



Focus: EU publishes 16th amendment (EU) 2023/1442 to Regulation (EU) 10/2011 on plastics in food contact material

On January 23, 2023, the European Union submitted to the WTO Circular G/SPS/N/EU/611, proposing to amend the contents of Table 1 (Union list), Table 2 (Group restriction of substances) and Table 3 (Notes on verification of compliance) in Annex I of the Food Contact Plastic Materials Regulation (EU) 10/2011. The proposed date of adoption of the draft regulation is March 31, 2023, and the proposed date of publish is April 3, 2023.

On July 12, 2023, the European Commission formally published the 16th amendment to Regulation (EU) 2023/1442 on plastics in food contact (EU) 10/2011 in the Official Journal of the European Union (OJ L 177, July 12, 2023, p. 45-58). It amends parts of Table 1 to Table 3 of Annex I of (EU) 10/2011, the amendments are basically the same as the draft (see HCT-202302-02), the main substances involved include: salicylic acid, untreated wood flour and fibers, o-toluene plasticizers, triethanolamine, perchlorate, antioxidant 1222 and so on. The new regulation will take effect in 20 days (August 1, 2023).

➤ The main revisions are as follows:

1. Revoke the authorization of FCM substance No. 96 (untreated wood flour and wood fiber) and FCM substance No. 121 (salicylic acid) (since then, there is only the authorization of FCM plant fiber substance No. 1060 "ground Sunflower seed hulls").

2. Strict requirements for o-benzene Plasticizer (DAP migration limit remains unchanged):

- ◆ The DBP migration limit has been reduced from 0.3mg/kg to 0.12mg/kg;
- ◆ The BBP migration limit has been reduced from 30mg/kg to 6mg/kg;
- ◆ The DEHP migration limit has been reduced from 1.5mg/kg to 0.6mg/kg;
- ◆ The migration limit values of DIDP and DINP * (Group 26 SML (T)) were reduced from 9mg/kg to 1.8mg/kg;

The sum of DBP, DIBP, BBP, and DEHP is the 36th group SML (T), and is expressed as the equivalent of DEHP by the following equation: the limit value of $DBP * 5 + DIBP * 4 + BBP * 0.1 + DEHP * 1$ is SML (T): 0.6mg/kg;

*DINP shall not be used in combination with FCM No.157, 159, 283, or 1085, also known as DBP/BBP/DEHP/DIBP.

3. The limit SML (T) of the 37th group of substances composed of Triethanolamine (CAS No. 102-71-6) and the dimer of FCM substance 1080 (Triethanolamine Perchloric acid sodium salt) (CAS No. 156157-97-0) is 0.05mg/kg, calculated as the sum of Triethanolamine and hydrochloride adducts;

4. Perchloric acid and its salt and the dimer of No. 1080 FCM substance (Triethanolamine - Perchloric acid sodium salt) (CAS No. 156157-97-0) constitute the 38th group of substances, with the limit of SML (T): 0.002mg/kg, calculated as Perchlorate (and in accordance with the requirements of point 4 of Table 3 in Annex I of EU 10/2011);

5. Group 7 substance SML (T) was added to FCM substance 1081 (N, N-bis (2-hydroxyethyl) stearamine partially esterified by saturated C16/C18 fatty acids), while Group 32 substance SML (T) was added to FCM substance 1078 (CAS No.3319-31-1) and FCM substance 1085 (DIBP);

6. Appendix I, Table 3, added Article 30 for the verification of compliance with FCM substance No. 1081;

7. In addition to the above six points, several authorized substances have also been revised accordingly, such as antioxidant 1222 (CAS No. 976-56-7), PHBH (CAS No. 147398-31-0), Phosphorous acid, triphenyl ester α - Several substances, including hydrogen omega hydroxy poly [oxygen (methyl-1,2-ethyl)] C10-16 alkyl ester polymer (FCM number 1076 substance), have been revised.



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➤ The transitional measures are as follows:

1. Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, which were first placed on the market before 1 February 2025 may remain on the market until the exhaustion of stocks.
2. In case a product from an intermediate stage of the manufacturing of plastic materials and articles or a substance intended for the manufacturing of such a product, material or article, which complies with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation and which is first placed on the market after 1 May 2024 does not comply with this Regulation, the declaration of compliance available for that substance or product shall indicate that it does not comply with the present rules, and that it can only be used in the manufacture of plastic materials and articles to be placed on the market before 1 February 2025.
3. Plastic materials and articles manufactured with salicylic acid (FCM No 121) or manufactured with untreated wood flour or fibres from a specific wood species may continue to be first placed on the market after 1 February 2025 provided that the following conditions are fulfilled:
 - (a) an application for the authorisation of that substance or of that untreated wood flour or fibre from a specific wood species has been submitted to the competent authority in accordance with Article 9 of Regulation (EC) No 1935/2004 before 1 August 2024;
 - (b) the use of that substance or of that untreated flour or fibre from a specific wood species to manufacture a plastic material and article, and the use thereof, is limited to the intended conditions of use described in the application;
 - (c) the information provided to the Authority in accordance with Article 9(1)(b) of Regulation (EC) No 1935/2004 includes a statement that the application is an application in accordance with this paragraph; and
 - (d) the Authority has considered the application valid.

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Original link : [\(EU\) 2023/1442](#)

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