II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 16 December 1997

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 1998 under Council Regulation (EC) No 3093/94 on substances that deplete the ozone layer

(Only the Dutch, English, Finnish, French, German, Italian and Spanish texts are authentic)

(Text with EEA relevance)

(98/67/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3093/94 of 15 December 1994 on substances that deplete the ozone layer [1], and in particular to Articles 3, 4 and 7 thereof,

Whereas, because of concerns for the ozone layer, the Community has already phased out the production and consumption of certain controlled substances;

Whereas essential uses have to be decided for chlorofluorocarbons (Articles 3.1 and 4.1); other fully halogenated chlorofluorocarbons (Articles 3.2 and 4.2); halons (Articles 3.3 and 4.3); carbon tetrachloride (Articles 3.4 and 4.4); 1,1,1 trichloroethane (Articles 3.5 and 4.5); and HBFCs (Articles 3.7 and 4.7);

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

1. 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;

2. 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;

Whereas Decision VII/9 of the Parties to the Montreal Protocol authorises the levels of production and consumption necessary to satisfy essential uses of controlled

[1] OJ L 333, 22. 12. 1994, p. 1.

substances for metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary disease (COPD);

Whereas Decisions VIII/10, VIII/11, VIII/12 and IX/19 set out further actions and measures to be taken by Parties to the Montreal Protocol to promote and facilitate a smooth and efficient transition away from CFC-based MDIs and request each Party to develop and submit to the Ozone Secretariat its agreed transition strategy, if possible by 1998;

Whereas Decision VIII/9 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;

Whereas the Commission has published a notice [1] to those companies in the European Community which use controlled substances that may be allowed for essential uses in the Community in 1998 pursuant to Council Regulation (EC) No 3093/94, and has thereby received applications for quantities of controlled substances for essential uses in 1998;

Whereas, 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 1998;

Whereas 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 16 of Council Regulation (EC) No 3093/94;

Whereas, 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; whereas the competent authority of the Member State concerned shall in turn notify the Commission well in advance of any such authorisation;

Whereas, pursuant to Decision VIII/9 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 1998;

Whereas the list of essential uses and the quantities of the controlled substances are hereby given in Annex II as information for producer and user industries;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 16 of Council Regulation (EC) No 3093/94,

HAS ADOPTED THIS DECISION:

Article 1

Companies which may take advantage of the essential uses for their own account for the manufacture of metered dose inhalers are listed in Annex I.

Article 2

The total quantities of controlled substances permitted for essential uses during 1998 shall be as specified in Annex II.

Article 3

Within the overall limits set out in Annex IIB, 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

1. This Decision is addressed to the companies listed in Annex I.

2. This Decision shall apply from 1 January 1998 to 31 December 1998.

Done at Brussels, 16 December 1997.

For the Commission

Ritt BJERREGAARD

Member of the Commission

[1] OJ C 285, 20. 9. 1997, p. 7.

ANEXO I — BILAG I — ANHANG I — ΠΑΡΑΡΤΗΜΑ I — ANNEX I — ANNEXE I — ALLEGATO I — BIJLAGE I — ANEXO I — LIITE I — BILAGA I

3M Health Care Ltd
Mrs L. Humphreys
3M House
Morley Street
Loughborough
Leicestershire LE11 1EP
United Kingdom

Laboratorio Aldo Unión SA
Dr. J. Sabater Sanmarti
Baronese de Imaldá 73
E-08950 Espluges de Llobregat

Laboratorio Astra España SA
Dr. E. Cabré Matas
Mestre Joan Corrales, 95-105
E-08950 Esplugues de Llobregat

Bespak plc
Mr T. Clutterbuck
North Lynn Industrial Estate
King's Lynn
Norfolk PE30 2JJ
United Kingdom

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

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

Chauvin Ankerpharm GmbH
Fr. Elzer-Vetter
Hansaallee 177 D
D-40549 Düsseldorf

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

Glaxo Wellcome
Mr Barry Rosenthal
Liverpool L24 9JD
United Kingdom

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

Leiras Oy
Mr Kai Buri,
Pansiontie 47
P.O. Box 415
FIN-20101 Turku

Laboratorios Lesvi SA
Sr. Alejandro Biel Andrés
Poligono Industrial Can Pelegrí
E-08740 Sant Andreu de la Barca

Laboratorios Miquel, SA
Sr. A. Costa Espelleta
Santanyí, 16
E-08016 Barcelona

Norton Waterford Ltd
Mr Jim Kennedy
Unit 301 Industrial Park
Waterford
Ireland

Nycomed Austria GmbH
Dr. Vorreither
St.-Peter-Straße 25
A-4020 Linz

Orion Corporation
Mr Pasi Salokangas
Orionintie 1
FIN-02200 Espoo

Rhône-Poulenc Rorer
Mr K. J. Bradley
London Road
Holmes Chapel
Cheshire CW4 8BE
United Kingdom

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

SICOR — Società italiana corticosteroidi SpA
Dott. Roberto Giani
Via Terrazzano, 77
I-20017 RHO (Milano)

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

Valois SA
M. Chris Hall
50, avenue de l'Europe
F-78160 Marly-le-Roi

Laboratorios Vita, SA
Sr. Alejandro Biel Andrés
Av. Barcelona, 69
E-08970 Sant Joan Despí

ANNEX II

A. **MEDICAL USES**

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

Company	1998 quota allocation in tonnes (CFCs)
3M (UK)	
Bespak (UK)	
Boehringer (D)	
CCL Pharm (UK)	
Chauvin Ankerpharm (D)	
Chiesi (I)	
Glaxo Wellcome (UK)	
IG Sprühtechnik (D)	
Lab. Aldo-Unión (E)	
Lab. Astra (E)	
Lab. Lesvi (E)	
Lab. Miquel (E)	
Lab. Vita (E)	
Leiras (FI)	
Norton (Irl)	
Nycomed (A)	
Orion (F)	
Rhône-Poulenc Rorer (UK)	
Schering-Plough (B)	
Sicor (I)	
Valeas (I)	
Valois (F)	
Total	5 462,5

B. **LABORATORY USES**

Total quantities of controlled substances which may be produced or imported and placed in the European Community during 1998 for laboratory and analytical uses.

Controlled substance	Quantitative limit (in tonnes)
CFCs	150
Carbon tetrachloride	100
1,1,1 trichloroethane	35
Other ODS	0,035

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 each controlled substance authorised during 1998 for laboratory and analytical purposes shall not exceed the quantities listed above.