JOURNAL OF AEROSOL MEDICINE
Volume 8, Supplement 1, 1995
Mary Ann Liebert, Inc., Publishers

The Montreal Protocol and Essential Use Exemptions

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ABSTRACT

The Montreal Protocol is an international treaty to phase out chlorofluorocarbons (CFCs) and other substances which destroy stratospheric ozone. The target date for the ban in developed countries, 1 January 2000, was subsequently advanced to 1 January 1996, with CFC production allowed temporarily for uses deemed 'essential' by the Parties. Seventeen governments submitted nominations to the United Nations (UN) Environment Programme requesting essential use exemptions for metered dose inhalers (MDIs). The nominations were reviewed by committees of technical experts and recommendations were considered at the Sixth Meeting of the Parties to the Protocol in October 1994. The Parties granted an exemption for the use of CFCs in MDIs for the treatment of asthma and chronic obstructive pulmonary disease (COPD) during 1996 and 1997. The European Union (EU) accelerated its own CFC phase-out date to 1 January 1995, also building in the possibility of 'essential use' exemptions. In July 1994 the European Commission announced exemption for MDIs from this deadline. Patients and physicians can be confident that MDIs will remain available for the foreseeable future. Furthermore, the small quantity of CFCs which has been exempted for use in MDIs will add very little to the existing environmental burden in the atmosphere.

INTRODUCTION

CFCs deplete the stratospheric ozone layer by transporting chlorine to upper levels of the atmosphere. In the stratosphere, CFCs are gradually decomposed by solar ultraviolet (UV) radiation generating chlorine radicals which in turn cause the catalytic destruction of ozone. This effect is clearly undesirable from an environmental perspective, hence the need to phase out the use of these ozone-depleting substances. This intention is manifest in the Montreal Protocol on Substances that Deplete the Ozone Layer, an international treaty which has been ratified by 139 countries around the world since its inception in 1987 (Montreal Protocol, 1987). The Protocol commits these countries to phasing out the production and use of CFCs and replacing them with ozone-sparing substitutes.

KEYWORDS: Montreal Protocol, 'essential use' exemption, CFC, MDI, ozone.

Timetable for Phase Out

The process was started by the Vienna Convention, a meeting organised by the UN which was held in Vienna in March 1985. At this convention it was recognized that ozone depletion was occurring and that CFCs were a major cause of this. The countries represented in Vienna agreed that it was necessary to do everything possible to protect the ozone layer. In 1987 46 countries signed the Montreal Protocol, an international treaty which undertook to reduce the production of ozone-depleting substances in developed countries by 50% by the year 2000. However, further research amassed evidence to show that the rate of depletion was greater than at first thought, and so subsequent meetings of the Parties to the Protocol advanced the phase-out schedule. In June 1990, at a meeting in London, the Parties announced a complete ban, rather than a 50% reduction, by the year 2000. In 1992 the phase-out date for developed countries was brought forward to 1st January 1996.

In deciding to implement the Montreal Protocol, the EU member states undertook to accelerate their own phase-out schedule so that the EU ban on CFC production would become effective from 1 January 1995 for all but essential uses (Council Regulation [EEC], 1991, 1992). The Montreal Protocol has already been effective in reducing the amount of CFCs which are produced within the EU. The peak of CFC production in the EU occurred in 1987, 2 years after the Vienna Convention (European Chemical Industry Council, 1994). At that time about 300,000 tonnes of CFC were produced in Europe for aerosols, foams, refrigeration, solvents and for other uses. As a result of the Montreal Protocol these industries have undertaken the necessary measures to reduce the amount of CFCs they use (Figure 1).

A number of these industries are using hydrocarbons or hydrofluoroalkanes (HFAs) as substitutes for CFCs, and they are well on target for phasing out CFC use entirely in accordance with the Protocol and EU Regulations. The one major exception is the manufacture of MDIs. The complexities of reformulating MDIs with the new HFA propellants, and fulfilling the regulatory requirements for approvals of reformulated products mean that MDIs are unable to meet the phase-out dates.

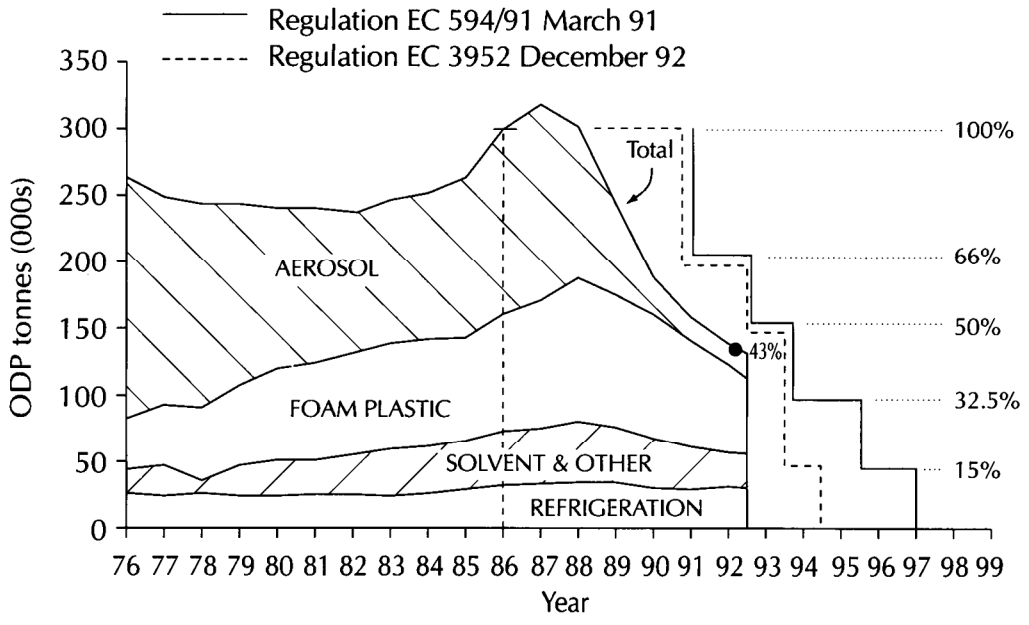

FIGURE 1.
CFC Usage in the EU (1976 - 1992) and Targets for Phase Out as a Result of Council Regulations.

'Essential Use' Exemption

In order to qualify for exemption from the phase-out date it must be shown that MDIs are, in fact, an 'essential use' as defined by the Montreal Protocol. There are four criteria agreed to by the Parties to the Protocol for defining what constitutes an essential use of CFCs (Decision IV/25, 1992). An essential use must be critical for the health, safety and wellbeing of society; there must be no technically or economically feasible alternatives or substitutes; all economically feasible steps must be taken to minimize CFC emissions; and the use of stockpiled or recycled CFCs should not be viable options.

Seventeen governments worldwide reviewed the case for MDIs and concluded that they clearly fulfil all of these criteria and do qualify as an 'essential use' of CFCs (Montreal Protocol, 1994). These countries submitted nominations to the UN Environment Programme (UNEP), which administers the Montreal Protocol, making the case for the exemption of MDIs. MDIs fulfil the first criterion because asthma is such a common and serious disease, and MDIs are the mainstay of treatment for this condition. MDIs are thus necessary for the health and safety of society. Secondly, although other forms of inhaled treatment do exist for asthma, such as powder inhalers and nebulizers, these alternatives cannot substitute for the use of MDIs in all cases. MDIs are used by approximately 80% of asthma patients, and they have an important place in asthma management. The second criterion is therefore fulfilled. Thirdly, manufacturers have made strenuous efforts to reduce CFC emissions during the production of MDIs and they have also introduced systems for recovery or destruction of CFCs from waste materials, thus fulfilling the third criterion. Finally, it is impossible to use recycled CFCs, eg from an air conditioner or refrigerator, in MDIs because of the possible contaminants and toxic impurities there might be in such recycled material. Thus all four criteria were fulfilled.

The essential use nominations were reviewed by committees set up by the UNEP (Montreal Protocol, 1994). The most detailed examinations were undertaken by the Technical Options Committee which is responsible for nominations of aerosols as an application. This Committee consists of experts from relevant disciplines eg respiratory disease specialists, aerosol technologists and pharmaceutical scientists. Their recommendation was reviewed initially, by the UNEP Technology and Economic Assessment Panel, subsequently, by representatives from the Parties to the Montreal Protocol, and finally, officials from the Parties. The final decision was taken by these senior officials.

The outcome of this review process occurred in October 1994 at the Sixth Meeting of the Parties to the Protocol (Decision VI/9, 1994). The Parties granted an exemption for the production of specified quantities of CFCs for use in MDIs for the treatment of asthma and COPD during 1996, and, for those countries which requested two year exemptions, 1997. The European Commission has also exempted MDIs from its accelerated phase out schedule during 1995 (Commission Decision, 1994). These initial exemptions are extendable subject to further nominations from Parties fulfilling the criteria for essentiality in future years. In summary, patients and physicians can have a high degree of confidence that MDIs will continue to be available for the treatment of asthma and COPD for the foreseeable future.

Environmental Impact

The environmental impact of the Montreal Protocol 'essential use' exemption is summarized in Figure 2. Industrial uses, such as aerosols, refrigeration, and foam blowing, account for the major proportion of CFCs produced (Grant Thornton, 1993). In 1987, the peak year of production, over a million metric tonnes of CFC were produced worldwide for these industrial uses and MDIs accounted for a very small proportion of the total, only 0.8%. Since the introduction of the Montreal Protocol the total production of CFCs has declined quite dramatically, having been halved to about 500,000 tonnes by 1992. MDIs accounted for around 7000 tonnes or 1.41% of the total production in 1992 (Dunn Group, 1992). By 1996 production of CFCs for industrial use in developed countries should be virtually nil because of the Montreal Protocol deadline. The residual production of about 10,000 tonnes, which has been exempted, will be predominantly for MDIs. Thus CFC production in 1996 and beyond will be minimal compared to the quantities produced in the past.

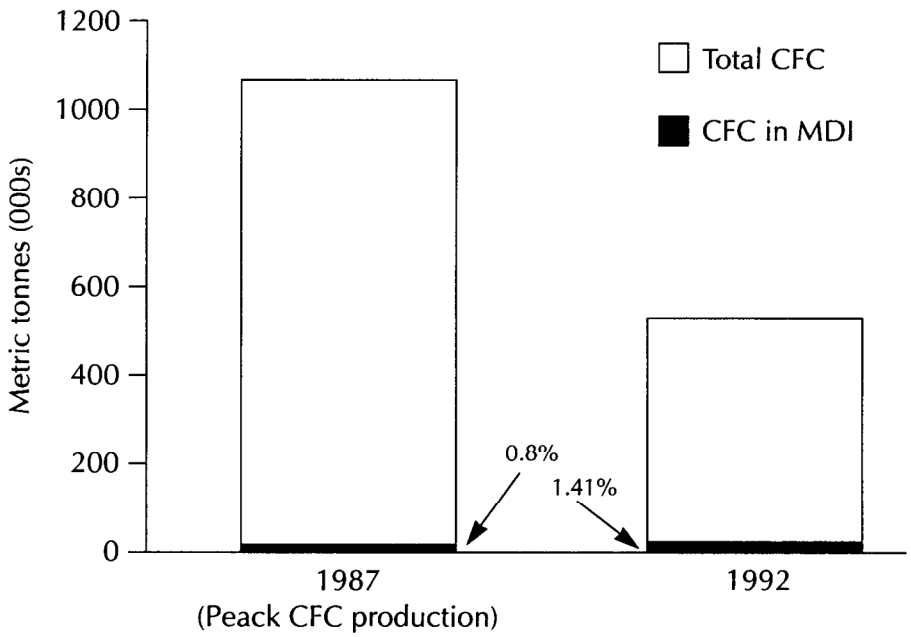

FIGURE 2.
Effect of the Montreal Protocol on CFC Production
(Data from European Chemical Industry Council).

The impact of this small exempted quantity has been assessed using a model (Pyle, 1993) which takes into account the fact that, in the 60 years since CFCs first came into widespread industrial use, over 19 million tonnes have been produced and used worldwide (Grant Thornton, 1993). These CFCs have an atmospheric residence time of 70 years or more, thus there is already a very large environmental burden in the upper atmosphere. The model assumes that 15,000 tonnes of CFCs will be used in MDIs each year for the next 4 years. This figure is an overestimate for the purposes of this model since the currently forecast requirement is less than 10,000 tonnes per annum.

In the context of the existing burden, the environmental impact of exemptions for MDIs will be extremely small (Pyle, 1993). On the basis of the model, the exemption of 15,000 tonnes of CFCs for the next 4 years has no significant impact on the peak value of the chlorine concentrations which will be achieved in the upper atmosphere. It also does not significantly affect the timing at which that peak will be attained, nor does it affect the rate at which chlorine will be cleared from the upper atmosphere to reach pre-ozone hole levels.

CONCLUSION

In conclusion, both Governments and the pharmaceutical industry worldwide are committed to phasing out the production and use of ozone-depleting CFCs as quickly as possible. They also recognize the medical need for the continued availability of CFCs for use in MDIs until suitable reformulated products, using alternative non-CFC propellants, are available. The 'essential use' exemptions granted thus far last until 1996/7 but they may be extended, depending on the rate at which MDI products can be reformulated and approved for marketing by regulatory authorities. The small quantity of CFCs which has been exempted for use in MDIs will add very little to the existing environmental burden in the atmosphere.

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