



EU – New amendment of plastic regulation (EU)10/2011

New COMMISSION REGULATION (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food has been published and become effective on January 31, 2019.

Highlights:

- > Replacing four substances and adding three completely new substances to the Union list of authorized substances (Table 1 to Annex I)
- > Adding one completely new entry for a group restriction of three substances. These are to be expressed as crotonic acid (Table 2 to Annex I)
- > Replacing the specification for 3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer (FCM substance no. 744) with a specific migration limit for crotonic acid
- > Replacing two rows on the use of food simulants for certain foods (Table 3 to Point 4 of Annex III):
 - > food simulant D1 will be used for all aqueous and alcoholic foods and milk products with a pH \geq 4.5;
 - > food simulant D1 and food simulant B will be used for all aqueous and alcoholic foods and milk products with a pH < 4.5



Should you have any queries or comments on Consumer Products, please contact your assigned ALS contact. Please find to the right the general hot line, email and website for your quick reference.

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EU – Four Phthalates added to RoHS

The European Commission published (EU) 2015/863 amending Annex II to Directive 2011/65/EU on the Restriction of certain Hazardous Substances (RoHS-Directive) bans certain chemicals from use in electrical or electronic equipment and will be effective on 22 July 2019.

(EU) 2011/65/EU prohibits the use of four heavy metals (Lead, Cadmium, Mercury and Hexavalent chromium), polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in electrical and electronic equipment placed on the Union market. The restriction of the use of these hazardous substances aiming to protect human health and environment. (EU) 2015/863 added four phthalates can be used as softener in plastic parts of E&E articles: Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP). Four added phthalates should not apply to toys and already restricted through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.

New list of restricted substances and limits:

Substance	Limit
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 will be effective on 22 July 2019 for all electrical and electronic equipment, except medical devices, including in vitro medical devices, and monitoring and control instruments, which can be placed on the market until 22 July 2021.

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