Regulatory Changes Affecting Refrigeration in the Life Sciences

The Environmental Protection Agency's AIM Act

Abstract

The life sciences industry depends on refrigerated systems to store and transport products. These systems must be able to maintain a stable environment and stay within predetermined temperature specifications. The refrigerants used to accomplish this are regulated by the EPA. In 2025, the American Innovation and Manufacturing (AIM) Act took effect, initiating a phase-down in the use of certain hydrofluorocarbons (HFCs) as refrigerants. This white paper examines the implications of these regulatory changes, the challenges they pose to life sciences storage, and provides practical solutions to help you stay compliant and operate more efficiently moving forward.

Overview of the 2025 Refrigerant Regulations

The AIM Act affects industries that rely on HFCs, including refrigeration, air conditioning, aerosols, and fire suppression. It introduces sector-specific restrictions, promotes the use of low-global-warming-potential alternatives, and sets guidelines for managing and reclaiming refrigerants to minimize environmental harm. The Act mandates a phasedown of HFCs across various applications to mitigate global warming and reduce greenhouse gas emissions. For the life sciences storage industry, this impacts refrigeration systems that use refrigerants with high global warming potential (GWP) values.

Key Changes:

- **700 GWP Refrigerant Limit:** As of January 1, 2025, equipment using refrigerants with a GWP over 700 will no longer meet the Environmental Protection Agency's (EPA's) regulatory requirements. This means the commonly used A1 refrigerant, R-404A, will be gradually phased out because it has a GWP of approximately 3,922.
- **Transition to A2L Refrigerants:** Low-GWP alternatives, such as A2L refrigerants like R-454B, are set to replace R-404A. They possess a lower environmental impact, but their mild flammability necessitates significant updates to building codes, installation practices, and safety standards.

These updated regulations align with the EPA's broader goals to reduce HFC usage 85% by 2036 and transition industries toward sustainable refrigerant alternatives[ii].

The ASHRAE safety standards are guidelines developed by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers that classify refrigerants based on their toxicity and flammability.

ASHRAE Standards		
Higher Flammability	A3	B3
Lower Flammability	A2, A2L*	B2, B2L*
No Flame Propagation	A1	B1
	Lower Toxicity	Higher Toxicity

**A2L and B2L are lower flammability refrigerants with a maximum burning velocity of <10cm/s.*

Challenges for the Life Sciences Industry

The life sciences industry has unique requirements when it comes to refrigeration systems. Regulatory compliance is a critical aspect of maintaining product integrity and safety, and these changes

introduce some pressing challenges for the industry, such as repair/replace decisions, budgeting for the cost of compliance, planning for downtime, and staying on top of the latest regulations.

Repair vs. Replace Guidelines

Refrigeration systems that currently use R-404A and other high-GWP refrigerants generally cannot be retrofitted to use A2L refrigerants because it would violate the EPA's SNAP Rule 23 . This is primarily because R-404A and R-410A systems are not engineered to handle the flammable nature of A2L refrigerants. They must be replaced with systems designed specifically for A2L refrigerants with the following stipulations:

- AIM regulations permit the installation of higher GWP refrigeration systems until January 1, 2027, provided the systems were manufactured or imported before January 1, 2026[iv].
- Existing refrigeration systems using R-410A or other high-GWP refrigerants can continue to operate and be serviced throughout their useful life.
- Replacing 75% or more of the evaporators (by number) and 100% of the compressor racks, condensers, and connected evaporator loads of an existing system will trigger the requirements of new systems[v].

When deciding to retain or replace existing high-GWP refrigeration systems, there are factors to consider beyond the requirements of the AIM Act:

- **The availability of A2L refrigerants, such as R-454B.** Manufacturers are struggling to keep up with the increased demand, primarily due to a lack of available A2L-approved cylinders. The result, at least temporarily, is a short supply and an increased cost[vi].
- **The age and condition of existing refrigeration systems.** Older systems may not be compatible with approved refrigerants and may need to be replaced. Consider the cost of maintaining high-GWP systems while being cognizant of the 75% replacement threshold.
- **The energy efficiency of current refrigeration systems.** Beyond lower GWP, modern systems with AIM-compatible refrigerants have the potential to provide operational savings through reduced energy useage.

What is GWP and how is it calculated?

A refrigerant's global warming potential (GWP) value is determined by assessing its impact on the Earth's atmosphere relative to carbon dioxide (CO_2), which has a GWP of 1. GWP is calculated based on the quantity of heat a greenhouse gas traps in the atmosphere over a specific timeframe, often 100 years. Each refrigerant's molecular composition determines its ability to absorb infrared radiation, contributing to its GWP rating. To quantify GWP, scientists consider the gas's radiative efficiency (its ability to trap heat) and its atmospheric lifetime (how long it persists in the atmosphere). This metric enables comparisons between refrigerants and guides the transition toward low-GWP alternatives that reduce environmental impact.

Other Implementation Costs

Beyond the obvious costs of replacing existing refrigeration systems, there are other expenses to consider, including:

- Training and certification for technicians so they can properly handle A2L refrigerants.
- Facility upgrades, including improved ventilation and leak detection systems to mitigate risks

associated with A2L refrigerants. Many facilities have never had to account for flammability or ventilation, so existing areas that are being retrofitted will need to be redesigned.

- Installing auto shut-off valves which are required to keep refrigerated circuits isolated in the event of a leak.
- The price volatility of A2L refrigerants due to the sudden increase in demand.

Planning for Operational Downtime

Life sciences companies should have a detailed plan to protect their operations and supply chain while transitioning to A2L refrigerants. It is wise to secure the required people, parts, and components in advance, as the heightened demand for these items may cause shortages. Failure to do so could result in unexpected delays that jeopardize operations and compromise compliance.

Account for the time needed to perform leak detection and required inspections to ensure compliance with the new safety standards. Depending on the number of refrigeration systems that need to be serviced or replaced, consider planning these transitions in stages or aligning them with your scheduled maintenance windows.

Keeping Up with Changing Standards

The regulations surrounding A2L refrigerants affect local building codes, safety protocols, and ASHRAE standards. Effective implementation requires a well-thought-out adoption strategy across all impacted facilities. Some industries may be granted "hardship extensions," so staying current with the latest regulations is essential.

Regulatory bodies, such as the EPA and the Occupational Safety and Health Administration (OSHA), provide guidelines and updates on the handling and implementation of A2L refrigerants. Industry standards organizations, such as ASHRAE, publish detailed standards, including ASHRAE Standard 15 and ASHRAE Standard 34, which outline safety requirements for the design, installation, and operation of refrigeration systems.

The best ways to stay informed about changing regulations are to:

- Subscribe to updates directly from the EPA.
- Attend industry conferences and webinars focused on environmental regulations.
- Engage actively with industry trade associations.
- Partner with regulatory consultants or third-party compliance experts who can provide valuable insights into upcoming changes and their implications.
- Implement an internal system for monitoring and communicating updates to relevant teams to ensure alignment with the latest requirements.

By staying current with the latest standards, organizations can mitigate risks and position themselves as leaders in adopting sustainable practices.

Best Transition Practices

Facilities need to assess the risks, including flammability concerns and system compatibility. This assessment should involve input from engineering, safety, and compliance teams to address all

potential hazards. A good strategy is to conduct an audit of the facilities and use that to develop a replacement timeline for implementing AIM-compliant refrigerated systems.

Conduct a Refrigeration Inventory Audit

Use a commercial refrigeration checklist to thoroughly audit current refrigeration systems, assessing their age, condition, and refrigerant specifications. Several good tools and resources are available online to guide the inspection. At a minimum, you'll need to document the following:

- The age of the refrigeration units and any replaced components.
- The type of refrigerant in use, and whether it exceeds the new GWP limit of 700.
- Overall condition. Check refrigerant levels and inspect door seals, gaskets, electrical components, fans, compressors, evaporator and condenser coils, etc., for signs of wear.

The findings from this audit will create a roadmap for the physical transition plan and guide decisions regarding the repair and replacement of equipment.

Develop a Replacement Timeline

After completing the refrigeration audit, prioritize which systems need repair or replacement, starting with equipment near the end of its lifecycle. Collaborate with manufacturers to identify the most efficient systems that can comply with the new regulations. Look for incentives, rebates, and grants for energy-efficient systems, which can help offset costs. When it's time to schedule repairs and installations, do so in stages to avoid conflict with critical operations.

By adopting a proactive, structured approach, facilities can align their refrigeration equipment with AIM standards, ensuring smooth operations and supporting their sustainability goals.

Key Elements of the AIM Act Affecting Refrigerants

The AIM Act aims to achieve several goals: (a) gradually phasing down the production and use of HFCs, (b) creating regulatory frameworks to support these changes, and (c) encouraging the adoption of efficient and environmentally friendly alternatives. Here's what you need to know:

The AIM Act rolls out in three main stages:

1. Starting January 1, 2025, the Act implements a 30% phase-down of HFCs over three years, utilizing an allocation system to reduce production and consumption gradually.
2. Measures are introduced to reduce emissions by addressing existing system leaks and enhancing refrigerant recovery practices.

GWP Values for Common Refrigerants

Refrigerant	GWP
CFC-11	4,750
CFC-12	10,900
HCFC-123	77
HCFC-22	1,810
HFC-134a	1,430
R-290 (C_3H_8)	4
R-404A	3,922
R-407F	1,825
R-448A	1,386
R-449A	1,396
R-454B	466
R-717 (NH_3)	0
R-744 (CO_2)	1

3. Industry-specific transitions are implemented to help sectors such as biopharmaceuticals, food and beverage, retail grocery, convenience stores, and HVAC systems adopt advanced refrigerants and technologies.

At the beginning of each subsequent year (2026, 2027, 2028), additional regulations take effect for specific refrigeration systems. The EPA organizes these transitions by technology sector and operating temperature. For example:

- Chillers for "comfort cooling" must comply by January 1, 2025.
- Chillers with exiting fluids above -30°C must comply by January 1, 2026.
- Chillers with exiting fluids from -30°C to -50°C must comply by January 1, 2028.

Plans are in place to address industrial process refrigeration with exiting fluid temperatures below –50°C.

The AIM Act also impacts the following physical components:

- Chambers will require low flammability (LFL) sensors on each unit to detect leaks.
- Chambers will require automated shut-off valves to contain the refrigerant charge in the event of a leak.
- Equipment replacement. The AIM Act doesn't mandate replacing existing refrigeration equipment but offers the following guidelines.
    - Individual components (like compressors, condensers, and evaporators) can be swapped out as needed.
    - If several components are replaced simultaneously, the AIM Act mandates that the entire system be re-engineered or replaced.

These step-by-step replacement strategies help facilities maintain compliance while minimizing disruptions to operations.

Summary

The EPA is currently reviewing HFC limits and timelines under the AIM Act to address the challenges faced by specific industries. This makes it more critical than ever to stay updated with regulatory changes using the resources outlined in this white paper. For now, life sciences companies should continue to prepare for the transition to A2L refrigerants in line with the current schedule, unless updated regulations are announced.

The AIM Act is driving significant changes in the life sciences industry by phasing down HFCs widely used in manufacturing and refrigeration. While these regulations may present some initial hurdles, they also open the door to innovation and to adopting cleaner, more sustainable technologies. By staying informed and taking a proactive approach, companies can meet their compliance requirements while demonstrating their commitment to environmental responsibility, paving the way for a more sustainable future across the industry.

Sources

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At Predictive Monitor, our mission is to develop and deploy innovative Industry 5.0 technology that improves patient lives by protecting life-saving products. We are accomplishing this by sharing our bold new vision for the future of biopharma storage, where reactive maintenance and late-night emergency repairs become a thing of the past.

Our motto is, “Early warnings predict success,” which means: When problems can be predicted, they can be prevented using proactive maintenance.

Our flagship product, OverShield®, is the culmination of over a decade’s worth of research in anomaly detection in refrigerated systems. It extends the life of refrigerated systems by enabling proactive repairs, preventing major issues that could necessitate costly replacements under the AIM Act guidelines.

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