COMMISSION DECISION

of 23 February 2005

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2004 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council

(notified under document number C(2005) 293)

(Only the Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Italian, Portuguese, Slovenian and Spanish texts are authentic)

(Text with EEA relevance)

(2005/171/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 of 29 June 2000 on substances that deplete the ozone layer [1], and in particular Article 3(1) thereof,

Whereas:

(1) The Community has already phased out the production and consumption of chlorofluorocarbons, other fully halogenated chlorofluorocarbons, halons, carbon tetrachloride,1,1,1-trichloroethane, hydrobromofluorocarbon and bromo-chloromethane.

(2) Each year the Commission has to determine essential uses for these controlled substances, the quantities that may be used and the companies that may use them.

(3) Decision IV/25 of the Parties to the Montreal Protocol on substances that deplete the ozone layer, hereinafter 'the Montreal Protocol', sets out the criteria used by the Commission for determining any essential uses and authorises the production and consumption necessary to satisfy essential uses of controlled substances in each Party.

(4) Decision XV/8 of the Parties to the Montreal Protocol authorises the production and consumption necessary to satisfy essential uses of controlled substances listed in Annexes A, B and C (Group II and III substances) of the Montreal Protocol 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, Decision VII/11 and Decision XI/15 of the Parties to the Montreal Protocol.

(5) Pursuant to paragraph 3 of Decision XII/2 of the 12th Meeting of the Parties to the Montreal Protocol on measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers (MDIs), Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Luxembourg, Norway, Portugal, the Netherlands, Sweden and the United Kingdom have notified the United Nations Environment Programme [2] that chlorofluorocarbons (CFCs) are no longer essential for the manufacture of specific short-acting beta agonist CFC-MDIs. Article 4(4)(i)(b) of Regulation (EC) No 2037/2000 prevents CFCs from being used and placed on the market unless they are considered essential under the conditions described in Article 3(1) of that Regulation. These non-essentiality determinations have reduced the demand for CFCs in the Community. In addition, Article 4(6) prevents CFC-MDI products being imported and placed on the market unless the CFCs in these products are considered essential under the conditions described in Article 3(1).

(6) The Commission published a notice [3] on 11 July 2003 to those companies in the Community (15) that request consideration by the Commission for the use of controlled substances for essential uses in the Community in 2004 and a further notification to companies in the 10 new Member States on 11 May 2004 [4], and has received declarations on intended essential uses of controlled substances in 2004.

(7) Commission Decision 2004/209/EC of 28 January 2004 on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2004 pursuant to Regulation (EC) No 2037/2000 of the European Parliament and of the Council [5] should be amended in order to take account of the inclusion of specific quantities of ozone depleting substances required for essential uses in the 10 new Member States from 1 May 2004.

(8) In the interests of legal clarity and transparency Decision 2004/209/EC should therefore be replaced.

(9) The measures provided for in this Decision are in accordance with the opinion of the Management Committee established by Article 18(1) of Regulation (EC) No 2037/2000,

[1] OJ L 244, 29.9.2000, p. 1. Regulation as last amended by Commission Regulation (EC) No 2077/2004 (OJ L 359, 4.12.2004, p. 28).

[2] www.unep.org/ozone/dec12-2-3.shtml

[3] OJ C 162, 11.7.2003, p. 19.

[4] OJ C 133, 11.5.2004, p. 12.

[5] OJ L 66, 4.3.2004, p. 36.

HAS ADOPTED THIS DECISION:

Article 1

1. The quantity of controlled substances of Group I (chlorofluorocarbons 11, 12, 113, 114 and 115) subject to Regulation (EC) No 2037/2000 which may be used for essential medical uses in the Community in 2004 shall be 1 428 533,000 ODP (ozone depletion potential) kilograms.

2. The quantity of controlled substances of Group I (chlorofluorocarbons 11, 12, 113, 114 and 115) and Group II (other fully halogenated chlorofluorocarbons) subject to Regulation (EC) No 2037/2000 which may be used for essential laboratory uses in the Community in 2004 shall be 73 336,765 ODP kilograms.

3. The quantity of controlled substances of Group III (halons) subject to Regulation (EC) No 2037/2000 that may be used for essential laboratory use in the Community in 2004 shall be 19 268,700 ODP kilograms.

4. The quantity of controlled substances of Group IV (carbon tetrachloride) subject to Regulation (EC) No 2037/2000 that may be used for essential laboratory uses in the Community in 2004 shall be 141 834,000 ODP kilograms.

5. The quantity of controlled substances of Group V (1,1,1-trichloroethane) subject to Regulation (EC) No 2037/2000 that may be used for essential laboratory uses in the European Union in 2004 shall be 529,300 ODP kilograms.

6. The quantity of controlled substances of Group VII (hydrobromofluorocarbons) subject to Regulation (EC) No 2037/2000 that may be used for essential laboratory uses in the Community in 2004 shall be 3,070 ODP kilograms.

7. The quantity of controlled substances of group IX (bromochloromethane) subject to Regulation (EC) No 2037/2000 that may be used for essential laboratory uses in the Community in 2004 shall be 13,248 ODP kilograms.

Article 2

The chlorofluorocarbon metered-dose inhalers (CFC-MDIs) listed in Annex I shall not be placed on markets that have determined CFCs for these products to be non-essential.

Article 3

During the period 1 January to 31 December 2004 the following rules shall apply:

1. The allocation of essential medical use quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 shall be to the companies indicated in Annex II.

2. The allocation of essential laboratory use quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons shall be to the companies indicated in Annex III.

3. The allocation of essential laboratory use quotas for halons shall be to the companies indicated in Annex IV.

4. The allocation of essential laboratory use quotas for carbon tetrachloride shall be to the companies indicated in Annex V.

5. The allocation of essential laboratory use quotas for 1,1,1-trichloroethane shall be to the companies indicated in Annex VI.

6. The allocation of essential laboratory use quotas for hydrobromofluorocarbons shall be to the companies indicated in Annex VII.

7. The allocation of essential laboratory use quotas for bromochloromethane shall be to the companies indicated in Annex VIII.

8. The essential use quotas for chlorofluorocarbons 11, 12, 113, 114 and 115, other fully halogenated chlorofluorocarbons, carbon tetrachloride, 1,1,1-trichloroethane, hydrobromofluorocarbons and bromochloromethane shall be as set out in Annex IX.

Article 4

Decision 2004/209/EC is repealed.

References to the repealed Decision shall be construed as references to this Decision.

Article 5

This Decision is addressed to the following undertakings:

3M Health Care Ltd
3M House Morley Street
Loughborough
Leicestershire LE11 1EP
United Kingdom

Aventis
London Road, Holmes Chapel
Cheshire CW4 8BE
United Kingdom

Bespak PLC
North Lynn Industrial Estate
King's Lynn
Norfolk PE30 2JJ
United Kingdom

Boehringer Ingelheim GmbH
Binger Strasse 173
D-55216 Ingelheim am Rhein

Chiesi Farmaceutici SpA
Via Palermo 26/A
I-43100 Parma

GlaxoSmithKline
Speke Boulevard
Speke
Liverpool L24 9JD
United Kingdom

IG Sprühtechnik GmbH
Im Hemmet 1
D-79664 Wehr

Inyx Pharmaceuticals Ltd
Astmoor Industrial Estate
9 Arkwright Road Runcorn
Cheshire WA7 1NU
United Kingdom

IVAX Ltd
Unit 301 Industrial Park
Waterford
Ireland

Jaba Farmaceutica SA
Rua da Tapada Grande, 2
P-2710-089, Abrunheira Sintra

Laboratorio Aldo Union SA
Baronesa de Maldá 73
Espluges de Llobregat
E-08950 Barcelona

Otsuka Pharmaceuticals (E)
Provenca, 388
E-08025 Barcelona

SICOR SpA
Via Terrazzano 77
I-20017 RHO Milano

Schering-Plough Labo NV
Industriepark 30
B-2220 Heist Op Den Berg

Valvole Aerosol Research Italiana
(VARI) Spa — LINDAL Group Italia
Via del Pino, 10
Olginate (LC)
I-23854 Italia

Valeas SpA Pharmaceuticals
Via Vallisneri, 10
I-20133 Milano

Valois SA
50 avenue de l'Europe
F-78160 Marly-Le-Roi

Acros Organics bvba
Janssen Pharmaceuticalaan 3a
B-2440 Geel

Airbus France
316, route de Bayonne
F-31300 Toulouse

Agfa-Gevaert NV
Septestraat 27
B-2640 Mortsel

Bie & Berntsen
Sandbækvej 7
DK-2610 Rødovre

Biosolove BV
Waalreseweg 17
5554 HA Valkenswaard
The Netherlands

Butterworth Laboratories Ltd
54 Waldegrave Road, Teddington
Middlesex TW11 8NY
United Kingdom

Carl Roth GmbH
Schoemperlenstr. 1—5
D-76185 Karlsruhe

Elcom Group
Okružní 988
CZ-735 14 Orlová — Lutyně

Environnement SA
111, Bld Robespierre
BP 4513
F-78304 Poissy

Fisher Scientific
Bishop Meadow Road
Loughborough LE11 5RG
United Kingdom

Health Protection Inspectorate-Laboratories
Paldiski mnt 81
EE-10617 Tallinn

Honeywell Specialty Chemicals
Wunstorfer Straße 40
Postfach 100262
D-30918 Seelze

Institut scientifique de service public (ISSeP)
Rue du Chéra 200
B-4000 Liège

Institut E. Malvoz (B)
Quai du Barbou, 4
B-4000 Liège

Ineos Fluor Ltd
PO Box 13, The Heath
Runcorn Cheshire WA7 4QF
United Kingdom

Katholieke Universiteit Leuven
Krakenstraat 3
B-3000 Leuven

Laboratoires sérobiologiques
3, rue de Seichamps
F-54425 Pulnoy

LGC Promochem GmbH
Mercatorstr. 51
D-46485 Wesel

Mallinckrodt Baker BV
Teugseweg 20
7418 AM Deventer
The Netherlands

Merck KgaA
Frankfurter Strasse 250
D-64271 Darmstadt

Mikro+Polo d.o.o.
Lackova 78
SLO-2000 Maribor

Panreac Química SA
Riera de Sant Cugat 1
E-08110 Montcada I Reixac (Barcelona)

Rohs Chemie GmbH
Berliner Str. 54
D-53819 Neunkirchen-Seelsheid

Sanolabor d.d.
Leskoškova 4
SLO-Ljubljana

SDS Solvants, Documentation, Synthèses SA
Z.I. de Valdonne, BP 4
F-13124 Peypin

Sigma Aldrich Chemie GmbH
Riedstrasse 2
D-89555 Steinheim

Sigma Aldrich Chimie SARL
80 rue de Luzais
L'Isle-d'Abeau Chesnes
F-38297 St-Quentin-Fallavier

Sigma Aldrich Company Ltd
The Old Brickyard
New Road Gillingham SP8 4XT
United Kingdom

Sigma Aldrich Laborchemikalien
Wunstorfer Straße 40, Postfach 100262
D-30918 Seelze

VWR I.S.A.S.
201, rue Carnot
F-94126 Fontenay-sous-bois

University Of Technology Vienna
Institut of Industrial Electronics and Material Science
Gusshausstrasse 27-29
A-1040 Wien

YA-Kemia Oy — Sigma-Aldrich Finland
Teerisuonkuja 4
FI-00700 Helsinki

Done at Brussels, 23 February 2005.

For the Commission

Stavros DIMAS

Member of the Commission

ANNEX I

Pursuant to paragraph 3 of Decision XII/2 of the 12th Meeting of the Parties to the Montreal Protocol on measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers (MDIs), the following Parties have determined that, due to the presence of suitable non-CFC MDIs, CFCs no longer qualify as 'essential' under the Protocol when combined with following products:

Country \ Product	Salbutamol	Terbutaline	Fenoterol	Orciprenaline	Reproterol	Carbuterol	Hexoprenaline	Pirbuterol	Clenbuterol	Bitolterol	Procaterol	Beclomethasone	Dexamethasone	Fluinisolide	Fluiticasone	Budesonide	Triamcinolone	Ipratropium bromide	Oxitropium Bromide
Austria	X	X	X	X	X	X	X	X	X	X	X								
Belgium	X	X	X	X	X	X	X	X	X	X	X								
Czech Republic	X	X	X	X	X	X	X	X	X	X	X								
Denmark	X	X	X	X	X	X	X	X	X	X	X								
Finland	X																		
France	X																		
Germany	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Greece	X	X	X	X	X	X	X	X	X	X	X								
Ireland	X																		
Luxembourg	X																		
Portugal	X	X	X	X	X	X	X	X	X	X	X								
The Netherlands	X	X	X	X	X	X	X	X	X	X	X								
Norway	X	X	X	X	X	X	X	X	X	X	X								
Sweden	X																		
UK	X																		

Source: www.unep.org/ozone/dec12-2-3.pdf

ANNEX II

ESSENTIAL MEDICAL USES

Quota of controlled substances of Group I that may be used in the production of metered-dose inhalers (MDIs) for the treatment of asthma and other chronic obstructive pulmonary diseases (COPDs) are allocated to:

3M (UK)
Aventis (UK)
Bespak (UK)
Boehringer Ingelheim (DE)
Chiesi (IT)
Glaxo Smith Kline (UK)
IG Sprühtechnik (DE)
Inyx Pharmaceuticals (UK)
IVAX (IE)
Jaba Farmaceutica (PT)
Lab. Aldo-Union (ES)
Otsuka Pharmaceuticals (ES)
Sicor (IT)
Schering-Plough (BE)
V.A.R.I. (IT)
Valeas (IT)
Valois (FR)

ANNEX III

ESSENTIAL LABORATORY USES

Quota of controlled substances of Group I and II that may be used for laboratory and analytical uses, are allocated to:

Agfa-Gevaert (BE)
Bie & Berntsen (DK)
Butterworth Laboratories (UK)
Biosolve (NL)
Carl Roth (DE)
Elcom Group (CZ)
Environnement SA (FR)
Honeywell Specialty Chemicals (DE)
Ineos Fluor (UK)
Katholieke Universiteit Leuven (BE)
LGC Promochem (DE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Química (ES)
SDS Solvants (FR)
Sanolabor (SI)
Sigma Aldrich Chemie (DE)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
University Of Technology Vienna (AT)
Ya Kemia Oy — Sigma Aldrich (FI)

ANNEX IV

ESSENTIAL LABORATORY USES

Quota of controlled substances of Group III that may be used for laboratory and analytical uses are allocated to:

Airbus France (FR)
Butterworth Laboratories (UK)
Ineos Fluor (UK)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)

ANNEX V

ESSENTIAL LABORATORY USES

Quota of controlled substances of Group IV that may be used for laboratory and analytical uses, are allocated to:

Acros Organics (BE)
Agfa-Gevaert (BE)
Bie & Berntsen (DK)
Biosolve (NL)
Butterworth Laboratories (UK)
Fisher Scientific (UK)
Health Protection Inspectorate-Laboratories (EE)
Institut E. Malvoz (BE)
Institut Scientifique de Service Public (ISSeP) (BE)
Katholieke Universiteit Leuven (BE)
Laboratoires Sérologiques (FR)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Química (ES)
Rohs Chemie (DE)
SDS Solvants (FR)
Sanolabor d.d. (SI)
Sigma Aldrich Chemie (DE)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Laborchemikalien (DE)
VWR I.S.A.S. (FR)
YA-Kemia Oy (FI)

ANNEX VI

ESSENTIAL LABORATORY USES

Quota of controlled substances of Group V that may be used for laboratory and analytical uses are allocated to:

Acros Organics (BE)
Agfa-Gevaert (BE)
Bie & Berntsen (DK)
Katholieke Universiteit Leuven (BE)
Mallinckrodt Baker (NL)
Mikro + Polo (SI)
Panreac Química (ES)
Sanolabor d.d. (SI)
Sigma Aldrich Chemie (DE)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)

ANNEX VII

ESSENTIAL LABORATORY USES

Quota of controlled substances of Group VII that may be used for laboratory and analytical uses are allocated to:

Acros Organics (BE)
Ineos Fluor (UK)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)

ANNEX VIII

ESSENTIAL LABORATORY USES

Quota of controlled substances of Group IX that may be used for laboratory and analytical uses are allocated to:

Ineos Fluor (UK)
Sigma Aldrich Chemie (DE)
Sigma Aldrich Chimie (FR)

ANNEX IX

(This Annex is not published because it contains confidential commercial information.)