COMMISSION DECISION
of 13 February 2001
(notified under document number C(2000) 4153)
(Only the Spanish, German, English, French, Italian, Dutch, Portuguese, Finnish and Swedish texts are authentic)
(Text with EEA relevance)
(2001/333/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 2037/2000 of the European Parliament and of the Council on substances that deplete the ozone layer (1), and in particular to Articles 3, 4 and 7 thereof,

Whereas:

(1) Because of concerns for the ozone layer, the Community has already phased out the production and consumption of certain controlled substances.

(2) Essential uses have to be decided for chlorofluorocarbons; other fully halogenated chlorofluorocarbons; halons; carbon tetrachloride; 1,1,1 trichloroethane; and hydrobromofluorocarbons (Article 3.1 and Article 4.4).

(3) The criteria used for assessing essential uses are in line with Decision IV/25 of the Parties to the Montreal Protocol and are:

I. That a use of a controlled substance should qualify as ‘essential’ only if:

A. it is necessary for the health, safety, or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

B. there are no technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

II. That production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(4) Decision XI/14 of the Parties to the Montreal Protocol authorises the levels of production and consumption necessary to satisfy essential uses of controlled substances for metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

(5) Decision XI/17 of the Parties to the Montreal Protocol authorises the production and consumption necessary to satisfy essential uses of controlled substances for laboratory and analytical uses as listed in Annex IV to the report of the Seventh Meeting of the Parties, subject to the conditions set out in Annex II to the report of the Sixth Meeting of the Parties and in Decision VII/11.

(6) The Montreal Protocol’s Technology and Economic Assessment Panel noted in its April 2000 report that the European Community’s stockpile of CFCs has increased and recommended that it be reduced as production of CFC-based MDIs declines.

(7) The Commission has published a notice (2) to those companies in the European Community that use controlled substances which may be allowed for essential uses in the Community in 2001 pursuant to Regulation (EC) No 2037/2000, and has thereby received applications for quantities of controlled substances for essential uses in 2001.

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

A. all economically feasible steps have been taken to minimise the essential use and any associated emission of the controlled substance; and

B. the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the needs of developing countries for controlled substances.

(8) In the framework of the Montreal Protocol nomination and assessment procedures for essential uses, Parties are requested to identify the users who may take advantage of essential uses in 2001.

(9) The Commission issues licenses to the users identified pursuant to Articles 3, 4 and 7 and in accordance with the procedure set out in Article 18 of Regulation (EC) No 2037/2000.

(10) Within this framework, a producer may be authorised by the competent authority of the Member State in which its relevant production is situated to produce the controlled substances for the purposes of meeting the licensed demands presented by the identified users; the competent authority of the Member State concerned shall in turn notify the Commission well in advance of any such authorisation.

(11) Pursuant to Decision XI/17 of the Parties to the Montreal Protocol, overall quantitative limits may be set for essential laboratory and analytical uses of controlled substances in the European Community during 2001.

(12) The list of essential uses and the quantities of the controlled substances are hereby given in the Annex as information for producer and user industries.

(13) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 18 of Regulation (EC) No 2037/2000.

HAS ADOPTED THIS DECISION:

**Article 1**

Companies which may take advantage of the essential uses for their own account during 2001 for the manufacture of metered dose inhalers and for the coating of cardiovascular surgical material are listed in Article 5.

**Article 2**

The total quantities of controlled substances permitted for essential uses during 2001 shall be as specified in the Annex.

**Article 3**

Within the overall limits set out in Part B of the Annex, the Commission shall issue licenses to acquire controlled substances from producers in the Community or by import for essential laboratory and analytical uses.

**Article 4**

This Decision shall apply from 1 January 2001 to 31 December 2001.

**Article 5**

Companies which may take advantage of the essential uses for their own account during 2001 for the manufacture of metered dose inhalers and for the coating of cardiovascular surgical material are:

- 3M Health Care Ltd
  Mr Brian Edwards
  3M House
  Morley Street
  Loughborough
  LE11 1EP
  United Kingdom

- Aventis
  Mr Bob Netrefa
  London Road
  Holmes Chapel
  CW4 8BE
  United Kingdom

- Bespak PLC
  Mr Chris Halley
  North Lynn Industrial Estate
  King's Lynn
  PE30 2JJ
  United Kingdom

- Boehringer Ingelheim GmbH
  J. Pink
  D-55216 Ingelheim am Rhein

- CCL Pharmaceuticals Ltd
  Ms C. King
  Astmoor Industrial Estate
  9 Arkwright Road
  Runcorn
  Cheshire
  WA7 1NU
  United Kingdom

- Chiesi Farmaceutici SpA
  Dr. P. Chiesi
  Via Palermo, 26/A
  I-43100 Parma

- Edwards Life Sciences
  Dr. A. Bronkhorst
  Energelaan 3
  PO Box 169
  5400 AD Uden
  Nederland

- GlaxoSmithKline
  Mr Barry Rosenthal
  Speke
  Liverpool
  L24 9JD
  United Kingdom

- IG Sprühtechnik GmbH
  F. Guck
  Im Hemmet 1
  D-79664 Wehr

- Jaba Farmacêutica SA
  Ana Maria Baptista de Almeida
  Rua da Tapada Grande n.º 2
  Abrunheira
  P-2710-089 Sintra

- Laboratorio Aldo Unión SA
  Dr. J. Sabater Sanmartí
  Baronesa de Maldá 73
  Esplugues de Llobregat
  E-08950 Barcelona
Norton Waterford Ltd  
Mr Jim Kennedy  
Unit 301 Industrial Park  
Waterford  
Ireland  

Orion Corporation  
Mr Pasi Salokangas  
Orionintie 1  
FIN-02200 Espoo  

Schering-Plough Labo NV  
Dhr P. Gyselinck  
Industriepark 30  
B-2220 Heist-op-den-Berg  

Valeas SpA Pharmaceuticals  
Dr. Virgilio Bernareggi  
Via Vallisneri, 10  
I-20133 Milano  

Valois SA  
M. Salim Haffar  
50, avenue de l’Europe  
F-78160 Marly-Le-Roi  

VARI  
Dr. Bruno Boccardo  
Via del Pino, 10  
I-23854 Olginate.  


For the Commission  
Margot WALLSTROM  
Member of the Commission
ANNEX

A. MEDICAL USES

Production of metered dose inhalers (MDIs) for the treatment of asthma and other chronic obstructive pulmonary diseases (COPDs)

<table>
<thead>
<tr>
<th>Company</th>
<th>2001 quota allocation (in kg (CFC))</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M (UK)</td>
<td></td>
</tr>
<tr>
<td>Aventis (UK)</td>
<td></td>
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<tr>
<td>Bespak (UK)</td>
<td></td>
</tr>
<tr>
<td>Boehringer (D)</td>
<td></td>
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<tr>
<td>CCL Pharmaceuticals (UK)</td>
<td></td>
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<tr>
<td>Chiesi (I)</td>
<td></td>
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<tr>
<td>Glaxo SmithKline (UK)</td>
<td></td>
</tr>
<tr>
<td>IG Sprühtechnik (D)</td>
<td></td>
</tr>
<tr>
<td>Jaba Farmacêutica (P)</td>
<td></td>
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<tr>
<td>Lab. Aldo-Unión (E)</td>
<td></td>
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<tr>
<td>Norton (IRL)</td>
<td></td>
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<tr>
<td>Orion (FIN)</td>
<td></td>
</tr>
<tr>
<td>Schering-Plough (B)</td>
<td></td>
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<tr>
<td>Valeas (I)</td>
<td></td>
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<tr>
<td>Valois (F)</td>
<td></td>
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<tr>
<td>VARI (I)</td>
<td></td>
</tr>
</tbody>
</table>

Total 2 614 662

B. LABORATORY USES

Total quantities of controlled substances that may be produced or imported during 2001 for laboratory and analytical uses

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Quantitative limit (in kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFCs</td>
<td>160 000</td>
</tr>
<tr>
<td>Carbon tetrachloride</td>
<td>190 000</td>
</tr>
<tr>
<td>1,1,1 trichloroethane</td>
<td>18 000</td>
</tr>
<tr>
<td>Others (other CFCs, halons, HBFCs)</td>
<td>420</td>
</tr>
</tbody>
</table>

Laboratory users or suppliers of laboratory chemicals needing to obtain controlled substances from producers or importers under this essential use exemption should apply to the Commission for authorisation. The total quantity of each controlled substance authorised during 2001 for laboratory and analytical purposes shall not exceed the quantities listed above.

C. CARDIOVASCULAR SURGICAL MATERIALS

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Quantity (in kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC 113</td>
<td>100</td>
</tr>
</tbody>
</table>