

**Draft Amendment of Annex XIV entries**

(changes under consideration are marked in grey shade)

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 derogation of point (a):  [18 months after entry into force] for uses in:  - food contact materials within the scope of Regulation (EC) No 1935/2004 <sup>1</sup> ;  - medical devices regulated by Directive 90/385/EEC <sup>2</sup> , Directive 93/42/EEC <sup>3</sup> or Directive 98/79/EC <sup>4</sup> ;  - immediate packaging of medicinal products covered under Regulation (EC) No 726/2004 <sup>5</sup> , Directive	(a) 21 February 2015  (b) By derogation of point (a):  [36 months after entry into force] for uses in:  - food contact materials within the scope of Regulation (EC) No 1935/2004;  - medical devices regulated by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC;  - immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;	<del>Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC</del>	-

<sup>1</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)

<sup>2</sup> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17)

<sup>3</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1)

<sup>4</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1)

<sup>5</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1)

			2001/82/EC <sup>6</sup> , and/or Directive 2001/83/EC <sup>7</sup> ; - mixtures containing DEHP between 0,1% and 0,3% weight by weight	- mixtures containing DEHP between 0,1% and 0,3% weight by weight		
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 derogation of point (a): [18 months after entry into force] for uses in mixtures containing BBP between 0,1% and 0,3% weight by weight	(a) 21 February 2015 (b) By derogation of point (a): [36 months after entry into force] for uses in mixtures containing BBP between 0,1% and 0,3% weight by weight	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC	-
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 derogation of point (a): [18 months after entry into force] for uses in mixtures containing DBP between 0,1% and 0,3% weight by weight	(a) 21 February 2015 (b) By derogation of point (a): [36 months after entry into force] for uses in mixtures containing DBP between 0,1% and 0,3% weight by weight	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC	-
7.	Diisobutyl phthalate ( <b>DIBP</b> ) EC No: 201-553-2 CAS No: 84-69-5	Toxic for reproduction (category 1B)  Endocrine disrupting properties (Article 57(f) - human health)	(a) 21 August 2013 (b) By derogation of point (a): [18 months after entry into force] for uses in mixtures containing DIBP between 0,1% and 0,3% weight by weight	(a) 21 February 2015 (b) By derogation of point (a): [36 months after entry into force] for uses in mixtures containing DIBP between 0,1% and 0,3% weight by weight	-	-

(1) Date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006

(2) Date referred to in Article 58(1)(c)(i) of Regulation (EC) No 1907/2006

<sup>6</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1)

<sup>7</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)