II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 11 April 2006

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2006 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council

(notified under document number C(2006) 1483)

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

(Text with EEA relevance)

(2006/540/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 bromochloromethane.

(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, as well as Decisions VII/11, XI/15 and XV/5 of the Parties to the Montreal Protocol.Decision XVII/10 of the Parties to the Montreal Protocol authorises the production and consumption of the controlled substance listed in Annex E of the Montreal Protocol necessary to satisfy laboratory and analytical uses of methyl bromide.

(5) Pursuant to paragraph 3 of Decision XII/2 of the Parties to the Montreal Protocol on measures to facilitate the transition to chlorofluorocarbon-free Metered-Dose Inhalers (MDIs), all Member States have notified [2] the United Nations Environment Programme that chlorofluorocarbons (CFCs) are no longer essential for the manufacture of salbutamol CFC-MDIs for placing on the market of the European Community.

[1] OJ L 244, 29.9.2000, p. 1. Regulation as last amended by Commission Regulation (EC) No 29/2006 (OJ L 6, 11.1.2006, p. 27).

[2] www.unep.org/ozone/Information_for_the_Parties/3Bi_dec12-2-3.asp

Austria, Belgium, Czech Republic, Denmark, Estonia, Germany, Greece, Hungary, Latvia, Lithuania, Norway, Portugal, The Netherlands, the Slovak Republic and Slovenia have notified UNEP that the use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contain the active ingredients belonging to the therapeutic category of 'short-acting beta agonist bronchiodilators', specifically terbutaline [1], fenoterol, orciprenaline, reproterol, carbuterol, hexoprenaline, pirbuterol, clenbuterol, bitolterol and procaterol.

Belgium, the Czech Republic, Estonia, Germany, Hungary, Latvia, the Netherlands, the Slovak Republic, Slovenia and Sweden have notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contain the active ingredients belonging to the therapeutic category of 'inhaled steroids', specifically beclomethasone, dexamethasone, flunisolide, fluticasone, budesonide [2] and triamcinolone.

Denmark (beclomethasone, fluticasone), Ireland (beclomethasone, fluticasone), Finland (beclomethasone, fluticasone), France (beclomethasone, fluticasone), Italy (beclomethasone, fluticasone, budesonide), Malta (fluticasone, budesonide), Portugal (fluticasone, budesonide), Slovenia (beclomethasone, fluticasone, budesonide), Spain (beclomethasone, fluticasone) and the United Kingdom (fluticasone) have notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contain the active ingredients belonging to the therapeutic category of 'inhaled steroids' shown in parentheses after each Member State.

Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Latvia, the Netherlands, the Slovak Republic and Slovenia have notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contain the active ingredients belonging to the therapeutic category of 'non-steroidal anti-inflammatories', specifically cromoglicic acid and nedrocromil.

Portugal has notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contains the active ingredient cromoglicic acid. Spain has notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contains the active ingredient nedrocromil.

Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Latvia, Malta, the Netherlands, the Slovak Republic, Spain, Sweden and the United Kingdom have notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contain the active ingredients belonging to the therapeutic category of 'anticholinergic bronchodilators', specifically ipatropium bromide and oxitropium bromide.

Portugal has notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contains the active ingredient ipatropium bromide.

Germany has notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contain the active ingredients belonging to the therapeutic category of 'long-acting beta agonist bronchiodilators', specifically formoterol and salmeterol.

Italy has notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contains the active ingredient formoterol.

Germany and the Netherlands have notified UNEP that use of CFCs is not considered essential for the manufacture of MDIs for placing on the market of the European Community that contain combinations of active ingredients.

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 therefore reduced the demand for CFCs used in MDIs that are placed on the market of the European Community. In addition, Article 4(6) of Regulation (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 [3] on 8 July 2005 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 2006 and has received declarations on intended essential uses of controlled substances for 2006.

[1] Except Denmark.
[2] Except Sweden.
[3] OJ C 168, 8.7.2005, p. 20.

(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 2006.

(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 2006 shall be 539 000,00 ODP ([1]) 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 2006 shall be 256 761,86 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 2006 shall be 482,70 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 2006 shall be 149 641,536 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 2006 shall be 754,00 ODP kilograms.

6. The quantity of controlled substances of Group VI (methyl bromide) subject to Regulation (EC) No 2037/2000 that may be used for laboratory and analytical uses in the Community in 2006 shall be 300,00 ODP kilograms.

([1]) Ozone-depleting Potential.

7. 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 2006 shall be 4,49 ODP kilograms.

8. 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 2006 shall be 13,308 ODP kilograms.

Article 2

The chlorofluorocarbon metered-dose inhalers listed in Annex I shall not be placed on markets where the Competent Authority has determined chlorofluorocarbonsfor metered-dose inhalers on those markets to be non-essential.

Article 3

During the period 1 January to 31 December 2006 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 laboratory and analytical critical use quotas for methyl bromide shall be to the companies indicated in Annex VII.

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

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

9. 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 X.

Article 4

This Decision shall apply from 1 January 2006 and shall expire on 31 December 2006.

Article 5

This Decision is addressed to the following undertakings:

3M Health Care Ltd 3M House Morley Street Loughborough Leicestershire LE11 1EP 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 on behalf of Boehringer Ingelheim (France)	Chiesi Farmaceutici SpA Via Palermo, 26/A I-43100 Parma
IVAX Ltd Unit 301 Industrial Park Waterford Ireland	Laboratorio Aldo Union SA Baronesa de Maldá, 73 Espluges de Llobregat E-08950 Barcelona
SICOR SpA Via Terrazzano, 77 I-20017 Rho (MI)	Valeas SpA Pharmaceuticals Via Vallisneri, 10 I-20133 Milano
Valvole Aerosol Research Italiana (VARI) Spa — LINDAL Group Italia Via del Pino, 10 I-23854 Olginate (LC)	
Acros Organics bvba Janssen Pharmaceuticalaan 3º B-2440 Geel	Airbus France route de Bayonne 316 F-31300 Toulouse
Biosolove B.V. Waalreseweg 17 5554 HA Valkenswaard Nederland	Bie & Berntsen Sandbækvej 7 DK-2610 Roedovre
Carlo Erba Reactifs-SDS Z.I. de Valdonne, BP 4 F-13124 Peypin	CNRS — Groupe de Physique des Solides Université Paris, 7 Denis Diderot & Paris 6 Pierre et Marie Curie F-75251 Paris Cedex 5
Health Protection Inspectorate-Laboratories Paldiski mnt 81 EE-10617 Tallinn	Honeywell Fluorine Products Europe Kempenweg 90 P.O. Box 264 6000 AG Weert Nederland
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-64271 Darmstadt	Mikro+Polo d.o.o. Lackova 78 SLO-2000 Maribor
Ministry of Defense Directorate Material RNL Navy PO Box 2070 2500 ES The Hague Nederland	Panreac Química SA Riera de Sant Cugat 1 E-08110 Montcada I Reixac (Barcelona)
Sanolabor d.d. Leskovškova 4 SLO-1000 Ljubljana	Sigma Aldrich Logistik GmbH Riedstraße 2 D-89555 Steinheim
Sigma Aldrich Chimie SARL 80, rue de Luzais L'isle-d'abeau Chesnes 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	Sigma Aldrich Chemie GmbH Riedstraße 2 D-89555 Steinheim
Tazzetti Fluids S.r.l. Corso Europa, 600/a I-10088 Volpiano (TO)	University of Technology Vienna Institut of Industrial Electronics&Material Science Gusshausstraße 27-29 A-1040 Wien
VWR I.S.A.S. 201, rue Carnot F-94126 Fontenay-sous-Bois	YA-Kemia Oy — Sigma Aldrich Finland Teerisuonkuja 4 FI-00700 Helsinki

Done at Brussels, 11 April 2006.

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:

Table 1

Country	Short-acting Beta Agonist Bronchodilators										
	Salbutamol	Terbutaline	Fenoterol	Orciprenaline	Reproterol	Carbuterol	Hexoprenaline	Pirbuterol	Clenbuterol	Bitolterol	Procaterol
Austria	X	X	X	X	X	X	X	X	X	X	X
Belgium	X	X	X	X	X	X	X	X	X	X	X
Cyprus	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
Estonia	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
Greece	X	X	X	X	X	X	X	X	X	X	X
Hungary	X	X	X	X	X	X	X	X	X	X	X
Ireland	X										
Italy	X										
Latvia	X	X	X	X	X	X	X	X	X	X	X
Lithuania	X	X	X	X	X	X	X	X	X	X	X
Luxembourg	X										
Malta	X										
Netherlands	X	X	X	X	X	X	X	X	X	X	X
Poland	X										
Portugal	X	X	X	X	X	X	X	X	X	X	X
Norway	X	X	X	X	X	X	X	X	X	X	X
Slovak Republic	X	X	X	X	X	X	X	X	X	X	X
Slovenia	X	X	X	X	X	X	X	X	X	X	X
Spain	X										
Sweden	X										
United Kingdom	X										

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

Table 2

Country	Inhaled steroids					
	Beclomethasone	Dexamethasone	Flunisolide	Fluticasone	Budesonide	Triamcinolone
Austria						
Belgium	X	X	X	X	X	X
Cyprus						
Czech Republic	X	X	X	X	X	X
Denmark	X			X		
Estonia	X	X	X	X	X	X
Finland	X			X		
France	X			X		
Germany	X	X	X	X	X	X
Greece						
Hungary	X	X	X	X	X	X
Ireland	X			X		
Italy	X			X	X	
Latvia	X	X	X	X	X	X
Lithuania						
Luxembourg						
Malta				X	X	
Poland						
Portugal				X	X	
Netherlands	X	X	X	X	X	X
Norway						
Slovak Republic	X	X	X	X	X	X
Slovenia	X	X	X	X	X	X
Spain	X			X		
Sweden	X	X	X	X		X
United Kingdom				X		

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

Table 3

Country	Non-steroidal anti-inflammatories					
	Cromoglicic acid	Nedrocromil				
Austria						
Belgium	X	X				
Cyprus						
Czech Republic	X	X				
Denmark	X	X				
Estonia	X	X				
Finland	X	X				
France	X	X				
Germany	X	X				
Greece	X	X				
Hungary						
Ireland						
Italy						
Latvia	X	X				
Lithuania						
Luxembourg						
Malta						
Poland						
Portugal	X					
Netherlands	X	X				
Norway						
Slovak Republic	X	X				
Slovenia	X	X				
Spain		X				
Sweden						
United Kingdom						

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

Table 4

Country	Anticholinergic Bronchodilators					
	Ipratropium bromide	Oxitropium Bromide				
Austria						
Belgium	X	X				
Cyprus	X	X				
Czech Republic	X	X				
Denmark	X	X				
Estonia	X	X				
Finland	X	X				
France						
Germany	X	X				
Greece	X	X				
Hungary	X	X				
Ireland	X	X				
Italy						
Latvia						
Lithuania						
Luxembourg						
Malta	X	X				
Netherlands	X	X				
Poland						
Portugal	X					
Norway						
Slovak Republic	X	X				
Slovenia						
Spain	X	X				
Sweden	X	X				
United Kingdom	X	X				

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

Table 5

Country	Long-acting Beta Agonist Bronchodilators					
	Formoterol	Salmeterol				
Austria						
Belgium						
Cyprus						
Czech Republic						
Denmark						
Estonia						
Finland						
France						
Germany	X	X				
Greece						
Hungary						
Ireland						
Italy	X					
Latvia						
Lithuania						
Luxembourg						
Malta						
Netherlands						
Poland						
Portugal						
Norway						
Slovak Republic						
Slovenia						
Spain						
Sweden						
United Kingdom						

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

Table 6

Country	Combinations of active ingredients in a single MDI					
Austria						
Belgium						
Cyprus						
Czech Republic						
Denmark						
Estonia						
Finland						
France						
Germany	X					
Greece						
Hungary						
Ireland						
Italy						
Latvia						
Lithuania						
Luxembourg						
Malta						
Netherlands						
Poland						
Portugal						
Norway						
Slovak Republic						
Slovenia						
Spain						
Sweden						
United Kingdom						

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)
Bespak (UK)
Boehringer Ingelheim (DE) on behalf of Boehringer Ingelheim France
Chiesi (IT)
IVAX (IE)
Lab Aldo-Union (ES)
Sicor (IT)
Valeas (IT)
V.A.R.I. (IT)

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:

Acros organics bvba (BE)
Bie & Berntsen (DK)
Biosolve (NL)
Carlo Erba Reactifs-SDS (FR)
CNRS — Groupe de Physique des Solides (FR)
Honeywell Fluorine Products Europe (NL)
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)
Sanolabor (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Logistik (DE)
Tazzetti Fluids (IT)
University of Technology Vienna (AT)

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)
Ineos Fluor (UK)
Ministry of Defense (NL)
Sigma Aldrich Chimie (FR)

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)
Bie & Berntsen (DK)
Biosolve (NL)
Carlo Erba Reactifs-SDS (FR)
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)
Sanolabor d.d. (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Laborchemikalien (DE)
Sigma Aldrich Logistik (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 Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Logistik (DE)
YA-Kemia Oy (FI)

ANNEX VII

LABORATORY AND ANALYTICAL CRITICAL USES

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

Sigma-Aldrich Chemie GmbH (DE)

ANNEX VIII

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)
Katholieke Universiteit Leuven (BE)
Sigma Aldrich Logistik (FR)
Sigma Aldrich Company (UK)

ANNEX IX

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)
Katholieke Universiteit Leuven (BE)
Sigma Aldrich Logistik (FR)
YA-Kemia Oy (FI)

ANNEX X

[This Annex is not published because it contains confidential commercial information.]