

Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.

欧盟法规 10/2011 食品接触塑料及容器

New EU Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food was published on 2011 Jan 15. This new regulation starts to effect on 2011 May 1. It repeals Commission Directive 2002/72/EC. There are several transitional provisions and are summarized in Table 1.

最新欧盟法规 10/2011 食品接触塑料及容器已于 2011 年 1 月 15 日发行，于 2011 年 5 月 1 日生效，亦废除了之前 2002/72/EC 欧盟指令，列表 1 总括了新法规及其有关证明文件之过渡转变。

Table 1 列表 1

Date (日期)	Transitional Provisions 实施阶段
Until 2012 Dec. 31 2012 年 12 月 31 日或之前	It may accept to place the following on the market 允许以下食品接触塑料投放在市场  - the food contact materials and articles which have been lawfully placed on the market before 2011 May 1 - 在 2011 年 5 月 1 日前已投放在市场而又符合当时法规之食品接触塑料
Date (日期)	FCM supporting documents transitional provisions 有关证明文件 ' 实施阶段
Until 2012 Dec. 31 2012 年 12 月 31 日或之前	Supporting documents shall be based on the basic rules for overall migration and specific migration testing set out in the Annex to Directive 82/711/EEC 有关证明文件是根据 82/711/EEC 附录之原则作全面迁移和特殊迁移测试
From 2013 Jan. 1 to 2015 Dec. 31 2013 年 1 月 1 日 - 2015 年 12 月 31 日	Supporting document for materials, articles and substances placed on the market may be based on either the new migration rules stated in Regulation (EU) No. 10/2011 or the rules set out in Annex to Directive 82/711/EEC 有关证明文件是根据欧盟新法规 10/2011 或 82/711/EEC 附录之原则作全面迁移和特殊迁移测试
From 2016 Jan 1 2016 年 1 月 1 日	Supporting documents shall be based on the rules for migration testing set out in Regulation (EU) No. 10/2011 有关证明文件是根据欧盟新法规 10/2011 之原则作全面迁移和特殊迁移测试

Note:  
1. Content of the support document refers to Table 2, D  
有关证明文件之内容，可参考列表 2，D 项

Table 2 列表 2

<div>A. Scope</div> <div>法规涵盖范围</div>	<div><div>1. Material and articles and parts thereof consisting exclusively of plastics 材料和容器及其部件组成的塑料</div><div>2. Plastic multi-layer materials and articles held together by adhesives or by other means 多层复合物料和物品以及粘合或其他方式组合一起的塑料</div><div>3. Materials and articles referred to in pointed 1 &amp; 2 that are printed and/or covered by a coating 带有印刷或涂层的以上两种材料或物品</div><div>4. Plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closure compose a set of two or more layers of different types of materials 塑料薄膜或塑料涂层，成型于盖子或其他密封物品内，由两种或多种不同材料连同盖子或密封物品组成的材料</div><div>5. Plastic layers in multi-material multi-layer materials and articles 多层复合材料或容器中的塑料</div></div>
<div>B. Exemption</div> <div>法规不含盖范围</div>	<div><div>1. Ion exchange resin 离子交换树脂</div><div>2. Rubber 橡胶</div><div>3. Silicones 硅胶</div></div>
<div>C. Substances behind functional barrier and nanoparticles</div> <div>被具有功能性障碍物阻隔的物质及纳米材料</div>	<div><div>Substances behind a functional barrier<sup>2</sup> 被具有功能性障碍物阻隔的物质<sup>2</sup></div><div><div>1. May be manufactured with substances not listed in the Union list 可被不列在此法规“授权物质清单表”之物质所制造</div><div>2. Shall comply with the restriction for vinyl chloride monomer Annex I (SML: Not detected, 1 mg/kg in finish product) 需符合附录1氯乙烯单体之要求 (特殊迁移含量: 不能驗出，总含量1 毫克/千克在製成品中)</div><div>3. Non-authorized substances may be used with a maximum level of 0.01 mg/kg in food 未被授权的物质使用的最大限量是0.01 毫克/千克食品或食品模拟物</div><div>4. Shall not belong to substances that are mutagenic, carcinogenic or toxic to reproduction without previous authorization 不能属于致癌，致畸或致生殖毒变的未授权的物质</div><div>5. Shall not belong to nanoform 不能属于纳米种类</div></div><div><div>Nanoparticles: 纳米材料:</div><div><div>1. Should be assessed on a case-by-case basis as regards their risk until more information is known 纳米材料根据其风险和具体情况来评估，直到有新的技术信息</div><div>2. Substances in nanoform shall only be used if explicitly authorized and mentioned in Annex I 只有授权及列明于附录1之纳米种类才可用</div></div></div></div>
<div>D. Supporting Documents</div> <div>有关证明文件</div>	<div><div>1. shall contain the conditions and results of testing, calculations, modelling, other analysis and evidence on the safety or reasoning demonstrating compliance 需包括测试条件及结果，计算，原型，其他分析的证据证明符合安全</div><div>2. shall be made available by the business operator to the national competent authorities on request 有需要时需由经营者提供给国家当局</div></div>

E. Overall migration & Specific Migration Limit  全面迁移和特殊迁移 限值	1. Overall Migration 全面迁移 - 10mg/dm² 10 毫克/平方分米 - 60mg/kg 60 毫克/千克  2. Specific Migration (Refer to Annex I Union List - When there is no specific migration limit or other restrictions are provided, a generic specific migration limit of 60 mg/kg shall apply) 特殊迁移(参考物质清单附录1 - 当没有提供特殊迁移限值或其他限制通常使用60mg/kg 的特殊迁移限值)
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Union List 附录

Annex I --Monomer and Additive  
附录 1——授权物质清单表

ANNEX I Contains 附录 1 包括:
1. Monomers or other starting substances 单体或其他初始物质
2. Additives excluding colorants 添加剂，不包括着色剂
3. Polymer production aids excluding solvents 生产助剂，不包括溶剂
4. Macromolecules obtained from microbial fermentation 微生物发酵生成的高分子
5. 885 authorized substances 885种授权物质

Annex II--General restriction on materials & Articles  
附录 2——材料和物品基本限值

Specific Migration of Heavy metal (mg/kg food or food simulant) 重金属特殊迁移(毫克/千克 食品或食品模拟物)
1. Barium (钡) = 1                      2. Cobalt (钴)= 0.05                      3. Copper (铜)= 5                      4. Iron (铁) = 48
5. Lithium (锂)= 0.6                      6. Manganese (锰)= 0.6                      7. Zinc (锌)= 25
Specific Migration of Primary Aromatic Amines (sum), Detection limit 0.01mg of substance per kg of food or food stimulant 初级芳香胺总和特殊迁移，检出上限为0.01毫克/千克食品或食品模拟物

Annex III-Food Simulants

附录3——食品模拟物

Food Simulants (食品模拟物)	Abbreviations (缩写)	Food Type (食物类型)
10% Ethanol (10%乙醇) Remark: Distilled water may be selected for some instances 备注: 在一些特别情况下可选择蒸馏水	Food Simulant A	food with hydrophilic character (水性食物)
3% Acetic Acid (3%醋酸)	Food Simulant B	acidic food (酸性食物)
20% Ethanol (20%乙醇)	Food Simulant C	food up to 20% alcoholic content (食品含有不多於 20%乙醇)
50% Ethanol (50%乙醇)	Food Simulant D1	food containing > 20% alcohol content (食品含有超过 20%乙醇) milk product (牛奶制品) food with oil in water (水包油食品)
Vegetable Oil (植物油)	Food Simulant D2	food have lipophilic character, free fats (油性食物)
Poly(2,6-diphenyl-p-phenyleneoxide), particle size 60-80mesh, pore size 200nm (聚 2,6-二苯基苯乙烷: 60-80 目,200nm)	Food Simulant E	dry food (干性食物)

Annex IV- Declaration of compliance (DOC)

附录4——遵守声明 (DOC)

<div>1. shall be issued by the business operator and shall contain the information in as in ANNEX IV<sup>3</sup> 由经营者提供，其内容可根据附录4<sup>3</sup>作参考</div> <div>2. at the marketing stages other than at the retail stage, DOC shall be available for plastics materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing 于销售其间提供，遵守声明需提供产品/器皿/物品制造的中间的阶段及蓄意用作生产中的物质资料</div> <div>3. Shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued 对产品制造的中间阶段的材料，物品或产品，允许提供简单的证明</div> <div>4. - The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request 物质的生产商需要知道其成分，如果有需要还需提供给国家当局</div>
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## Annex V -Testing Condition

### 附录5——测试条件

#### Testing condition for Overall Migration/Specific Migration 全面迁移/特殊迁移测试条件

Test No.	Contact time in days (d) or hour(h) at contact temperature in °C 测试温度和时间	Intended food contact conditions 接触食品的条件
OM1	10d at 20°C 20 度 10 天	Any food contact at frozen and refrigerated conditions 冷冻和冷藏
OM2	10d at 40°C 40 度 10 天	Any long term storage at room temperature or below, including heating up to 70°C for up to 2 hours, or heating up to 100°C for up to 15 minutes 于 70 度 2 小时或 100 度 15 分钟加热后，再长时间保存于室温或以下
OM3	2h at 70°C 70 度 2 小时	Any contact conditions that include heating up to 70°C for up to 2 hours, or up to 100°C for up to 15minutes, which are not followed by long term room or refrigerated temperature storage. 于 70 度 2 小时或 100 度 15 分钟加热后，不再长时间保存于室温或冷冻条件下
OM4	1h at 100°C 100 度 1 小时	High temperature applications for all food stimulants at temperature up to 100°C 温度达到 100 度
OM5	2h at 100°C or at reflux/alternatively 1 h at 121°C 水浴加热回流或 100 度 2 小时 / 121 度 1 小时	High temperature application up to 121°C 温度达到 121 度
OM6	4h at 100°C or at reflux 100 度或水浴加热回流 4 小时	Any food contact conditions with food stimulants A, B or C, at temperature exceeding 40°C 高于 40 度的任何食品接触条件，只限于食品模拟物 A,B,C <b>Remark: It represents the worst case conditions for all food simulants in contact with polyolefins</b> 备注：水性模拟物最严格条件，针对非聚烯烃材料
OM7	2h at 175°C 175 度 2 小时	High temperature applications with fatty foods exceeding the conditions of OM5 油性食物温度超过 121 度 <b>Remark: In case it is technically NOT feasible to perform OM7 with food simulant D2 the test can be replaced by test OM 8 or OM9</b> 备注: 如果技术上无法使用 D2 进行 OM7 测试，可用 OM8 或 OM9 代替
OM8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C 食品模拟物E，175度2小时，食品模拟物D2，100度2小时	High temperature applications only 高温条件 <b>Remark: When it is technically NOT feasible to perform OM7 with food simulant D2</b> 备注: 当技术上无法使用D2进行OM7测试时
OM9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C 食品模拟物E，175度2小时，食品模拟物D2，40度10天	High temperature applications including long term storage at room temperature 高温条件，并常温下长期保存 <b>Remark: When it is technically NOT feasible to perform OM7 with food simulant D2</b> 备注: 当技术上无法使用D2进行OM7测试时

#### Note:

1. Functional barrier is a layer within food contact materials or articles preventing the migration of substances from behind that barrier into the food.  
具有功能性障碍物是一层防止从功能性障碍物后面迁移到食物的障碍

2. For details of the DOC content, please refer to ANNEX IV of Regulation (EC) No. 10/2011.

有關DOC所需之詳情，請瀏覽歐盟新法規10/2011，附录4

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>

## Repeal of EU directive

### 废除的欧盟指令

1. 80/766/EEC, Commission Directive method of analysis for the official control of the vinyl chloride monomer level in material contact with food  
[80/766/EEC 指令，食品接触材料中氯乙烯单体的测试方法](#)
2. 81/432/EEC, Commission Directive method of analysis for the official control of the vinyl chloride release by material and article into foodstuffs  
[81/432/EEC 指令，食品接触材料中氯乙烯迁移的测试方法](#)
3. 2002/72/EC, Commission Directive relating to plastic materials and article for foodstuffs  
[2002/72/EC指令，食品接触塑料的指令](#)