COMMISSION

COMMISSION DECISION

of 28 March 2003

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 2003 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council

(notified under document number C(2003) 747)

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

(Text with EEA relevance)

(2003/316/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], as last amended by Commission Decision 2003/160/EC [2], and in particular to Articles 3(1) and 7 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, hydrobromofluorocarbons and bromochloromethane.

(2) Each year the Commission has 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.

(4) Decision X/19 of the Parties to the Montreal Protocol authorises the production and consumption necessary to satisfy essential uses of controlled substances listed in Annexes A and B 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, Decision VII/11 and Decision XI/15 of the Parties to the Montreal Protocol.

(5) Substances required for essential uses that are not listed in Annexes A and B of the Montreal Protocol must be specifically approved by the Parties. This requirement applies to essential uses of hydrobromofluorocarbons and bromochloromethane that are listed in Annex C of the Montreal Protocol.

(6) 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), Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Luxembourg, Norway, Portugal, the Netherlands and the United Kingdom have recently determined that chlorofluorocarbons (CFCs) are no longer essential for the manufacture of specific short-acting beta agonist CFC-MDIs [3]. 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 reduced the

[1] OJ L 244, 29.9.2000, p. 1.
[2] OJ L 65, 8.3.2003, p. 29.
[3] www.unep.org/ozone/dec12-2-3.shtml

demand for CFCs in the Community. In addition, Article 4(6) of Regulation (EC) No 2037/2000 prevents products being imported and placed on the market containing CFCs unless the CFCs are considered essential under the conditions described in Article 3(1).

(7) The Commission has published a notice [1] to those companies in the Community that intend to use controlled substances for essential uses in the Community in 2003, and has received declarations on intended essential uses of controlled substances in 2003.

(8) The measures provided for in this Decision are in accordance with the opinion of the Committee that followed the procedures established under Article 18 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 2003 shall be 1 895 260,00 ODP (ozone depletion potential) 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 2003 shall be 87 211,365 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 2003 shall be 6 358,70 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 2003 shall be 133 811,70 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 Community in 2003 shall be 789,68 ODP kilograms.

6. 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 2003 shall be 11 335 ODP kilograms

7. The quantity of controlled substances of group 'New' (bromochloromethane) subject to Regulation (EC) No 2037/2000 that may be used for essential laboratory uses in the Community in 2003 shall be 1 248 ODP kilograms.

Article 2

The chlorofluorocarbon metered-dose inhalers (CFC-MDIs) listed in Annex I shall not be placed on markets that have determined CFCs for these products to be non-essential.

Article 3

During the period 1 January to 31 December 2003 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 essential laboratory use quotas for hydrobromofluorocarbons shall be to the companies indicated in Annex VII;

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

8. 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 IX.

[1] OJ C 193, 13.8.2002, p. 20.

Article 4

This Decision is addressed to:

3M Health Care Ltd
3M House Morley Street
Loughborough
Leicestershire LE11 1EP
United Kingdom

Acros Organics bvba
Janssen Pharmaceuticalaan 3a
B-2440 Geel

Agfa-Gevaert NV
Septestraat 27
B-2640 Mortsel

Atofina SA
Cours Michelet — La Défense 10
F-92091 Paris La Défense

Aventis
London Road, Holmes Chapel
Cheshire CW4 8BE
United Kingdom

Bespak PLC
North Lynn Industrial Estate
King's Lynn
Norfolk PE30 2JJ
United Kingdom

Bie & Berntsen A/S
Sandbækvej 7
DK-2610 Rødovre

Biosolve BV
Waalreseweg 17
5554 HA Valkenswaard
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Boehringer Ingelheim GmbH
Binger Straße 173
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Butterworth Laboratories Ltd
54 Waldegrave Road, Teddington
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Carl Roth GmbH
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Chiesi Farmaceutici SpA
Via Palermo 26/A
I-43100 Parma

Dow Benelux BV
Herbert H. Dowweg
4542 NM Hoek
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Ecotechnics SpA
Via L. Longo 21/23
I-50019 Sesto Fiorentino, Firenze

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111, Bd Robespierre, BP 4513
F-78304 Poissy

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GlaxoSmithKline
Speke Boulevard
Speke
Liverpool L24 9JD
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Université Paris 7 Denis-Diderot et Paris 6 Pierre et Marie Curie
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Ineos Fluor Ltd
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IVAX Ltd
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Waterford
Ireland

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9 Arkwright Road RUNCORN
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United Kingdom

Otsuka Pharmaceuticals SA (E)
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E-08025 Barcelona

Panreac Química SA
Riera de Sant Cugat 1
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Rathburn Chemicals Mfg Ltd
Caberston Road
Walkerburn EH43 6AS
Scotland

Rohs Chemie GmbH
Berliner Str. 54
D-53819 Neunkirchen-Seelsheid

Schering-Plough Labo NV
Industriepark 30
B-2220 Heist Op Den Berg

SDS Solvants, Documentation, Synthèses SA
ZI de Valdonne, BP 4
F-13124 Peypin

SICOR S.p.A
Via Terrazzano 77
I-20017 Rho Milano

Sigma Aldrich Chemie GmbH
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D-89555 Steinheim

Sigma Aldrich Chimie SARL
80, rue de Luzais, L'Îsle d'Abeau
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Sigma Aldrich Company Ltd
The Old Brickyard
New Road
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Sigma Aldrich Laborchemikalien
Wunstorfer Straße 40, Postfach 100262
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Valeas SpA Pharmaceuticals
Via Vallisneri, 10
I-20133 Milano

Valois SA
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F-78160 Marly-le-Roi

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

YA-Kemia Oy
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FIN-00700 Helsinki

Done at Brussels, 28 March 2003.

For the Commission
Margot WALLSTRÖM
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 Parties have determined in December 2002 that, due to the presence of suitable non-CFC MDIs, CFCs no longer qualify as 'essential' under the Protocol when combined with following products:

List of Non-Essential Substances

Product / 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
Denmark	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
Ireland	x										
Luxembourg	x										
Norway	x	x	x	x	x	x	x	x	x	x	x
Portugal	x	x	x	x	x	x	x	x	x	x	x
The Netherlands	x	x	x	x	x	x	x	x	x	x	x
United Kingdom	x										

Source: www.unep.org/ozone/dec12-2-3.pdf

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 (UK)
Aventis (UK)
Bespak (UK)
Boehringer Ingelheim (D)
Chiesi (I)
Glaxo Smith Kline (UK)
IG Sprühtechnik (D)
IVAX (IRL)
Jaba Farmaceutica (P)
Lab Lesvi (E)
Lab Vita (E)
Lab. Aldo-Union (E)
MIZA Pharmaceuticals (UK)
Otsuka Pharmaceuticals (E)
Schering-Plough (B)
Sicor (I)
Valeas (I)
Valois (F)
VARI (I)

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:

Agfa-Gevaert (B)
Atofina (F)
Bie & Berntsen (DK)
Biosolve (NL)
Butterworth Laboratories (UK)
Carl Roth (D)
Dow Benelux (NL)
Ecotechnics SpA (I)
Environnement SA (F)
Groupe de Physique des Solides (F)
Honeywell Specialty Chemicals (D)
Ineos Fluor (UK)
Katholieke Universiteit Leuven (B)
LGC Promochem (D)
Merck KGaA (D)
Panreac Quimica (E)
Rathburn Chemicals (UK)
SDS Solvants (F)
Sigma Aldrich Chemie (D)
Sigma Aldrich Chimie (F)
Sigma Aldrich Company (UK)
VWR ISAS (F)

ANNEX IV

Essential laboratory uses

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

Butterworth Laboratories (UK)
Ineos Fluor (UK)
Sigma Aldrich Company (UK)

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 (B)
Agfa-Gevaert (B)
Bie & Berntsen (DK)
Biosolve (NL)
Dow Benelux (NL)
Fisher Scientific (UK)
Katholieke Universiteit Leuven (B)
Laboratoires Sérologiques (F)
Merck KGaA (D)
Panreac Quimica (E)
Rathburn Chemicals (UK)
Rohs Chemie (D)
SDS Solvants (F)
Sigma Aldrich Chemie (D)
Sigma Aldrich Chimie (F)
Sigma Aldrich Company (UK)
Sigma Aldrich Laborchemikalien (D)
VWR ISAS (F)
YA-Kemia Oy (FIN)

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 (B)
Agfa-Gevaert (B)
Dow Benelux (NL)
Katholieke Universiteit Leuven (B)
Merck KGaA (D)
Panreac Quimica (E)
Rathburn Chemicals (UK)
Sigma Aldrich Chemie (D)
Sigma Aldrich Chimie (F)
Sigma Aldrich Company (UK)
VWR ISAS (F)

ANNEX VII

Essential laboratory uses

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

Acros Organics (B)
Ineos Fluor (UK)
Sigma Aldrich Chimie (F)
Sigma Aldrich Company (UK)

Each quota cannot be debited until the Commission has notified each enterprise that the Parties to the Montreal Protocol have approved the use of hydrobromofluorocarbons in 2003 for Essential Uses.

ANNEX VIII

Essential laboratory uses

Quota for bromochloromethane that may be used for laboratory and analytical uses are allocated to:

Ineos Fluor (UK)
Sigma Aldrich Chimie (F)

Each quota cannot be debited until the Commission has notified each enterprise that the Parties to the Montreal Protocol have approved the use of bromochloromethane in 2003 for Essential Uses.

ANNEX IX

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