COMMISSION DECISION

of 18 December 2008

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2009 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council on substances that deplete the ozone layer

(notified under document number C(2008) 8398)

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

(2009/52/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) The Parties to the Montreal Protocol authorised the production in the European Community of 22 tonnes of chlorofluorocarbons (CFCs) in 2009 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 critical 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 the United Nations Environment Programme the active ingredients for which chlorofluorocarbons (CFCs) are no longer essential for the manufacture of 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 [2] to those companies in the Member States that request consideration by the Commission for the use of controlled substances for essential uses in the Community in 2009 and has received declarations on intended essential uses of controlled substances for 2009.

[1] OJ L 244, 29.9.2000, p. 1.

[2] OJ C 114, 9.5.2008, p. 27.

(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 2009 shall be 21 360,00 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 and analytical uses in the Community in 2009 shall be 60 280,8 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 and analytical use in the Community in 2009 shall be 115,7 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 and analytical uses in the Community in 2009 shall be 129 390,8 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 and analytical uses in the Community in 2009 shall be 355,65 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 critical uses in the Community in 2009 shall be 36,3 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 and analytical uses in the Community in 2009 shall be 57,96 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 and analytical uses in the Community in 2009 shall be 11,088 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 2009 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 and analytical 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 and analytical use quotas for halons shall be to the companies indicated in Annex IV.

4. The allocation of essential laboratory and analytical use quotas for carbon tetrachloride shall be to the companies indicated in Annex V.

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

8. The allocation of essential laboratory and analytical 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 and the laboratory and analytical critical use quotas for methyl bromide shall be as set out in Annex X.

Article 4

This Decision shall apply from 1 January 2009 and shall expire on 31 December 2009.

Article 5

This Decision is addressed to the following undertakings:

Acros Organics bvba Janssen Pharmaceuticalaan 3a B-2440 Geel	Airbus France 316, route de Bayonne F-31300 Toulouse
Carlo Erba Réactifs-SDS Z.I. de Valdonne, BP 4 F-13124 Peypin	Chiesi Farmaceutici SpA Via Palermo 26/A I-43100 Parma
CNRS — Groupe de physique des solides Université Paris 7 Denis Diderot et Paris 6 Pierre et Marie Curie F-75251 Paris Cedex 5	Harp International Gellihirion Industrial Estate Rhondda, Cynon Taff Pontypridd CF37 5SX UNITED KINGDOM
Honeywell Specialty Chemicals Wunstorfer Straße 40 Postfach 10 02 62 D-30918 Seelze	Ineos Fluor Ltd PO Box 13, The Heath Runcorn Cheshire WA7 4QF UNITED KINGDOM
Institut scientifique de service public Rue du Chéra 200 B-4000 Liège	LGC Standards 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. Zagrebška cesta 22 SI-2000 Maribor	Ministry of Defense Defence Fuel Lubricants and Chemicals PO Box 10 000 1780 CA Den Helder Nederland
Panreac Química SA Pol. Ind. Pla de la Bruguera, C/Garraf, 2 E-08211 Castellar del Vallès Barcelona	Sigma Aldrich Chimie SARL 80, rue de Luzais L'Isle d'Abeau Chesnes F-38297 Saint-Quentin-Fallavier
Sigma Aldrich Company The Old Brickyard, New Road Gillingham SP8 4XT UNITED KINGDOM	Sigma Aldrich Laborchemikalien Wunstorfer Straße 40 Postfach 10 02 62 D-30918 Seelze
Sigma Aldrich Logistik GmbH Riedstraße 2 D-89555 Steinheim	Solvay Organics GmbH Hans-Böckler-Allee 20 D-30173 Hannover

Tazzetti Fluids SRL Corso Europa 600/a I-10088 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 ISAS 201, rue Carnot F-94126 Fontenay-sous-Bois

Done at Brussels, 18 December 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	X	X	X	X	X	X
Czech Republic	X	X	X	X	X	X
Denmark	X	X	X	X	X	X
Estonia	X	X	X	X	X	X
Finland	X	X	X	X	X	X
France	X	X	X	X	X	X
Germany	X	X	X	X	X	X
Greece	X	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	X	X	X
Sweden	X	X	X	X	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	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	X	X
Germany	X	X
Greece	X	X
Hungary	X	X
Ireland	X	X
Italy		X
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	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	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	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		
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:

Chiesi Farmaceutici SpA (IT)
Valeas SpA Pharmaceuticals (IT)
(VARI) SpA — LINDAL Group Italia (IT)

ANNEX III

ESSENTIAL LABORATORY AND ANALYTICAL USES

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

Carlo Erba Réactifs-SDS (FR)
CNRS — Groupe de physique des solides (FR)
Harp International (UK)
Honeywell Specialty Chemicals (DE)
Ineos Fluor (UK)
LGC Standards (DE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Química (ES)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Logistik (DE)
Tazzetti Fluids (IT)

ANNEX IV

ESSENTIAL LABORATORY AND ANALYTICAL USES

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

Airbus France (FR)
Ineos Fluor (UK)
Ministry of Defence (NL)

ANNEX V

ESSENTIAL LABORATORY AND ANALYTICAL USES

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

Acros Organics (BE)
Carlo Erba Réactifs-SDS (FR)
Honeywell Specialty Chemicals (DE)
Institut Scientifique du Service Publique (BE)
Mallinckrodt Baker (NL)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Quimica (ES)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Laborchemikalien (DE)
Sigma Aldrich Logistik (DE)
VWR ISAS (FR)

ANNEX VI

ESSENTIAL LABORATORY AND ANALYTICAL USES

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

Acros Organics (BE)
Merck KGaA (DE)
Mikro + Polo (SI)
Panreac Química (ES)
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:

Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Logistik (DE)

ANNEX VIII

ESSENTIAL LABORATORY AND ANALYTICAL USES

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

Ineos Fluor (UK)
Sigma Aldrich Logistik (DE)
Solvay Organics (DE)

ANNEX IX

ESSENTIAL LABORATORY AND ANALYTICAL USES

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

Ineos Fluor (UK)
Sigma Aldrich Chimie (FR)
Sigma Aldrich Company (UK)
Sigma Aldrich Logistik (DE)

ANNEX X

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