

Commission Regulation (EU) 2023/1442 – 16th Amendment of Plastic Food Contact Materials Regulation

TÜV Rheinland Products - Information

July 2023

Several amendments have been made to Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food since its introduction. On July 12th, 2023, the European Commission published the 16th amendment, Commission Regulation (EU) 2023/1442, amending the Union list of authorized substances that may be intentionally used in the manufacture of plastic food contact materials (Table 1) and Group restriction of substances (Table 2) under Annex I of EU No 10/2011. This amendment will enter into force on August 1st, 2023. The main changes related to this amendment will be explained below.

REVOKE THE AUTHORIZATION OF WOOD FLOUR AND FIBERS, UNTREATED (FCM NO 96)

The substance 'wood flour and fibres, untreated' (FCM No 96) is authorised to be used as an additive (filler) in the manufacture of plastic food contact materials. It is based on a rather old assessment by the Scientific Committee on Food, which concluded that wood flour and fibres are an inert material. However, based on an updated scientific opinion, it could not validate the grounds for that conclusion due to the many low molecular weight substances it may contain and potentially can migrate out. As the use of this substance cannot rule out the safety risk anymore with Article 3 of Regulation (EC) No 1935/2004, the authorisation should be revoked. Though, wood flour and fibres still can be used upon a valid application. Due to the fact that the chemical differences in the composition of plant materials, the safety of migrants from these materials must be evaluated on a case-by-case basis.

UPDATE SPECIFIC MIGRATION LIMIT (SML) AND GROUP RESTRICTION FOR PHTHALATES

Phthalic acid, dibutyl ester (FCM No 157, 'DBP'), phthalic acid, benzyl butyl ester (FCM No 159, 'BBP'), phthalic acid, bis(2-ethylhexyl) ester (FCM No 283, 'DEHP') and phthalic acid, diesters with primary, saturated C₈-C₁₀ branched alcohols, more than 60 % C₉ (FCM No 728, 'DINP')) are some common phthalates that are authorized to be used in the manufacture of plastic food contact materials. Based on the latest scientific opinion, individual SMLs and SML(T)s of these substances should be updated. A comparison table is shown below:

FCM No	Substance	16 th amendment (new)			Until July 31 st 2023		
		SML (mg/kg)	SML(T) Group No	SML(T) (mg/kg)	SML (mg/kg)	SML(T) Group No	SML(T) (mg/kg)
157	DBP	0.12	32	60	0.3	32	60
			36	0.6			
159	BBP	6	32	60	30	32	60
			36	0.6			
283	DEHP	0.6	32	60	1.5	32	60
			36	0.6			
728	DINP	No SML	26	1.8	No SML	26	9
			32	60		32	60
1085*	DIBP	Not listed	32	60			
			36	0.6			

NOTE:

* Diisobutyl phthalate (FCM No 1085, 'DIBP') with CAS number 84-69-5 is not listed as an authorised substance in Table 1 of Annex I. However, it may co-occur with other phthalates as a consequence of its use as an aid to polymerisation and is included in group restrictions with the assignment FCM No 1085.

OTHER CHANGES RELATED TO THIS AMENDMENT

- Revoke the authorization of salicylic acid (FCM No 121)
- 5 new entries. (FCM No 1078, 1080, 1081, 1082 and 1083) are added in Table 1 of Annex I
- 3 new entries (Group Restriction No 36, 37 and 38) are added in Table 2 of Annex I

TRANSITIONAL PERIOD

This amendment will enter into force on August 1st, 2023 with the following transitional measures:

- Plastic materials and articles complying with EU No 10/2011 before the entry into force of this amendment, which were first placed on the market before February 1st, 2025 may remain on the market until the exhaustion of stocks.
- For product or substance from intermediate manufacturing stage, which complies with EU No 10/2011 before the entry into force of this amendment and which is first placed on the market after May 1st, 2024 does not yet comply with this amendment, the operator shall provide a declaration of compliance indicating that product or substance does not comply with the present rules and can only be used in the manufacture of plastic materials and articles to be placed on the market before February 1st, 2025.

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- Plastic materials and articles manufactured with salicylic acid or with untreated wood flour or fibers from a specific wood species may continue to be first placed on the market after February 1st, 2025 with a valid application.

Further information on current legal changes can also be found on our homepage at www.tuv.com or <https://www.tuv.com/regulations-and-standards/en/>.

Further technical information can be obtained from:

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