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)

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).

(8) The Commission has published a Notice[(3)] 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 155 460,0 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 56 213,6 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.

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	Ritodrine	Bambuterol	Broxaterol	Procaterol
Austria	X	X	X	X	X	X	X	X	X	X	X	X	X
Belgium	X	X	X	X	X	X	X	X	X	X	X	X	X
Bulgaria	X	X	X	X	X	X	X	X	X	X	X	X	X
Cyprus	X	X	X	X	X	X	X	X	X	X	X	X	X
Czech Republic	X	X	X	X	X	X	X	X	X	X	X	X	X
Denmark	X	X	X	X	X	X	X	X	X	X	X	X	X
Estonia	X	X	X	X	X	X	X	X	X	X	X	X	X
Finland	X	X	X	X	X	X	X	X	X	X	X	X	X
France	X	X	X	X	X	X	X	X	X	X	X	X	X
Germany	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	X	X
Hungary	X	X	X	X	X	X	X	X	X	X	X	X	X
Ireland	X	X	X	X	X	X	X	X	X	X	X	X	X
Italy	X	X	X	X	X	X	X	X	X	X	X	X	X
Latvia	X	X	X	X	X	X	X	X	X	X	X	X	X
Lithuania	X	X	X	X	X	X	X	X	X	X	X	X	X
Luxembourg	X	X	X	X	X	X	X	X	X	X	X	X	X
Malta	X	X	X	X	X	X	X	X	X	X	X	X	X
Netherlands	X	X	X	X	X	X	X	X	X	X	X	X	X
Poland	X	X	X	X	X	X	X	X	X	X	X	X	X
Portugal	X	X	X	X	X	X	X	X	X	X	X	X	X
Romania	X	X	X	X	X	X	X	X	X	X	X	X	X
Slovakia	X	X	X	X	X	X	X	X	X	X	X	X	X
Slovenia	X	X	X	X	X	X	X	X	X	X	X	X	X

Table 1

Short-acting beta agonist bronchodilators

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	

Table 2

Inhaled steroids

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				

Table 3						
Non-steroidal anti-inflammatories						
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				

Table 4						
Anticholinergic bronchodilators						
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				

Table 5						
Long-acting beta agonist bronchodilators						
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					

Table 6						
Combinations of active ingredients in a single MDI						
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.

(**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

(**3**) OJ C 164, 18.7.2007, p. 37.