



Council of the  
European Union

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MI 152  
ENT 44  
COMPET 165  
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CHIMIE 29

#### COVER NOTE

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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

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No. Cion doc.:	<a href="#">[...]</a> (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)

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

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



Brussels, **XXX**  
D071308/02  
**[...]**(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 <sup>(1)</sup>	Sunset date <sup>(2)</sup>		
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;  (c) By derogation of point (a):  27 November 2023 for uses	(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 May 2025 for uses in	-	-

			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.		
5.	Benzyl butyl phthalate <b>(BBP)</b> EC No: 201-622-7 CAS No: 85-68-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(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.	-	-
6.	Dibutyl phthalate <b>(DBP)</b> EC No: 201-557-4 CAS No: 84-74-2	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(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	(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	-	-

			<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>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>		
7.	<p>Diisobutyl phthalate <b>(DIBP)</b> EC No: 201-553-2 CAS No: 84-69-5</p>	<p>Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)</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>(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>	-	-'