



Brussels, **XXX**  
[...] (2014) **XXX** draft

ANNEX 1

**ANNEX**

**to the**

**Commission Delegated Directive**

**amending Annex II to Directive 2011/65/EU of the European Parliament and of the  
Council as regards the list of restricted substances**

## ANNEX

### ‘ANNEX II

#### **Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials**

Lead (0,1 %)

Mercury (0,1 %)

Cadmium (0,01 %)

Hexavalent chromium (0,1 %)

Polybrominated biphenyls (PBB) (0,1 %)

Polybrominated diphenyl ethers (PBDE) (0,1 %)

Bis (2-ethylhexyl) phthalate (DEHP) (0,1 %)

Butyl benzyl phthalate (BBP) (0,1 %)

Dibutyl phthalate (DBP) (0,1 %)

Diisobutyl phthalate (DIBP) (0,1 %)

The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.’