COMMISSION DECISION

of 17 April 2008

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2008 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council

(notified under document number C(2008) 1403)

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

(Text with EEA relevance)

(2008/409/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 XIX/13 of the Parties to the Montreal Protocol authorises the production in the European Community of 200 tonnes of chlorofluorocarbons (CFCs) in 2008 for the manufacturing and use of Metered-Dose Inhalers (MDIs) qualifying for essential uses of CFCs as defined in Decision IV/25.

(5) Decision XIX/18 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.

(6) Pursuant to paragraph 3 of Decision XII/2 of the Parties to the Montreal Protocol on measures to facilitate the transition to chlorofluorocarbon-free MDIs, all Member States have notified [2] 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.

(7) 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).

[1] OJ L 244, 29.9.2000, p. 1. Regulation as last amended by Commission Decision 2007/540/EC (OJ L 198, 31.7.2007, p. 35).

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

(8) The Commission has published a Notice [1] on the 18 July 2007 to those companies in the Community of 27 Member States that request consideration by the Commission for the use of controlled substances for essential uses in the Community in 2008 and has received declarations on intended essential uses of controlled substances for 2008.

(9) 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 2008.

(10) 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 2008 shall be 155 460,00 ozone-depleting potential (ODP) 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 2008 shall be 56 213,60 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 2008 shall be 418,7 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 2008 shall be 150 832,836 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 2008 shall be 381,5 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 2008 shall be 150,00 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 2008 shall be 0,96 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 2008 shall be 13,368 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 2008 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.

[1] OJ C 164, 18.7.2007, p. 37.

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 2008 and shall expire on 31 December 2008.

Article 5

This Decision is addressed to the following undertakings:

Acros Organics bvba Janssen Pharmaceuticalaan 3A° B-2440 Geel	Airbus France Service EVICS BP M6322 Route de Bayonne 316 F-31060 Toulouse Cedex 16
Bie & Berntsen Sandbækvej 7 DK-2610 Rødovre	Boehringer Ingelheim GmbH Binger Straße 173 D-55216 Ingelheim am Rhein
Carlo Erba Reactifs-SDS ZI de Valdonne, BP 4 F-13124 Peypin	Chiesi Farmaceutici SpA Via Palermo 26/A I-43100 Parma
CNRS — Département Galilée Observatoire de la Côte d'Azur — Siège Social Boulevard de l'Observatoire, BP 4229 F-06304 Nice Cedex 4	Eras Labo 222 RN 90 F-38330 Saint-Nazaire-les-Eymes
Harp International Gellihirion Industrial Estate Rhondda, Cynon Taff Pontypridd CF37 5SX United Kingdom	Health Protection Inspectorate-Laboratories Paldiski mnt 81 EE-10617 Tallinn
Honeywell Specialty Chemicals Seelze GmbH Wunstorfer Straße 40 Postfach 100262 D-30918 Seelze	Ineos Fluor Ltd PO Box 13 The Heath Runcorn Cheshire WA7 4QX United Kingdom
Laboratorio Aldo-Union SA Baronesa de Maldá 73 Espluges de Llobregat E-08950 Barcelona	LGC Standards GmbH Mercatorstraße 51 D-46485 Wesel

Mallinckrodt Baker EMEA Teugseweg 20 7418 AM Deventer Nederland	Mebrom Assenedestraat 4 B-9940 Rieme Ertvelde
Merck KGaA Frankfurter Straße 250 D-64271 Darmstadt	Mikro+Polo d.o.o. Zagrebška cesta 22 SI-2000 Maribor
Ministry of Defense Defence Fuel Lubricants and Chemicals Service/ Chemical Laboratory PO Box 10.000 1780 CA Den Helder Nederland	Panreac Química SAU Pol. Ind. Pla de la Bruguera C/Garraf 2 E-08211 Castellar del Vallès — Barcelona
Sanolabor d.d. Leskoškova 4 Ljubljana Slovenia	SICOR SpA Via Terrazzano 77 I-20017 Rho
Sigma Aldrich Chimie SARL 80, rue de Luzais L'Isle d'Abeau Chesnes F-38297 St-Quentin-Fallavier	Sigma Aldrich Company The Old Brickyard, New Road Gillingham SP8 4XT United Kingdom
Sigma Aldrich Laborchemikalien GmbH Wunstorfer Straße 40 D-30926 Seelze	Sigma Aldrich Logistik GmbH Riedstraße 2 D-89555 Steinheim
Tazzetti Fluids SRL Corso Europa n. 600/a I-10070 Volpiano (TO)	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)	VWR I.SAS. 201, rue Carnot F-94126 Fontenay-sous-Bois

Done at Brussels, 17 April 2008.

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:

LIST OF NON-ESSENTIAL SUBSTANCES

Table 1

Short-acting beta agonist bronchodilators

Country	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
Bulgaria	X	X	X	X	X	X	X	X	X	X	X
Cyprus	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
Estonia	X	X	X	X	X	X	X	X	X	X	X
Finland	X	X	X	X	X	X	X	X	X	X	X
France	X	X	X	X	X	X	X	X	X	X	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	X	X	X	X	X	X	X	X	X	X
Italy	X	X	X	X	X	X	X	X	X	X	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	X	X	X	X	X	X	X	X	X	X
Malta	X	X	X	X	X	X	X	X	X	X	X
Netherlands	X	X	X	X	X	X	X	X	X	X	X
Poland	X	X	X	X	X	X	X	X	X	X	X
Portugal	X	X	X	X	X	X	X	X	X	X	X
Romania	X	X	X	X	X	X	X	X	X	X	X
Slovakia	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	X	X	X	X	X	X	X	X	X	X
Sweden	X	X	X	X	X	X	X	X	X	X	X
United Kingdom	X	X	X	X	X	X	X	X	X	X	X

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
Bulgaria	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	X		X	X	X	X
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		
Netherlands	X	X	X	X	X	X
Poland	X	X	X	X	X	X
Portugal	X	X	X	X	X	X
Romania	X	X	X	X	X	X
Slovakia	X	X	X	X	X	X
Slovenia	X	X	X	X	X	X
Spain	X			X	X	
Sweden	X			X		
United Kingdom				X		

Table 3

Non-steroidal anti-inflammatories

Country	Cromoglicic acid	Nedrocromil				
Austria	X	X				
Belgium	X	X				
Bulgaria	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				
Netherlands	X	X				
Poland	X	X				
Portugal	X					
Romania	X	X				
Slovakia	X	X				
Slovenia	X	X				
Spain		X				
Sweden	X	X				
United Kingdom	X	X				

Table 4

Anticholinergic bronchodilators

Country	Ipratropium bromide	Oxitropium bromide				
Austria	X	X				
Belgium	X	X				
Bulgaria	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	X	X				
Portugal	X					
Romania	X	X				
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				
Bulgaria	X	X				
Cyprus	X					
Czech Republic	X	X				
Denmark		X				
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	X				
Poland	X	X				
Portugal	X	X				
Romania	X	X				
Slovakia	X	X				
Slovenia	X	X				
Spain		X				
Sweden	X	X				
United Kingdom	X	X				

Table 6

Combinations of active ingredients in a single MDI

Country						
Austria	X All products					
Belgium	X All products					
Bulgaria	X All products					
Cyprus						
Czech Republic	X All products					
Denmark	X All products					
Estonia						
Finland	X All products					
France	X All products					
Germany	X All products					
Greece	X All products					
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	X All products					
Poland	X All products					
Portugal	X All products					
Romania	X All products					
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:

Boehringer Ingelheim GmbH (DE)
Chiesi Farmaceutici SpA (IT)
Laboratorio Aldo Union SA (ES)
SICOR SpA (IT)
Valeas SpA Pharmaceuticals (IT)
(VARI) SpA — LINDAL Group Italia (IT)

ANNEX III

ESSENTIAL LABORATORY USES

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

Bie & Berntsen (DK)
Carlo Erba Reactifs-SDS (FR)
CNRS — Département Galilée (FR)
Harp International (UK)
Honeywell Specialty Chemicals (DE)
Ineos Fluor (UK)
LGC Standards (DE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Quimica (ES)
Sanolabor (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Logistik (DE)
Tazzetti Fluids (IT)
VWR ISAS (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 Defence (NL)

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)
Carlo Erba Reactifs-SDS (FR)
Health Protection Inspectorate-Laboratories (EE)
Honeywell Specialty Chemicals (DE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Quimica (ES)
Sanolabor d.d. (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Laborchemikalien (DE)
Sigma Aldrich Logistik (DE)
VWR ISAS (FR)

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)
Merck KgaA (DE)
Mikro + Polo (SI)
Panreac Quimica (ES)
Sanolabor d.d. (SI)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
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)

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 Company (UK)
Sigma Aldrich Logistik (DE)

ANNEX X

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