COMMISSION

COMMISSION DECISION

of 13 February 2001

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2001 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council on substances that deplete the ozone layer

(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:

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.

(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.

[1] OJ L 244, 29.9.2000, p. 1.

[2] OJ C 224, 5.8.2000, p. 16.

(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
Energielaan 3
PO Box 169
5400 AD Uden
Nederland

Glaxo SmithKline
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 Maldà 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.

Done at Brussels, 13 February 2001.

For the Commission

Margot WALLSTRÖM

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)

(in kg (CFC))

Company	2001 quota allocation
3M (UK)	
Aventis (UK)	
Bespak (UK)	
Boehringer (D)	
CCL Pharmaceuticals (UK)	
Chiesi (I)	
Glaxo SmithKline (UK)	
IG Sprühtechnik (D)	
Jaba Farmacêutica (P)	
Lab. Aldo-Unión (E)	
Norton (IRL)	
Orion (FIN)	
Schering-Plough (B)	
Valeas (I)	
Valois (F)	
VARI (I)	
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

(in kg)

Controlled substance	Quantitative limit
CFCs	160 000
Carbon tetrachloride	190 000
1,1,1 trichloroethane	18 000
Others (other CFCs, halons, HBFCs)	420

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**

(in kg)

Controlled substance	Quantity
CFC 113	100