7 February 2024

Draft Amendment of Annex XIV entries

(changes under consideration are marked in grey shade)

			Transitional arrangements			
Entry Nr.	**Substance**	**Intrinsic property(ies) referred to in Article 57**	**Latest application date[1]**	**Sunset date[2]**	**Exempted (categories of) uses**	**Review periods**
6.	Dibutyl phthalate (**DBP**) EC No: 201-557-4 CAS No: 84-74-2	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): 14 June 2023 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 DBP at or above 0,1 % and below 0,3% weight by weight. (c) By way of derogation from points (a) and (b): [18 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** or Regulation 2017/745 and Regulation 746/746;	(a) 21 February 2015 (**) (b) By derogation of point (a): 14 December 2024 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 DBP at or above 0,1 % and below 0,3 % weight by weight. (c) By derogation of points (a) and (b): [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** or Regulation 2017/745 and Regulation 746/746;		

(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

* Council Directives 90/385/EEC and 93/42/EEC have been repealed and are gradually replaced by the Medical Devices Regulation 2017/745 from 26 May 2021

** Council Directive 98/79/EC has been repealed and replaced by the In Vitro Diagnostic Medical Devices Regulation 2017/746 from 26 May 2022