

COMMISSION

COMMISSION DECISION

of 27 March 2007

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2007 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council

(notified under document number C(2007) 1285)

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

(Text with EEA relevance)

(2007/211/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⁾ to the United Nations Environment Programme the active ingredients for which chlorofluorocarbons (CFCs) are no longer essential for the manufacture of CFC-MDIs for placing on the market of the European Community.

(6) 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

⁽¹⁾ OJ L 244, 29.9.2000, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

⁽²⁾ www.unep.org/ozone/Information_for_the_Parties/3Bi_dec12-2-3.asp

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).

- (7) The Commission has published a Notice ⁽¹⁾ on the 22 July 2006 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 2007 and has received declarations on intended essential uses of controlled substances for 2007.
- (8) 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 2007.
- (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,

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 2007 shall be 316 257,00 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 2007 shall be 65 900,9 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 2007 shall be 718,7 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 2007 shall be 147 110 436 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 2007 shall be 672,0 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 2007 shall be 150,0 ODP kilograms.
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 2007 shall be 3,52 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 2007 shall be 12 048 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 chlorofluorocarbons for metered-dose inhalers on those markets to be non-essential.

Article 3

During the period 1 January to 31 December 2007 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.

⁽¹⁾ OJ C 171, 22.7.2006, p. 27.

⁽²⁾ Ozone-depleting potential.

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 hydro-bromofluorocarbons 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, hydro-bromofluorocarbons and bromochloromethane shall be as set out in Annex X.

Article 4

This Decision shall apply from 1 January 2007 and shall expire on 31 December 2007.

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 Europe Ltd North Lynn Industrial Estate Bergen Way, 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 (PR)
Inyx Pharmaceuticals Ltd Astmoor Industrial Estate 9 Arkwright Road Runcorn Cheshire WA7 1NU United Kingdom	IVAX Ltd Unit 301, Waterford Industrial Estate Waterford, Ireland
Laboratorio Aldo Union S.A. Baronesa de Maldá 73 Esplugues de Llobregat E-08950 Barcelona	SICOR SpA Via Terrazzano 77 I-20017 Rho (MI)
Valeas SpA Pharmaceuticals Via Vallisneri, 10 I-20133 Milano (MI)	Valvole Aerosol Research Italiana (VARI) SpA — LINDAL Group Italia Via del Pino, 10 I-23854 Olginate (LC)
Acros Organics bvba Janssen Pharmaceuticalaan 3a B-2440 Geel	Airbus France 316, route de Bayonne F-31300 Toulouse
Bie & Berntsen A-S Transformervej 8 DK-2730 Herlev	Carlo Erba Reactifs-SDS Z.I. de Valdonne, BP 4 F-13124 Peypin
Eras Labo 222, RN 90 F-38330 Saint-Nazaire-les-Eymes	Harp International Gellihirion Industrial Estate, Rhondda, Cynon Taff, UK-Pontypridd CF37 5SX
Health Protection Inspectorate-Laboratories Paldiski mnt 81 EE-10617 Tallinn	Honeywell Specialty Chemicals Wunstorfer Straße 40 Postfach 10 02 62 D-30918 Seelze

Institut scientifique de service public (ISSeP) Rue du Chéra, 200 B-4000 Liège	Ineos Fluor Ltd PO Box 13, The Heath Runcorn, Cheshire WA7 4QF United Kingdom
LGC Promochem GmbH Mercatorstr. 51 D-46485 Wesel	Mallinckrodt Baker BV Teugseweg 20 7418 AM Deventer Nederland
Mebrom NV Assenedestraat 4 B-9940 Rieme Ertvelde	Merck KgaA Frankfurter Straße 250 D-64271 Darmstadt
Mikro+Polo d.o.o. Zagrebska 22 SI-2000 Maribor	Ministry of Defense Directorate Material RNL Navy P.O. Box 2070 2500 ES The Hague Nederland
Panreac Química S.A. Pol. Ind. Pla de la Bruguera C/ Garraf 2 E-08211 Castellar del Vallès, Barcelona	Sanolabor d.d. Leskoškova 4 SI-1000 Ljubljana
Sigma Aldrich Chimie SARL 80, rue de Luzais L'Isle d'Abeau-Chesnes F-38297 Saint-Quentin-Fallavier	Sigma Aldrich Laborchemikalien Wunstorfer Straße 40 Postfach 10 02 62 D-30918 Seelze
Sigma Aldrich Logistik GmbH Riedstraße 2 D-89555 Steinheim	Tazzetti Fluids Srl Corso Europa, 600/a I-10088 Volpiano (TO)
VWR I.S.A.S. 201, rue Carnot F-94126 Fontenay-sous-Bois	

Done at Brussels, 27 March 2007.

For the Commission
Stavros DIMAS
Member of the Commission

Table 2

Inhaled steroids

Country	Beclomethasone	Dexamethasone	Flunisolide	Fluticasone	Budesonide	Triamcinolone
Austria	X	X	X	X	X	X
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	X	X	X
Latvia	X	X	X	X	X	X
Lithuania	X	X	X	X	X	X
Luxembourg	X	X	X	X	X	X
Malta				X	X	
Poland						
Portugal	X			X	X	
The Netherlands	X	X	X	X	X	X
Norway						
Slovakia	X	X	X	X	X	X
Slovenia	X	X	X	X	X	X
Spain	X			X		
Sweden	X			X		
United Kingdom				X		

Table 3

Non steroidal anti inflammatories

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

Table 4

Anticholinergic bronchodilators

Country	Ipratropium bromide	Oxitropium Bromide				
Austria	X	X				
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	X	X				
Lithuania	X	X				
Luxembourg	X	X				
Malta	X	X				
Netherlands	X	X				
Poland						
Portugal	X					
Norway						
Slovakia	X	X				
Slovenia	X	X				
Spain	X	X				
Sweden	X	X				
United Kingdom	X	X				

Table 5

Long acting beta agonist bronchodilators

Country	Formoterol	Salmeterol				
Austria	X	X				
Belgium	X	X				
Cyprus	X					
Czech Republic	X	X				
Denmark						
Estonia	X	X				
Finland	X	X				
France	X	X				
Germany	X	X				
Greece						
Hungary	X	X				
Ireland	X	X				
Italy	X	X				
Latvia	X	X				
Lithuania	X	X				
Luxembourg	X	X				
Malta	X	X				
Netherlands	X					
Poland						
Portugal						
Norway						
Slovakia	X	X				
Slovenia	X	X				
Spain		X				
Sweden	X	X				
United Kingdom						

Table 6

Combinations of active ingredients in a single MDI

Country						
Austria	X All products					
Belgium	X All products					
Cyprus						
Czech Republic	X All products					
Denmark						
Estonia						
Finland	X All products					
France	X All products					
Germany	X All products					
Greece						
Hungary	X All products					
Ireland						
Italy	Budesonide + Fenoterol	Fluticasone + Salmeterol				
Latvia	X All products					
Lithuania	X All products					
Luxembourg	X All products					
Malta	X All products					
Netherlands						
Poland						
Portugal						
Norway						
Slovakia	X All products					
Slovenia	X All products					
Spain						
Sweden	X All products					
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:

3 M Health Care Ltd (UK)
Bespak Europe Ltd (UK)
Boehringer Ingelheim GmbH (DE)
Chiesi Farmaceutici SpA (IT)
Inyx Pharmaceuticals Ltd (UK)
Ivax Ltd (IE)
Laboratorio Aldo Union SA (ES)
SICOR SpA (IT)
Valeas SpA Pharmaceuticals (IT)
Valvole Aerosol Research Italiana (VARI)
SpA — LINDAL Group Italia (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 A-S (DK)
Carlo Erba Reactifs-SDS (FR)
Harp International (UK)
Honeywell Specialty Chemicals (DE)
Ineos Fluor (UK)
LGC Promochem (DE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro+Polo d.o.o. (SI)
Panreac Química S.A. (ES)
Sanolabor d.d. (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Logistik (DE)
Tazzetti Fluids (IT)
VWR I.S.A.S. (FR)

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)
Eras Labo (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 A-S (DK)
Carlo Erba Reactifs-SDS (FR)
Health Protection Inspectorate-Laboratories (EE)
Honeywell Specialty Chemicals (DE)
Institut scientifique de service public (ISSEP) (BE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro+Polo d.o.o. (SI)
Panreac Química S.A. (ES)
Sanolabor d.d. (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Laborchemikalien (DE)
Sigma Aldrich Logistik (DE)

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 A-S (DK)
Merck KGaA (DE)
Mikro+Polo d.o.o. (SI)
Panreac Química S.A. (ES)
Sanolabor d.d. (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Logistik (DE)

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:

Mebrom NV (BE) Sigma Aldrich Logistik (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) Sigma Aldrich Chimie (FR)

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) Sigma Aldrich Logistik (DE)

ANNEX X

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