II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 23 August 2005

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2005 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council

(notified under document number C(2005) 333)

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

(Text with EEA relevance)

(2005/626/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 is required 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 Twelfth Meeting of the Parties to the Montreal Protocol on measures to facilitate the transition to chlorofluorocarbon-free Metered-Dose Inhalers (MDIs), Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Poland, Norway, Portugal, The Netherlands, Slovak Republic, Slovenia, Spain, Sweden and the United Kingdom have notified the United Nations Environment Programme [2] that chlorofluorocarbons (CFCs) are no longer essential for the manufacture of CFC-MDIs that contain active ingredients belonging to the therapeutic categories of 'short-acting beta agonist bronchiodilators', 'inhaled steroids' and 'anticholinergic bronchiodilators'. 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) of Regulation

[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

(EC) No 2037/2000 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 has published a Notice [1] on the 22 July 2004 to those companies in the Community of 25 Member States that request consideration by the Commission for the use of controlled substances for essential uses in the Community in 2005 and has received declarations on intended essential uses of controlled substances in 2005.

(7) For the purpose of ensuring that interested companies and operators may continue to benefit in due time from the licensing system, it is appropriate that the present decision shall apply from 1 January 2005.

(8) 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,

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 2005 shall be 1 029 770,00 ODP [2] 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 2005 shall be 63 081,71 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 2005 shall be 70,705 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 2005 shall be 145 240,293 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 2005 shall be 815,30 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 2005 shall be 3,04 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 2005 shall be 12,048 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 2005 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.

[1] OJ C 187, 22.7.2004, p. 24.
[2] Ozone-depleting Potential.

Article 4

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 PE30 2JJ — Norfolk 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 L24 9JD — Liverpool 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
GlaxoSmithKline Pharmaceuticals SA Siedziba w Poznaniu ul. Grunwaldzka 189 60-322 Poznań Poland	IVAX Ltd Unit 301 Industrial Park Waterford Ireland
Laboratorio Aldo Union SA Baronesa de Maldá, 73 Espluges de Llobregat E-08950 Barcelona	SICOR S.p.A Via Terrazzano 77 I-20017 Rho (MI)
Valeas SpA Pharmaceuticals Via Vallisneri, 10 I-20133 Milano	Valois SA 50, avenue de l'Europe F-78160 Marly Le Roi
Valvole Aerosol Research Italiana (VARI) Spa — LINDAL Group Italia Via del Pino, 10 Olginate (LC) I-23854	Acros Organics bvba Janssen Pharmaceuticalaan 3a B-2440 Geel
Agfa-Gevaert NV Septestraat 27 B-2640 Mortsel	Bie & Berntsen Sandbækvej 7 DK-2610 Rødovre
Biosolove BV Waalreseweg 17 5554 HA Valkenswaard Nederland	Carl Roth GmbH Schoemperlenstraße 3—5 D-76185 Karlsruhe
Elcom Group Okružní 988 CZ-735 14 Orlová-Lutyně	Health Protection Inspectorate-Laboratories Paldiski mnt 81 EE-10617 Tallinn
Honeywell Specialty Chemicals Wunstorfer Straße 40 Postfach 100262 D-30918 Seelze	Ineos Fluor Ltd PO Box 13, The Heath Runcorn Cheshire WA7 4QF United Kingdom
Institut scientifique de service public (ISSeP) Rue du Chéra, 200 B-4000 Liège	Katholieke Universiteit Leuven Krakenstraat 3 B-3000 Leuven

LGC Promochem GmbH Mercatorstraße 51 D-46485 Wesel	Mallinckrodt Baker BV Teugseweg 20 7418 AM Deventer Nederland
Merck KGaA Frankfurter Straße 250 D-64293 Darmstadt	Mikro+Polo d.o.o. Zagrebška cesta 22 SI-2000 Maribor
Ministry of Defense Directorate Material RNLNavy PO Box 2070 2500 ES The Hague Nederland	Panreac Quimica SA Riera de Sant Cugat, 1 E-08110 Montcada I Reixac (Barcelona)
Rohs Chemie GmbH Berliner Str. 54 D-53819 Neunkirchen-Seelscheid	Sanolabor d.d. Leskovškova 4 SI-1000 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 Chesne F-38297 Saint-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
YA-Kemia Oy — Sigma-Aldrich Finland Teerisuonkuja 4 FI-00700 Helsinki	

Article 5

This Decision shall apply from 1 January 2005 and shall expire on 31 December 2005.

Done at Brussels, 23 August 2005.

For the Commission
Stavros DIMAS
Member of the Commission

ANNEX I

Pursuant to paragraph 3 of Decision XII/2 of the Twelfth Meeting of the Parties to the Montreal Protocol on measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers (MDIs), the following countries 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 active ingredients:

Country	Salbutamol	Terbutaline	Fenoterol	Orciprenaline	Reproterol	Carbuterol	Hexoprenaline	Pirbuterol	Clenbuterol	Bitolterol	Procaterol	Beclamethasone	Dexamethasone	Flunisolide	Fluticasone	Budesonide	Triamcinolone	Ipratropium bromide	Oxitropium bromide
Austria	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Belgium	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Cyprus	✓																		
Czech Republic	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Denmark	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓								
Estonia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Finland	✓																		
France	✓																		
Germany	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Greece	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Hungary	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Ireland	✓																		
Latvia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Lithuania	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Luxembourg	✓																		
Poland	✓																		
Portugal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
The Netherlands	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Norway	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Slovak Republic	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Slovenia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Spain	✓																		
Sweden	✓																		
UK	✓																		

Source: www.unep.org/ozone/Information_for_the_Parties/3Bi_dec12-2-3.asp

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 Health Care (UK)
Aventis (UK)
Bespak (UK)
Boehringer Ingelheim (DE)
Chiesi (IT)
Glaxo Smith Kline (ES, FR, PL, UK)
IG Sprühtechnik (DE)
Inyx Pharmaceuticals (UK)
IVAX (IE)
Laboratorio Aldo-Unión (ES)
Sicor (IT)
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)
Biosolve (NL)
Carl Roth (DE)
Elcom Group (CZ)
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)

ANNEX IV

ESSENTIAL LABORATORY USES

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

Ineos Fluor (UK)
Ministry of Defense (NL)
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)
Health Protection Inspectorate-Laboratories (EE)
Institut Scientifique de Service Public (ISSeP) (BE)
Katholieke Universiteit Leuven (BE)
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)
Bie & Berntsen (DK)
Katholieke Universiteit Leuven (BE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Química (ES)
Sanolabor d.d. (SI)
Sigma Aldrich Chemie (DE)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
VWR I.S.A.S. (FR)
YA-Kemia Oy (FI)

ANNEX VII

ESSENTIAL LABORATORY USES

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

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)

ANNEX IX

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