Notice to users of controlled substances in the European Union allowed for essential uses in the Community in 2005 pursuant to Regulation (EC) No 2037/2000 of the European Parliament and of the Council on substances that deplete the ozone layer [1]

(2004/C 187/05)

This Notice concerns the following substances:

— chlorofluorocarbons (CFCs) 11, 12, 113, 114 and 115,

— other fully halogenated chlorofluorocarbons,

— carbon tetrachloride,

— halons,

— 1,1,1 trichloroethane,

— hydrobromofluorocarbons (HBFCs),

— bromochloromethane.

This notice is addressed to users that intend to:

1. use the above substances within the Community for the manufacture of metered dose inhalers (MDIs);

2. acquire the above substances for laboratory and analytical uses directly from a producer or by import into the Community and not from a distributor of the substances.

Controlled substances for essential uses may be obtained from production within the Community and, if necessary, by import from sources outside the Community.

Decision IV/25 of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer sets out criteria and a procedure for determining 'essential uses' for which continued production and consumption is allowed after phase-out.

Article 3(1) of Regulation (EC) No 2037/2000, as amended by Regulation (EC) No 2038/2000, requires the determination of quantities for essential uses of the abovementioned controlled substances which may be permitted in the Community in 2004, in accordance with Decision IV/25 of the Parties to the Montreal Protocol

Decision XV/4 of the Parties to the Montreal Protocol authorised the levels of production and consumption necessary to satisfy essential uses of CFCs for metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary diseases as specified in annex I, subject to the conditions established by the meeting of the Parties in paragraph 2 of its Decision VII/28. For the production of MDIs in the European Community in 2005, the quantity of CFCs 11, 12, 113 and 114 authorised by the Parties in Decision XV/4 is 1 030 000,00 kilograms (one million thirty thousand ODP-kilograms).

In accordance with Decision X/19 of the Parties to the Montreal Protocol, the purity of controlled substances for laboratory purposes should be at least 99,0 % for 1,1,1-trichloroethane and 99,5 % for CFCs and carbon tetrachloride. These high purity substances and mixtures containing controlled substances shall be supplied only in re-closable containers or high pressure cylinders smaller than three litres or in 10 millilitre or smaller glass ampoules, marked clearly as substances that deplete the ozone layer, restricted to laboratory use and analytical purposes and specifying that used or surplus substances should be collected and recycled, if practical. The material should be destroyed if recycling is not practical.

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.

The procedures for allocating quantities of controlled substances for the above essential uses carried out under Regulation (EC) No 2037/2000 and Regulation (EC) No 2038/2000 is the following:

1. An enterprise that has not been issued with a quota in 2004 and that requests consideration by the Commission for an essential use quota for the period 1 January 2005 to 31 December 2005 should make itself known to the Commission no later than 3 September 2004:

Ozone Layer Protection
European Commission
Directorate-General Environment
Unit ENV.C.2 – Climate change
BU5 2/25
B - 1049 Brussels
Fax: (32-2) 299 87 64
Email: env-ods@cec.eu.int

[1] OJ L 244, 29.9.2000, p. 1. Regulation as amended by Regulation (EC) 1804/2003 (OJ L 265, 16.10.2003, p. 1).

2. Essential use applications may be made by any user of substances listed at the beginning of this Notice. For CFCs for use in MDIs, each applicant should provide the information requested on the spreadsheet available on the ODS website http://europa.eu.int/comm/environment/ods/home/home.cfm. For laboratory uses, each applicant should provide the information requested in the form on the website.

   A copy of the application should also be sent to the competent authority of the Member State (refer to Annex I for appropriate address).

3. Only applications received by 3 September 2004 will be considered by the Commission in accordance with the procedure set out in Article 18 of Regulation (EC) No 2037/2000.

4. The Commission will issue quotas to those users and shall notify them of the use for which they have authorisation, the substance they are authorised to use and the quantity of the controlled substances concerned.

5. Following the above procedure, the Commission on the basis of a Decision will notify applicants of the quantities of controlled substances authorised in the Community for 2005 for which production and importation of controlled substances will be permitted.

6. Those users holding an essential use quota for a controlled substance for 2005 will be able to make a request to a Community producer via the ODS website or, if necessary, request an import licence from the Commission for a controlled substance up to their quota limit. The producer must be authorised by the competent authority of the Member State in which its relevant production is situated to produce the controlled substance for meeting that licensed demand. The competent authority of the Member State shall notify the Commission well in advance of any such authorisation.

ANEXO/PŘÍLOHA/BILAG/ANHANG/ΠΑΡΑΡΤΗΜΑ/ANNEX/LISA/ANNEXE/MELLÉKLET/ALLEGATO/PRIEDAS/PIELIKUMS/ANNESS/BIJLAGE/ZAŁĄCZNIK/ANEXO/PRÍLOHA/PRILOGA/LIITE/BILAGA

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