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REGULATIONS & LAWS, RECALL CASES STUDY



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编辑团队联系方式

Dennis Zhang

电话: 021-53396292

邮箱: dennis.zhang@intertek.com

网址: www.intertek.com.cn



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PART1 Children products 儿童产品

1. Vermont/USA - Approved to Amend Chemicals of High Concern in Children's Products Rule (9/2/2020)

美国佛蒙特州-批准修订儿童产品高度关注化学物质申报规则

The Vermont Department of Health has approved to amend the Chemicals of High Concern in Children's Products Rule (Code of Vermont Rules CVR 13-140-077). The amendment shall be effective from 1 September 2020. The amendment is summarized as follows:

美国佛蒙特州卫生部已批准修订儿童产品高度关注化学物质申报规则（佛蒙特州规则 CVR 13-140-077），并于 2020 年 9 月 1 日起生效。该修订的要点如下：

- 1) The listed chemical "formaldehyde" shall include substances that are intentionally added to release formaldehyde, including
所列化学物质“甲醛”应包括故意添加以释放甲醛的物质，包括：
 - A. 5-Bromo-5-nitro-1,3-dioxane (5-溴-5-硝基-1,3-二恶烷)
 - B. Bronopol (溴硝丙二醇)
 - C. Diazolidinyl urea (重氮烷基脲)
 - D. DMDM hydantoin (DMDM 乙内酰脲)
 - E. Imidazolidinyl urea (咪唑烷基脲)
 - F. Methanol, (phenylmethoxy) ((苯基甲氧基)甲醇)
 - G. Methenamine (六亚甲基四胺)
 - H. Quaternium-15 (季铵盐-15)
 - I. Sodium N-(hydroxymethyl)glycinate (N-羟甲基甘氨酸钠)



- 2) The reporting deadline shall be adjusted to 31 January of each year, starting from 2022. According to the previous rules, this year's deadline has just passed on 31 August. The next deadline will be 31 January 2022 due to the rule amendment.

申报的截止日期从 2022 年开始调整为每年的 1 月 31 日。根据以前的规则，今年的申报截止日期是 8 月 31 日。由于规则修订，下一个截止日期是 2022 年 1 月 31 日。

- 3) For any children's products that are introduced for sale or distribution between 31 January and 31 July of a year, the manufacturer shall report the products containing Chemicals of High Concern on or before 31 July of the same year.

对于在一年的 1 月 31 日至 7 月 31 日之间销售或分销的任何儿童产品，制造商应在同年 7 月 31 日或之前申报含有高度关注化学物质的产品。

2. United Arab Emirates - Approved Control Scheme for Child Care Articles (9/11/2020)

阿拉伯联合酋长国-批准儿童护理用品管制方案

United Arab Emirates (UAE) has published Cabinet Decision No. 34 of 2019 on UAE Control Scheme for Child Care Articles. This Decision has been effective. Here are the highlights:

阿拉伯联合酋长国 (UAE) 就儿童护理用品管制方案发布 2019 第 34 号内阁决议，该决议已生效。以下是重点内容：



1) Scope 范围

This control scheme applies to the products listed in the attached tables, whether the products are traded in the UAE's markets or intended for export.

该管制方案适用于下表中列出的产品，无论这些产品是在阿联酋市场上交易还是用于出口。

Table 1:

	Number of the standard 标准号	The approved standard specification 已批准的标准规范
1	UAE.S/GSO 2079	Babies elastomeric feeding bottle teats 婴儿弹性奶嘴
2	UAE.S/GSO 2015	Soothers for babies and young children - Part 1: General safety requirements 婴幼儿安抚奶嘴-第 1 部分:通用安全要求
3	UAE.S/GSO 2016	Soothers for babies and young children - Part 2: Chemical requirements and tests 婴幼儿安抚奶嘴-第 2 部分:化学要求和测试
4	UAE.S/GSO 2073	Soothers for babies and young children - Part 3: Physical requirements 婴幼儿安抚奶嘴-第 3 部分:物理要求
5	UAE.S/GSO 2074	Soothers for babies and young children - Part 4: Test methods for physical requirements 婴幼儿安抚奶嘴-第 4 部分:物理要求的测试方法



6	UAE.S/GSO 2164	Child use and care articles- Drinking equipment - Part 1: General and physical requirements 儿童使用和护理用品-饮具-第 1 部分:通用和物理要求
7	UAE.S/GSO 2168	Child use and care articles - Drinking equipment - Part 2: Test methods of general and physical requirements 儿童使用和护理用品-饮具-第 2 部分:通用和物理要求的 测试方法
8	UAE.S/GSO 2163	Child use and care articles - Drinking equipment - Part 3: Chemical requirements 儿童使用和护理用品-饮具-第 3 部分:化学要求
9	UAE.S/GSO 2167	Child use and care articles - Drinking equipment - Part 4: Test methods of chemical requirements 儿童使用和护理用品-饮具-第 4 部分:化学要求的测试方 法
10	UAE.S/GSO 1833	Single Use Disposable Baby Diapers 一次性婴儿尿布
11	UAE.S/GSO 839	Food Packages - Part 1: General Requirements 食品包装-第 1 部分:通用要求
12	UAE.S/GSO 1863	Food packages - Part 2: Plastic package - General - requirements 食品包装-第 2 部分:塑料包装的通用要求
13	UAE.S/GSO 2231	General Requirements for the materials intended to come into contact with food 食品接触材料的通用要求



Table 2 :

Number of the standard 标准号	Reference standard 参考标准
EN 14372	Child use and care articles. Cutlery and feeding utensils. Safety requirements and tests 儿童使用和护理用品-儿童餐具和喂食用具的安全要求和测试方法

2) Supplier Obligation 供应商义务

The supplier shall comply with the following at any stage of the supply chain:
 供应商在供应链的任何阶段均应遵守以下规定：

- A. Carry out the activity through a registered individual company or enterprise that is also licensed in accordance with relevant legislations.
 通过注册的个体公司或企业进行交易活动，该个体公司或企业需要获得相关法律许可；
- B. Obtain a Certificate of Conformity for the product before it is put on the market, according to the ECAS and the Conformity Assessment Form B.
 根据 ECAS(阿联酋合格评定计划)和合格评定类型 B，在产品投放市场之前，需要获得合格证书；
- C. Cooperate with the Authority (ESMA)'s staff and the competent entities and provide the required documents including test reports, upon request.
 与 ESMA（阿联酋标准化与计量局）的工作人员和主管实体合作，并根据要求提供所需的文件，包括测试报告；
- D. Ensure that the product meets the requirements of this scheme.
 确保产品符合此方案的要求；



- E. Comply with the conformity verification procedures mentioned in this scheme.

遵守此方案中提到的合格验证程序；

- F. Submit all the technical documents, certificates, and all data and information that confirm the product's compliance with the requirements of this scheme.

提交所有能够确认产品符合此方案要求的技术文件、证书以及所有数据和信息；

- G. Any other obligations determined by ESMA in coordination with the competent entity.

ESMA（阿联酋标准化与计量局）与主管机构协调确定的其他义务。

3) Technical requirements 技术要求

For the product prepared offering or trading within UAE, supplier shall ensure that the product meets the technical and labelling requirements of the standards as listed in the two tables, moreover, the following shall be fulfilled:

对于在阿联酋境内准备交易的产品，供应商应确保该产品满足以上两个表格中所列标准的技术和标签要求，此外，还应满足以下要求：

- A. Pictures and expressions used on the package shall not be contrary to the public order, public morals and Islamic values prevailing in the UAE.

包装上使用的任何图片和表述不得与阿联酋普遍存在的公共秩序、公共道德和伊斯兰价值观相抵触；

- B. All the information used in the labelling shall be correct and scientifically and laboratory proven.

标签上使用的所有信息均应正确、有理有据并经过实验室验证。



3. Korea - Approved Amendments to Standards for Snow Board for Children (Annex 9) and Snow-skis and other Snow-skis Equipment for Children (Annex 8) under Suppliers Conformity Confirmation System (9/4/2020)

韩国 - 批准对供应商一致性确认系统中关于儿童滑雪板（附件 9）和儿童滑雪板和其他滑雪板设备标准（附件 8）的修正案

The Korean Ministry of Trade, Industry and Energy (MOTIE) has issued Notice No. 2020-141 to approve and adopt the whole amendments on the Standards for Snow Board for Children (Annex 9) and Snow-skis and other Snow-ski Equipment for Children (Annex 8) under Suppliers Conformity Confirmation System as informed previously. This notice will be effective from 25th Feb 2021.

韩国贸易、工业和能源部（MOTIE）发布第 2020-141 号通告，批准并通过供应商符合性确认系统中关于儿童滑雪板（附件 9）和儿童滑雪板及其他滑雪设备（附件 8）标准的全部修正案。本通告自 2021 年 2 月 25 日起生效。



4. Philippines - Approved New Technical Regulation for Child Restraint Systems (9/16/2020)

菲律宾-批准儿童约束系统新技术法规

The Philippines' Department of Trade and Industry (DTI) has published Administrative Order No. 20-03 on new mandatory certification requirements for child restraint systems. The Order shall take effect 15 days after its publication in a national newspaper of general circulation.

菲律宾工业贸易部（DTI）公布了关于儿童约束系统新的强制性认证要求的第 20-03 号行政令。该行政令应在全国性流通的报纸上刊登 15 天后生效。

1) Scope 范围

The Order shall cover the following types of child restraint systems:
行政令涵盖以下类型的儿童约束系统：

- A. Lateral facing (carry cot) 侧向（手提式摇篮）
- B. Rearward facing 后向
- C. Forward facing 前向
- D. Combination (rearward/forward facing) 组合（向后/向前）
- E. Booster cushion/seat 垫高垫/座椅
- F. Other types for similar purposes 其他类似用途的产品类型



2) Test requirements 测试要求

A. Product testing shall be conducted by a BPS-recognized testing laboratory, which includes but not limited to:

产品测试应由 BPS 认可的测试实验室进行，包括但不限于：

- ✓ Laboratory accredited by the Philippine Accreditation Bureau
菲律宾认证局认可的实验室
- ✓ Laboratory recognized by the Bureau of Philippine Standards (BPS) under the ASEAN Mutual Recognition Arrangement (MRA), APEC MRA and other regional and bilateral MRAs entered by the Government of the Philippines through the DTI
菲律宾标准局（BPS）根据东盟互认协议（MRA）、亚太经合组织 MRA 和菲律宾政府通过 DTI 签订的其他区域和双边 MRA 认可的实验室。

BPS shall issue Recognition Certificate upon successful application for the recognition.

申请认可成功后，BPS 应签发认可证书。

B. Corrosion test, overturning and dynamic tests shall be performed on assembled child restraint systems, in accordance with the following standards as applicable:

应根据以下适用标准，对装配好的儿童约束系统进行腐蚀试验、倾覆试验和动态试验：

- ✓ PNS UN R 44:2018 Uniform provisions concerning the approval of restraining devices for child occupants of power-driven vehicles ("Child Restraint Systems")



PNS UN R 44:2018 关于批准机动车儿童乘员约束装置（“儿童约束系统”）的统一规定

- ✓ PNS UN R 129:2018 Uniform provisions concerning the approval of Enhanced Child Restraint Systems used onboard of motor vehicles

PNS UN R 129:2018 关于批准机动车上使用的增强型儿童约束系统的统一规定

- C. If a later edition of the PNS is published, the newer standard shall be used with effect from 1 year after promulgation.

如果发布了新版本的 PNS，则应使用新标准，自发布后 1 年起生效。

3) Labelling requirements 标签要求

A. On product 产品上

- ✓ Manufacturer's name, initials or trademark
制造商名称、首字母缩写或商标
- ✓ Year of production 生产年份
- ✓ Instructions for correct installation and use (appropriate pictograms/symbols, correct webbing path, configuration, etc.)
正确安装和使用说明（适当的象形图/符号、正确的织带路径、配置等）
- ✓ Country of origin 原产国
- ✓ Serial/Batch number 序列号/批号
- ✓ PS License Mark or ICC Sticker PS 许可证或 ICC 标签



B. On packaging 包装上

- ✓ Trade name or brand name 商品名或商标名
- ✓ Duly registered trademark 正式注册商标
- ✓ Duly registered business name and address of manufacturer
制造商正式注册的商业名称和地址
- ✓ Duly registered business name and address of importer (for imported products) 进口商正式注册的商业名称和地址（对于进口产品）

4) Certification requirements 认证要求

A. Domestic products 国内产品

- ✓ Local manufacturers selling or distributing child restraint systems in the Philippine market shall obtain a Philippine Standard (PS) Safety Mark License.
在菲律宾市场销售或分销儿童约束系统的当地制造商应获得菲律宾标准（PS）安全标志证书。
- ✓ The PS licensing scheme involves annual quality system and product audit at the factory, and random inspection of the factory/warehouse/market, and random testing if necessary.
PS 许可方案涉及工厂年度质量体系和产品审核，工厂/仓库/市场的随机检验，必要时进行随机测试。
- ✓ The license holder shall place the PS Certification Mark on the products.
持证人应在产品上标注 PS 认证标志。



- ✓ The PS License shall be valid for 3 years. License renewal shall be applied through written notice at least 6 months before the expiration date.
PS 证书有效期为 3 年。证书更新应在有效期届满前至少提前 6 个月书面通知申请。

B. Imported products 进口产品

Imported products can be legally marketed through one of the following ways: 进口产品可以通过下列方式之一合法销售:

- ✓ Applying for a PS License by the foreign manufacturers, and a Statement of Confirmation (SOC) by the importer to ensure the products came from a valid PS License holder company; or
由国外制造商申请 PS 证书，并由进口商出具确认声明 (SOC)，以确保产品来自有效的 PS 持证公司；或
- ✓ Applying for an Import Commodity Clearance (ICC) on a per shipment, per Bill of Lading/Airway Bill basis
基于提单/空运提单，申请每批货物的进口商品清关 (ICC)

5) Transitional arrangements 过渡期安排

- A. All new child restraint systems imported to the Philippines before effectivity of the Order, and are in the possession of the importers, distributors or retailers, shall be certified within 12 months from the effectivity of the Order.

行政命令生效前进口到菲律宾的所有新儿童约束系统，以及进口商、经销商或零售商所拥有的，应在命令生效后 12 个月内进行认证。



- B. In the absence of a BPS-recognized testing laboratory,
在没有 BPS 认可的检测实验室的情况下，
- a. PS License applicants/holders shall nominate a laboratory accredited by an accreditation body signatory to ILAC/APAC MRA to conduct the product testing.
PS 证书申请人/持有人应指定一个由 ILAC/APAC MRA 签字认可的实验室进行产品测试。
- b. Importers not applying for a PS License shall guarantee their products conform to the standard through the following:
未申请 PS 证书的进口商应通过以下方式保证其产品符合标准：
- ✓ Supplier's/manufacture's declaration of conformity on a per shipment per Bill of Lading/Airway Bill basis;
每份提单/空运提单的供应商/制造商的符合性声明；
 - ✓ Copy of valid test report for each type/model per brand of product issued within 2 years from the date of filing of application by a laboratory accredited by an accreditation body signatory to ILAC/APAC MRA; and
由 ILAC/APAC MRA 签字认可的实验室提交申请之日起 2 年内签发的每种产品类型/型号的有效试验报告副本；以及
 - ✓ Copy of valid ISO 9001 certificate of the manufacturer
制造商的有效 ISO 9001 证书副本



5. Taiwan - Draft Amendment to Mandatory Inspection Requirements for Children's Bed Guards (9/21/2020)

台湾- 拟修订儿童用床边护栏的强制检验要求

The Bureau of Standards, Metrology and Inspection (BSMI) of Taiwan has proposed the amendment to "Inspection requirements for children's bed guards" under the BSMI Notice No. 10920005530. Here are the highlights:

台湾标准、计量和检查局已发布第 10920005530 号通知，拟修订儿童用床边护栏的检验要求。以下是主要内容：

- A. The inspection requirements shall be updated from CNS 15911:2016 to CNS 15911:2017, CNS 15503:2011 to CNS 15503:2019 and CNS 15138-1:2012 shall be deleted, as below:

检验要求应更新，CNS 15911:2016 更新为 CNS 15911:2017，CNS 15503:2011 更新为 CNS 15503:2019，标准 CNS 15138-1:2012 将删除，如下所示：

Item 项目	Proposed updated testing standard 拟议的新测试标准	Current testing standard 现行测试标准
Children's bed guards 儿童用床边护栏	<ol style="list-style-type: none"> 1. CNS 15911:2017 2. CNS 15503:2019 	<ol style="list-style-type: none"> 1. CNS 15911:2016 2. CNS 15503:2011 3. CNS 15138-1:2012



- B. If approved as proposed, from the date of publication, children's bed guards shall be inspected according to CNS 15911:2017 and CNS 15503:2019. The inspection methods shall be either Type approved batch-by-batch inspection or Registration of Product Certification (RPC) Scheme (Type Test + Declaration of Conformity).

如提议案获得批准，自发布之日起，应根据 CNS 15911:2017 和 CNS 15503:2019 对儿童用床边护栏进行检验。检验方法应采用型式认可的逐批检验或产品认证（RPC）注册计划（型式试验+符合性声明）。

- C. Inspection arrangement for Type approved batch-by-batch inspection and Registration of Product Certification (RPC) Scheme:

型式认可 - 逐批检验及产品认证（RPC）注册计划的检验安排

- a. New applicants shall apply for certification according to the revised requirements from the date of publication. Certification that are issued to successful applicants shall be valid for 3 years.

新申请人自公布之日起按修改后的要求申请认证，证书有效期为 3 年。

- b. Certification issued in compliance with current requirements shall be valid during the originally designated period. Certificate holders may apply for certificate extension or re-apply the certificate, provided that test reports are submitted to show compliance with the current requirements.

按照现行要求签发的证书在原指定期限内仍有效。证书持有人可以申请证书延期或重新申请证书，前提是提交的测试报告能证明产品符合当前要求。



Note 注:

- CNS 15911:2017 Child use and care articles – Children’s bed guards for domestic use
CNS 15911:2017 儿童使用和护理用品-家用儿童床边护栏
- CNS 15503:2019 General safety requirements for children’s products
CNS 15503:2019 儿童产品一般安全要求
- CNS 15138-1:2012 Method of test for determination of phthalates plasticizers in plastic products - Part 1: Gas chromatography/mass spectrometry
CNS 15138-1:2012 塑料制品中邻苯二甲酸酯类增塑剂测定的测试方法-第1部分:气相色谱/质谱法

6. Taiwan - Draft Mandatory Inspection Requirements for Cribs and Cradles for Domestic Use (9/24/2020)

台湾-拟修订家用婴儿床和摇篮的强制检验要求

The Bureau of Standards, Metrology and Inspection (BSMI) of Taiwan has published Notice No. 10920005670 to propose the mandatory inspection requirements for cribs and cradles for domestic use. Here are the highlights:

台湾标准、计量和检查局已发布第 10920005670 号通知，拟修订家用婴儿床和摇篮的强制检验要求。以下是主要内容：

1) Scope and inspection standard 范围和检验标准

✓ Scope 范围:

Cribs and cradles for domestic use 家用婴儿床和摇篮



✓ Inspection standard **检验标准:**

CNS 12990:2017 *Cribs and cradles for domestic use* 家用婴儿床和摇篮

2) **Conformity assessment requirements 合格评定要求**

A. If approved, products shall follow either:

如果获得批准，则产品应符合以下任一条件：

a. Batch-by-Batch Inspection (Type Approval); or

逐批检查（型式认可）；或

b. Module II and Module III of the Registration of Product Certification (RPC) Scheme, where:

产品认证注册计划的模块 II 和模块 III，其中：

✓ Module II - Type Test Module: The applicant or the production premises shall submit technical documents together with the type samples and obtain a type-test report indicating that the types are in compliance with specified standards or relevant technical regulations from the BSMI or designated testing laboratories recognized by the BSMI.

模块 II-型式检验模块：申请人或生产场所应将技术文件与型式样品一起提交，并获得型式试验报告，以表明该类型符合 BSMI 或其认可实验室的指定标准或相关技术法规。

✓ Module III - Declaration of Conformity: The applicant shall declare and ensure that its production premises are registered under their consent, and are the actual factories manufacturing the registered commodities which comply with those types in Module II.

模块 III-符合性声明：申请人应声明并确保其生产场所在其同意下进行注册，并且是生产符合模块 II 中那些类型的注册商品的实际工厂



- B. After passing the conformity assessment, products shall be labelled with the Commodity Inspection Mark on the prominent place of the product.

通过合格评定后，产品应在产品显眼位置贴上商品检验标记。

- C. The product certificate shall be valid for 3 years.

产品证书有效期为 3 年。

- D. Multifunctional cribs and cradles that fall within the scope of inspection shall comply with relevant inspection requirements. Any accessories of cribs and cradles which are included in the scope of inspection shall also comply with the relevant inspection requirement.

属于强制检查产品范围内的多用途婴儿床和摇篮应符合相关的检查要求。属于强制检查范围婴儿床和摇篮的任何附件也应符合相关的检查要求。



PART2 Toys 玩具

7. EU - Proposed Limits for Aniline in Certain Toys under Toy Safety Directive 2009/48/EC (9/9/2020)

欧盟-提议增加玩具安全指令 2009/48/EC 中的苯胺限用

The European Commission has drafted a Commission Directive amending Directive 2009/48/EC as regards specific limit values for aniline in certain toys.

2020 年 9 月，欧盟委员会起草委员会指令，将修订玩具安全指令（指令 2009/48/EC），对某些玩具材料中的苯胺设定限值。

The Commission proposed to add an entry in Appendix C to Annex II to the Toy Safety Directive, which specifies the limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth:

欧盟委员会提议将苯胺限值增添至玩具安全指令附件 II 附录 C 中，其规定了 36 个月以下儿童使用的玩具或其他意图放入口中的玩具中有害化学物的要求：

Substance 物质	CAS No CAS 号	Limit value 限值
Aniline 苯胺	62-53-3	<ul style="list-style-type: none"> 30 mg/kg after reductive cleavage in textile toy material and leather toy material 30 mg/kg，对于经还原裂解后，玩具的纺织品材料和皮革材料中的苯胺 10 mg/kg as free aniline in finger paints 10 mg/kg，对于指画颜料中的游离苯胺 30 mg/kg after reductive cleavage in finger paints 30 mg/kg，对于经还原裂解后，指画颜料中的苯胺



8. India - Deferred Effective Date of Toy (Quality Control) Order 2020 (9/16/2020)

印度 - 《2020 玩具(质量控制)令》延期生效

The Ministry of Commerce and Industry of India has approved the Toys (Quality Control) Amendment Order, 2020 to defer the effective date of the Toys (Quality Control) Order, 2020 to 1 January 2021.

印度工商部批准《2020 玩具(质量控制)修订令》，该令对《2020 玩具(质量控制)令》的生效日期进行修订并延期至 2021 年 1 月 1 日生效。

9. Ukraine - Draft Amendment to Technical Regulation on Safety of Toys (9/28/2020)

乌克兰-提议修订玩具安全技术法规

The Ministry for Development of Economy, Trade and Agriculture of Ukraine has proposed the amendment to Technical Regulation on safety of toys, aiming at aligning with the amendments to the EU Directive 2009/48/EC, including Commission Directives 2018/725, 2019/1922 and 2019/1929. Here are the highlights:

乌克兰经济、贸易和农业发展部已提出了《玩具安全技术法规》修正案，旨在与欧盟指令 2009/48/EC 的修正案保持一致，这些欧盟修正案包括欧盟委员会指令 2018/725、2019/1922 和 2019/1929。以下是主要内容：



- A. Migration limits of aluminium and chromium VI in Table 3 of Annex II “Special safety requirements” shall be revised as follows:

附件 II “特殊安全要求”的表 3 中铝和六价铬的迁移限量作如下修订：

Element	in dry, brittle, powder-like or pliable toy material	in liquid or sticky toy material	in scraped-off toy material
元素	干燥、易碎、粉末状或脆性的玩具材料	液体或粘性的玩具材料	可刮削的玩具材料
Aluminium 铝	2250 mg/kg	560 mg/kg	28130 mg/kg
Chromium (VI) 六价铬	0.02 mg/kg	0.005 mg/kg	0.053 mg/kg

- B. The limit value for formaldehyde shall be added to Appendix C to Annex II “Special safety requirements” as follows:

在附件 II “特殊安全要求”的附录 C 中增加如下甲醛的限量值：

Substance	CAS No.	Limit value
化学物质	CAS 号	限量值
Formaldehyde 甲醛	50-00-0	<ul style="list-style-type: none"> Migration limit: 1.5 mg/l in polymeric toy material 迁移限量：1.5 mg/l (聚合物玩具材料) Emission limit: 0.1 ml/m³ in resin-bonded wood toy material 释放量限量：0.1 ml/m³(树脂胶合木玩具材料) Content limit: 30 mg/kg in textile toy material



		<p>限量：30 mg/kg (纺织品玩具材料)</p> <ul style="list-style-type: none"> Content limit: 30 mg/kg in leather toy material <p>限量：30 mg/kg (皮革玩具材料)</p> <ul style="list-style-type: none"> Content limit: 30 mg/kg in paper toy material <p>限量：30 mg/kg (纸质的玩具材料)</p> <ul style="list-style-type: none"> Content limit: 10 mg/kg in water-based toy material <p>限量：10 mg/kg (水基的玩具材料)</p>
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PART3 Food Contact Materials 食品接触产品

10. EU - Approved Amendments to Regulation (EU) No 10/2011 on Plastic Food Contact Materials and Articles (9/3/2020)

欧盟 - 批准 (EU) No 10/2011 关于塑料食品接触材料和物品法规的修正案

The European Commission has published Regulation (EU) 2020/1245 to amend Regulation (EU) No 10/2011 on plastic food contact materials and articles. The amendment shall enter into force on 23 September 2020.

欧盟委员会发布了法规(EU) 2020/1245 修订(EU) No 10/2011 关于塑料食品接触材料和物品的法规。该法规将于 2020 年 9 月 23 日生效。



Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before 23 September 2020, and which were first placed on the market before 23 March 2021 may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks.

在 2021 年 3 月 23 日之前首次投放市场，且符合 2020 年 9 月 23 日前的 (EU) No 10/2011 法规的塑料材料及物品，可继续投放市场至 2022 年 9 月 23 日，并且可以到库存清完。

Here is the summary of the amendment 以下是修订的概要:

1) Annex I - Table 1: Union list of authorised materials

附件 I - 表 1: 欧盟授权材料清单

A. Amendments to existing authorised substances

对现有授权物质的修订

- a. Entry 236: 1,3-phenylenediamine - Adding a detection limit of 0.002 mg/kg food or food simulant

第 236 项: 1,3-苯二胺 - 增加 0.002 mg/kg 食品或食品模拟液的检出限

- b. Entry 398: Antimony trioxide - Specific migration limit of 0.04 mg/kg food or food simulant and its note on compliance verification will be included in Annex II

第 398 项: 三氧化二锑 - 将 0.04 mg/kg 食品或食品模拟液的特定迁移限值，和对它的符合性验证的说明列入附件 II

B. Additions of authorised substances

增加授权物质



- a. Entry 1075: Montmorillonite clay modified with hexadecyltrimethylammonium bromide
第 1075 项：经十六烷基三甲基溴化铵修饰的蒙脱土

- b. Entry 1076: Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediy)], C10-16 alkyl ester, CAS No. 1227937-46-3
第 1076 项：亚磷酸三苯酯与 α -氢- ω -羟基-聚[氧(甲基-1,2-亚乙基)], C10-16 烷基酯的聚合物, CAS 号：1227937-46-3

- c. Entry 1077: Titanium dioxide surface-treated with fluoride-modified alumina
第 1077 项：表面经氟化物改性氧化铝处理的二氧化钛

2) Annex II - Specific migration limits

附件 II - 特定迁移限值

- A. There will be a new table on the general list of migration limits
增加一个迁移限值清单的表格:

	Salts allowed in accordance with Article 6(3)(a) 根据第 6(3)(a)条允许的盐	Specific migration limit (mg/kg food or food simulant) 特定迁移限值 (mg/kg 食品或食品模拟液)
Aluminium 铝	Yes 是	1
Ammonium 铵	Yes 是	-
Antimony 锑	No 否	0.04



Arsenic 砷	No 否	Not detected (Limit of detection 0.01) 不得检出 (检出限 0.01)
Barium 钡	Yes 是	1
Cadmium 镉	No 否	Not detected (Limit of detection 0.002) 不得检出 (检出限 0.002)
Calcium 钙	Yes 是	-
Chromium 铬	No 否	Not detected [please refer to point c(i)] 不得检出 [请参见第 c(i)点]
Cobalt 钴	Yes 是	0.05
Copper 铜	Yes 是	5
Europium 铕	Yes 是	0.05 [please refer to point c(ii)] 0.05 [请参见第 c(ii)点]
Gadolinium 钆	Yes 是	0.05 [please refer to point c(ii)] 0.05 [请参见第 c(ii)点]
Iron 铁	Yes 是	48
Lanthanum 镧	Yes 是	0.05 [please refer to point c(ii)] 0.05 [请参见第 c(ii)点]
Lead 铅	No 否	Not detected (Limit of detection 0.01) 不得检出 (检出限 0.01)
Lithium 锂	Yes 是	0.6
Magnesium 镁	Yes 是	-
Manganese 锰	Yes 是	0.6
Mercury 汞	No 否	Not detected (Limit of detection 0.01) 不得检出 (检出限 0.01)
Nickel 镍	No 否	0.02
Potassium 钾	Yes 是	-



Sodium 钠	Yes 是	-
Terbium 铽	Yes 是	0.05 [please refer to point c(ii)] 0.05 [请参阅第 c(ii)点]
Zinc 锌	Yes 是	5

Here are some key points related to the above table 以下是关于上表的一些要点：

- a. The existing migration limits remain unchanged.
现有的迁移限值保持不变。
- b. Article 6(3)(a) regarding the derogation of certain salts of authorised acids, phenols and alcohols will be incorporated into the second column of the above table.
将第 6(3)(a)条关于经授权的酸类、酚类、醇类的某些盐的豁免将加入上表的第二列。
- c. There are additional remarks for some limits. The significant ones are:
一些限值具有额外的备注。重要的备注有：
 - i. For total chromium, the detection limit of 0.01 mg/kg shall apply. However, if the operator who place the food contact material on the market can prove that the presence of chromium (VI) is excluded, a limit of 3.6 mg/kg shall apply.
对于总铬，0.01 mg/kg 的检出限应适用。但是，如果将食品接触材料投放市场的经营者能够证明其中不存在六价铬，则 3.6 mg/kg 的总铬限值适用。
 - ii. For lanthanide substances (europium, gadolinium, lanthanum and terbium)
对于镧系物质（铕、钆、镧、铽）
 - The sum of all lanthanide substances migrating to food or food simulant shall not exceed the specific migration limit of 0.05 mg/kg
迁移到食品或食品模拟液的所有镧系物质的总和不得超过 0.05 mg/kg 的特定迁移限值。



- *There shall be analytical evidence using a well described methodology demonstrating the lanthanide substance(s) used are present in dissociated ionic form in the food or food simulant. The evidence shall form part of the supporting documentation referred to in Article 16.*

应有使用详细描述的方法的分析证据，来证明所用的镧系物质以解离的离子形式存在于食品或食品模拟液。该证据应成为第 16 条所述的证明文件的一部分。

- B. The detection limit for primary aromatic amines (PAAs) will be amended as follows:

初级芳香胺(PAAs)的检出限将被修改如下：

- a. For PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH Regulation (EC) No 1907/2006, if no migration limit is specified in Table 1 of Annex I to Regulation (EU) No 10/2011, they shall not be detectable with a limit of detection of 0.002 mg/kg food or food simulant applied to each individual PAA.

对于已列入 REACH 法规((EC) No 1907/2006)附录 XVII 第 43 项相关的附录 8 中的 PAAs，如果在法规(EU) No 10/2011 附件 1 的表 1 中未指定迁移限值，则它们应不得检出（对每种单独的 PPA，检出限为 0.002 mg/kg 食品或食品模拟液）。

- b. For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to REACH Regulation, if no migration limit is specified in Annex I to Regulation (EU) No 10/2011, the sum of those PAAs shall not exceed 0.01 mg/kg in food or food simulant.

对于非第(a)点所述的 PAAs，如果在法规(EU) No 10/2011 附件 1 的表 1 中未指定迁移限值，则这些 PAAs 的总和不得超过 0.01 mg/kg 食品或食品模拟液。



3) Annex IV - Declaration of compliance 附件 IV - 符合性声明

The information requirements under point 6 of Annex IV will be strengthened to ensure adequate information on the presence of substances listed in Annex II.

第 6 点对信息的要求将会变得更严格，以确保与附件 II 所列物质的存在相关的信息足够充分。

4) Annex V - Compliance testing 附件 V - 符合性测试

- A. Testing rules will be added for food processing equipment and appliances.
增加对食品加工设备和电器的测试规则。
- B. For repeated use materials and articles, the regulation will require the specific migration between subsequent tests does not increase.
对于重复使用的材料和物品，法规将要求其迁移值在连续的迁移测试中不会增加。
- C. A new standard testing condition (OM0) for overall migration will be added: 30 minutes at 40 °C for materials and articles intended for use only at cold or ambient temperatures for 30 minutes or less.
对于全面迁移，将添加新的标准测试条件(OM0)：针对意图仅仅用于寒冷或环境温度下、少于等于 30 分钟的材料和物品，测试条件为 40°C 下 30 分钟。
- D. For the overall migration testing condition OM4, reflux condition will be available as an option when testing at 100 °C is technically difficult.
对于全面迁移的测试条件 OM4，当测试在 100°C 时因技术原因难以进行时，回流条件可作为一个可选的选项。
- E. The amendment corrects some of the wording related to overall migration testing.



修订纠正了与全面迁移测试相关的一些措词。

1.1. Germany - Revised Draft Ordinance for Food Contact Paper on Aromatic Mineral Oil Hydrocarbon Migration (9/3/2020)

德国-关于芳香族矿物油碳氢化合物迁移的食品接触用纸相关条例修订草案

The Federal Ministry of Food and Agriculture of Germany has published a revised draft to restrict aromatic mineral oil hydrocarbons (MOAH) released from paper food contact articles and packaging under Consumer Goods Ordinance (BedGgstV).

德国联邦食品和农业部发布修订草案，按照《消费品条例》（BedGgstV）的相关规定，限制纸质食品接触产品和包装中释放的芳香族矿物油碳氢化合物（MOAH）。

The proposed requirements are as follows:

草案要求如下：

- A. Food contact materials made of paper, paperboard or cardboard using recycled paper may only be manufactured and placed on the market if a functional barrier ensures that no MOAH are transferred to food, unless:

使用再生纸制成的食品接触用纸、纸板或纸制品只有在功能性阻隔层能确保 MOAH 不会迁移到食品中的情况下才可以制造并投放市场，除非：

- ✓ here is a low content of MOAH in the food contact article; or
食品接触产品本身的 MOAH 含量低；或



- ✓ Other appropriate measures have been taken to prevent MOAH migration.

已采取其他适当措施防止迁移。

B. The detection limit of MOAH migration shall be set at:

MOAH 迁移的检测限为:

- ✓ 0.5 mg/kg of food; or
0.5 mg/kg 食物; 或
- ✓ 0.15 mg/kg of food simulant
0.15 mg/kg 食品模拟物

C. Food business operators may bring recycled paper food contact materials without a functional barrier into contact with food by packaging or in any other way, if they:

食品经营者可以通过包装或者其他方式，采用无功能性阻隔层的再生纸制食品接触材料用于与食品接触，前提是：

- ✓ Declare in writing or electronically on the absence of functional barrier on the food packaging before food delivery; and

在食品出售前，以书面或电子方式声明食品包装上没有功能性阻隔层；以及

- ✓ Take appropriate measures to prevent MOAH migrating to food (this is not needed if the nature of food or intended use of food packaging does not make the MOAH migration possible).

采取适当措施防止 MOAH 迁移到食品中（如果食品的性质或食品包装的预期用途不能使 MOAH 迁移成为可能，则无需采取此措施）。



- D. Documentation shall be provided upon request to prove the MOAH migration is below the detection limit if a functional barrier is not applied to paper food contact articles.

如果纸质食品接触产品未设置功能性阻隔层，应根据要求提供证明 MOAH 迁移量低于限量的文件。

Note 注

- A. "Aromatic mineral oil hydrocarbons" (MOAH) means alkylated aromatic hydrocarbons with carbon numbers C16 to C35 which contain one or more rings, with the exception of diisopropylnaphthalenes.

"芳香族矿物油碳氢化合物" (MOAH) 是指碳数为 C16 至 C35 的烷基化芳烃，其中包含一个或多个环，但二异丙基萘除外。

- B. "Functional barrier" means:

"功能性隔层"是指：

- One or more layers or coatings of a food contact material; or
食品接触材料的一层或多层或涂层；或
- The wrapping of food.
食品的包装。

which ensures that certain substances from food contact materials do not migrate to food.

用以确保某些来自食品接触材料中的物质不会迁移到食物中。



12. China - Approved New Substances related to Food Contact Materials And Articles (9/2/2020)

中国-批准与食品接触材料和物品有关的新物质

The National Health Commission of the People's Republic of China (NHC) has published Notice No. 6 of 2020 to approve 16 kinds of substances for food contact materials and articles. This notice has already come into force. The usage conditions of the substances are shown as follows:

中华人民共和国国家卫检委（NHC）发布了 2020 年第 6 号公告，批准了 16 种可用于食品接触材料和物品的物质。该通知已经生效。该物质的使用条件如下：

1) New additives for food contact materials and articles

食品接触材料和新添加剂

Chemical name 化学名称	CAS No. CAS 号	Scope 范围	Maximum amount to be used 最大使用量	Specific Migration Limit (SML) 特定迁移限量	Maximum Residue (QM) 最大残留量	Note 备注
Microfibrillated cellulose pulp 微纤化纤维素纸浆	65996- 61-4	Paper and cardboard 纸和纸板	5% (as fiber dry weight 以纤维 干重计)	-	-	-



<p>2-Butenedioic acid (2E)-, dibutyl ester, homopolymer 富马酸二丁酯均聚物</p>	-	<p>Coating 涂料及涂层</p>	2%	-	-	<p>Coatings added with this substance shall not be used in contact with infant formula food and breast milk, and the temperature of usage shall not exceed 121 °C</p> <p>添加了该物质的涂料及涂层不得用于接触婴幼儿食品和母乳，使用温度不得超过 121°C</p>
<p>2-Propenoic acid, ethyl ester, polymer with 2-methyl-2-propenamamide 2-丙烯酸乙酯与 2-甲基-2-丙烯酰胺的聚合物</p>	25085-36-3	<p>Plastic: Acrylonitrile-butadiene-styrene copolymer (ABS) 塑料：丙烯腈-丁二烯-苯乙烯共聚物 (ABS)</p>	1%	<p>6 mg/kg (as acrylic acid) (以丙烯酸计) ND (Methacrylamide, DL=0.01mg/kg 甲基丙烯酰胺, 检出限 = 0.01mg / kg)</p>	-	-

2) Expansion of the scope of additives used in food contact materials and articles

扩大使用范围的食物接触材料和制品用添加剂



Chemical name 化学名称	CAS No. CAS 号	Scope 范围	Maximum amount to be used 最大使用量	Specific Migration Limit (SML) 特定迁移限量	Maximum Residue (QM) 最大残留量	Note 备注
Calcium stearate 硬脂酸钙	1592-23-0	Plastic: Polyether ether ketone (PEEK) 塑料: 聚醚醚 PEEK	0.03%	-	-	-
2,5-Furandione, dihydro-, mono-C15~20-alkenyl derivs. 单 C15~C20 烯基-二氢-2,5-呋喃二酮衍生物	68784-12-3	Plastic: Polyethylene (PE), Polypropylene (PP) 塑料: 聚乙烯 (PE)、聚丙烯 (PP)	0.48%	30 mg/kg (as maleic acid 以马来酸计)	-	The temperature of usage of plastic materials and articles added with this substance shall not exceed 100 °C; not to be used in contact with infant food and breast milk 添加了该物质的 PE、PP 塑料材料及制品使用温度不得超过 100°C; 不得用于接触婴幼儿食品和母乳
Polyethylene 聚乙烯	9002-88-4	Rubber 橡胶	2%	-	-	Only used to produce reusable rubber materials and articles 仅用于生产可重复使用的橡胶材料及制品
C.I. Solvent Violet 36; 1,8-bis[(4-Methylphenyl)amino]-9,10-anthracenedione C.I.溶剂紫 36	82-16-6	Plastic: acrylonitrile-styrene copolymer (AS) 塑料: 丙烯腈-苯乙烯共聚物 (AS)	0.0005%	-	-	This substance shall meet the requirements for the purity of colorants in Appendix A of GB 9685-2016; the temperature of usage of AS plastic materials and articles added with this substance shall not



						exceed 100°C 该物质应符合 GB 9685-2016 附录 A 中对着色剂纯度的要求；添加了该物质的 AS 塑料材料及制品使用温度不得超过 100°C
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate β-(3,5-二叔丁基-4-羟基苯基)丙酸十八醇酯	2082-79-3	Plastic: Polybutene-1 (PB-1) 塑料: 聚 1-丁烯 (PB-1)	0.045%	6 mg/kg	-	-

3) New resin substances used in food contact materials and articles

新批准的食品接触材料和制品用树脂

Chemical name 化学名称	CAS No. CAS 号	Scope 范围	Maximum amount to be used 最大使用量	Specific Migration Limit (SML) 特定迁移限量	Maximum Residue (QM) 最大残留量	Note 备注
Fatty acid, C18-unsaturated, dimers, polymers with caprolactam and hexamethylenediamine C18-不饱和脂肪酸二聚体与己内酰胺和六亚甲基二胺的聚合物	206809 7-08-3	Plastic 塑料	-	—15 mg/kg (as caprolactam) (以内酰胺计) ; —2.4 mg/kg (Hexamethylene diamine 己二胺); —0.05 mg/kg (as the total of Unhydrogenated unsaturated fatty	-	Plastic materials and articles manufactured with this substance as raw materials shall not be used in contact with infant formula food and breast milk. The conditions of use are filling at room temperature and long-term storage at room temperature (including hot filling and pasteurization under T≤70 °C, t≤2h or T≤100 °C, t≤15min)



				acid (C18) dimer and Hydrogenated dimerized C18 unsaturated fatty acids 以未氢化不饱和脂肪酸 (C18) 二聚物和氢化二聚 C18 不饱和脂肪酸之和计)		以该物质为原料生产的塑料材料及制品不得用于接触婴幼儿食品和母乳, 使用条件为室温灌装并在室温下长期贮存 (包括 T≤70 °C, t≤2h 或 T≤100 °C, t≤15min 条件下的热灌装及巴氏消毒)
Styrene block polymers with 2-methyl-1,3-butadiene and 1,3-butadiene, hydrogenated 氢化的苯乙烯与 2-甲基-1,3-丁二烯和 1,3-丁二烯的嵌段聚合物	132778-07-5	Plastic 塑料	-	- ND (2-methyl-1,3-butadiene 2-甲基-1,3-丁二烯; DL = 0.01 mg/kg) - ND (1,3-butadiene 1, 3-丁二烯; DL = 0.01 mg/kg);	-1 mg/kg (2-methyl-1,3-butadiene 2-甲基-1,3-丁二烯); -1 mg/kg (1,3-butadiene 1, 3-丁二烯); -0.5% (styrene 苯乙烯)	-
Phenol, 4,4'-(1-methylethylidene)bis-, polymer with (chloromethyl)oxirane, benzoate 4,4'-(1-甲基亚乙基)二苯酚与 2-(氯甲基)环氧乙烷苯甲酸酯的聚合物	52907-82-1	Coating 涂料及涂层	19.7% (as coating formula 以涂料配方计)	0.6 mg/kg (Bisphenol A 双酚 A)	1 mg/kg (Epichlorohydrin 环氧氯丙烷)	Coatings manufactured with this substance as raw materials shall not be used in contact with infant foods and breast milk 以该物质为原料生产的涂料及涂层不得用于接触婴幼儿食品和母乳
					1 mg/kg (as isocyanate)	Coatings manufactured with this substance as raw



<p>Polymer of 1,4-bis(hydroxymethyl)cyclohexane, 2-methylpropane-1,3-diol, tricyclo(5.2.1.02,7)decane-4,8-dimethanol, benzene-1,4-dicarboxylic acid, benzene-1,3-dicarboxylic acid, cis-butenedioic acid, 5-isocyanato-1-isocyanatomethyl-1,3,3-trimethylcyclohexane</p> <p>1,4-二(羟甲基)环己烷与 2-甲基-1,3-丙二醇、4,8-三环 [5.2.1.02,7]癸烷二甲醇、对苯二甲酸、间苯二甲酸、顺丁烯二酸和 5-异氰酸根合-1-(异氰酸根合甲基)-1,3,3-三甲基环己烷的聚合物</p>	-	Coating 涂料及涂层	30% (as coating formula 以涂料配方计)	<p>- 5 mg/kg (2-methyl-1,3-propanediol 2-甲基-1,3-丙二醇);</p> <p>- 0.05 mg/kg (4,8-tricyclo [5.2.1.02,7] decanedimethanol 4,8-三环 5.2.1.02,7] 癸烷二甲醇);</p> <p>- 7.5 mg/kg (as terephthalic acid 以对苯二甲酸计) ;</p> <p>-5 mg/kg (as isophthalic acid 以间苯二甲酸计) ;</p> <p>-30 mg/kg (maleic acid 顺丁烯二酸)</p>	以异氰酸根计)	<p>materials shall not be used in contact with infant foods and breast milk</p> <p>以该物质为原料生产的涂料及涂层不得用于接触婴幼儿食品和母乳</p>
<p>Polymer of butanediol-1,4, ethylene glycol, propylene glycol-1,2, trimethylolpropane, dimethyl terephthalate, isophthalic acid and sebacic acid</p> <p>1,4-丁二醇与乙二醇、1,2-丙二醇、三羟甲基</p>	-	Coating 涂料及涂层	30% (as coating formula 以涂料配方计)	<p>-5 mg/kg (as 1,4-butanediol 以 1,4-丁二醇计);</p> <p>-30 mg/kg (as ethylene glycol 以乙二醇计) ;</p> <p>- 6 mg/kg (trimethylolpropane</p>	-	<p>Coatings manufactured with this substance as raw materials shall not be used in contact with infant foods and breast milk</p> <p>以该物质为原料生产的涂料及涂层不得用于接触婴幼儿</p>



<p>丙烷、对苯二甲酸二甲酯、间苯二甲酸和癸二酸的聚合物</p>				<p>三羟甲基丙烷); - 5 mg/kg (as isophthalic acid 以间苯二甲酸计)</p>		<p>食品和母乳</p>
<p>1,3-Benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid and 1,2-ethanediol 1,3-苯二甲酸与 1,4-苯二甲酸和 1,2-乙二醇的聚合物</p>	<p>24938-04-3</p>	<p>Coating 涂料及涂层</p>	<p>20% (as coating formula 以涂料配方计)</p>	<p>- 5 mg/kg (as 1,3-phthalic acid 以 1,3-苯二甲酸计) ; - 7.5 mg/kg (as 1,4-phthalic acid 以 1,4-苯二甲酸计) ; - 30 mg/kg (as ethylene glycol 以乙二醇计) ;</p>	<p>-</p>	<p>Coatings manufactured with this substance as raw materials shall not be used in contact with infant foods and breast milk; the temperature of usage shall not exceed 130 °C 以该物质为原料生产的涂料及涂层不得用于接触婴幼儿食品和母乳；使用温度不得超过 130°C</p>
<p>2-Propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, 2-(chloromethyl)oxirane, ethenylbenzene, ethyl 2-propenoate, 4,4'-(1-methylethylidene)bis[phenol] and 2-propenoic acid, reaction products with 2-(dimethylamino)ethanol 甲基丙烯酸与甲基丙烯酸丁酯、环氧氯丙烷、苯乙烯、丙烯酸乙酯、4,4'-(1-甲基亚乙基)双酚</p>	<p>-</p>	<p>Coating 涂料及涂层</p>	<p>85% (as coating formula 以涂料配方计)</p>	<p>- 6 mg/kg (as methacrylate 以甲基丙烯酸酯计) ; - ND (Epichlorohydrin 环氧氯丙烷, DL = 0.01 mg/kg) - 6 mg/kg (as acrylic acid 以丙烯酸计) - 0.6 mg/kg (Bisphenol A 双酚 A) - 18 mg/kg</p>	<p>1 mg/kg (Epichlorohydrin , 环氧氯丙烷)</p>	<p>Coatings manufactured with this substance as raw materials shall not be used in contact with infant foods and breast milk; the temperature of usage shall not exceed 130 °C 以该物质为原料生产的涂料及涂层不得用于接触婴幼儿食品和母乳；使用温度不得超过 130°C</p>



和丙烯酸酯的聚合物与 2-(二甲氨基)乙醇的反应产物				(2-(Dimethylamino)ethanol 2-(二甲氨基)乙醇)		
1,3-benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 1,4-butanediol, 1,8-octanedicarboxylic acid and 1,2-ethanediol 1,3-苯二甲酸与 1,4-苯二甲酸、1,4-丁二醇、癸二酸和乙二醇的聚合物	61039-00-7	Coating 涂料及涂层	50% (as coating formula 以涂料配方计)	-5 mg/kg (as 1,3-phthalic acid 以 1,3-苯二甲酸计) ; -7.5 mg/kg (as 1,4-phthalic acid 以 1,4-苯二甲酸计) ; - 5 mg/kg (as butanediol 以丁二醇计) - 30 mg/kg (as ethylene glycol 以乙二醇计)	-	Coatings manufactured with this substance as raw materials shall not be used in contact with infant foods and breast milk; the temperature of usage shall not exceed 130 °C 以该物质为原料生产的涂料及涂层不得用于接触婴幼儿食品和母乳；使用温度不得超过 130°C

Note 注:

- *ND: Not detected* 不得检出
- *DL: Detection limit* 检出限



13. China - Draft Revision of GB 4806.9 Metal Food Contact Materials and Articles (9/18/2020)

中国- GB 4806.9 食品接触用金属材料及制品的修订草案

The National Health Commission of the People's Republic of China (NHC) has proposed to revise GB 4806.9 metal food contact materials and articles. If approved, the current GB 4806.9-2016 shall be replaced. Here are the highlights:

国家卫生健康委员会提议修订 GB 4806.9《食品接触用金属材料及制品》。如提议修订案被批准，将取代现行的 GB 4806.9-2016。以下是主要变更部分:

1) Requirements for raw materials 对原料要求

A. The metal substrate, metal plating and welding materials used in metal food contact materials and articles shall not be harmful to human health.

食品接触用金属材料及制品所使用的金属基材、金属镀层和焊接材料不应对人体健康造成危害。

B. The manufacturer shall control the substances used and residues in the metal surface treatment process (such as pickling, oxidation, phosphating, polishing, anti-rust oiling, etc.), so that under recommended conditions of use, metal food contact articles and materials shall not

食品接触用金属材料及制品的生产企业应对金属表面处理（如酸洗、氧化、磷化、抛光、防锈涂油等）过程中使用到的物质以及残留的物质进行控制，在推荐的使用条件下，食品接触用金属材料及制品不应：



a. transfer their constituents to food in quantities which could endanger human health.

使得其成分大量转移到食物中，危害人体健康。

b. bring about changes to composition, structure or organoleptic characteristics of food, and cause any technical effect in food, unless otherwise specified.

导致食物的成分、结构或者感官特性发生变化，并对食物产生任何方面的技术影响，但是另有规定的可以除外。

C. Lead (Pb), cadmium (Cd), arsenic (As), mercury (Hg), antimony (Sb), beryllium (Be) and lithium (Li) shall not be used as alloying elements for metal substrates. The impurity content of the metal material used in the substrate and plating shall meet the following requirements.

不应使用以铅、镉、砷、汞、锑、铍和锂作为金属基材的合金元素。金属基材和镀层所用的金属材料的杂质元素含量应满足如下表要求。

Metal substrate and coating material 金属基材和镀层材料	Impurity element 杂质元素	Content (%) 含量 (%)
Stainless steel 不锈钢	Arsenic (As) 砷(As)	≤ 0.01
	Cadmium (Cd) 镉(Cd)	≤ 0.01



	Lead (Pb) 铅(Pb)	≤ 0.01
Sheet steel for food packaging 食品包装用薄钢板	Arsenic (As) 砷(As)	≤ 0.03
	Cadmium (Cd) + Lead (Pb) 镉(Cd)+铅(Pb)	≤ 0.01
Aluminium and aluminium alloy materials 铝及铝合金材料	Arsenic (As) 砷(As)	≤ 0.01
	Cadmium (Cd) + Lead (Pb) + Mercury (Hg) 镉(Cd)+铅(Pb)+汞(Hg)	≤ 0.01
Other metal substrates and plating materials 其他金属基材和镀层材料	Arsenic (As) 砷(As)	≤ 0.03
	Cadmium (Cd) 镉(Cd)	≤ 0.01
	Lead (Pb) 铅(Pb)	≤ 0.01



D. The composition of the material such as metal substrate and plating shall match with the labelling claim.

金属基材和镀层等材料成分应与产品所标识成分或牌号的相应成分一致。

E. If it is necessary to determine the content of the above-mentioned metal components or identify the labelling claim through testing, national standard test methods shall be used. In the absence of national standard test methods, other technically validated methods can be used.

如需通过检测确定以上提到的金属成分含量或进行标识声称的确认，应采用国家标准方法进行测定。在没有国家标准方法的情况下，可以采用其他经过技术验证的方法。

2) Sensory properties 感官要求

Metal food contact materials and articles shall meet the following
食品接触用金属材料及制品应满足下列感官特性要求

Item 项目	Requirement 要求
Sensory properties 感官	Food contact surfaces shall be clean; metal plating shall not crack and flake; welding surfaces shall be smooth, non-pores, without cracks and burrs 接触食品的表面应洁净，镀层不应开裂、剥落、焊接部分应光洁，无气孔、裂缝、毛刺。
Soaking solutions 浸泡液	Soaking solutions shall be free from odour. 迁移实验所得浸泡液不应有异臭。



3) Chemical requirements 化学要求

A. Migration limits of impurity elements 杂质元素迁移限量

The migration limits of impurity elements shall meet the following requirements 杂质元素迁移限量应符合如下规定：

Item 项目	Limit 指标 (mg/kg)	Test method 测试方法
Arsenic (As) 砷(As)	≤ 0.018 (for uncoated iron frying pans 无涂层铁制煎炒锅) ≤ 0.002 (for other materials and articles 其他金属材料及制品)	Part 2 of GB 31604.49-2016 GB 31604.49-2016 第二部分
Cadmium (Cd) 镉(Cd)	≤ 0.002	Part 2 of GB 31604.49-2016 GB 31604.49-2016 第二部分
Lead (Pb) 铅(Pb)	≤ 0.01	Part 2 of GB 31604.49-2016 GB 31604.49-2016 第二部分
Antimony (Sb) 锑(Sb)	≤ 0.04	Part 2 of GB 31604.49-2016 GB 31604.49-2016 第二部分



B. Migration limits of alloying elements 合金元素迁移限量

The migration limits of alloying elements shall meet the following requirements 合金元素迁移限量应符合如下规定：

Item 项目	Limit 限量(mg/kg)	Test method 测试方法
Aluminium (Al) 铝(Al)	≤ 5 (for uncoated aluminium and aluminium allo 无铝涂层及铝合金制品) ≤ 1 (for other alloys 其他合金)	GB XXXX (in draft sate) GB XXXX (制定中)
Chromium (Cr) 铬(Cr)	≤ 0.25	Part 2 of GB 31604.49-2016 GB 31604.49-2016 第二部分
Cobalt (Co) 钴(Co)	≤ 0.02	GB XXXX (in draft sate) GB XXXX (制定中)
Copper (Cu) 铜(Cu)	≤ 4	GB XXXX (in draft sate) GB XXXX (制定中)
Manganese (Mn) 锰(Mn)	≤ 2.0	GB XXXX (in draft sate) GB XXXX (制定中)
Molybdenum (Mo) 钼(Mo)	≤ 0.12	GB XXXX (in draft sate) GB XXXX (制定中)



Nickel (Ni) 镍(Ni)	≤ 0.14	Part 2 of GB 31604.49-2016 GB 31604.49-2016 第二部分
Tin (Sn) 锡(Sn)	≤ 100 (not applicable for tin plate sheet container 不适用于镀锡薄板容器)	GB XXXX (in draft state) GB XXXX (制定中)
Zinc (Zn) 锌(Zn)	≤ 5	Part 2 of GB 31604.49-2016 GB 31604.49-2016 第二部分

^aThe test elements can be determined according to the material composition (for example, the martensitic stainless steel grade 32Cr13Mo shall be tested for manganese (Mn), chromium (Cr), nickel (Ni), and molybdenum (Mo); for metal plating, the test elements shall be determined according to the metal composition).

可根据材料成分确定待测元素（如对于牌号 32Cr13 的马氏体不锈钢需测定锰、铬、镍和钼；对金属镀层，根据镀层金属成分确定待测元素）

4) Other technical requirements 其他技术要求

- A. Coatings, inks, and adhesives used in metal food contact materials and articles shall meet the requirements of the relevant national food safety standards. Metal food contact materials and articles with coatings, inks and adhesives shall also comply with the physical and chemical requirements in the relevant national food safety standards for coatings, inks and adhesives. When there are different specifications for the same parameter in different standards, the applicable requirement shall be determined according to the provisions of GB 4806.1.



食品接触用金属材料及制品使用的涂料、油墨、粘合剂应符合相应食品安全国家标准的规定。使用了涂料、油墨和粘合剂等材料的食品接触用金属材料及制品，还应符合涂层、油墨和粘合剂等相应食品安全国家标准中理化指标的规定；当不同的标准具有相同项目时，应按照 GB 4806.1 的规定确定适用的限量。

- B. The amount of tin migrated from tin plate sheet containers to the food shall meet the requirements of GB 2762 and other relevant national food safety standards.

镀锡薄板容器迁移到食品中的锡量应满足 GB 2762 及其他相关食品安全国家标准的要求。

5) Labelling requirements 标签标识

In addition to labelling requirements in GB 4806.1, metal food contact materials and articles shall also meet the following labelling requirements:

标签标识除符合 GB 4806.1 的规定外，食品接触用金属材料及制品标签还应符合如下规定：

- A. The metal substrate shall clearly indicate its material type and material composition. If its composition is consistent with the relevant national standard grades, national standard notations for types or grades can be used, such as: 不锈钢 06Cr19Ni10 or 不锈钢 S30408 and 铝合金 3004 (meaning: stainless steel 06Cr19Ni10 or stainless steel S30408 and aluminium alloy 3004).



金属基材还应明确标示其材料类型及材料成分。如果其成分与我国国家标准牌号的相应成分一致，也可采用我国国家标准牌号或统一数字代号表示，例如“**不锈钢 06Cr19Ni10**”或“**不锈钢 S30408**”、“**铝合金 3004**”等。

- B. If the food contact surface is covered with a metal plating, the plating material shall also be marked, such as: **镀铬** (meaning: **chrome plating**), **镀锌镍合金** (meaning: **zinc-nickel alloy plating**). Metal plating with multiple layers shall be labelled in the order of “bottom layer - middle layer - surface layer (food contact layer)” and separated with slashes, such as: **镀铜/镍/铬** (means: **Copper /Nickel/Chromium plating**).

食品接触面覆有金属镀层的，还应标识镀层材料，如“**镀铬**”、“**镀锌镍合金**”等。金属镀层不止一层时，按照底部镀层-中间镀层-面镀层（接触食品面上的镀层）的顺序标出各层金属成分，并以斜杠隔开，如“**镀铜/镍/铬**”。

Note 注:

- *GB 31604.49-2016 Food contact materials and articles: determination of arsenic (As), cadmium (Cd), chromium (Cr), lead (Pb) and determination of migration of arsenic (As), cadmium (Cd), chromium (Cr), nickel (Ni), lead (Pb), antimony (Sb) and zinc (Zn).*
GB 31604.49-2016 食品安全国家标准 食品接触材料及制品 砷、镉、铬、铅的测定和砷、镉、铬、镍、铅、锑、锌迁移量的测定
- *GB 4806.1 General safety requirements for food contact materials and articles*
GB 4806.1 食品接触材料及制品 通用安全要求
- *GB 2762 Limits of contaminants in food*
GB 2762 食品中污染物限量



14. MERCOSUR - Deferred Adapting New Positive List of Additives for Plastic Food Contact Materials (GMC Resolution No. 39/2019)

南方共同市场-推迟采用食品接触用塑料添加剂肯定列表（GMC决议第 39/2019 号）（9/1/2020）

The Mercosur has published GMC Resolution No. 11/2020 to allow Member States to adapt the requirements of Resolution No. 39/2019 Technical Regulation on Positive List of Additives for Plastic Material and Polymer Coating that Contact Food by 11 August 2021.

南方共同市场(MERCOSUR)颁布 GMC（共同市场组织）决议第 11/2020 号，允许成员国在 2021 年 8 月 11 日之前采用 GMC 决议第 39/2019 号《食物接触用塑料和聚合物涂层用添加剂的肯定列表的技术法规》。

15. Colombia - Approved Extension of Emergency Technical Regulation for Ceramic, Glass and Glass-Ceramic Food Contact Articles

哥伦比亚-批准陶瓷、玻璃和玻璃陶瓷食品接触件应急技术法规延期（9/1/2020）

The Ministry of Health and Social Protection of Colombia has published Resolution No. 1163 of 2020 to extend the validity of Resolution No. 1893 of 2019 Emergency Technical Regulation for ceramic, glass and glass-ceramic food contact articles and ceramic cookware for 6 months. The validity shall end on 15 January 2021.

哥伦比亚卫生和社会保护部发布 2020 年第 1163 号决议，将 2019 年第 1893 号决议《陶瓷、玻璃和微晶玻璃食品接触产品和陶瓷炊具应急技术法规》的有效期延长 6 个月。有效期至 2021 年 1 月 15 日。



PART4 Others 其它

16. EU- Article Suppliers Shall Submit SCIP Notification on the SVHC in Articles from 5 January 2021

欧盟- 2021 年 1 月 5 日起欧盟物品供应商须对物品中的 SVHC 物质进行 SCIP 通报

From 5 January 2021, if SVHC substances are present in an article placed on the EU market in a concentration above 0.1 % w/w, the supplier of that article needs to submit a SCIP notification to ECHA (European Chemicals Agency) under Article 9(1)(i) of the Waste Framework Directive (WFD, Directive 2008/98/EC).

从 2021 年 1 月 5 日起，投放欧盟市场上的物品中的 SVHC 物质（高度关注物质）浓度若超过 0.1%（质量分数），则该物品的供应须向 ECHA（欧洲化学品管理局）进行 SCIP 通报。信息须提交至 SCIP 数据库。

The information shall be submitted to the SCIP database (“Substances of Concern in Articles, as such or in Complex Objects (Products)”).

SCIP 数据库全称为“物品及复杂对象（产品）中关注物质数据库”。SCIP 通报是欧盟废弃物框架指令（WFD，指令 2008/98/EC）第 9(1)(i)款对欧盟中的物品供应商的要求。

The following suppliers of articles need to submit the SCIP notification to ECHA 以下供应商需要向 ECHA（欧洲化学品管理局）进行 SCIP 通报：

- ✓ EU producers and assemblers 欧盟生产商和装配商;
- ✓ EU importers 欧盟进口商;



- ✓ EU distributors of articles and other actors who place articles on the market 欧盟经销商和其他将物品投放市场的行为人。

Those not covered by the obligation to submit the SCIP notification to ECHA are 无须向 ECHA 进行 SCIP 通报的行为人：

- ✓ Retailers and other supply chain actors supplying articles directly to consumers 直接向消费者提供物品的零售商和供应链中的其他行为人；
- ✓ Companies outside of the EU 欧盟以外的公司。

Companies outside of the EU are not subject to the SCIP notification obligation and are not allowed to submit SCIP notifications. However, a non-EU supplier of articles should support its EU customers by providing them with the necessary information about the presence of SVHC substances in the supplied articles.

欧盟之外的公司无 SCIP 通报的义务，不允许进行 SCIP 通报。但非欧盟地区的供应商应将其所提供物品中的 SVHC 物质信息告知其欧盟买家。

The SCIP notification under the WFD Directive complements the current SVHC communication and SVHC notification under the REACH Regulation. These obligations are different in criteria, actors concerned, information to provide:

欧盟废弃物框架指令(WFD)所要求的 SCIP 通报义务，是对现时 REACH 法规所规定的 SVHC 信息交流（传递信息）和 SVHC 通报的补充。三种义务的触发标准、涉及的行为人和须提供的信息不同。详见下表：



Table 1 - Comparison of SCIP Notification, SVHC Communication and SVHC notification

表 1 - SCIP 通报、SVHC 信息传递和 SVHC 通报对比表

	SCIP Notification SCIP 通报	SVHC Communication SVHC 信息传递	SVHC Notification SVHC 通报
Application Date 实施日期	From 5 January 2021 从 2021 年 1 月 5 日起	From 1 June 2007 从 2007 年 6 月 1 日起	From 1 June 2008 从 2008 年 6 月 1 日起
Legal Basis 法规依据	WFD (Directive 2008/98/EC), Article 9(1)(i) 废弃物框架指令 (WFD 指令 2008/98/EC) 第 9(1)(i)款	REACH (Regulation (EC) No 1907/2006), Article 33(1) and 33(2) REACH 法规(EC) No 1907/2006) 第 33(1)款和第 33(2)款	REACH (Regulation (EC) No 1907/2006), Article 7(2) REACH 法规(EC) No 1907/2006) 第 7(2)款
Obligation 法律义务	Article supplier provides information to ECHA 物品供应商提供信息给 ECHA	Article supplier provides information to recipients and consumers 物品供应商提供信息给物品接收者和消费者	Article producer/importer provides information to ECHA 物品生产商/进口商提供信息给 ECHA
Criteria (Threshold) 触发限值 (阈值)	SVHC > 0.1% SVHC 物质在物品中浓度 > 0.1%		SVHC > 0.1%, and SVHC quantity > 1 tonne/year SVHC 在物品中浓度 > 0.1%; 且 SVHC 年生产量/年进口量 > 1 吨
Actors Concerned 须进行通报/信息交流的行为人	- EU producers and assemblers - 欧盟生产商和装配商 - EU importers 欧盟进口商 - EU distributors of articles and other actors who place articles on	- EU/EEA suppliers of articles - 欧盟/欧洲经济区供应商	- EU/EEA producers, - EU/EEA importers. 欧盟/欧洲经济区生产商- 欧盟/欧洲经济区进口商



	<p>the market.</p> <p>- 欧盟经销商和其他将物品投放市场的行为人</p>		
<p>Minimum Information to Provide</p> <p>至少须提供的信息</p>	<p>(1) Identification of the article 物品的辨识信息;</p> <p>(2) Name, concentration range and location of SVHC substance in the article SVHC 物质的名称、浓度范围和其在物品中的部位;</p> <p>(3) Safe use information 安全使用信息;</p> <p>(4) Information to ensure proper management of the article once it becomes waste 确保物品成为废弃物后得到恰当管理的信息。</p>	<p>(1) Name of the substance; 物质名称</p> <p>(2) Safe use information. 安全使用信息。</p>	<p>(1) Identity and contact details of producer/importer 生产商/进口商的身份信息和联系方式;</p> <p>(2) Registration number if available 注册号 (如有) ;</p> <p>(3) Identity of the substance 物质的辨识信息;</p> <p>(4) Classification of the substance 物质分类;</p> <p>(5) Brief description of the use of the substance 对物质用途的简要说明;</p> <p>(6) Tonnage range of substance 物质的吨位范围。</p>



17. EU- Public Consultation on 2 Potential Substances of Very High Concern (9/1/2020)

欧盟 - 对 2 项被提议的新 SVHC 高度关注物质物质进行公众咨询

On 1 September 2020, the European Chemical Agency (ECHA) has launched a Public Consultation on 2 potential Substances of Very High Concern (SVHC). The proposed substances in the consultation are listed as below, the deadline for commenting is 16 October 2020.

2020 年 9 月 1 日，欧洲化学品管理局（ECHA）对被提议加入高度关注物质（SVHC）清单的 2 项物质开展公众咨询，关于这些物质的信息如下表所示。公众咨询截止至 2020 年 10 月 16 日。

Name 物质名称	EC No. EC 号	CAS No. CAS 号	Proposing authority 提议国家	Reason for proposing 提议理由
bis(2-(2-methoxyethoxy)ethyl) ether 四乙二醇二甲醚	205-594-7	143-24-8	Austria 奥地利	Toxic for reproduction (Article 57c) 生殖毒性（条款 75c）
Diocetyl tin dilaurate, stannane, dioctyl-, bis(cocoacyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety 二辛基二月桂酸锡；锡烷，二辛基，双(椰油酰氧基)衍生物；以及其他任何锡烷，二辛基，双(脂肪酰氧基)衍生物，其中脂肪酰氧基基团的主要碳原子数为 12	-	-	Sweden 瑞典	Toxic for reproduction (Article 57c) 生殖毒性（条款 75c）



18. EU - Proposed Commission Delegated Regulation Amending Annex I to POPs Regulation (EU) 2019/1021 Regards PFOA (9/17/2020) 欧盟-提议修订持久性有机污染物(POPs)法规中关于全氟辛酸的限制项

The European Commission has proposed Commission Delegated Regulation (EU) to amend Annex I to Persistent Organic Pollutants Regulation (EU) 2019/1021 as regards the entry of perfluorooctanoic acid (PFOA). The specific exemption of PFOA shall be amended as following:

2020年9月，欧盟委员会起草了授权法规，将修订持久性有机污染物(POPs)法规(EU) 2019/1021 附录 I 中有关全氟辛酸(Perfluorooctanoic acid, PFOA)，其盐和全氟辛酸相关化合物的限制项。将对其中的豁免进行以下修改：

- 1) In point 3, "perfluoro" shall be added before carbon chain.
在第3点中，在“碳链”一词之前增加“全氟”字样。
- 2) In point 4, the limit of ionizing irradiation 400 kilograys shall be removed.
在第4点中，将去除“电离辐射”前的“高达400 kilograys”字样。
- 3) Point 10 shall be newly added as following 将新增以下第10点：

For the purposes of this entry, exemption from the control measures shall apply to concentrations of PFOA and its salts and/or PFOA-related compounds equal to or below 2 mg/kg (0.0002 % by weight) where they are present in medical devices other than invasive devices and implantable devices. This exemption shall be reviewed and assessed by the Commission no later than two years after these amendments enter into force.



此限制项中，对于非侵入性和非可植入性的医疗器械，作为微量污染物的全氟辛酸(PFOA)及其盐类和/或全氟辛酸相关化合物，浓度可等于或低于 2 mg/kg (0.0002%)（按重量计）。欧盟委员会应在此修订生效后两年内重新审查和评估此项豁免。

Note 注

Annex I: Substances prohibited to be used for manufacturing, placing on the market and use.

附录 I: 《禁止用于制造、投放市场和使用的物质》

19. EU- Proposed Commission Delegated Regulation Amending Annex I to POPs Regulation (EU) 2019/1021 Regards PCP

欧盟-提议修订持久性有机污染物(POPs)法规中关于五氯苯酚的限制项

In September 2020, the European Commission has proposed Commission Delegated Regulation (EU) to amend Annex I to Persistent Organic Pollutants Regulation (EU) 2019/1021 as regards the entry of pentachlorophenol (PCP) and its salts and esters. According to the proposed Commission Delegated Regulation, the following specific exemption shall be added:



2020年9月，欧盟委员会起草了授权法规，将修订持久性有机污染物(POPs)法规(EU) 2019/1021 附录 I 中有关五氯苯酚(Pentachlorophenol, PCP)及其盐类和酯类的限制项。根据该授权法规草案，将增加以下豁免：

For the purposes of this entry, the exemption from control measures shall apply to concentrations of pentachlorophenol and its salts and esters equal to or below 5 mg/kg (0.0005 % by weight) where they are present in substances, mixtures or articles.

此限制项中，豁免作为微量污染物而存在于物质、混合物或物品中的，浓度等于或小于 5 mg/kg (0.0005%)（按重量计）的五氯苯酚及其盐类和酯类。

Note 注

Annex I: Substances prohibited to be used for manufacturing, placing on the market and use.

附录 I：禁止用于制造、投放市场和使用的物质



20. EPA/ USA- Finalizes Amendments to SNUR for Long-chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances

美国 EPA- 确定对长链全氟烷基羧酸盐和全氟烷基磺酸盐化学物质的 SNUR 修正案

On July 27, 2020, the U.S. Environmental Protection Agency (EPA) promulgated the significant new use rule (SNUR) for long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate chemical substances, and an amendment to make inapplicable the exemption for persons who import a subset of LCPFAC chemical substances as part of surface coating on articles.

2020 年 7 月 27 日，美国环境保护署（EPA）颁布了关于长链全氟烷基羧酸盐（LCPFAC）和全氟烷基磺酸盐化学物质的显著新用途规则（SNUR），以及一项修正案，规定豁免不适用进口作为物品表面涂层一部分的 LCPFAC 子集化学物质的人员。

This final rule requires persons to notify the EPA at least 90 days before commencing the manufacture (including import) or processing of these chemical substances for the significant new uses described in this notice. The required significant new use notification initiates the EPA's evaluation of the conditions of use associated with the significant new use. Manufacturing (including import) or processing for the significant new use are prohibited from commencing until the EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. The EPA states that as with any SNUR, the final rule excludes ongoing uses as ongoing uses cannot be subject to a SNUR.



这一最终规则要求人们在开始制造（包括进口）或加工这些化学物质用于申报中所述的显著新用途之前至少 90 天通知 EPA。所需的显著新用途申报将启动 EPA 对与显著新用途相关的使用条件的评估。在 EPA 对该申报进行审查，对该申报做出适当决定并采取与该决定有关的必要行动之前，禁止针对显著新用途进行制造（包括进口）或加工。EPA 声明与任何 SNUR 一样，最终规则也将持续使用排除在外，因为持续使用不受 SNUR 的约束。

Effective date of the final rule is September 25, 2020.

最终规则的生效日期是 2020 年 9 月 25 日。

Manufacture (including import), processing, or distribution in commerce of chemical substances and mixtures in the class of LCPFAC and perfluoroalkyl sulfonate chemical substances may be potentially affected by this action.

LCPFAC 和全氟烷基磺酸盐类化学物质和混合物的制造（包括进口）、加工或商业分销可能会受到此行动的影响。

The final SNUR will require persons to notify the EPA at least 90 days before commencing:

最终 SNUR 要求人员在活动前至少 90 天通知 EPA:

- ✓ The manufacturing (including importing) or processing of a subset of LCPFAC chemical substances for any use that was not ongoing after December 31, 2015;

2015 年 12 月 31 日后未持续使用的 LCPFAC 子集化学物质的制造（包括进口）或加工；



- ✓ The manufacturing (including importing) or processing of all other LCPFAC chemical substances for which there were no ongoing uses as of January 21, 2015 (the date of the original proposed SNUR);

2015 年 1 月 21 日（最初提议的 SNUR 日期）后未持续使用的所有其它 LCPFAC 化学物质的制造（包括进口）或加工；

- ✓ The import of a subset of LCPFAC chemicals as part of a surface coating on articles; and
作为物品表面涂层一部分的 LCPFAC 子集化学物质的进口；以及
- ✓ The import of perfluoroalkyl sulfonate chemical substances as part of carpets.
作为地毯一部分的全氟烷基磺酸盐化学物质的进口。

This final SNUR will preclude the commencement of such manufacturing and processing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

最终 SNUR 将阻止此类制造和加工的开始，直到 EPA 对该申报进行了审查，对该申报做出了适当的决定并采取了与该决定相关的必要措施。

This final SNUR also modifies the requirements for a subset of LCPFAC chemical substances in the existing SNUR at 40 CFR 721.10536 by:

最终 SNUR 还修改了 40 CFR 721.10536 中现有 SNUR 对 LCPFAC 子集化学物质的要求：

- ✓ Designating manufacturing (including importing) or processing of LCPFAC chemical substances listed in the list of LCPFAC chemical substances in



this unit for any use that was no longer ongoing after December 31, 2015, as a significant new use; and

本单元 LCPFAC 化学物质清单中列出的 LCPFAC 化学物质的制造（包括进口）或加工用于 2015 年 12 月 31 日之后不再继续使用的任何用途指定为显著新用途；以及

- ✓ Designating manufacturing (including importing) or processing of perfluorooctanoic acid (PFOA) or its salts, which are considered LCPFAC chemical substances, and all other LCPFAC chemical substances for any use not ongoing as of January 21, 2015, the date on which the proposed rule was published, as a significant new use.

全氟辛酸（PFOA）或其盐（被视为 LCPFAC 化学物质）以及所有其它 LCPFAC 化学物质的制造（包括进口）或加工用于 2015 年 1 月 21 日（提议规则发布的日期）后不再继续使用的任何用途指定为显著新用途。

21. Brazil - Approved Amendment on Requirements for School Articles Regards to Toxicological Test (9/3/2020)

巴西-批准关于学校用品毒理测试的修正法案

The National Institute of Metrology, Quality and Technology (INMETRO) of Brazil has published Ordinance No.237/2020 to approve the amendments on regulation for School Articles, which were approved by the Ordinance No.481/2010.



巴西国家计量、质量和技术研究所 (INMETRO) 发布了 INMETRO 法令第 237/2020 号以修改学校用品法规, 该修正案已被 INMETRO 法令第 481/2010 号批准。

According to this Ordinance, if the certification process is delayed due to the toxicological tests of school articles (containing paints, glues, gouaches, watercolor and powder material), the issuance of the certificate and/or confirmation of maintenance by the Product Certification Bodies can be done upon proof of contracting the Primary Dermal Irritability tests. The Certified Body shall review the Certificate of Conformity and/or Confirmation of Maintenance, including the data related to the toxicological tests after it's finished. It shall be allowed until 9 January 2021. After this date, toxicological tests (Acute Oral Toxicity and / or Dermal Irritability) shall be finished before the issuance.

根据该法令, 在 2021 年 1 月 9 日之前, 如果是由于学校用品 (含油漆, 胶水, 水粉, 水彩和粉状材料) 的毒理测试而导致认证过程延迟, 允许产品认证机构通过初始皮肤刺激性测试来签发证书和/或维持确认证书。认证机构应审查合格证书和/或维持确认证书, 包括毒理测试相关的数据。在 2021 年 1 月 9 日之后, 相关产品的毒理测试 (急性口腔毒性和/或皮肤刺激性) 应在证书签发前完成。

School items as paint, glue, gouache, watercolor and powder material in a mass less than 3g per unit of use that are exempt from toxicological tests (according to ABNT NBR 15236) shall have their toxicological safety confirmed through a self-declaration issued by the manufacturer accompanied by a toxicological report from the supplier of the school articles (paint, glue, gouache, watercolor, powder material).

油漆、胶水、水粉、水彩和粉状材料的用量小于 3g (每单位) 的学校用品可豁免毒理测试 (根据标准 ABNT NBR 15236), 但应通过制造商自我



声明连同学校用品的油漆、胶水、水粉、水彩和粉状材料的原料供应商的毒理报告来确认其毒理安全性。

22. California/USA - Approved Ban on Fur Products (9/4/2020)

加利福尼亚/美国-批准禁止毛皮制品

The Governor of California has signed Bill AB44 into law, banning the sale and manufacture of fur products. The law shall become operative on 1 January 2023.

加州州长签署了 AB44 法案，禁止销售和制造毛皮制品。该法案将于 2023 年 1 月 1 日生效。

From 1 January 2023 从 2023 年 1 月 1 日起，

1) It shall be unlawful to sell, offer for sale, display for sale, trade, or otherwise distribute for monetary or nonmonetary consideration a fur product in the state.

以货币或非货币对价出售、要约出售、陈列出售、买卖或以其他方式分销毛皮制品，均属违法。

2) It shall unlawful to manufacture a fur product in the state for sale.

在州内生产销售的毛皮制品是违法的。

3) The prohibitions shall not apply to the following

禁止不适用于下列情况：



- A. A used fur product. 二手毛皮制品。
- B. A fur product used for religious purposes.
用于宗教目的的毛皮制品。
- C. A fur product used for traditional tribal, cultural, or spiritual purposes by a member of a federally recognized Native American tribe or a non-federally recognized California Native American tribe listed on the California Tribal Consultation List maintained by the Native American Heritage Commission.
毛皮制品，用于传统的部落、文化或精神目的，由联邦认可的美国土著部落成员或非联邦认可的加利福尼亚土著美洲部落的成员在由印第安人遗产委员会维护的加利福尼亚部落咨询名单上列出。
- D. Any activity expressly authorized by federal law.
联邦法律明确授权的任何活动。

- 4) A person who sells or trades any used fur product or fur product described in Point 3 shall maintain a record of each sale or trade of one of those exempt fur products for at least one year.
售卖或买卖二手毛皮制品或第 3 点中提及毛皮制品，须将获豁免毛皮制品的每次售卖或买卖纪录保存至少一年。

Note 注:

- *"Fur" means any animal skin or part thereof with hair, fleece, or fur fibres attached thereto, either in its raw or processed state.*
"毛皮"是指任何动物皮肤或其部分，其上附着有毛发、绒毛或毛皮纤维，无论是原材料还是加工制品。
- *"Fur product" means any article of clothing or covering for any part of the body, or any fashion accessory, including, but not limited to, handbags, shoes, slippers, hats, earmuffs, scarves, shawls,*



gloves, jewellery, keychains, toys or trinkets, and home accessories and decor, that is made in whole or in part of fur.

"毛皮制品"是指全部或部分毛皮制成的任何服装或身体任何部位的覆盖物，或任何时尚配饰，包括但不限于手提包、鞋子、拖鞋、帽子、耳罩、围巾、披肩、手套、珠宝、钥匙链、玩具或小饰物，以及家居配件和装饰。

- **"Fur product"** does not include any of the following:

"毛皮制品"不包括以下任何一项：

- A dog or cat fur product, as defined in Section 1308 of Title 19 of the United States Code, as that section read on 1 January 2020.*

《美国法典》第19编第1308节中定义的狗或猫毛皮产品，该节阅于2020年1月1日。

- An animal skin or part thereof that is to be converted into leather, which in processing will have the hair, fleece, or fur fibre completely removed.*

一种动物的毛皮或其一部分，生产加工成皮革，在加工过程中会完全去除毛发、绒毛或毛皮纤维。

- Cowhide with hair attached thereto. 带毛的牛皮制品。*

- Deerskin, sheepskin, or goatskin with hair attached thereto.*

鹿皮、羊皮或山羊皮的附毛制品。

- The pelt or skin of an animal that is preserved through taxidermy.*

通过动物标本保存下来的动物毛皮或皮。

- A product made pursuant to Section 3087 or 4303 of the California Code.*

根据《加利福尼亚州法典》第3087节或第4303节制造的产品。



- *"Used fur product" means fur in any form that has been worn or used by an ultimate consumer.*
"二手毛皮产品"指最终消费者穿着或使用过的任何形式的毛皮。

23. United Kingdom Approved the Environmental Protection (Plastic Straws, Cotton Buds and Stirrers) (England) Regulations 2020 英国批准《环境保护（塑料吸管、棉签和搅拌棒）（英格兰）法规 2020》(9/22/2020)

On 10 September 2020, the Department for Environment, Food and Rural Affairs of United Kingdom has published SI 2020/971 The Environmental Protection (Plastic Straws, Cotton Buds and Stirrers) (England) Regulations 2020, which prohibit the use of single use plastic straws, cotton buds and stirrers, with some exemptions. This regulation shall apply to England only. The following is the detail of the regulation:

2020年9月10日，英国环境、食品和农村事务部发布了法规 SI 2020/971——《环境保护（塑料吸管、棉签和搅拌棒）（英格兰）法规 2020》。此法规禁止一次性塑料吸管、棉签和搅拌棒的使用，并设立了一些豁免情况。本法规只适用于英格兰。以下为法规详情：

1) Single use plastic straws 一次性塑料吸管

- A. Single use plastic straw, as well as drink products with attached plastic straws shall be prohibited to be supplied on the market to an end user.

禁止在市场上将一次性塑料吸管，以及附有塑料吸管的饮料产品提供给最终用户。



B. The prohibition on single use plastic straws shall not apply to the following products

对一次性塑料吸管的禁止不适用于下列产品

a. A single use plastic straw supplied by a retail pharmacy business

零售药店供应的一次性塑料吸管；

b. A catering establishment of a single use plastic straw together with food or drink which is supplied immediate consumption unless it is visible or requested by the consume;

餐饮机构中的与即食食物或饮料一同提供的一次性塑料吸管。前提是该一次性塑料吸管对消费者不可见并且是由消费者进行索要；

c. A single use plastic straw that is used as a relevant device or for medical purposes;

用作相关设备或医疗用途的一次性塑料吸管；

d. A single use plastic straw that is a packaging;

作为包装的一次性塑料吸管；

e. A single use plastic straw used in

用于以下场所的一次性塑料吸管：

- A care home 护理中心；
- Premises used for early years provision
用于满足早教需求的场所；
- A school; or 学校； 或
- A prison or other place of detention 监狱或其他拘留场所。



2) Single use plastic stemmed cotton buds 一次性塑料棉签

A. Single use plastic stemmed cotton buds shall be prohibited to be supplied on the market to an end user.

禁止在市场上将一次性塑料棉签提供给最终用户。

B. The prohibition on single use plastic stemmed cotton buds shall not apply to the following products:

对一次性塑料棉签的禁止不适用于下列产品：

a. A single use plastic stemmed cotton bud that is used as a relevant device or for medical purposes;

用作相关设备或医疗用途的一次性塑料棉签；

b. A single use plastic stemmed cotton bud that is supplied by a forensic service provider;

由法医服务提供者所供应的一次性塑料棉签；

c. A single use plastic stemmed cotton bud that is used for scientific purposes.

用于科学目的的一次性塑料棉签。

3) Single use plastic drink stirrer 一次性塑料饮料搅拌棒

Single use plastic drink stirrer shall be prohibited to be supplied on the market to an end user.

禁止在市场上将一次性塑料饮料搅拌棒提供给最终用户。



4) Effective date 生效日期

- A. 1 October 2020: prohibitions (with the relevant exemptions) other than the prohibition of plastic straws attaching on drink products (with the relevant exemptions).

2020 年 10 月 1 日：针对除饮料产品上附带的塑料吸管（以及相关豁免）以外的其他禁止（以及相关豁免）。

- B. 3 July 2021: prohibition of plastic straws attaching on drink products (with the relevant exemptions).

2021 年 7 月 3 日：针对饮料产品上附带的塑料吸管（以及相关豁免）的禁止。

Note 注释：

- A. *Attached plastic straw: a single use plastic straw which is attached to the packaging of a drink product and is intended to be used to consume that drink.*

随附的塑料吸管：附在饮料产品的包装上的，并用于饮用该饮料的一次性塑料吸管。

- B. *Catering establishment: a restaurant, canteen, club, public house or similar establishment (including a vehicle or a fixed or mobile stall) which supplies food or drink that is ready for consumption without further preparation.*

餐饮机构：餐厅、食堂、俱乐部、公共房屋或提供即食食物或饮料（无需进一步制作）的类似机构（包括车辆、固定或移动摊档）。



24. Taiwan - Approved Amendments to the Management Requirements for Toxic Chemical Substances (9/17/2020)

台湾-批准有毒化学物质管理要求修正案

The Environmental Protection Administration (EPA) of Taiwan has approved the amendments on certain provisions in “Categories and Management of Handling for Toxic Chemical Substances” under the Notice No. 1098000452A, which concern PBDEs, Dicofol and other substances. The Notice has already come into force. The new provisions are shown as follows:

台湾环境保护署发布第 1098000452A 号公告，批准对“有毒化学物质的种类及处理管理”中关于多溴二苯醚、二甲酚及其他物质条款的修订。该公告已实施。新的条款如下：

No	Substance name 物质名称	CAS No. CAS 号	Restrictions 限制	Exemptions 豁免
1	Octabromodiphenyl ether 八溴联苯醚	32536-52-0	Prohibit to manufacture, import, sale and use. However, it is not prohibited for research, experiment, or educational purposes. 禁止制造、进口、销售及使用。但为研究、实验或教育目的，不受禁止	Research, testing and education 研究、测试和教育
2	Pentabromodiphenyl ether 五溴联苯醚	32534-81-9 60348-60-9		
3	Tetrabromodiphenyl ether 四溴联苯醚	40088-47-9 5436-43-1		
4	2,2',4,4',5,5'- hexabromodiphenyl ether 2,2',4,4',5,5'-六溴联苯醚	68631-49-2		
5	2,2',4,4',5,6'-	207122-15-4		



	hexabromodiphenyl ether 2,2',4,4',5,6'-六溴联苯醚			
6	2,2',3,3',4,5',6- heptabromodiphenyl ether 2,2',3,3',4,5',6-七溴联苯醚	446255-22-7		
7	2,2',3,4,4',5',6- heptabromodiphenyl ether 2,2',3,4,4',5',6-七溴联苯醚	207122-16-5		
8	Perfluorooctane sulfonic acid 全氟辛基磺酸	1763-23-1		1. Research, testing and education; 研究、测试和教育;
9	Lithium perfluorooctane sulfonate 十七氟-1-辛烷磺酸锂	29457-72-5	No specific restrictions (Note) 无特别限制(注)	2. Usage in hard metal plating in closed systems; 在封闭系统用于硬质合金电镀;
10	Perfluorooctane sulfonyl fluoride 全氟辛基磺酰氟 (newly added 新增加)	307-35-7		1. Class B fire extinguishing foam in fire extinguishing equipment before 31 December 2022. 灭火设备中 B 类灭火泡沫在 2022 年 12 月 31 日之前。
11	Perfluorooctanoic acid (PFOA) 全氟辛酸 (newly added 新增加)	335-67-1	No specific restrictions (Note) 无特别限制(注)	1. Research, testing and education 研究、测试和教育; 2. Semiconductor photolithography or etching process 半导体光刻和蚀刻过程; 3. Manufacture of photographic film coating 制造照相胶片涂料; 4. Manufacture of labor textiles with oil and water repellency;



				<p>防水防油的劳保纺织品;</p> <p>5. Class B fire extinguishing foam in fire extinguishing equipment before 31 December 2022. 灭火设备中 B 类灭火泡沫, 在 2022 年 12 月 31 日之前。</p> <p>6. Manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride film (PVDF) for industrial waste heat exchangers and industrial sealants 生产聚四氟乙烯(PTFE)和聚偏二氟乙烯(PVDF)电影工业废料热交换器和工业密封胶;</p> <p>7. Manufacture of fluorinated ethylene propylene (FEP) for high-voltage wires and cables 生产氟化乙烯丙烯(聚全氟乙丙烯)高压电线和电缆;</p> <p>8. Manufacture of circular rings, triangle belts and plastic parts for automotive interior. 制造圆形环、三角皮带和塑料零件汽车内饰。</p>
12	Dicofol 三氯杀螨醇 (newly added 新增加)	115-32-2 10606-46-9	Prohibit to manufacture, import, sale and use. However, it is not prohibited for	Research, testing and education 研究、测试和教育



		<p>research, experiment, or educational purposes.</p> <p>禁止制造、进口、销售及 使用。但为研究、实验或教育目的，不受禁止</p>	
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Note: Unless there are specific prohibitions or exemptions, any person who intends to manufacture, import or sell any of the above-mentioned chemicals above the threshold amount and exceeding specific concentration shall apply for a permit to do so. Other obligations like registration, labelling and reporting of activities shall apply.

注: 除特殊禁止或豁免外，任何人士如欲制造、进口或销售上述化学品，超过阈值及特定浓度，须申请许可证。注册、标签和报告等其他义务也适用。



25. Korea - Approved Amendments to Labelling Standards for Sanitary Products (9/24/2020)

韩国 - 批准对卫生用品的标签标准的修订

The Korean Ministry of Food and Drug Safety (MFDS) has issued Notice No. 2020-79 to approve and adopt the whole amendments on "Labelling Standards and for Sanitary Products" as informed previously. This notice shall be effective from 1st July 2022. It shall apply to the sanitary products which are manufactured, processed, subdivided, sanitarily treated or imported after implementation. If the products are manufactured, processed, subdivided, sanitarily treated or imported according to previous regulation, it can be allowed to sell (if there is expiration date, until expiration date) until stock exhaustion.

韩国食品药品安全部（MFDS）发布了第 2020-79 号公告，批准并采用对《卫生用品的标签标准》的全部修订。该公告将于 2022 年 7 月 1 日生效，适用于在公告实施后生产、加工、再分、卫生处理或进口的卫生用品。如果产品是按照先前的规定制造、加工、再分、卫生处理或进口的卫生用品，则可以允许其销售（如果有截止日期，直到截止日期）至库存耗尽。



26. Ukraine - Draft Amendment to Annex 3 and 4 to RoHS Regulation

乌克兰-提议修订 RoHS 法规附件 3 和附件 4 (9/30/2020)

The Ministry for Development of Economy, Trade and Agriculture of Ukraine has proposed to amend Annex 3 and 4 to Technical Regulation on restriction of hazardous substances in electrical and electronic equipment (RoHS), aiming at aligning with the amendments to the EU Directive 2011/65/EC. Here are the highlights:

乌克兰经济、贸易和农业发展部提议修订《关于限制电气和电子设备中有害物质的技术法规》（RoHS）的附件 3 和 4，旨在与欧盟指令 2011/65/EC 的修订保持一致。以下是重点内容：

1) Amendments to Annex 3 to RoHS Regulation

RoHS 法规附件 3 的修订

Exemption number 豁免编号	Exemption 豁免	Scope and term of application 应用范围
9	<p>Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75 % by weight in the cooling solution</p> <p>吸热式电冰箱中作为碳钢冷却系统防腐剂的六价铬，其在冷却液中的含量不得超过 0.75%。</p>	<p>-Before July 21, 2021 - for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments</p> <p>2021 年 7 月 21 日前-第 8、9 类（体外诊断医疗设备及工业监控设备除外）</p> <p>- Before July 21, 2023 – for category 8 in vitro diagnostic medical devices</p>



		<p>2023 年 7 月 21 日前-第 8 类中的体外诊断医疗设备</p> <p>- Before July 21, 2024 - for category 9 industrial monitoring and control instruments, and category 11</p> <p>2024 年 7 月 21 日前-第 9 类中的工业监控设备和第 11 类</p>
<p>9(a) -I (newly added) 新增加)</p>	<p>Up to 0.75% hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators (including minibars) designed to operate fully or partly with electrical heater, having an average utilised power input < 75 W at constant running conditions</p> <p>恒定运行条件下平均输入功率 < 75 W，设计为完全或部分与电加热器一起运行的吸热式电冰箱（包括迷你冰箱）碳钢冷却系统的冷却液中用作防腐剂的六价铬，其含量不得超过 0.75%。</p>	<p>- Before March 5, 2021 - for categories 1-7, 10</p> <p>2021 年 3 月 5 日前 - 第 1-7、10 类</p>
<p>9(a) -II (newly added 新增 加)</p>	<p>Up to 0.75% hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators:</p> <p>吸热式电冰箱中用作碳钢冷却系统防腐剂的六价铬，其含量不得超过 0.75%:</p> <p>a. designed to operate fully or partly with electrical heater, having an average utilised power input \geq 75 W at constant running conditions;</p> <p>恒定运行条件下平均输入功率 \geq 75 W，设计为完全或部分与电加热器一起运行；</p> <p>b. designed to fully operate with non-electrical heater.</p>	<p>- Before July 21, 2021 - for categories 1-7, 10</p> <p>2021 年 7 月 21 日前 - 第 1-7、10 类</p>



	设计为完全与非电加热器一起运行。	
41	<p>Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines</p> <p>由于技术原因，必须直接安装在手持式内燃机的曲轴箱或气缸或内部点火模块，以及其他电子电气引擎控制系统中所含焊料和电子电气部件端接剂中的铅，以及印刷电路板饰面中的铅。</p>	<p>-Before March 31, 2022 - for categories 1-7, 10 and 11 2022 年 3 月 31 日前 - 第 1-7、10 和 11 类</p> <p>-Before July 21, 2021 - for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments 2021 年 7 月 21 日前 - 第 8、9 类（体外诊断医疗设备及工业监控设备除外）</p> <p>- Before July 21, 2023 - for category 8 in vitro diagnostic medical devices 2023 年 7 月 21 日前 - 第 8 类体外诊断医疗设备</p> <p>- Before July 21, 2024 - for category 9 industrial monitoring and control instruments 2024 年 7 月 21 日前 - 第 9 类中的工业监控设备</p>
43 (newly added 新增加)	<p>Bis(2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use and provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin and the concentration value of bis(2-ethylhexyl) phthalate does not exceed:</p> <p>发动机系统橡胶组件中的邻苯二甲酸双（2-乙基己基）</p>	<p>- Before July 21, 2024 - for category 11 2024 年 7 月 21 日前 - 第 11 类</p>



	<p>酯，旨在用于非专用于消费者的设备，且确保塑性材料和人体粘膜接触或与人体皮肤长时间接触时其邻苯二甲酸二(2-乙基己基)酯的值不超过：</p> <p>a. 30 % by weight of the rubber for 作为以下用途的橡胶重量的 30%</p> <ul style="list-style-type: none"> i. gasket coatings 垫片涂层; ii. solid-rubber gaskets 固体橡胶垫片; or 或 iii. rubber components included in assemblies of at least three components using electrical, mechanical or hydraulic energy to do work, and attached to the engine. 利用电能、机械能或液压工作的至少包含三个部件的组件中所使用的橡胶部件，且该组件和发动机相连接。 <p>b. 10 % by weight of the rubber for rubber-containing components not referred to in point a. a 中未提及的包含橡胶的部件，含量为橡胶的重量 10%。</p> <p>For the purposes of this entry, 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.</p> <p>本条目中，“与人的皮肤长时间接触”是指持续接触时间超过 10 分钟或每天间断接触达 30 分钟。</p>	
<p>44 (newly added 新增 加)</p>	<p>Lead in solder of sensors, actuators, and engine control units of combustion engines installed in equipment used at fixed positions while in operation which is designed for</p>	<p>- Before July 21, 2024 - for category 11 2024 年 7 月 21 日前 - 第 11 类</p>



	<p>professionals, but also used by non-professional users</p> <p>安装在固定位置使用的设备中的内燃机传感器、执行器和发动机控制单元的焊锡中的铅，这些设备是为专业人士设计的，但也供非专业用户使用。</p>	
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2) Amendments to Annex 4 to RoHS Regulation
RoHS 法规附件 4 的修订

Exemption number 豁免编号	Exemption 豁免	Scope and term of application 应用范围
37	<p>Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:</p> <p>应用于至少以下情况之一电导率测试所用镀铂电极中的铅：</p> <p>a. wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0.1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;</p> <p>在未知浓度的实验室应用中，测试的电导率范围超过一个数量级（如范围在 0.1mS/m 和 5mS/m 间）；</p> <p>b. measurements of solutions where an accuracy of +/- 1 % of the sample range and where high corrosion resistance of the electrode are required</p>	<p>- Before December 31, 2025 2025 年 12 月 31 日前</p>



	<p>for any of the following: 精确度要求+/-1%并且在以下任意一种需高耐腐蚀性电极溶液中的测试:</p> <ul style="list-style-type: none"> ✓ solutions with an acidity < pH 1; 酸性溶液 pH < 1 ✓ solutions with an alkalinity > pH 13; 碱性溶液 pH >13 ✓ corrosive solutions containing halogen gas 含卤素气体的腐蚀性溶液 <p>c. measurements of conductivities above 100 mS/m that must be performed with portable instruments. 必须使用便携式仪器，进行的电导率超过 100 mS/m 的测试。</p>	
<p>41</p>	<p>Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases</p> <p>铅作为聚氯乙烯 (PVC) 中的热稳定剂，用作电流、电位和电导电化学传感器的基础材料，这些传感器用于体外诊断医疗设备中，用于分析血液和其他体液和人体气体</p>	<p>- Before March 31, 2022 2022 年 3 月 31 日前</p>
<p>44 (newly added 新增加)</p>	<p>Cadmium in radiation tolerant video camera tubes designed for cameras with a centre resolution greater than 450 TV lines which are used in environments with ionising radiation exposure exceeding 100 Gy/hour and a total dose in excess of 100kGy</p>	<p>- Before March 31, 2027 - for category 9 2027 年 3 月 31 日前-第 9 类</p>



	<p>分辨率大于 450 TV lines 的耐辐射摄像管中的镭， 该摄像机用于辐射暴露超过 100 Gy/小时但辐射总 量不超过 100kGy。</p>	
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 400 886 9926

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