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PART1 Food Contact Materials 食品接触产品

1 3/10/2020- EU - Draft Amendments to Regulation (EU) No 10/2011 on Plastic Food Contact Materials and Articles 欧盟- (EU) No 10/2011 塑料食品接触材料法规修订草案

The European Commission has proposed to amend Regulation (EU) No 10/2011 on plastic food contact materials and articles. Here is the summary of the proposal:

欧盟委员会提议修订(EU) No 10/2011 关于塑料食品接触材料和物品的法规。
以下是该提议的摘要：

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 stimulant

第 236 项：1,3-苯二胺 - 增加 0.002 mg/kg（食品或食品模拟液）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其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改性的蒙脱土



b. Entry 1076: Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanedyl)], C10-16 alkyl ester, CAS No. 1227937-46-3

第 1076 项：亚磷酸三苯酯与 α - 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:

增加一个迁移限值列表的表格:

	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 [<i>please refer to point c(i)</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 [<i>please refer to point c(ii)</i>] 0.05 [请参见第 c(ii)点]
Gadolinium 钆	Yes 是	0.05 [<i>please refer to point c(ii)</i>] 0.05 [请参见第 c(ii)点]
Iron 铁	Yes 是	48
Lanthanum 镧	Yes 是	0.05 [<i>please refer to point c(ii)</i>] 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 [<i>please refer to point c(ii)</i>] 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，适用 0.01 mg/kg 的检出限。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 other than those mentioned in point (a), if no migration limit is specified in Table 1 of 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 will be strengthened to ensure adequate information on the presence of substances listed in Annex II.



第 6 点关于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.
将添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. 4.
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。



2 3/16/2020- Mexico - Approved Mandatory Standard for Cookware with Non-stick Coating (NOM-225-SCFI-2019)

墨西哥- 批准不粘锅炊具强制性标准(NOM-225-SCFI-2019)

The Secretary of Economy of Mexico has published a mandatory standard for cookware with non-stick coating (NOM-225-SCFI-2019). All the previously proposed provisions have been approved. The standard shall come into force on 7 September 2020. Products that are legally manufactured, imported or in transit in accordance with the corresponding bill of lading before 7 September 2020 can be marketed in Mexico while stock lasts.

墨西哥经济部长公布不粘涂层炊具的强制性标准（NOM-225-SCFI-2019），之前提出的修订均已被批准。该标准将于 2020 年 9 月 7 日生效。2020 年 9 月 7 日之前根据相应提货单合法制造、进口或运输的产品可以在墨西哥销售至存货售罄。

3 3/19/2020- China - Proposed New Substances related to Food Contact Materials And Articles

中国 – 提议与食品接触材料和制品相关的新物质

The China National Center for Food Safety Risk Assessment (CFSA) has proposed 10 kinds of substances related to food contact materials and articles. Here are the highlights:

中国国家食品安全风险评估中心（CFSA）提议了与食品接触材料和制品相关的 10 种新物质。以下为要点：



1) Expansion of the scope of additive used in food contact material and article

食品接触材料和制品中使用的添加剂使用范围扩大

Items 项目	CAS No.	Newly added Scope 范围 新增	Maximum amount to be used 最大使用 量	Specific Migration Limit 特定迁 移限 SML	Maximum Residue 最 大残留量 QM	Note 备注
Calcium stearate 硬脂酸钙	1592- 23-0	Plastic: Polyether ether ketone (PEEK) 塑料: 聚 醚醚酮 (PEEK)	0.03%	-	-	-
2,5- Furandione, dihydro-, mono- C ₁₅ -20- alkenyl -derivs. 单 C ₁₅ ~C ₂₀ 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) 30mg/kg (以 马来酸计)	-	The temperature of usage of plastic materials and products added with this substance shall not exceed 100 °C; plastic materials and products added with this substance shall not be used in contact with infant food and breast milk 添加该物质的塑料 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



2) New additive of food contact material and article 新的食品接触材料和制品添加剂

Items 项目	CAS No.	Newly added Scope 新增范围	Maximum amount to be used 最 大使用量	Specific Migration Limit 特定迁移 限量 SML	Maximum Residue 最大残留 量 QM	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) 5% (以纤维 干重计)	-	-	-
2-Butenedioic acid (2E)-, dibutyl ester, homopolymer 富马酸二丁酯 均聚物	-	Coating 涂 层	2%	-	-	Coating 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 添加了该物质的涂料及涂 层不得用于接触婴幼儿配 方食品和母乳，使用温度 不得超过 121°C



3) New resin substance used in food contact material and article

新的食品接触材料和制品中使用的树脂

Items 项目	CAS No.	Newly added Scope 新增范 围	Maximum amount to be used 最 大使用量	Specific Migration Limit 特定 迁移限量 SML	Maximum Residue 最大 残留量 QM	Note 备注
Fatty acid, C ₁₈ - 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	20680 97-08- 3	Plastic 塑料	-	<ul style="list-style-type: none"> 15 mg/kg (as caprolactam) 15mg/kg (以己内酰胺 计) ; 2.4 mg/kg (Hexamethylene diamine) 2.4mg/kg (己二胺) ; 0.05 mg/kg (as the total of <i>Unhydrogenated unsaturated fatty acid (C₁₈) dimer and Hydrogenated dimerized C₁₈ unsaturated fatty acids</i>) 0.05mg/kg (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 	-	Plastic materials and products 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) 以该物质为原料生 产的塑料材料及制 品不得用于接触婴 儿配方食品和母 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)
2-Propenoic acid, 2-	26589- 46-8	Coating	-	<ul style="list-style-type: none"> 6 mg/kg (as methacrylate) 	-	Food contact coatings



<p>methyl-, polymer with N-(butoxymethyl)-2-propenamide, ethenylbenzene and ethyl 2-propenoate</p> <p>2-甲基-2-丙烯酸与 N-(丁氧甲基)-2-丙烯酰胺、苯乙烯和 2-丙烯酸乙酯的聚合物</p>		<p>涂料及涂层</p>		<p>6mg/kg (以甲基丙烯酸计) ;</p> <ul style="list-style-type: none"> 6 mg/kg (as acrylic acid) 6mg/kg (以丙烯酸计) ; ND (N- (butoxymethyl) -2-acrylamide, DL=0.01mg/kg) ND (N-(丁氧甲基)-2-丙烯酸酰胺, DL=0.01mg/kg) 		<p>manufactured with this substance as raw materials shall not be used in contact with acidic foods with a pH below 3.64, oils and fats, foods with oil on the surface, infant foods, and breast milk, and the temperature of usage shall not exceed 121 °C</p> <p>以该物质为原料生产的食品接触用涂料及涂层不得用于接触 pH 低于 3.64 的酸性食品、油脂、表面含油脂食品及婴幼儿食品和母乳, 使用温度不得超过 121 °C</p>
<p>Styrene block polymers with 2-methyl-1,3-butadiene and 1,3-butadiene, hydrogenated</p> <p>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</p>	<p>13277-8-07-5</p>	<p>Plastic 塑料</p>		<ul style="list-style-type: none"> ND (1,3-butadiene: SML, DL = 0.01) ND (1,3-丁二烯) SML, DL = 0.01) ND (2-methyl-1,3-butadiene: SML, DL = 0.01) ND (2-甲基-1,3-丁二烯: SML, DL = 0.01) 	<p>0.5% (styrene)</p> <p>0.5% (苯乙烯);</p> <p>1 mg/kg(1, 3-butadiene)</p> <p>1mg/kg (1,3-丁二烯);</p> <p>1 mg/kg (2-methyl-1,3-butadiene)</p> <p>1mg/kg (2-甲基-1,3-丁二烯)</p>	
<p>Phenol, 4,4'-(1-methylethylidene)bis-, polymer with (chloromethyl)oxirane, benzoate</p>	<p>52907-82-1</p>	<p>Coating 涂料及涂层</p>	<p>19.7% (as coating formula)</p> <p>19.7% (以涂料配方计)</p>	<p>0.6 mg/kg (Bisphenol A)</p> <p>0.6 mg/kg (双酚 A)</p>	<p>1 mg/kg (Epichlorohydrin)</p> <p>1mg/kg (环氧氯丙烷)</p>	<p>Food contact coatings manufactured with this substance as raw materials shall not be used in contact with infant foods and breast milk</p>



<p>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</p>						<p>以该物质为原料生产的食品接触用涂料及涂层不得用于接触婴幼儿食品和母乳</p>
<p>Polymer of 1,4-bis(hydroxymethyl)cyclohexane,2-methylpropane-1,3-diol, tricyclo(5.2.1.0^{2,7})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[5.2.1.0^{2,7}]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>		<p>Coating 涂料及涂层</p>	<p>30% (as coating formula) 30% (以涂料配方计)</p>	<ul style="list-style-type: none"> • mg/kg (2-methyl-1,3-propanediol) 5mg/kg (2-甲基-1,3-丙二醇) ; • 0.05 mg/kg (4,8-tricyclo[5.2.1.0^{2,7}]decanedimethanol); 0.05mg/kg (4,8-三环[5.2.1.0^{2,7}]癸烷二甲醇) ; • 7.5 mg/kg (as terephthalic acid) 7.5mg/kg (以对苯二甲酸计) ; • mg/kg (as m-benzene Dicarboxylic acid meter) 5mg/kg (以间苯二甲酸计) ; • 30 mg/kg (maleic acid) 30mg/kg (顺丁烯二酸) 	<p>1 mg/kg (as isocyanate) 1mg/kg (以异氰酸根计)</p>	<p>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</p>
<p>Polymer of butanediol-1,4, ethylene glycol, propylene glycol-1,2, trimethylolpropane, dimethyl terephthalate, isophthalic acid and</p>		<p>Coating 涂料及涂层</p>	<p>30% (as coating formula) 30% (以涂料配方计)</p>	<ul style="list-style-type: none"> • mg/kg (as 1,4-butanediol) 5mg/kg (以 1,4-丁二醇计) ; • 30 mg/kg (as ethylene glycol); 30mg/kg (以乙二醇计) ; 		<p>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</p>



sebacic acid				<ul style="list-style-type: none"> mg/kg (trimethylolpropane) 6mg/kg (三羟甲基丙烷) ; mg/kg (as isophthalic acid) 5mg/kg (以间苯二甲酸计) 		产的涂料及涂层不得用于接触婴幼儿食品和母乳
1,4-丁二醇与乙二醇、1,2-丙二醇、三羟甲基丙烷、对苯二甲酸二甲酯、间苯二甲酸和癸二酸的聚合物						

Note 注

1. ND: Not detected 不得检出
2. DL: Detection limit 检出限

PART2 Toys 玩具

4 3/17/2020- Indonesia - Elaboration of Type 5 Certification System of Regulation No. 29 of 2018 Amendment to the Regulation of Technical Specifications for Toys

印度尼西亚- 修订玩具技术法规，细化 2018 年第 29 号法规类型 5 认证体系

The Ministry of Industry of Indonesia issued a letter No. 257/BPPI/VIII/2019, which describe the detail procedures of type 5 certification system of the Regulation No. 29 of 2018, which is the third amendment of Regulation No.24/M-IND/PER/4/2013 Mandatory Implementation of SNI Standards and Technical Specifications for Toys. The following are the highlight:



印度尼西亚工业部发布第 257/BPPI/VIII/2019 号函，阐述 2018 年第 29 号法规类型 5 认证体系的实施细则，这是第 24/M-IND/PER/4/2013 号法规的第三次修正案，该法规强制执行玩具的 SNI 标准和技术规范。以下是重点摘要：

1) Mandatory testing standards for different kind of products:

各种产品的强制性测试标准

No. 序号	Type of Toy 玩具类型	Tariff No. / HS Code 关税编号/ HS 编码	Standards 标准
1.	Baby Walker 婴儿学步车	9403.70.10	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛) EN 71-5 (Phthalates 邻苯二甲酸酯)
2.	Tricycles, scooters, pedal cars and similar wheeled toys, dolls' carriages 三轮车、踏板车、脚踏车和类似的带轮玩具、娃娃车	9503.00.10	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI IEC 62115:2011 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛) EN 71-5 (Phthalates 邻苯二甲酸酯)
3.	Dolls 玩偶	9503.00.21	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛)



			EN 71-5 (Phthalates 邻苯二甲酸酯)
4.	Electric trains, including tracks, signals and other accessories 电动火车、包括轨道、信号机和其他配件	9503.00.30	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI IEC 62115:2011 EN 71-5 (Phthalates 邻苯二甲酸酯)
5.	Reduced size ("scale") models and similar recreational models, working or not 缩小“比例”的模型和类似的娱乐模型，无论是否在操作状态	9503.00.40	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛) EN 71-5 (Phthalates 邻苯二甲酸酯)
6.	Construction sets and other construction toys from materials other than plastic 用塑料以外的材料制成的建筑玩具和其他建筑玩具	9503.00.50	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛)
7.	Stuffed toys resemble animals or other than humans 类似于动物的毛绒玩具或人类以外的毛绒玩具	9503.00.60	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛) EN 71-5 (Phthalates 邻苯二甲酸酯)
8.	Puzzles of all types 各种拼图	9503.00.70	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛)



			EN 71-5 (Phthalates 邻苯二甲酸酯)
9.	Numerical, alphabetical or animal blocks or cut-outs; word builder sets; word making and talking sets; toy printing sets; toy counting frames (abaci); toy sewing machines; toy typewriters 数字、字母或动物积木或剪切片；单词生成器；造词和谈话集；玩具印花套；玩具计数器(算盘)；玩具缝纫机；玩具打字机	9503.00.91	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI IEC 62115:2011 EN 71-5 (Phthalates 邻苯二甲酸酯)
10.	Skipping rope 跳绳	9503.00.92	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛) EN 71-5 (Phthalates 邻苯二甲酸酯)
11.	Marbles 弹珠	9503.00.93	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010
12.	Other toys, from rubber 橡胶制的其它玩具	9503.00.94	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010 (Azo Dyes and Formaldehyde 偶氮染料和甲醛) EN 71-5 (Phthalates 邻苯二甲酸酯)
13.	Other toys other than those referred to in numbers 2 to 12, are made of all types of material, both electrically operated and not	9503.00.99	SNI ISO 8124-1:2010 SNI ISO 8124-2:2010 SNI ISO 8124-3:2010 SNI 7617:2010



<p>electrically operated, in the form of 除上述 2 至 12 所指玩具之外的其 它玩具类别，由所有类型的材料 制成，包括电动的和非电动的， 可以是以下其中任意一个形式：</p> <p>a. balloons, swimming buoys for children or other toys that are blown or pumped, made of rubber and / or plastic 橡胶和/或塑料制成 的气球、儿童游泳浮标或其它可 吹或可充气的玩具</p> <p>b. toy gun / pistol; and / or 玩具枪/手 枪; 和/或</p> <p>c. Other toys 其它类别玩具</p>		<p>(Azo Dyes and Formaldehyde 偶氮染料和甲醛)</p> <p>EN 71-5 (Phthalates 邻苯二甲酸酯)</p>
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2) The procedure of type 5 certification system is mentioned in detail in this letter. Here are some highlights:

此函中详细说明类型 5 认证体系的程序. 以下为摘要:

A. Domestic and oversea manufacturers shall follow the respective procedures of type 5 certification.

国内外制造商应遵循相应的类型 5 认证程序



B. Testing laboratory shall be accredited by KAN and appointed by the Minister of Industry. If the testing laboratory is external resource of the LSPro (Product Certification Institute), it shall have a Subcontract Agreement

测试实验室应获得 KAN 认可，并由工业部长指定。如果测试实验室是 LSPro(产品认证协会)的外部资源，则应签订分包协议。

C. Testing requirements: 测试要求:

- Testing on azo dye and formaldehyde shall only apply to toys made of fabric and toys containing fabric components.

偶氮染料和甲醛的测试仅适用于由纺织物制成的玩具和包含纺织物成分的玩具。

- The total amount for phthalate DEHP, DBP, BBP, DINP, DIDP and DNOP shall be $\leq 0.1\%$. Alternative test method shall be CPSC CH-C1001-09.

邻苯二甲酸酯 DEHP、DBP、BBP、DINP、DIDP 和 DNOP 的总量应 $\leq 0.1\%$ ，替代测试方法应为 CPSC CH-C1001-09。

5 3/19/2020- EU - Proposed Amending Allergenic Fragrance Requirements under Toy Safety Directive 2009/48/EC

欧盟 - 提议修订玩具安全指令 2009/48/EC 中有关致敏性芳香物质的要求

The European Commission has drafted two Directives to amend Annex II to Toy Safety Directive 2009/48/EC, regarding allergenic fragrances in toys. Here is the summary of the proposal:

欧盟委员会已起草了两项指令，以修订玩具安全指令 2009/48/EC 的附录 II 涉及玩具中的致敏性芳香物质的要求。以下为提议案概要：



1) Amendments to the list of allergenic fragrances which require labelling 修订需标识的致敏性芳香物质清单

According to the current requirement in Part III, Annex II to the Directive, the name of allergenic fragrance listed in Paragraph 3 of Point 11 shall be stated on a toy, on an affixed label, on the packaging or in an accompanying leaflet, if the fragrance is added to the toy or component at a concentration exceeding 100 mg/kg.

根据指令附录 II 第三部分的要求，第 11 点第 3 段中列出的致敏性芳香物质如果添加到玩具或部件中的含量超过 100 mg/kg，应把相应的芳香物质名称标识在玩具、标签、包装或随附的传单上。

The Commission proposed to amend the list by:

委员会提议对列表修改如下：

- Adding 2 CAS numbers to Citronellol, 1117-61-9 and 7540-51-4
对于香茅醇，添加 2 个 CAS No.: 117-61-9 和 7540-51-4;
- Adding 61 allergenic fragrances to the list
在列表中添加 61 种致敏性芳香物质。



2) Prohibition of 3 allergenic fragrances 禁止 3 种致敏性芳香物质

The 3 allergenic fragrances intended to be banned are: 拟禁止使用的 3 种致敏性芳香物质为：

No 序号	Name of the allergenic fragrance 致敏性芳香物质名称	CAS number CAS 编号
(56)	Atranol (2,6-Dihydroxy-4-methyl-benzaldehyde) 苔黑醛 (2,6-二羟基-4-甲基苯甲醛)	526-37-4
(57)	Chloroatranol (3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde) 氯三醇 (3-氯-2,6-二羟基-4-甲基苯甲醛)	57074-21-2
(58)	Methyl heptine carbonate 2-辛酸甲酯	111-12-6

Methyl heptine carbonate is currently one of the allergenic fragrances which require labelling. It shall be delisted if it becomes a prohibited fragrance.

2-辛酸甲酯目前是需要标识的致敏性芳香物质之一，如果成为禁止使用的芳香物质，则应将其从清单中删除。



PART3 Children products 儿童产品

6 3/16/2020- Taiwan - Approved BSMI Mandatory Inspection
Requirements for Soft Carriers (3/16/2020)

台湾- 批准软背带（袋）BSMI 强制性检验要求

The Bureau of Standards, Metrology and Inspection (BSMI) of Taiwan has published Notice No. 10920001620 to approve the mandatory inspection requirements for soft carriers. The BSMI inspection service shall be available from 1 July 2020, and all products shall comply with the requirements by 1 January 2021.

台湾标准计量检验局（BSMI）公布第 10920001620 号公告，批准软背带（袋）的强制性检验要求。BSMI 检验服务应于 2020 年 7 月 1 日起提供，所有产品应在 2021 年 1 月 1 日前符合要求。

The RPC certificate shall be valid for 3 years. If the certificate is issued before 1 January 2021, it shall be valid from 1 January 2021 to 31 December 2023.

RPC 证书有效期为 3 年。如果证书是在 2021 年 1 月 1 日之前签发的，则其有效期为 2021 年 1 月 1 日至 2023 年 12 月 31 日。



7 3/19/2020- Brazil – Draft Amendment on Requirements for School Articles Regards to Toxicological Test

巴西-关于学生用品毒性测试要求的修订草案

The National Institute of Metrology, Quality and Technology (INMETRO) of Brazil has published Draft Ordinance No.02/2020 for amendments on regulation for School Articles, which were approved by the Ordinance No.481/2010.

巴西国家标准局（INMETRO）已发布第 02/2020 号法令草案以修订第 481/2010 号法令所批准的学生用品法规。

According to this Draft, 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 the 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 will only be allowed for the limit period of 180 days, counting from the date of publication of the Ordinance. After that, the Primary Dermal Irritability test must be finished before the issuance.

根据本草案，如果因学生用品（包括油漆、胶水、水粉、水彩和粉末材料）的毒性测试而导致认证流程延迟，经皮肤刺激性试验认证后，产品认证机构可以签发证书和/或进行维持确认。认证机构应审核符合性证书和/或维持确认书，包括完成后的毒性测试有关的数据。从条例发布之日算起，实施期限为 180 天。之后必须在证书发布前完成主要皮肤刺激性测试。

School items that are exempt from toxicological tests (according to ABNT NBR 15236) must have their toxicological safety confirmed through a self-declaration issued by the manufacturer. It shall apply only to school articles that contain paints, glues, gouaches, watercolors or powder material in their composition.



豁免毒性测试（根据 ABNT NBR 15236）的学生用品，必须通过制造商的自我声明确认其毒性安全。此要求仅适用于油漆、胶水、水粉、水彩或粉末材料的这些学生用品。

PART4 Others 其它

8 3/6/2020- EU - Approved Amending Exemptions from Chemical Restriction under RoHS Directive 2011/65/EU

欧盟 - 批准 RoHS 指令 2011/65/EU 化学限制豁免的修订

The European Commission has published 4 Delegated Directives to amend Annexes III and IV to Directive 2011/65/EU on restriction of hazardous substances in electrical and electronic equipment (RoHS), regarding exemptions from chemical restrictions.

欧盟委员会发布 4 个授权指令以修订关于限制电气和电子设备中有害物质的 RoHS 指令 2011/65/EU 附件三和四关于化学限制豁免的修订。

1) Amendments to Annex III to Directive 2011/65/EU (*Member States shall apply the amendments from 1 April 2021*)

RoHS 指令 2011/65/EU 附件三的修订（成员国应于 2021 年 4 月 1 日实施修订内容）



Exemption number in Annex III and Application 附件三中的豁免编号和应用	Applicable product categories 应用的产品类别	Expiry date of exemption 豁免期限
9	Categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments 第 8、9 类（体外诊断医疗设备及工业监控设备除外）	21 July 2021 2021 年 7 月 21 日
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 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%。	Categories 8 in vitro diagnostic medical devices 第 8 类中的体外诊断医疗设备	21 July 2023 2023 年 7 月 21 日
	Category 9 industrial monitoring and control instruments, and Category 11 第 9 类中的工业监控设备和第 11 类	21 July 2024 2024 年 7 月 21 日



<p>9(a)-I</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>Categories 1-7,10</p> <p>第 1-7、10 类</p>	<p>5 March 2021</p> <p>2021 年 3 月 5 日</p>
<p>9(a)-II</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> <ul style="list-style-type: none"> designed to operate fully or partly with electrical heater, having an average utilised power input \geq 75 W at constant running conditions; designed to fully operate with non-electrical heater. <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> <ul style="list-style-type: none"> 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>Categories 1-7,10</p> <p>第 1-7、10 类</p>	<p>21 July 2021</p> <p>2021 年 7 月 21 日</p>



<ul style="list-style-type: none"> 设计为完全与非电加热器一起运行。 		
<p>41</p>	<p>Categories 1-7, 10 and 11 第 1-7、10 和 11 类</p>	<p>31 March 2022 2022 年 3 月 31 日</p>
<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 (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council</p>	<p>Categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments 第 8、9 类（体外诊断医疗设备 及工业监控设备除外）</p>	<p>21 July 2021 2021 年 7 月 21 日</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（*指令 97/68/EC 中的类别 SH:1、SH:2、SH:3），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>Category 8 in vitro diagnostic medical devices 第 8 类中的体外诊断医疗设备</p>	<p>21 July 2023 2023 年 7 月 21 日</p>
	<p>Category 9 industrial monitoring and control instruments 第 9 类中的工业监控设备</p>	<p>21 July 2024 2024 年 7 月 21 日</p>



2) Amendments to Annex IV to Directive 2011/65/EU

RoHS 指令 2011/65/EU 附件四的修订

A. Entry 37 shall be amended as follows: (Member States shall apply this from 1 April 2021)

条目 37 将修订如下 (成员国应于 2021 年 4 月 1 日实施修订内容)

37. Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies: 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:

(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;

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) ;

(b) measurements of solutions where an accuracy of +/- 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following:

精确度要求 +/-1% 并且在以下任意一种需高耐蚀性电极溶液中的测试:

(i) solutions with an acidity < pH 1; 酸性溶液 pH < 1;

(ii) solutions with an alkalinity > pH 13; 碱性溶液 pH >13;

(iii) corrosive solutions containing halogen gas;

含卤素气体的腐蚀性溶液;

(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。

Expires on 31 December 2025 有效期至 2025 年 12 月 31 日



B. Entry 44 shall be added to Annex IV: (Member States shall apply this from 1 September 2020)

条目 44 将加入附件四 (成员国应于 2020 年 9 月 1 日实施)

44. 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.

分辨率大于 450TV lines 的耐辐射摄像管中的镉，该摄像机用于辐射暴露超过 100Gy/小时，但辐射总量不超过 100kGy。

Applies to category 9. Expires on 31 March 2027 **适用于第 9 类，2027 年 3 月 31 日到期。**

9 3/6/2020- EU – Approved Commission Delegated Directive (EU) 2020/366 Amending Exemptions from Chemical Restriction under RoHS Directive 2011/65/EU Regard Lead in PVC
欧盟 - 批准欧盟委员会授权指令 (EU) 2020/366 以修订 RoHS 指令 2011/65/EU 关于 PVC 中铅的化学限制豁免

The European Commission has published Commission Delegated Directive (EU) 2020/366 to amend entry 41 of Annex IV to Directive 2011/65/EU on restriction of hazardous substances in electrical and electronic equipment (RoHS). This amendment shall be effective from 1 April 2021.

欧盟委员会发布了欧盟委员会授权指令 (EU) 2020/366，以修订关于限制电气和电子设备中有害物质的 RoHS 指令 2011/65/EU 附件四第 41 条。本修正案自 2021 年 4 月 1 日起生效。



According to the amendment, entry 41 of Annex IV of RoHS Directive shall be amended as follow:

根据修正案，RoHS 指令附件四第 41 条应修改如下：

“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.

“用于血液、体液和体内气体分析的体外诊断医疗器械中电流、电位和电导传感器聚氯乙烯(PVC)基材中作为热稳定剂的铅。

Expires on 31 March 2022 有效期至 2022 年 3 月 31 日

10 3/23/2020- Turkey - Approved Product Safety and Technical Regulation (Law 7223)

土耳其 - 批准产品安全和技术法规（第 7223 号法规）

The Turkey Government published Official Gazette No 31066 to approve Law No. 7223 Product Safety and Technical Regulation. This Law shall enter into force on 12 March 2021. The previous Law No 4703 Technical Regulation on Products shall be repealed accordingly. The following are the highlight of this Law:

土耳其政府发布第 31066 号政府公报，批准《产品安全和技术法规》（第 7223 号法规）。本法规自 2021 年 3 月 12 日起施行。原第《产品技术规程》（第 4703 号法规）相应废止。以下是法规摘要：



1) Purpose 目的

The purpose of this Law is to ensure products shall be safe and comply with the relevant technical regulations.

法规的目的是保证产品的安全和符合有关技术规定。

2) Scope 范围

All products that are intended to be placed on the market
准备投放市场的所有产品。

3) Requirements 要求

- The product shall be safe.
产品应保证安全。
- The product that comply with the relevant technical regulation is considered to be safe. If there is no technical regulation applicable to the product, the evaluation of the product safety shall be done according to the general product safety legislation.
符合相关技术规范的产品被认为是安全的。没有适用于产品的技术规范的，应当按照通用产品安全法规进行产品安全性评价。
- Technical file and declaration of conformity shall be prepared if they are required by the relevant technical regulation. The technical file shall be retained for ten years or more.
相关技术法规有要求时，应编制技术性文件和符合性声明。技术性文件应保存十年以上。
- Conformity mark shall be marked on products if it is required by the technical regulation.
相关技术法规有要求时，应在产品上标明合格标志。



- Manufacturer's, importer's or/and distributor's name (or brand name) and address shall be marked on products (if possible), packaging, or/and document accompany with the product.

制造商、进口商或/和经销商的名称（或商标名称）和地址应标记在产品（如有可能）、包装或/和产品附带的文件上。

- The information, instruction and safety rules of the product shall be in Turkish. 产品的标签、说明书和安全警句应使用土耳其语。

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