



**United Nations  
Environment  
Programme**



Distr.  
Limited

UNEP/OzL.Pro/ExCom/28/48  
11 June 1999

ORIGINAL: ENGLISH

---

EXECUTIVE COMMITTEE OF  
THE MULTILATERAL FUND FOR THE  
IMPLEMENTATION OF THE MONTREAL PROTOCOL  
Twenty-eighth Meeting  
Montreal, 14-16 July 1999

**THE STERILANTS SECTOR**

## Introduction

1. In Decision 27/12, the Executive Committee requested the Secretariat, in coordination with the Implementing Agencies and other experts, to develop guidelines on the approach to be applied in the consideration of projects for approval under the sterilants subsector.

## Background

2. Sterilants are part of the “aerosols and miscellaneous” sector in TEAP nomenclature but are often confused with the solvents sector.

3. Only two projects have so far been approved by the Executive Committee:

- the first, Hindustan Syringe, manufacture and sterilisation of syringes, a solvent sector project, was approved at the 13<sup>th</sup> Meeting. Phase-out 50 ODP tonnes of CFC-12. C/E US \$9.6/kg;
- the second, Asisthos, Argentina, contract sterilisation, a sterilant (new sector) project, was approved at the 27<sup>th</sup> Meeting. Phase-out 21 ODP tonnes of CFC-12. C/E US \$19.1/kg.

4. Hindustan Syringe was a typical industrial conversion project where the sterilisation takes place as part of the manufacturing process. The project was completed in December 1996 and the ODS equipment destroyed in 1998. The project completion report indicates that the project was completed satisfactorily but does not provide detail of any particular lessons learned. Asisthos is not a manufacturer but offers contract sterilisation as a service, similar to contract fillers in the aerosol sector.

## Discussion

### Approach

5. With only two projects so far approved there is little information for determination of guidelines/cost effectiveness thresholds on the basis of experience.

6. However it is possible even at this stage to characterise conversion activities, technology choices, hardware and facilities requirements, operating cost items etc. from which can be drawn general guidelines. Additional details on eligibility and cost effectiveness can be added as more information becomes available.

### Outline of typical sterilisation projects

#### *Enterprise structure and ODS consumption*

7. The enterprise structure is likely to be either an institution such as a hospital, an enterprise producing medical products or a private business offering sterilisation services on a

contract basis (such as the Asisthos project). In each case conversion is only necessary when current equipment uses a mixture of CFC-12 and ethylene oxide (EO) as the sterilising gas. The combination of ethylene oxide and CFC-12, typically at 88% and 12% respectively has for many years been the preferred sterilant of choice due to CFC-12's inert characteristics which counters the highly flammable nature of ethylene oxide and the relatively inexpensive cost and availability of CFC-12. Steam sterilisation does not involve ODS.

8. Noting the likely prevalence of contract sterilisation services in this sector, a minimum of three years' records of the quantities of product sterilised and the corresponding level of consumption of CFC-12/EO sterilising gas used is necessary to establish with confidence the level of consumption of ODS and the proposed phase-out and project cost effectiveness.

#### *Technology choice*

9. There are four main options for replacing CFC-12 in a sterilisation operation: use a drop-in HCFC replacement gas with minor or no costs to upgrade existing equipment; replace the gas with a nonflammable mixture of ethylene oxide/ carbon dioxide (EO/CO<sup>2</sup>) if possible; upgrade the existing sterilising equipment and facility with the appropriate safety features for use with 100% EO and nitrogen; or replace the main sterilising equipment and perform the same facility upgrades. In addition to these four main options, enterprises doing their own CFC-12 sterilisation and in some cases hospitals may consider sending their product to a contract sterilisation service provider. The options are fully described in the 1994 report of the Aerosols, Sterilants and Miscellaneous Uses Technical Options Committee of the TEAP and updated in the 1998 TEAP Assessment Report.

10. The first option has very low capital costs but could incur - at least for the present - high operating costs (due to the cost of the HCFC gas). It is more likely to be used in hospitals where the equipment is smaller, there are limits on capital expenditure and/or it is impractical to install safety systems. The second option can require equipment modification or replacement (a sterilizer utilizing nonflammable mixture of 8.5% EO / 91.5% CO<sup>2</sup> must run at higher operating pressures and will require at minimum some equipment changes) but has a considerably lower operating cost than HCFC sterilants, which depending upon the cost of upgrading, may result in a long term savings. Because there are no flammability requirements with EO/CO<sup>2</sup>, the cost of upgrades to the facility are avoided. The third and fourth options offer an even greater operating savings but will require higher equipment and facility upgrade costs (i.e. intrinsically safe wiring, explosion-proof motors, damage limiting construction) since 100% ethylene oxide is highly flammable). However the gas costs are low. This option will typically be preferred for contract sterilisation services where the utilisation of the equipment is high and large quantities of sterilising gas are required.

11. One-year incremental operating costs of the HCFC technology could conceivably exceed the capital costs of the 100% EO option. Comparative costs will need to be presented in all project proposals to provide support for the cost-effectiveness of the technology choice.

#### *Capital equipment*

12. The HCFC sterilant is considered a "drop in" replacement to the CFC-12 because there is very little change required to the sterilisation system. TEAP observes that Article 5.1 parties

could convert to EO/HCFC-124 sterilant gas rapidly with minimal cost and no changes in operating procedure. For the EO/CO<sup>2</sup> option, the capital equipment will need to be modified or replaced, since the EO/CO<sup>2</sup> mixture operates at a higher pressure, however the gas mixture is not flammable, thus no fire/explosive safety equipment is needed. The Hindustan Syringe project (1994) used EO/CO<sup>2</sup> technology and new sterilising chambers were specified at a cost of around US \$100,000 each.

13. Conversion to a 100% EO operation, could incur high investment cost in both the facility and the sterilisation system. However, a new, automated sterilising chamber can cost up to US 400,000 for internationally made equipment. (In the Argentine project, locally made equipment was specified at a cost of US \$285,000). For large or relatively new sterilisers where the chamber pressure vessel is considered valuable it may be economical to refurbish the chamber and replace the piping, wiring, components, motors and control system. For economical reasons, refurbishing a steriliser usually must be done at a sterilizer manufacturer's facility, at a capital cost of up to some US \$150,000. This was common practice in the U.S. where many sterilisers were converted from using EO/CFC-12 to 100% EO and nitrogen.

14. Special construction may be required due to the flammability of 100% EO. This construction, sometimes referred to as Damage Limiting Construction (DLC), consists of enclosing the hazardous areas (i.e. steriliser, gas storage and dispensing room) with pressure retaining and pressure relieving walls designed to vent an explosive mixture out of a out a specific area of the room, typically the roof.

15. These hazardous areas also require electrical installations meeting relevant local national or international safety standards such as the IEC series of electrical codes, or the US code NEC Class 1, Division 2, Group B or C, for countries following US standards. The hazardous areas should have special ventilation and gas detection which are not unlike those required for hydrocarbon foam blowing and refrigeration. International standards for the hazardous areas are also available to guide equipment selection and layout. Because of the new construction required, the layout of the plant is likely to change and it is possible that the enterprise may wish to incorporate other changes (e.g. to sizes of product handling areas and associated air-conditioning arrangements). These may not all be associated with phase-out and thus may not be eligible for funding. Project proposals need to address the issue of non-eligible factory improvements and technological upgrade.

#### *Operating costs*

16. There are no particular difficulties with the calculation of operating costs or savings. However it is necessary to determine the duration of the transitional period for which operating costs or savings will be taken into account. Projects involving HCFC technology are likely to have very high IOC. Projects involving EO/CO<sup>2</sup> may have savings. Projects involving 100% ethylene oxide technology are likely to have savings. Contract sterilising enterprises which use large quantities of gas are likely to have substantial savings.

17. The two projects so far approved have had IOC/savings periods of two years and three years. The two year figure was used in the Hindustan Syringe project approved at the 13<sup>th</sup> Meeting. The three year period was a negotiated decision taken for the Asisthos project approved at the 27<sup>th</sup> Meeting.

18. However, like the aerosols and solvents sectors, projects may have either incremental operating costs or savings depending on technologies and individual circumstances. Because of this, and in the absence of any specific technical reasons evident at present which would have a bearing on the duration, it may be appropriate to maintain the duration for the calculation of IOC at four years, pending specific information or evidence to support a different time period.

#### *Cost-effectiveness*

19. Initial indications are that projects in the sterilants sector may be in the higher cost effectiveness ranges of US \$9-20 per kg. A sample of two projects is too small to draw any firm conclusions. For instance it may be possible that projects so far considered are not typical and others could have lower costs. However it seems unlikely that cost effectiveness will decrease to levels typical in the foam or aerosol sectors.

20. Projects could be considered on a case-by case basis for the time being, with the aim of revisiting the issue of a threshold when the sample size of approved projects was larger and more representative.

#### Implications for the Multilateral Fund

21. In its April 1997 report, the Aerosols TOC reported that the 1997 global consumption of CFC-12 for sterilisation was expected to be 500 metric tonnes, decreasing to virtually zero in 1999. In its 1998 Assessment the TEAP reported that global consumption was difficult to estimate but was less than 1000 tonnes. The report also noted that there were indications of increased use in some Article-5 countries. On this basis, while there is little specific information available on the likely emergence of projects in this sector, it appears that this will not become a major area of activity for the Multilateral Fund.

#### **Possible initial guidelines**

22. Drawing on the above, the following could be considered as initial guidelines for the submission of projects in the sterilants sector, pending the approval of a sufficient number of projects to enable more detailed requirements to be included.

- (a) Project proposals should be consistent with all the policies and decisions of the Executive Committee, especially those relating to facilities established after 25 July 1995, and to exports.
- (b) To avoid confusion between the sterilants and solvents sectors, a sector strategy should be prepared when a country has more than one enterprise involved in sterilisation activities.
- (c) The choice of technology should be fully explained. In particular, noting the requirement for cost-effective solutions consistent with national industrial strategies, an outline cost comparison between the principal technological options should be provided. Where a solution involving the use of HCFCs is proposed, it should be fully consistent with all decisions relating to the use of HCFCs.

- (d) Standards for safety. The project should be designed to appropriate norms consistent with industry recognised national or international standards, for instance the US National Fire Protection Association standard NFPA 560 “Standard for the Storage, Handling and Use of Ethylene Oxide for Sterilization and Fumigation” and the electrical installation standard “NEC Class 1, Division 2, Group B or C” or the equivalent classification in the international IEC codes.
- (e) Technological upgrade and non-eligible costs. Noting the changes to plant layout likely in some of these projects and the installation of computer operated equipment, proposals should include detailed description of baseline, and separate costs directly associated with ODS phase-out from those related to factory improvements, which are not eligible for funding. Incremental costs proposed should be fully consistent with relevant Executive Committee decisions concerning technological upgrade.
- (f) To facilitate the establishment of consumption data, information on the level of business of the enterprise and of annual ODS consumption should be provided for a minimum of three years prior to the preparation of the project.
- (g) Based on the existing rules and policies of the Multilateral Fund, the operating costs should be calculated for a duration of four years. The operating costs for each of the alternative sterilants EO/HCFC, EO/CO<sup>2</sup> and 100% EO should be considered in the choice of technology for each project. An outline calculation of comparative IOC/savings should be included in the project document in support of the choice of technology.
- (h) These initial guidelines will be considered for review after sufficient projects in this sector have been considered, to enable general conclusions on costs to be drawn. The review will include consideration of a cost effectiveness threshold.
- (i) Pending a review, the cost effectiveness of project proposals will be considered on a case-by-case basis.

### **Recommendation**

23. The Executive Committee might wish to adopt the initial guidelines for projects in the sterilants sector contained in paragraph 22 above.