RESIDENTIAL AIR CONDITIONING

SOCIETAL IMPORTANCE

Residential air conditioning is essential in today's society. The increase in global population has produced an expansion into hotter climates as the need for living space increases. Without air conditioning, this growth would not be possible. Air conditioning provides comfortable, clean living, and it is critical in ensuring safe living conditions. In addition, persons with respiratory ailments are now able to endure the hottest days of summer due to the availability of residential air conditioning.

Critical Application Considerations

Air-conditioned homes, which were a luxury 30 years ago are now commonplace in North America. The air conditioning systems vary in type from central systems that provide climate control for an entire home to window units that are designed to cool only one or two rooms. Additionally, ductless split systems are growing in use as an alternative to ducted systems. Meanwhile in Asia and Australia the surge in home air conditioning has been even more robust. With increases in urbanization, consumer purchasing power and more widespread and stable power distribution both continents are witnessing growth rates of 7-8% annually. It is imperative that the HVAC industry continues to provide society with the

most appropriate solutions for maintaining comfortable and clean environments while also responding to changing environmental pressure. Also, cost and size considerations must be taken into account.

Home air conditioning is necessary for many people. For those with allergies and breathing issues, air conditioning has become essential in order to live a comfortable and productive life. Twenty years ago, those with allergies would have to endure the high pollen counts in the spring and late summer. Today they are able to escape those conditions with the use of air conditioning.

Environmental Considerations

Historically, our industry relied mainly on HCFCs; however, the last decade or more has witnessed a transition from ozone-depleting substances (such as HCFC-22) to non-ozonedepleting compounds such as HFC-410A. Many HFCs have relatively high GWPs and are now also under regulatory pressure to be replaced with lower GWP options. **However**, **the GWP of a refrigerant cannot be the only measure utilized when developing more environmentally responsible solutions**. Efficiency of the resulting system can be the dominant factor affecting total global climate change impact. Therefore the Life Cycle Climate Performance (LCCP) of a refrigerant must be calculated in order to have a true assessment of a refrigerant's climatic effect.

In addition to working fluid concerns, technician training on responsible refrigerant handling practices is needed. Also, many options are made available for recovering used refrigerant in the field and returning it for reclamation and/or destruction.

Today's homeowners have several options for air conditioning their homes. Each

solution has its own benefits and advantages. Also, new system designs go beyond alternative air handling systems. Over the past 30 years, manufacturers have increased energy efficiency by over 50% through enhanced system and new technologies such as heat pumps which utilize the earth as a heat sink.

Predominantly the refrigerant used in central ducted air conditioning and ductless split systems has been HCFC-22. Currently, this is being replaced by the non-ozone-depleting HFC-410a, a blend of HFC-32 and HFC-125. Due to its higher operating pressures, HFC-410a requires new equipment designs that can operate at these higher pressures. Additionally, in a retrofit this solution requires all new equipment and line sets. Window units have been available for over 50 years. The primary use of these units is for cooling one or two rooms in a house. Their benefits include affordability and easy installation. Additionally, the cost of operation is relatively low. Traditionally, these units were charged with HCFC-22. However, this equipment was redesigned to use HFC-410a, which was commercialized in the early 2000s.



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COMMERCIAL AIR CONDITIONING

SOCIETAL IMPORTANCE

As the world's growing population dictates the development of all geographic climates, commercial air conditioning has become essential for health and comfort, worker productivity and economic vitality. The economies of many countries throughout the world are directly tied to an ability to cool the air in commercial buildings. Commercial air conditioning is used in stores, restaurants, schools, offices, hotels, long-term care facilities, hospitals, and other public places. Even in mild climates, commercial air conditioning has become a requirement to maintain health, productivity, and comfort.

Critical Application Considerations

The commercial air conditioning sector spans a broad range of applications running from small commercial package

units (air and water source) to larger air source package units. Air-cooled and water-cooled chillers using scroll, screw, and centrifugal compressors in cooling and heat pump modes are very common. This broad range of equipment has traditionally driven multiple refrigerant solutions from high pressure (scroll compressor applications) to medium pressure (screw and centrifugal compressor applications) to low pressure (centrifugal compressor applications) solutions. **Challenges include balancing a simultaneous need for reducing size and cost while maximizing energy efficiency.** Historically, tradeoffs have been made and continue to be identified when looking for alternatives to existing HCFCs and higher GWP HFCs. The service industry is accustomed to servicing different types of refrigerants. Therefore, it can accept multiple refrigerants across this portfolio. In addition, larger charge sizes for this segment are more suitable for refrigerant recovery.

Environmental Considerations

Since commercial air conditioning equipment uses a significant amount of energy, environmental concerns include but go beyond the direct environmental impacts of the fluid on the climate. These aspects are important, but the indirect impact that energy efficiency can have on climate change is the dominant effect. For example, heat pumps provide more heating energy than they use, unlike conventional direct heating systems. When considering a Life Cycle Climate Performance (LCCP) measurement that takes into account both direct and indirect impacts, one finds that the indirect impact represents 80-95% of the total climate change impact across this sector.

Leak rates can also have an impact on the direct ozone layer and climate impacts. Therefore refrigerant technology that can help minimize refrigerant emissions is also a key consideration. On a related basis, endof-life recovery and reclamation processes are an important means towards responsible refrigerant handling. Safety is an important attribute that must also be considered when looking at a balanced environmental solution. Given the larger charge sizes associated with equipment in this sector, and the fact that refrigerant is commonly circulated through the occupied space, hydrocarbons have seen very limited use given their high flammability.

After HCFCs are no longer available, HFCs, widely used in equipment today, offer a proven, safe, and energy efficient solution for commercial air conditioning in a wide range of equipment from small room air conditioners to multi-split variable refrigerant flow (VRF) systems, to large chillers. HFCs provide efficient cooling in both existing and new equipment. But the policy pressures on high GWP compounds mandate a balanced approach. Considerations such as safety, energy efficiency, ozone depletion and GWP are even more important and should guide choices for retaining appropriate HFCs and selecting alternatives. There is active development of new fluids and blends that offer significant reductions in GWP but can also be energy efficient, such as HFO-1234ze(E) and HFO-1234yf which was initially

designed for the mobile air conditioning application but has operating pressures and capacity similar to HFC-134a. In addition, HFC-32, which comprises 50% of the blend HFC-410A, is being reconsidered based on its good energy efficiency and capacity and its 67% lower GWP when used with scroll chillers. Some of the new HFOs, HFC-32, and ammonia are mildly flammable which requires safety standards to be re-examined to drive appropriate use of these new fluids. While the next generation solutions are not yet identified, the Alliance principles can help guide the work to select the eventual alternatives.



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HOUSEHOLD APPLIANCES

SOCIETAL IMPORTANCE

Throughout the world, household appliances such as refrigerators/freezers, room air conditioners, portable air conditioners and dehumidifiers are an integral part of today's home, adding convenience and comfort to the lives of their owners. Home appliances also are a success story in terms of energy efficiency and environmental protection. New appliances often represent the most effective choice a consumer can make to reduce home energy use and costs.

Critical Application Considerations

Energy use has been significantly reduced in major home appliances, while at the same time features and capacities have increased. For example, household refrigerators/ freezers provide convenient and safe food preservation and help improve quality of life, as well as reducing their impact on the environment. A typical refrigerator uses 50 percent less energy than 20 years ago, while its average capacity in the US has grown 20 percent. As these efficiencies have improved, the need for energy has diminished, helping to reduce emissions from power plants. The appliance industry also has moved to cooling and insulation systems that are much better for the environment because they are using non-ozone depleting substances that have lower global warming impact.

Refrigeration and home comfort products use refrigerant to remove heat (or water for dehumidifiers) from the air. Refrigerator/ freezers also have thermal insulation that uses a "blowing agent" that is used to spray the foam to provide insulation qualities. Both refrigerants and blowing agents must be safe, and energy efficient substances.

Since the mid-1980s, these household products have made costly, but environmentally beneficial transitions from CFCs, to HCFCs, and then to nonozone-depleting compounds such as HFCs and very low global warming potential compounds such as hydrocarbons.

Environmental Considerations

In the past, a household refrigerator's environmental impact had been principally a result of energy consumption of the product. Over the last 20 years, significant gains have been made in energy efficiency. Today, the appliance industry is using life cycle climate performace (LCCP) to evaluate the full environmental impact of the refrigerator. This not only takes into consideration its energy efficiency, but also the chemicals used in the refrigerant system, foam and foam blowing agents, manufacturing processes, performance, durability, and end-of-life impacts. The appliance industry has joined with Underwriters Laboratories Environment and CSA International to develop a set of sustainability standards for major appliances, beginning with refrigeration appliances. Through the use of sustainability standards, buyers are informed of the impacts on the environment. Manufacturers can use these standards to predict the impact of design changes on the full environmental impact of the product.

Environmental impact reduction opportunities exist by improving energy consumption. This can involve both the quality of insulation and choice of refrigerant. In doing this, manufacturers must balance other environmental factors, such as recyclability, durability, and safety. Today, there is much work being done to advance appliances to the next generation of environmental and energy efficiency benefits through the development of "smart" technology. Smart appliances will be able to receive signals from the electric grid and automatically adjust operation to use energy in a more beneficial way from a system perspective. Vast amounts of energy could be saved by reducing electricity losses along congested transmission and distribution lines, reducing the number of power plants that will need to be built, and, most importantly, save the consumer energy and money.

Tremendous advancements have been made in the development of new materials used in refrigeration appliances over the last few years. Energy efficiency still remains a key demand driver for the overall environmental impact. Both the insulating qualities and the compatibility of chemicals are critical to providing a safe, reliable, and long-lived appliance to people around the world. We continue to look forward with new refrigerant and foam blowing agent materials. Refrigerators continue to be one of the most sought-after appliances in the developing world. They provide a significant change to the overall lifestyle allowing families to store foods at safe temperatures. These products provide a tremendous economic value for the individual family and society as a whole. It is important to continue the development of materials that are safe, reliable, and outstanding values for the consumer.



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SOCIETAL IMPORTANCE

Commercial refrigeration preserves and protects food for societies around the world. Globally, studies show an average of 25% or more of harvested produce never reaches the market because of inadequate refrigeration. This percentage is often significantly higher in developing countries. Population growth increases world food production and delivery pressure, necessitating adequate refrigeration to minimize hunger, famine, and disease.

Critical Application Considerations

Consumers purchase food from supermarkets and retail food stores at the cold chain end. The equipment ranges from small kiosk-type refrigerator/freezer display cases to large refrigerated storage rooms. A large variety of perishable food products require diverse temperature controls to maximize shelf-life. As many as seven or eight different refrigerated storage areas may be required. However, equipment manufacturers must practically limit product offerings and operating temperatures may be compromised.

Fruits and vegetables typically use water spray systems to keep humidity high and sustain appropriate wet bulb temperatures since they are intolerant to low temperatures and low humidity. Meat, milk and dairy products are stored near the freezing point with minimal humidity. Fish are kept on ice and are separated to avoid smell and taste contamination. Ice cream requires the lowest temperatures (-23°C/-11°F) to prevent crystallization and softening.

Display cases distributed throughout a modern supermarket present significant equipment and servicing challenges. Central systems circulate refrigerant throughout the store to remote units. Many connections and coils can make leak control difficult. System reliability and serviceability are essential to prevent food spoilage costs.

Environmental Considerations

Commercial refrigeration has undergone the transition from CFCs to HCFCs, and more recently to HFCs. Now, lower climate impact solutions are beginning to be employed. System efficiency and effectiveness are also critical and require LCCP approaches. Historically supermarket systems have been criticized for high leak rates. More recently, manufacturers have made significant design improvements to reduce leaks throughout equipment life. Innovative charge minimizing designs and configurations, leak-resistant fittings and an emphasis on preventative maintenance have all resulted in lower average emissions and higher recovery rates.

Traditionally, supermarket refrigeration equipment used a central system connected to remote display cases, walk-in refrigerators and freezers or self-contained display cases. Newer distributed equipment place refrigeration compressors and components closer to cases or walk-in refrigerator/ freezers, thereby eliminating lengthy tubes of refrigerant. Indirect systems use a primary refrigerant to cool a secondary fluid, which circulates through cases or equipment coils. In each case, the choice of refrigerant will depend on the specific requirements of the application.

Looking Forward

Currently, HFC-134a, HFC-404A and R-507 are the most common refrigerants in commercial refrigeration. As pressure to reduce GWP is recognized, there has been an increased use of hydrocarbons, carbon dioxide and even ammonia in certain markets. Experience shows that with a suitable emphasis on minimizing safety risks and effective training of service personnel, this can be done with considerable success. HFOs, alone or in blends with HFCs, have the potential to maintain high efficiency with lower direct global warming impact. However, broad commercialization, of such equipment is probably several years away. It is important that equipment designers have access to a broad choice of working fluids to optimize energy efficiency, safety, affordability, and sustainability.

Manufacturers of commercial refrigeration systems have also improved the energy efficiency of equipment by using variable speed compressors, fans and pumps with improved efficiency, low energy lighting (LEDs), night curtains and doors, among other enhancements. These improvements have been embraced by store owners and customers.

The commercial refrigeration industry is committed to providing products that preserve the world's food chain in the most safe and sustainable manner possible. While providing cooling for very diverse storage conditions, manufacturers have focused on minimizing the environmental impact of their equipment through minimizing leaks and improving energy efficiency through recent design improvements. As climate concerns require lower GWP options, this industry will employ a variety of refrigerant solutions while maintaining a high level of energy efficiency in its products.



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INSULATION

SOCIETAL IMPORTANCE

Growth in thermal insulation foams continues to be driven by increasing energy efficiency requirements in appliances, transport applications, and buildings. Buildings (as an example) account for over 40% of the world's total primary energy consumption and 24% of global carbon dioxide (CO_2) emissions¹. One of the more effective strategies to lower energy consumption and improve energy efficiency is to increase the use of thermal insulation²,³.

Polyurethane (PU) and extruded polystyrene (XPS) foams and other types of foam insulation products are used to attain high energy efficiency in buildings while reducing CO_2 -equivalent emissions from the building heating and cooling. These insulation products utilize "foaming agents" or "blowing agents" to create the "cell size" within a given insulation product and it is this cell structure that delivers the insulating value of the foam. There are 16 major types of insulating foams produced globally that are primarily used for appliance insulation, residential and commercial building insulation, and specialty applications such as refrigerated storage, transport, and pipe insulation.

Critical Application Considerations

In a 2007 McKinsey study that analyzed the cost vs. the benefit of potential programs that will save greenhouse gases, "building insulation" ranks as one of the best opportunities for abatement. Foam insulation is one of the key contributors for this because of its unique attributes. The results show that while manufacturing foam insulation consumes energy, the energy saved far exceeds HFC manufacturing energy consumed, plus the direct blowing agent contribution. Energy efficiency in buildings is heavily influenced by the choice of blowing agent. For example, non-ozone-depleting HFCs can currently produce 10%-100% more efficient foams compared to other materials at the same mass and thickness. HFCs are manmade chemicals that were mainly developed as alternatives to ozone-depleting substances and are used as foam expansion agents (FEAs). Insulation materials utilizing HFC technology are high performance products that exhibit significant insulation (or R) values per thickness, thus providing cost-effective solutions to the building industry as it looks to substantially increase the energy efficiency of both new and existing buildings.

Environmental Considerations

The current landscape of technology choices is complex and is dependent upon the specific foam insulation sector, regional climate differences, availability of technology, and many other variables.

Solely using GWP as selection criteria for foam blowing agents could lead to the selection of alternative technologies that provide a reduced R-value and over time would result in more GHG emissions than would be emitted from the foam insulation itself. In other cases, alternatives may have properties that would preclude their use in certain applications. Based on these factors (among others) energy efficiency needs based on a Life Cycle Climate Performance (LCCP) approach should be a primary driver in determining the most appropriate foam technology options as there continues to be pressure to improve the overall thermal performance of foams across multiple use sectors.

Technology Trends

As of 2010, HCFC phaseout was virtually complete in all developed countries and HFCs have made this transition possible without the loss of thermal performance in buildings or appliances. While efforts continue to evaluate potential alternatives, these need to be balanced against the resources used to complete the most recent transition(s) as these evaluations will take time and additional resources associated with a demanding product range and a variety of manufacturing processes. Although hydrocarbons continue to be the primary solution in several applications in developed countries, there is increasing pressure in several application sectors to further optimize the foaming agent technology by blending multiple technologies. In developing countries, decisions need to be made to meet HCFC phaseout management plan initiatives. Within several sectors, previously identified low-GWP alternatives to HCFCs have yet to be fully validated and/or will require a significant transition investment.

Looking Forward

There continues to be a need to characterize the performance of foams made from low-GWP alternatives in a wide range of applications. This is an on-going exercise, but is particularly important for technologies that do not have a significant use history. Key drivers in this effort will continue to be both regulatory and socio-economic across both developed and developing countries. As new lower GWP foaming agent technologies continue to be evaluated, HFCs will continue to be a key contributor toward energy efficiency goals in the near- to medium- term. Any future transitions to new technologies need to take into account the time, costs, and other resources associated with an industry conversion that would need to occur without compromising current energy efficiency performance.

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MOBILE AIR CONDITIONING

SOCIETAL IMPORTANCE

Mobile air conditioning is an important part of an integrated system that provides cooling, heating, defrosting, demisting, air filtering and humidity control for both passenger comfort and vehicle safety. Its reliability and convenience are often taken for granted but it is the key to keeping passengers safe and comfortable in more than 600 million vehicles worldwide.

Critical Application Considerations

Mobile air conditioning presents a severe test for systems and refrigerants. The

system will operate for many years under widely varying weather conditions, even though it is exposed to hostile environments and is subject to vibration and temperature variations under the hood. It is desirable to have relatively rapid cool-down. It is important that the load on the engine is minimized to avoid an excessive carbon footprint from operating power demand. Because of the vibrations and adverse conditions, leakage has been historically high, but it has been reduced by tightening the systems. To further reduce direct impacts on the climate, there has been consideration of new refrigerant options with a lower GWP. The European Union, in Directive 2006/40/EC, mandated new auto air conditioning systems to use a refrigerant with a GWP of 150 or less in new car platforms beginning in 2011 and a full transition of new equipment to such alternatives by 2017. To accomplish this, three major options were developed for this application. These included CO., HFC-152a and a newly introduced unsaturated compound known as HFO-1234yf. HFO-1234yf has an atmospheric lifetime of only 11 days and a GWP of 4 versus 1430, the GWP of HFC-134a. It exhibits energy efficiency equal to that of HFC-134a. Use of this low GWP option will greatly reduce the carbon footprint for use in mobile air conditioning.

Environmental Considerations

New refrigerant options included HFC-152a, HFO-1234yf, and CO₂. Each presents additional environmental concerns and technological challenges. **The most important factors in choosing the optimum system are energy efficiency, safety, and Life Cycle Climate Performance (LCCP).**

A cooperative study under the auspices of US EPA, Mobile Air Conditioning Society (MACS), and Japan Automobile Manufacturers Association (JAMA), utilizing the holistic metric of LCCP found that HFO-1234yf was the best performing option in all four selected climate regions: Frankfurt, Tokyo, Athens and Phoenix. The LCCP for CO₂ systems was found to be more competitive under lower ambient temperature conditions but did not provide energy efficient cooling in hotter climates where air conditioning demand is most stringent. Several automobile manufacturers are planning transitions to HFO-1234yf systems. Use of this system is viewed as near drop-in. Some may still be considering CO₂. Some manufacturers are considering hydrocarbons which provide energy efficient cooling but introduce costly safety challenges and complexity for their successful use.

Mobile air conditioning has been one of the most visible and successful applications where environmental improvements have been demonstrated and implemented. Initially the commonly used refrigerant was CFC-12 which was completely eliminated in new vehicle use during the early- to mid-1990s. The replacement HFC-134a was a zero ODP option with a GWP about one sixth that of CFC-12 resulting in far reduced climate change impact. Studies indicated that a 50% reduction in refrigerant losses could be achieved with only a small additional investment in improved seals, hoses and practices which illustrated a potential to reduce leakage to the environment. Finally, manufacturers improved the systems to allow charge sizes to be smaller that further reduced HFC-134a climate impact.

Based on cooperative test results, plans and investments, the current view is that HFO-1234yf will serve as a major alternative refrigerant to HFC-134a. The industry will continue to examine how best to use HFO-1234yf while at the same time be open to other alternatives and technologies. **The metrics will continue to be LCCP, cost, safety and efficacy.**

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TRANSPORT REFRIGERATION

SOCIETAL IMPORTANCE

Transport refrigeration is essential in today's society to preserve and protect food, pharmaceuticals and medical supplies for people worldwide. It includes transport of refrigerated products with reefer ships, intermodal refrigerated containers, refrigerated railcars and road transport including trailers, diesel trucks and small trucks. While the use of transport refrigeration is fairly mature in developed countries, it remains at the early stages of use in many developing countries and is a necessary part of a solution to the problem of high food spoilage rates. Spoilage rates of 25% and higher are found in a number of developing countries and improvement is not anticipated without introduction of a strong "cold chain" of commercial and transport refrigeration of products from the "farm to the table."

Critical Application Considerations

To achieve accurate, cost-effective temperature control of commodities and maximum product quality under all operating conditions, the refrigerant selection, foam blowing agent, refrigeration system design, materials and operating methods are critical. Transport refrigeration equipment is extremely complex and must be capable of operating efficiently in exterior temperatures that range from -40°C to 55°C while maintaining precise internal temperatures that range from -40°C to 30°C. Under extreme ambient operating conditions, it is especially important that the refrigerant discharge pressures and temperatures remain within safe operating limits. HFC foam blowing agents are effective at maintaining these conditions and are currently 10% to 100% more efficient than compared to other materials at the same mass and thickness.

Refrigerants such as HFCs, and CO₂ in some applications, satisfy these conditions and stringent safety requirements, while simultaneously meeting customer control requirements. Refrigerants for this sector must have proven levels of reliability and a trained service network, which most effectively manages a strong "cold chain" ensuring that food, drugs and other products that require refrigeration reach their destination without deterioration, and do not endanger public health.

There are important safety considerations that affect refrigerant selection. Transport refrigeration equipment must be serviced worldwide. Flammable refrigerant introduction presents significant problems for the service technicians who are accustomed to working with non-flammable refrigerants, and may be a particular problem in developing countries. Extensive training in safe handling practices for both the equipment and use of flammable refrigerants is required. In addition, container units may be placed inside a ship's hull where a potentially concentrated refrigerant leak could lead to a significant increase in the risk of a fire if that refrigerant is flammable. It would be very difficult to eliminate all ignition sources from all areas where these refrigeration systems are used.

Power for transport refrigeration units typically comes from dedicated diesel units or from electricity generated from the primary diesel engine of the truck.

Environmental Considerations

While a refrigerant can impact the environment directly through its ozone depletion potential and its direct global warming potential, it can also impact the environment indirectly through its ability to deliver energy efficiency, which can increase or reduce fuel (typically diesel in transport refrigeration). The direct environmental impact of the refrigerant occurs only upon release to the atmosphere, so leak reduction is important. From a Life Cycle Climate Performance perspective, the majority of climate change impact will come from the indirect effect (energy efficiency) so this element must remain a major focus for any transition toward a lower GWP fluid.

Technology Trends

HFCs remain the primary solution in today's applications when all factors are considered, along with recent technology introductions for carbon dioxide in marine container

applications and in certain trailer and truck applications in some regions. Ammonia and hydrocarbons are being used to a lesser extent.



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METERED DOSE INHALERS

SOCIETAL IMPORTANCE

Metered dose inhalers (MDIs) are pressurized, hand-held devices that use propellants to deliver doses of medication to the lungs of a patient. MDIs and the medicines they deliver are critically important to public health and play a particularly significant role in treating respiratory illnesses such as asthma and chronic obstructive pulmonary disease (COPD). Stringent technical and performance criteria must be met (e.g., low toxicity) in order for a propellant to be deemed safe for patient use.

Critical Application Considerations

HFCs are the solely available medical propellants that have been demonstrated to be safe and effective for patients. No alternatives have been identified. Therefore it is critical to ensure that HFCs remain available to meet public health needs.

Asthma is a disease of the lungs and airways with symptoms of breathlessness, tightness of the chest, wheezing and cough. It is a chronic condition and frequently impacts individuals beginning in childhood and continuing throughout their lives. Asthma varies in severity from very mild to severe, and can be life-threatening. With proper, ongoing treatment asthma can be well-managed, and serious complications prevented. Asthma currently affects more than 300 million people worldwide. COPD, such as emphysema and chronic bronchitis, are progressive diseases and while the symptoms can be managed, the diseases are generally irreversible and often lead to premature death. COPD also impacts hundreds of millions of individuals globally and is currently the fourth leading cause of death worldwide.

Inhaled therapy is the mainstay of treatment for asthma and COPD. Inhalers deliver drugs directly to the lungs enhancing the symptomatic benefit and minimizing side effects. In addition to MDIs, dry powder inhalers (DPIs) are also inhalation devices used to treat asthma and COPD. It is important to note that not all devices are compatible with all drug products, or suitable for all patients. Selecting a therapy for a patient, including choosing a device, is a complex process driven primarily by the physician and patient. It is imperative to preserve a range of therapeutic options for patients. The Medical Technical Options Committee (MTOC) under the Montreal Protocol noted that "no single delivery system is considered universally acceptable for all patients" and "any consideration of policy measures to control HFCs should carefully assess patient health implications with the goals of ensuring patient health and maintaining a range of therapeutic options." The MTOC also recognized that "each country has its own unique and complex makeup in terms of availability of medicines, overarching health care systems, and patient preferences."

Environmental Considerations

For decades, CFC-based MDIs served as the "gold standard" inhalation treatment for patients with asthma and COPD

illnesses. In response to the mandates of the Montreal Protocol, pharmaceutical manufacturers undertook an exhaustive search for chemically, environmentally, and medically suitable alternative to CFCs. Once HFCs emerged as the single viable alternative medical propellant, companies jointly conducted multi-year pre-clinical safety testing programs. In parallel, individual companies embarked on lengthy, resourceintensive efforts to research and develop HFC-based alternatives to their specific CFC MDI formulations. Reformulating MDIs with HFCs was an enormously complex and timeconsuming effort. Most CFC MDI components proved incompatible with HFCs and had to be newly engineered. Each new HFC MDI was required to undergo the rigorous testing, regulatory review, and an approval process

associated with researching and developing wholly new drug products. The challenging transition to CFC-free alternatives was an unprecedented and resource-intensive undertaking impacting millions of patients and their health care providers.

The CFC MDI transition is still underway in several countries, but substantial progress toward closure of the essential use process has been achieved in recent years. It is currently estimated that developing countries will cease nominating essential use CFCs for MDIs by 2015-2016 and many countries around the world have already completed their transition. It is critical that the transition to HFC MDIs and other CFC-free alternatives proceed toward closure without questions or concerns regarding the long-term availability of pharmaceutical-grade HFCs.

Technology Trends

No alternative medical propellant to HFCs currently exists. Medical propellants must be very low in toxicity and must also meet several other stringent criteria, including nonflammability, chemical stability, appropriate solvency and density, and acceptable smell and taste. The industry concurs with the MTOC's assessment that "for a new propellant development programme, there is major risk, significant investment, and no guarantee of success." The MTOC also appropriately recognized the reality that for existing MDIs there would be "limited benefit to patients" given that the "active ingredient will remain the same and the performance characteristics are likely to be comparable to saturated HFCs." Therefore, pharmaceutical-grade HFCs must remain readily available to meet patient need for MDIs.

The use of HFCs in MDIs is quite small, as compared to other sectors (estimated at approximately 2-3% of overall global HFC usage). HFC MDIs have approximately 8 times less climate impact than CFC MDIs. The major impact in reducing global warming potential with respect to MDIs is the completion of the CFC MDI transition. Sound MDI manufacturing operations and responsible disposal/ recycling are critical to minimizing HFC emissions.



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The Alliance is an industry coalition that was organized in 1980 to address the issue of stratospheric ozone depletion. It is presently composed of about 100 manufacturers and businesses which rely on HCFCs and HFCs.

AEROSOLS

SOCIETAL IMPORTANCE

Nearly 95% of all aerosols do not use fluorocarbons. Flammability, pressure, safety, and efficacy make fluorocarbons uniquely suited for certain applications such as safety horns, lubricants, and technical aerosols. Many products that consumers depend on today can only be effectively delivered from an aerosol package.

Critical Application Considerations

Aerosol packaging is chosen for a variety of reasons. Most significant is safety since aerosols are sanitary and tamper resistant. Aerosol products are also efficient and easy to use. There is no evaporation, deterioration, or contamination of the contents. In addition, the ingredients do not need to be mixed separately before use, they are spill-proof, and aerosols can be used to effectively target a specific area. Because of their unique delivery system, aerosols are efficient at using 100% of the contents of the can, leaving no waste. Some products are not available in any other form such as shaving foams, silicone sprays, expanding packaging foams, and surgical sutures.

Environmental Considerations

In the US today, the predominant propellants used in aerosols are hydrocarbons.

These, paired with carbon dioxide and nitrogen, account for nearly 95% of all aerosol propellants. The preponderance of the remaining products use HFCs as propellants, which are chosen for their distinct and specialized performance properties. Specifically, HFCs used in consumer products are either non-flammable (HFC-134a), or are much less flammable than hydrocarbons (HFC-152a). Both are low in toxicity, and are not volatile organic compounds (VOCs). All of the current aerosol propellants used in the US are non-ozone depleting, and were chosen as replacements for CFCs and HCFCs, which were phased out for use in the US under the Montreal Protocol. Total HFCs used as propellants account for less than 0.2% of US total global climate change emissions. HFC-152a has a very low global warming potential (GWP) and can be used safely in many consumer products, while HFC-134a, with a higher GWP, is used in a small percentage of technical aerosols where a completely non-flammable propellant is necessary, such as tire inflators, marine signal horns, and mold release sprays.

Recently, HFC-134a had been the only nonflammable liquefied propellant available. However, the US EPA has approved a newly invented compound, HFO-1234ze, which can be used in many similar applications. **This** new propellant has an extremely low GWP, is non-flammable, and is not a VOC. In addition, it has very low conversion costs, which may make it a viable replacement for HFC-134a in certain aerosol products.



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