

Envirotainer°

Envirotainer AB

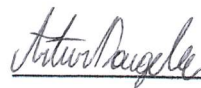
2023

Comments for Annex XV restriction report

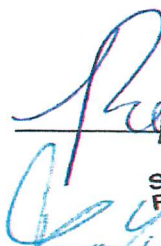
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Summary

Temperature-controlled air transport is crucial for rapid end-to-end supply chain of sensitive pharmaceuticals. A recent example of this was the quick response and rapid transportation of vaccines during the Covid-19 Pandemic. Today, Envirotainer ships over a billion medicine doses per year globally. Proposed restrictions on per- and polyfluoroalkyl substances (PFAS) will impact rapid pharmaceutical transport due to strict safety regulations stipulated by European Aviation Safety Agency (EASA). Additional development time is required to develop safety systems of flammable (A2L – A3) refrigerants, or technical development of a CO₂ solution. Three alternative additions/amendments are suggested. A separate derogation for pharmaceutical transport is the only solution identified that we believe would grant enough development time. We recommend:

1. Amend/Add to Annex XVII entry PFASs (Restriction Option 2), column 2. By way of derogation, paragraphs 1 and 2 shall not apply to: **xx. refrigerants in active temperature controlled containers certified for air freight by European Union Aviation Safety Agency (EASA) until 13.5 years after EIF.**

- or, minimally -

2. Add the transport definition found in Annex E.2.10 "...all modes of transport, by road, rail, air and sea." as the "Transport Refrigeration" definition in Annex XV.

- alternatively -

3. Amend Annex XVII entry PFASs (Restriction Option 2), column 2: By way of derogation, paragraphs 1 and 2 shall not apply to: **q. refrigerants in transport and air freight refrigeration other than in marine applications until 6.5 years after EIF.**

It is vital that temperature-controlled air transport is not interrupted for the safety of the end-users. We hope that ECHA will consider our suggested derogation to ensure sufficient development time and a transition to natural refrigerants for active cooled air freight containers.

Please note that we will in future send more data and reports to strengthen the arguments within this text.

For additional information, data or inquiry, our submitter and contact person is:

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Introduction

Temperature-controlled air transport is vital in the end-to-end supply chain for delicate pharmaceuticals, such as vaccines and biopharmaceuticals. Deviations in transport protocol may render these products ineffective or harmful to patients. Consequently, global pharmaceutical firms, forwarders, and recipients increasingly depend on active temperature-controlled air freight containers for rapid and secure transportation. The rapidity of this means of transport is important for quick-response delivery, for example during the Covid-19 pandemic. However, there are strict safety regulations in the air-freight sector. Refrigerated containers are classed as ULDs (Unit Load Devices) following EASA/FAA regulations. This imposes, for example, strict flammability demands of materials such as batteries and refrigerants.

This market consists of actively and passively refrigerated containers, with active containers being up to 90% more sustainable than passive solutions. Active containers use vapor compression to maintain consistent temperatures within the cooled space. An important advantage of active containers is that they can be utilized without disruption anywhere where electrical power is available. Passive solutions are limited in time, after which they need to be regenerated. This requires an advanced infrastructure of stationary cooling/freezing facilities and training of personnel in handling of hazardous materials.

For the air freight cold chain, additional derogations are required to develop technical solutions where these do not yet exist, beyond the suggested RO1 timeline. Suggested derogations and the proposition in whole overlooks parts of the cold chain industry that are vital for global medicine delivery. We can provide a socioeconomic and consequence analysis of this before the second consultation meeting.

Alternative refrigerants such as natural refrigerants require a long development time to ensure alignment with existing safety regulations. To ensure avoidance of long-term interruption to the air freight cold chain, we suggest adding a derogation period of 13.5 years after EIF for this specific application. This would allow the cold chain industry to develop safe, sustainable solutions without use of PFAS. For a derogation period, the effects of PFAS are minimal, as the amount of refrigerant used in this application is very small. Please see attached documents for information about refrigerant use amount.

Minimally, we hope that a minimum derogation could be provided by making sure active refrigerating containers fall under the transport derogation. This solution may still heavily impact the air freight cold chain industry and may force production stops or alternative stop-gap production solutions. If falling under RO1, the active transport refrigeration industry would be shut down or would need to be re-located to areas outside of legislative jurisdiction to ensure un-interrupted transport of medicine.

Problem Formulation

The proposed restriction report would prohibit the use of refrigerants, including R134a and R1234yf, as both refrigerants degrade into substances covered by PFAS prohibition. R134a has been an ideal refrigerant for the heavily regulated aviation industry due to no flammability or toxicity. All safe HFC and HFO alternative refrigerants will be prohibited according to the proposition, thus limiting alternatives. Other alternatives are phased out according to procedure 2022/0099/COD, which follow similar timelines. Remaining alternatives are natural refrigerants, such as R290, R600a, R744 and R717. To amend the environmental effect and health effects of these substances, a phase-in to natural refrigerants is the only solution. For the air freight active cold chain application, solutions, and challenges in tables 1 and 2 are identified.

In addition, derogations are suggested due to similar needs of other industries. The refrigerated air freight application requires significantly longer development time due to heavily regulated safety, weight and space concerns coupled with the strict temperature, reliability and redundancy demands of pharmaceutical transport. The following derogations are found on table "Proposed restriction - Annex XVII entry PFASs (Restriction Option 2)", column 2, points 5h, 5n, 5p, 5q.

1. Centrifuges have no safe non-flammable alternatives.
2. Diagnostic testing equipment lacks alternatives.
3. ICU vehicles need to re-design systems to address higher pressures of CO₂ and secondary loop systems.
4. Transport refrigeration suffers capacity reduction and size constraints to switch to alternative refrigerants.

Time is needed to re-design the climate modules to address higher pressures of CO₂ systems, or to implement secondary loop systems when using flammable natural refrigerants. Capacity reduction and size constraints further increase the challenge and development time. No other alternatives besides flammable refrigerants or CO₂ are currently identified. It is not guaranteed that a solution is possible in air freight for the short or medium-term. CO₂ has no available components with the correct dimensioning parameters, and flammable refrigerants are likely to not be approved by regulators, forwarders and air shipping companies.

Challenge	Refrigerant R744 (CO ₂)	Development Time* (Years)	Development Need
Technical Solution	Unavailability of components for small-scale application (sub-1kW). CO ₂ refrigerant presents challenges due to operational requirements of refrigerated shipping containers. Transcritical systems, ejectors, liquid-receivers need to be developed for the extreme weight and size requirements.	6-12	Very High
Safety System	Analysis required due to the high pressures of CO ₂ .	2-3	Low-Medium
Regulatory Confirmation	No added difficulty anticipated compared to existing HFC solution, but re-validation from regulatory, forwarders and pharmaceutical companies required.	2-3	Low-Medium

Table 1: Development needed for R744 system.

*More data backing these claims will be provided before the second consultation meeting.

Challenge	Refrigerant R290, R600 (Propane, Isobutane)	Development Time* (Years)	Development Need
Technical Solution	Component availability for small-capacity chillers is good.	4-6	Low
Safety System	Development of safety systems, such as leak-detection, shutoff valves, hermetic sealing, low-pressure zones and LEL analysis within active containers has not begun or ever been attempted by this industry. No solution for small size chillers.	6-12	Very High
Regulatory Confirmation	Testing that is required for validation and approval from regulatory players such as EASA and FAA, as well as technical validation from the Shipping and Pharma players is extensive due to the flammability and safety concerns of these solutions.	4-6	Very High

Table 2: Development needed for R290, R600 system.

*More data backing these claims will be provided before the second consultation meeting.

Proposed Solution/Amendment

We have identified three amendments to the proposal from ECHA that would allow sufficient time to develop new, sustainable solutions for the air freight cold chain industry.

Proposition 1: Derogation Period for Air-Freight Cold Chain Application

A specific derogation for actively refrigerated containers for air freight would ensure sufficient time to find a solution. The use of refrigerant breaking down to PFAS is extremely low, as very little refrigerant is needed per container. The impact of such a derogation would be minimal. See attached refrigerant use in production.

Column 1	Column 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 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)-).	5. By way of derogation, paragraphs 1 and 2 shall not apply to: x. refrigerants in active temperature controlled containers certified for air freight by the European Union Aviation Safety Agency (EASA) until 13.5 years after EIF;

Proposition 2: Clarify definition of "Transport Refrigeration"

Alternatively, we believe that a clear transport definition, given in Annex XV would ensure more time. Note that this solution may still risk consequences until a new alternative is developed.

ECHA Proposal	Proposal for amendment
- No Current Definition in Annex XV -	<u>Add</u> the transport definition found in Annex E.2.10 "...all modes of transport, by road, rail, air and sea as the "Transport Refrigeration" definition in Annex XV.

Proposition 3: Amendment Suggestion for Transport Derogation

Alternatively, an amendment to the proposed restriction - Annex XVII entry PFASs (Restriction Option 2), column 2, points 5q is suggested. Note that this suggestion still risks production stop until a new alternative can be developed.

ECHA Proposal	Proposal for amendment
5. By way of derogation, paragraphs 1 and 2 shall not apply to: q. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF;	5. By way of derogation, paragraphs 1 and 2 shall not apply to: q. refrigerants in transport and air freight refrigeration other than in marine applications until 6.5 years after EiF;

Conclusion

To allow sufficient development time of active refrigerated container air freight alternatives, three alternative amendments are suggested. A specific derogation for refrigerated containers for air freight would give enough time to move to a natural refrigerant solution. To ensure an uninterrupted cold chain, we hope that a sufficient derogation time can be proposed.

The consequences of an insufficient derogation time would likely necessitate production stop or move, insufficient infrastructure for pharmaceutical delivery, much lower response time of delivery and a return to solutions with much larger environmental impact.

We are open to other solutions, through amendments or additions, that would allow for sufficient time for development. We are confident that a solution will be found, but the needed time to find it is currently insufficient.