

## TÜV Rheinland LGA Products – Information

**03/2018**

### **Commission Regulation (EU) 2018/213: Changes in the limitation of Bisphenol A for Food Contact Materials**

On 12 February 2018 the European Commission adopted Commission Regulation (EU) 2018/213 which restructures the requirements on the use and on possible migration of Bisphenol A (BPA) from food contact materials.

In their latest statement on BPA the European Food Safety Authority (EFSA) concluded that the health concern for BPA is low at the estimated levels of exposure through dietary and non-dietary sources for all consumer groups including infants, children and adolescents. Nevertheless, the European Commission took preventive measures about the use of BPA based on the precautionary principle that is applicable in a situation in which there is scientific uncertainty, even if the risk, notably to human health, has not yet been fully demonstrated.

#### **Bisphenol A requirements for Plastic Materials**

Limitations on BPA for plastic materials will stay within Regulation (EU) No 10/2011 but they are changed.

- The Specific Migration Limit (SML) for BPA will be lowered to 0.05 mg/kg food or food simulant. This is by factor 12 lower than the present one.
- To serve the precautionary principle especially for infants and young children, the ban of BPA from polycarbonate infant feeding bottles will be extended to polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children.
- The conditions for issuing a Declaration of Conformity acc. to. Regulation (EU) No 10/2011 stay unchanged.

#### **Bisphenol A requirements for Varnished and Coated Materials**

In addition to its use in plastic food contact materials, BPA is widely used in epoxy resins for varnishes and coatings. Specific measures have not been adopted with regards to BPA in varnishes and coatings at union level yet. Several member states maintained or adopted national provisions on BPA in varnishes and coatings. Regulation (EU) 2018/213 lies down a harmonized restriction for BPA used in varnishes and coatings taking into account the contribution to dietary exposure of BPA from canned food due to the extensive use of BPA in epoxy resins for varnishes and coatings.

- The SML for BPA will be set to 0.05 mg/kg food or food simulant for general use articles.
- For materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children or milk-based drinks and similar products specifically intended for young children (as referred to in Regulation (EU) No 609/2013) no migration of BPA will be permitted. "No migration" refers to the definition in Article 11 of Regulation (EU) No 10/2011 and equals to lower than 0.01 mg/kg food or food simulant.
- Similar to the requirements for plastic materials business operators need to issue a written declaration of compliance containing the information laid down in Annex I of Regulation (EU) 2018/213 for varnished or coated materials containing BPA. The declaration shall be available at all stages of manufacture, processing and distribution other than the retail stage.

## Summary and Timeline on Bisphenol A requirements

	Current requirement on EU harmonized level	Regulation (EU) 2018/213 (Effective from 6th Sept 2018)
Plastic food contact materials – general use	SML 0.6 mg/kg food or food simulant	SML 0.05 mg/kg food or food simulant
Plastic food contact materials – used for infants and young children	Use of BPA banned for the manufacture of polycarbonate infant feeding bottles	Use of BPA banned for the manufacture of polycarbonate infant feeding bottles and for polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children
Varnished or coated food contact materials – general use	Regulation (EU) No 10/2011 not applicable	SML 0.05 mg/kg food or food simulant
Varnished or coated food contact materials for infant and young children food under Regulation (EU) No 609/2013	Regulation (EU) No 10/2011 not applicable	No detectable migration

The new regulation will apply from 6th September 2018.

Varnished or coated materials and articles and plastic materials and articles that were lawfully placed on the market before 6 September 2018 may remain on the market until exhaustion of stocks.

## References

- Commission Regulation (EU) 2018/213  
<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R0213>
- Regulation (EU) No 10/2011  
<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520413455627&uri=CELEX:32011R0010>
- Regulation (EU) No 609/2013  
<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520413555113&uri=CELEX:32013R0609>

**For further information please contact:**

TÜV Rheinland LGA Products GmbH  
Retail Technical Competence Center  
Dr. Ansgar Wennemer  
Am Grauen Stein  
51105 Köln

Tel. +49 221 806-2062  
Fax +49 221 806-2882  
[Wennemer@de.tuv.com](mailto:Wennemer@de.tuv.com)

**Disclaimer of Liability**

This information covers information of general nature without concrete connection to specific natural or legal persons, objects or circumstances. This information should not be considered a legal advisory and does in no case replace one. The TÜV Rheinland LGA Products GmbH (TRLP) cannot guarantee that the wording conforms to the corresponding official version. The TRLP puts every attempt into ensuring the correctness and actuality of the information provided; however errors and ambiguities can never be completely excluded. Therefore the TRLP does not assume liability for the actuality, correctness, completeness or quality of the information provided. For the official text please reference the Official Journal of the European Union. Liability claims against the TRLP, whether referring to material or non-material damages that result from the use or non-use of the presented information, or use of incorrect and incomplete information, are principally excluded.