol Annex 2, Heading 26 on Environment, energy efficiency.

Summary of the Act

This Regulation:

- lays down rules on containment, use, recovery, recycling, reclamation and destruction of fluorinated greenhouse gases and on related ancillary measures, such as certification and training, which includes the safe handling of fluorinated greenhouse gases and of alternative substances that are not fluorinated;
- imposes conditions on the production, import, export, placing on the market, subsequent supply and use of fluorinated greenhouse gases, and of specific products and equipment containing fluorinated greenhouse gases or whose functioning relies upon those gases;
- imposes conditions on specific uses of fluorinated greenhouse gases;
- establishes quantitative limits for the placing on the market of hydrofluorocarbons (HFCs);
- establishes rules on reporting.

- We are unaware of any changes to this act since it was first proposed.

Department(s) Responsible

- **Department of Agriculture, Environment and Rural Affairs (DAERA, lead) – Minister Muir**
- **Department of Health (DoH, interest) – Minister Swann**

Initial Assessment of Impact

- Currently, the Department of Health does not have an expectation that this EU amendment and replacement will have a significant impact specific to everyday life of communities in Northern Ireland (NI) in a way that is liable to persist. This reasonable based assessment is based on the information received presently.

- Under Windsor Framework arrangements, from 1 January 2025, the majority of medicines authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) will be UK wide authorisations, covering both Great Britain (GB) and Northern Ireland, with the requirement that product labelling is the same for both territories. Therefore, marketing authorisation holders with UK wide authorisations will need to comply with all UK requirements, including GB and/ or NI specific requirements, in order to place their products on the UK market. The MHRA indicated that under Regulation 267 of the Human Medicines Regulations 2012, any changes to the labelling of authorised medicines in the UK must be notified to MHRA for approval.

- The Department of Environment, Food and Rural Affairs (DEFRA) has been engaging with stakeholders, including the pharma industry, and after having initial discussions DEFRA do not have concerns regarding the labelling requirements for meter dosed inhalers (MDIs) under this legislation. DEFRA will remain engaged with industry, NHS and other relevant stakeholders on this matter. From their engagements, the pharma industry has also indicated that it anticipates new MDIs that use alternative propellant gases would become available to the market by 2030, pending regulatory approvals.

- In 2023, Health and Social Care Trusts (HSC) had reported that the use of desflurane had mainly stopped and been replaced with less environmental damaging alternatives. The prohibition of desflurane from 1 January 2026 unless it is strictly required, and no other anaesthetic can be used on medical grounds appears to be in line with the work that clinicians and anaesthetists have been doing within HSC organisations and other parts of the UK.

- Currently, the Department of Health also does not have an expectation that this EU amendment and replacement, if not applied to NI, will have a significant impact to everyday life of communities in NI. This is again based on reasonable assessment of current information received.

- It is worth noting that the European Commission is obliged to produce a report in 2028 about the impact the rules have had on the healthcare sector. This means pharma industry have an opportunity to raise any concerns about this legislation before the full adjustments for MDIs come into line with other sectors' phasedown obligations commence.

UK Government Explanatory Memorandum

- The UK Government (UKG) produced an Explanatory Memorandum (EM) in respect of this regulation on the 17 May 2022 – this was produced by the Department for Environment, Food and Rural Affairs (DEFRA). (see [link] – attached in PDF format at **Annex 1**)

- The subject matter is outlined and further discussed in the memorandum – the Regulation would apply to F-gases and some products and equipment containing F-gases regulated under Regulation (EU) No 517/2014, known as the F-gas Regulation. The F-gas Regulation has applied in NI under the NI Protocol since the end of the transition period on 1 January 2021.

- The F-gas Regulation controls and reduces the placing on the market of hydrofluorocarbons (HFCs), required under the Kigali Amendment to the Montreal Protocol, through the implementation of a phasedown and quota system. The proposed regulation amends the existing phasedown and sets a new ambitious HFC phasedown through to 2048 and onwards (including removal of the quota exemption for metered dose inhalers (such as asthma inhalers)).

- The proposal also includes labelling requirements for the placing on the market of F-gases in containers and in certain equipment. This includes extending the existing labelling requirements to hydrofluoroolefins (HFOs), introducing the requirement for labelling for metered dose inhalers (those containing F-gases), as week as HFCs exempted from the quota requirements to enable enforcement of those exemptions.

- The use of desflurane is to be prohibited for use as an anaesthetic gas.

- The EM outlines the relevant parliamentary scrutiny to the document and clarifies the UKG Minister with policy responsibility as the DEFRA Minister.

- The EM discusses the interest of devolved administrations (DA's) indicates the policy area is devolved and covered by a common framework; GB-wide F-Gas regulatory regime agreed and jointly run by UKG, Scottish & Welsh Governments; NI remains subject to EU F-gas legislation under the NI Protocol.

- The EM indicates the NI Executive were consulted and remain involved in discussion via the common framework arrangements; DEFRA further commits to continuing engagement with DA's as the EU proposal evolves.

- The legal basis and timings related and anticipated with the EU regulation are also outlined in the EM – expected EU adoption at the time of EM

drafting was for the end of 2023.

- Policy Implications are discussed within the EM with the application of EU F-gas legislation to NI under the NI Protocol a key consideration - further tightening of the EU's HFC phasedown will be felt between GB and NI, although UKG may choose to implement similar measures to support achieving net zero.

- The implementation of new bans under the EU's proposed revised F-gas Regulation may also have an impact on movements of goods between GB and NI, depending on whether our GB review results in different approaches to such bans. As GB review of F-gas legislation being progressed the EM indicates further engagement with the EU to better understand the proposals and emerging changes; informing the legislative review with alignment between GB and NI a consideration.

- Continuing stakeholder engagement by UKG noted on the EM and potential financial implications to be clearer depending on the EU proposals evolution and its application to NI.

Analysis by the European Commission on its Impact Assessment

- The European Commission published an impact assessment (IA) related to this proposed regulation on the 5 April 2022 (see [link] – attached in PDF format at **Annex 2**)

- The IA outlined in detail the anticipated impacts of the legislation across relevant sectors including in respect of metered dose inhalers (the main focus for DoH), their suppliers and users.

- The IA described the methodology used for consultation by the EC and this was extremely comprehensive and detailed involving seeking views from a wide range of stakeholders. These views were sought from industry, members states, competent authorities and regulators plus groups of external experts.

- Views on impacts were sought on the basis of how the current regulation works against the perceived working of the future regulations – these views were gathered through a number of means such as public online consultation, workshops held by the EC and direct interviews with stakeholders.

- From the available text NI stakeholders' input cannot be identified however from a DoH perspective and with a focus on metered dose inhalers (MDI's) no major impacts were documented. The preferred option highlighted in the IA, page 50, suggests cost increases for MDIs will be minimal (<1%). While users of pharmaceutical MDIs that continue to use HFCs will have to pay HFC price premium costs, the HFC premium costs compared to the total product price is very low, at 0.1%.

- The IA also states that industry stakeholders for MDIs such as gas producers and some MDI manufacturers pointed out that lower- global warming potential (GWP) alternatives are being developed and will be introduced to the market from 2025 onwards. Other manufacturers and patient organisations pointed out the fact that sufficient time is needed to introduce the alternatives, also due to the need of following the regulatory processes, and that the interest of the patient should be kept in mind.

- The IA states medical experts feel desflurane and isoflurane, as human medicines, are not required in approximately 99% of cases as sevoflurane is suitable to be used as an inhalation anaesthetic. However, isoflurane routinely used as a veterinary medicine.

Departmental Engagement

- Department of Agriculture, Environment and Rural Affairs (DAERA) initially shared this with the Department of Health on 28 February 2024. The Department of Health then engaged with the Department of Health and Social Care (DHSC) on this regulation through correspondences and scheduled meetings. Further information was sought from DEFRA and MHRA through correspondences.