



Brussels, **XXX**
[...](2020) **XXX** draft

ANNEX

ANNEX

to the

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

of XXX

**amending Annex XIV to Regulation (EU) 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): ...[OJ please insert the date - 18 months after entry into force of this amending Regulation] for uses in: <ul style="list-style-type: none">- 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): ... [OJ please insert the date - 36 months after entry into force of this amending Regulation] for uses in: <ul style="list-style-type: none">- 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.	<p>Benzyl butyl phthalate (BBP)</p> <p>EC No: 201-622-7 CAS No: 85-68-7</p>	<p>Toxic for reproduction (category 1B)</p> <p>Endocrine disrupting properties (Article 57(f) - human health)</p>	<p>(a) 21 August 2013*</p> <p>(b) By way of derogation from point (a):</p> <p>... [OJ please insert the date 18 months after entry into force of this amending Regulation] for uses in:</p> <ul style="list-style-type: none"> - 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. 	<p>(a) 21 February 2015**</p> <p>(b) By way of derogation from point (a):</p> <p>... [OJ please insert the date 36 months after entry into force of this amending Regulation] for uses in:</p> <ul style="list-style-type: none"> - 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.	<p>Dibutyl phthalate (DBP)</p> <p>EC No: 201-557-4 CAS No: 84-74-2</p>	<p>Toxic for reproduction (category 1B)</p> <p>Endocrine disrupting properties (Article 57(f) - human health)</p>	<p>(a) 21 August 2013*</p> <p>(b) By way of derogation from point (a):</p> <p>... [OJ please insert the date 18 months after entry into force of this amending Regulation] for uses in:</p> <ul style="list-style-type: none"> - immediate packaging of medicinal products covered under 	<p>(a) 21 February 2015**</p> <p>(b) By way of derogation from point (a):</p> <p>... [OJ please insert the date 36 months after entry into force of this amending Regulation] for uses in:</p> <ul style="list-style-type: none"> - 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 (DIBP) 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): ... [OJ 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): ... [OJ 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>	-	-'