



主题：欧盟食品接触塑料材料和制品法规（EU）10/2011 修订重金属迁移限量

日期：2016-08-28

摘要：2016年8月25日，欧盟官方公报发布法规(EU)2016/1416，修订欧盟食品接触塑料材料及物品法规(EU)10/2011 中重金属的迁移限量，对许用物质列表进行了调整和新增，并调整了全面迁移和特殊迁移的测试条件。

2016年8月25日，欧盟官方公报发布法规(EU)2016/1416，修订欧盟食品接触塑料材料及物品法规(EU)10/2011 中重金属的迁移限量，对许用物质列表进行了调整和新增，并调整了全面迁移和特殊迁移的测试条件。

自(EU)10/2011 法规采纳以来，欧盟食品安全署(EFSA)对于食品接触材料的物质进行了进一步的研究，并发布了最新的物质报告。此外该法规还有部分用词错误或比较模糊，为使法规与最新科学观点一致，消除困惑，欧盟委员会决定对该法案进行修订和更正。

物质限制修订：

1	许用物质清单调整了某些物质的限制及规范。 新增编号为 871、1031、1034、1045、1046、1048、1050、1051、1052、1053 等许用物质及其要求。
2	修订了特殊迁移限量 (SML)。 新增对重金属铝的 SML 要求：每千克食品或食品模拟物中铝迁移不得超过 1 mg/kg； 重金属锌的 SML 修订：由之前的 25mg/kg 调整至 5mg/kg。
3	调整了对初级芳香胺物质的要求。 除 (EU) 10/2011 附件 I 表 1 中许用的初级芳香胺之外，其他的初级芳香胺物质不得检出，初级芳香胺总量检出限仍为 0.01mg/kg 不变。同时，除非有特殊规定，否则 0.01mg/kg 的检出限适用于所有要求不得检出的物质或物质类型。
4	删除附件 I 中未给出明确 SML 的所有物质的通用特殊迁移限量 60mg/kg。

测试方面修订：

1	修订了食品模拟物限制条件。 对于食品模拟物 D2，对原来的植物油进一步限制条件，要求作为食品模拟物的植物油中非皂化物质含量少于 1%。
2	变更部分食品的食品模拟物。 同时严格区分在迁移测试中食品模拟物 D1 和 D2 的应用场景。
3	新增测试温度要求。 测试温度新增 175°C < T < 200°C 以及 T > 200°C 两个梯度的要求。
4	修订了全面迁移 OM2 和 OM3 的测试条件。 新增“热灌装”概念。规定了在此种情况下测试时间与测试温度及接触温度的关系。 $t_2 = t_1 * \text{Exp}(9627 * (1/T_2 - 1/T_1))$

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除此之外，(EU) 2016/1416 还重新定义了“非脂肪物质”“技术参数”等概念。

希科检测提醒，(EU) 2016/1416 将在 OJ 发布后第 20 天生效，但是作为过渡，在此之前适用(EU) No 10/2011 的塑料材料和物品，2017 年 9 月 14 日前仍可继续投放市场，直至库存清空。此外，关于重金属铝迁移和锌迁移的修订以及部分食品的食品模拟物的调整于 2018 年 9 月 14 日起开始实施，相关企业需注意应对。

相关链接：

[欧盟官方公报 \(EU\) 2016/1416](#)

[English](#)

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Title: EU amends food contact plastic and articles regulation

Date: 28 August 2016

Abstract: On 25 August 2016, EU released Regulation (EU) 2016/1416 to amend Regulation (EU) 10/2011 on plastic materials and articles that intended to come into direct contact with food as regards specific migration limits of heavy metals, union list of authorised substances, test methods for overall and specific migration.

On 25 August 2016, EU released Regulation (EU) 2016/1416 to amend Regulation (EU) 10/2011 on plastic materials and articles that intended to come into direct contact with food as regards specific migration limits of heavy metals, union list of authorised substances, test methods for overall and specific migration.

Since the Regulation's adoption, the European Food Safety Authority ('the Authority') has published further reports on particular substances that may be used in food contact materials as well as on the permitted use of substances that have been authorised previously. In addition, certain textual errors and ambiguities were identified. In order to ensure that the Regulation reflects the most recent findings of the Authority and in order to remove any doubt as regards its correct application, the Regulation should be amended and corrected.

Revisions on limits

1.	Adjust on union list of some authorised substances under Annex I Add requirements on FCM Nos. 871, 1031, 1034, 1045, 1046, 1048, 1050, 1051, 1052, 1053
2.	Revise specific migration limits (SMLs) Aluminium = 1 mg/kg food or food stimulant (new) Zinc = 5 mg/kg food or food simulant. (previous: 25 mg/kg)
3.	Amend primary aromatic amines Primary aromatic amines which are not listed in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant in accordance with Article 11(4). The detection limit (0,01 mg/kg) referred to in the second subparagraph of Article 11(4) applies to the sum of primary aromatic amines released.
4	Delete the provision "For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply." in Annex I.

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Revisions on selection of testing conditions

1.	<p>Revise conditions for food simulants</p> <p>For food simulant D2, the food stimulant has been changed as “Any vegetable oil containing less than 1 % unsaponifiable matter”</p>
2.	<p>Some food simulants are changed</p> <p>Since the Regulation distinguishes between food simulants D1 and D2, the references to food simulant D should be replaced by more specific references to food simulant D1 or D2 for all substances.</p>
3.	<p>New selections of test temperatures</p> <p>New requirements for 175°C<T<200°C and T>200°C</p>
4.	<p>Amend testing conditions of overall migration (OM2, OM3)</p> <p>A definition of the term ‘hot-fill’ is provided to specify the temperatures at which such restrictions apply.</p> $t_2 = t_1 * \text{Exp} (9627 * (1/T_2 - 1/T_1))$

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, may be placed on the market until 14 September 2017 and may remain on the market until exhaustion of stocks. The provisions on the specific migration limits for aluminium and for zinc set out in point 2(a) of the Annex and the assignments of food simulants in point 3(c) of the Annex shall apply from 14 September 2018. C&K Testing advises businesses to deal with due care.

Further information

[Regulation \(EU\) 2016/141](#)

[中文阅读](#)

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