



Council of the
European Union

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ADD 1

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COVER NOTE

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

date of receipt: 9 March 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.: [...] (2021) XXX draft - D 071308/02 ANNEX

Subject: ANNEX to the COMMISSION REGULATION (EU) No.../.. amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Delegations will find attached document [...] (2021) XXX draft - D 071308/02 ANNEX.

Encl.: [...] (2021) XXX draft - D 071308/02 ANNEX



Brussels, **XXX**
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[...](2021) **XXX** draft

ANNEX

ANNEX

to the

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

amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

ANNEX

Entries 4 to 7 in the table in Annex XIV to Regulation (EC) No 1907/2006 are replaced by the following entries:

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date ⁽¹⁾	Sunset date ⁽²⁾		
'4.	Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health) Endocrine disrupting properties (Article 57(f) - environment)	(a) 21 August 2013* (b) By way of derogation from point (a): ...[PO please insert the date - 18 months after entry into force of this amending Regulation] for uses in: - food contact materials within the scope of Regulation (EC) No 1935/2004; - immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; - mixtures containing DEHP at or above 0,1% and below 0,3% weight by weight;	(a) 21 February 2015** (b) By way of derogation from point (a): ... [PO please insert the date - 36 months after entry into force of this amending Regulation] for uses in: - food contact materials within the scope of Regulation (EC) No 1935/2004; - immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; - mixtures containing DEHP at or above 0,1% and below 0,3% weight by weight;	-	-
			(c) By derogation of point (a): 27 November 2023 for uses	(c) By derogation of point (a): 27 May 2025 for uses in		

5.	Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)		in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	
			(a) 21 August 2013* (b) By way of derogation from point (a): ... [PO please insert the date 18 months after entry into force of this amending Regulation] for uses in: – immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; – mixtures containing BBP at or above 0,1% and below 0,3% weight by weight.	(a) 21 February 2015** (b) By way of derogation from point (a): ... [PO please insert the date 36 months after entry into force of this amending Regulation] for uses in: – immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; – mixtures containing BBP at or above 0,1% and below 0,3% weight by weight.		
			(a) 21 August 2013* (b) By way of derogation from point (a): ... [PO please insert the date 18 months after entry into force of this amending Regulation] for uses in: – immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; – mixtures containing BBP at or above 0,1% and below 0,3% weight by weight.	(a) 21 February 2015** (b) By way of derogation from point (a): ... [PO please insert the date 36 months after entry into force of this amending Regulation] for uses in: – immediate packaging of medicinal products covered under		
			(a) 21 August 2013* (b) By way of derogation from point (a): ... [PO please insert the date 18 months after entry into force of this amending Regulation] for uses in: – immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; – mixtures containing BBP at or above 0,1% and below 0,3% weight by weight.	(a) 21 February 2015** (b) By way of derogation from point (a): ... [PO please insert the date 36 months after entry into force of this amending Regulation] for uses in: – immediate packaging of medicinal products covered under		

7.	Diisobutyl phthalate (DIBP) EC No: 201-553-2 CAS No: 84-69-5	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	<p>Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;</p> <p>- mixtures containing DBP at or above 0,1% and below 0,3% weight by weight.</p> <p>(a) 21 August 2013*</p> <p>(b) By way of derogation from point (a): ... [PO please insert the date - 18 months after entry into force of this amending Regulation] for uses in mixtures containing DIBP at or above 0,1% and below 0,3% weight by weight.</p>	<p>Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;</p> <p>- mixtures containing DBP at or above 0,1% and below 0,3% weight by weight.</p> <p>(a) 21 February 2015**</p> <p>(b) By way of derogation from point (a): ... [PO please insert the date - 36 months after entry into force of this amending Regulation] for uses in mixtures containing DIBP at or above 0,1% and below 0,3% weight by weight.</p>		
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