



Council of the
European Union

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ENT 159
MI 601
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SAN 450
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CHIMIE 68
CONSOM 271

COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 7 July 2023

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: [...] (2023) XXX draft - D 090165/1 ANNEX

Subject: ANNEX to the COMMISSION REGULATION (EU) No.../.. amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards the substance bis(2-ethylhexyl) phthalate (DEHP) in medical devices

Delegations will find attached document [...] (2023) XXX draft - D 090165/1 ANNEX.

Encl.: [...] (2023) XXX draft - D 090165/1 ANNEX



Brussels, XXX
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[...] (2023) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) No.../..

**amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council
as regards the substance bis(2-ethylhexyl) phthalate (DEHP) in medical devices**

ANNEX

In the table in Annex XIV to Regulation (EC) No 1907/2006, entry nr 4 concerning the substance bis(2-ethylhexyl) phthalate (DEHP) is amended as follows:

(1) in column 4 'Latest application date', point (c) is replaced by the following:

'(c) by way of derogation from point (a):

1 January 2029 for uses in medical devices within the scope of Regulations (EU) 2017/745 and (EU) 2017/746.';

(2) in column 5 'Sunset date', point (c) is replaced by the following:

'(c) by way of derogation from point (a):

1 July 2030 for uses in medical devices within the scope of Regulations (EU) 2017/745 and (EU) 2017/746.'