



Greater China

# Toy Safety Directive 2009/48/EC

## 欧盟玩具安全指令



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## Introduction

### ⌘ Technological developments on toys market 玩具市场的技术

- > Raise new issues 引发新问题
- > Increase consumer concerns 日益受到消费者的关注  
on the safety of toys 玩具安全性

### ⌘ Objective

- > To ensure a high level of protection of children against risks due to
  - (i) Chemical substances in toys;
  - (ii) Use of dangerous substances e.g. CMR, allergenic substances and certain metals
- > To protect the health of children from certain substances in toys
  - 为保证对儿童的高水平保护，使其免受玩具中化学物质的危害
  - 保护儿童健康不受玩具中某些物质的危害



## Scope

- Apply to products designed or intended for use in play by *children under 14 years of age*.

适用于为 **14 岁以下儿童** 而设计，或供其玩耍用的产品，无论是否专门为其设计或供其使用

- But not apply to

- (a) Playground equipment intended for public use;

公用活动场地的设备

- (b) Automatic playing machines, whether coin operated or not, intended for public use;

供公共使用的自动游戏机，不论是否需要放入游戏币

- (c) Toy vehicles equipped with combustion engines;

装配有内燃机的玩具车

- (d) Toy steam engines; 玩具蒸汽机

- (e) Slings and catapults. 投射器和弹射器



## Safety Requirements 安全要求

- (i) Physical and Mechanical Properties 物理和机械特性
- (ii) Flammability 易燃性
- (iii) Chemical Properties 化学性能**
- (iv) Electrical Properties 电气性能
- (v) Hygiene 卫生
- (vi) Radioactivity 放射性



<b>Toy Safety Directive (88/378/EEC)</b>	<b>New Toy Safety Directive (2009/48/EC)</b>
Migration of certain heavy metals (8 heavy metals) 金属迁移	Migration of certain heavy metals (19 heavy metals) 金属迁移
--	Carcinogens, Mutagens and Reproductive Toxins (CMR) 致癌的、致基因突变的或有生殖毒性的物质
--	Fragrances 芳香物质
--	Nitrosamines and Nitrosable substances 亚硝酸胺及亚硝酸胺化合物



## Chemical Requirements

### A. Migration of certain elements

金属迁移

### B. Carcinogens, Mutagens and Reproductive Toxins (CMRs)

致癌的、致基因突变的或有生殖毒性的物质

### C. Fragrances

芳香物质

### D. Nitrosamines and Nitrosable substances

亚硝酸胺及亚硝酸胺化合物

### E. Cosmetic Toys



## A. Migration of certain elements 金属迁移

- Update the limits for the heavy elements allowed for the original 8 elements and bring 11 further elements into the restricted list.

\*The tables below show the new and existing requirements.

限制元素范围19种



# 2009/48/EC - Chemical Requirement



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## A. Migration of certain elements 金属迁移

### Toy Safety Directive (88/378/EEC)

Elements	Limit (mg/kg)	
	Any toy materials excluding modeling clay	Modeling clay
Antimony 锑	60	60
Arsenic 砷	25	25
Barium 钡	1000	250
Cadmium 镉	75	50
Chromium 铬	60	25
Lead 铅	90	90
Mercury 汞	60	25
Selenium 硒	500	500

### New Toy Safety Directive (2009/48/EC)

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped off toy material
Aluminum	5625	1406	70000
Antimony	45	11.3	560
Arsenic	3.8	0.9	47
Barium	4500	1125	56000
Boron	1200	300	15000
Cadmium	1.9	0.5	23
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.2
Cobalt	10.5	2.6	130
Copper	622.5	156	7700
Lead	13.5	3.4	160
Manganese	1200	300	15000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4500	1125	56000
Tin	15000	3750	180000
Organic tin	0.9	0.2	12
Zinc	3750	938	46000

These limits apply to accessible toys or accessible components of toys



## B. Carcinogens, Mutagens and Reproductive Toxins (CMRs)

致癌的、致基因突变的或有生殖毒性的物质

☒ CMRs are not allowed in the toys.

Carcinogens (C): substances that causes or tends to cause cancer;

Mutagen (M): chemical or physical agent that induces permanent, transmissible genetic change;

Reproductive toxins (R): substances that may damage reproductive capacities or functions.

The revised directive adopts latest terminology for CMR categories.

Instead of CMR categories 1, 2 or 3 the following categories apply:

- Category 1A CMRs (previously CMRs 1)
- Category 1B CMRs (previously CMRs 2)
- Category 2 CMRs (previously CMRs 3)

Does not apply to nickel in stainless steel.

- 针对玩具中CMR物质（致癌、致基因突变、或致生殖毒性）的特别条款。
- 1272/2008/EC归入1A,1B和2类物质不能在玩具，玩具组成或玩具部件中使用



## B. Carcinogens, Mutagens and Reproductive Toxins (CMRs)

致癌的、致基因突变的或有生殖毒性的物质

α CMRs are allowed

> inaccessible to children in any form, including by inhalation

这些物质和混合物不能以任何形式（包括吸入）被儿童接触到

> present in concentrations equal to or smaller than the relevant concentrations for classification of mixtures containing the substances (Directive 1999/45/EC or Regulation 1272/2008)

这些物质和混合物被包含于单份含量中，其浓度等于或小于(Directive 1999/45/EC or Regulation 1272/2008)部分中（有关包含这些物质的混合物分类）所指的欧共体法案中确立的相关浓度标准。



## C. Fragrances 芳香物质

- α Shall not contain 55 allergenic fragrances in toys
- α The presence of traces of these fragrances shall be allowed
  - > if it is technically unavoidable under good manufacturing practice
  - > Limit  $\leq 100$  mg/kg
  
- α 11 other potentially allergenic fragrances are permitted
  - > if the concentration level  $\geq 0,01\%$  by weight (100 mg/kg)
  - > Require affixed label
  - > on packaging or in accompanying leaflet
- 共66种香料物质受到限制，其中55种含量不能超过100mg/kg
- 另外11种如果超过100mg/kg，则需要在产品标签或包装上标明

**Warning : “Contains fragrances that may cause allergies”**



## C. Fragrances 芳香物质

### Example

#### (i) Olfactory board games 嗅觉板玩具

- *assist a child to learn to recognise different odours or flavours*

帮助儿童学习辨识不同气味和香味的玩具

#### (ii) Cosmetics kits 成套化妆用具

- *assist a child to learn to make products such as fragrances, soaps, creams, shampoos, bath foams, glosses, lipsticks, other make-up, tooth-paste and conditioners*

辅助儿童学习制作诸如香料、肥皂、面霜、洗发水、沐浴液、唇彩、口红或其它化妆品、牙膏和护发素等为目的的玩具

#### (iii) Gustative games 味觉玩具

- *To allow children to make sweets or dishes which involve the use of food ingredients such as sweets, liquids, powders and aromas*

允许儿童制作糖果或菜肴，其中涉及使用食品成分如糖果、液体、粉末和香料等为目的的玩具

## C. Fragrances 致敏性芳香物质

No	Name of the allergenic fragrance	CAS number
(1)	Anisyl alcohol	105-13-5
(2)	Benzyl benzoate	120-51-4
(3)	Benzyl cinnamate	103-41-3
(4)	Citronellol	106-22-9
(5)	Farnesol	4602-84-0
(6)	Hexyl cinnamaldehyde	101-86-0
(7)	Lilial	80-54-6
(8)	d-Limonene	5989-27-5
(9)	Linalool	78-70-6
(10)	Methyl heptine carbonate	111-12-6
(11)	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

## D. Nitrosamines and Nitrosable Substances

### 亚硝酸胺及亚硝酸胺化合物

- α Prohibited for use in toys
  - > intended for use by children under 36 months  
36 个月以下婴儿玩耍的玩具
  - > in other toys intended to be placed in the mouth  
口含玩具严禁使用亚硝酸胺和亚硝酸胺化合物



Substance	Limit
Nitrosamines	$\leq 0.05$ mg/kg
Nitrosable Substances	$\leq 1$ mg/kg

## E. Cosmetic toys

- Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.
- Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months.
- 化妆品玩具也必须符合76/768/EEC号
- 指令关于化妆品的规定







<b>New Toy Safety Directive (2009/48/EC)</b>	<b>Testing Methods</b>
Migration of certain heavy metals (19 heavy metals) 金属迁移	New chemical standards (EN 71-3, EN 71-9, EN71-10 and EN71-11)
Carcinogens, Mutagens and Reproductive Toxins (CMR) 致癌的、致基因突变的或有生殖毒性的物质	New chemical standards (EN 71-3, EN 71-9, EN71-10 and EN71-11)
Fragrances 致敏性芳香物质	New chemical standards
Nitrosamines and Nitrosable substances 亚硝酸胺及亚硝酸胺化合物	New chemical standards

# Time Line for New Toy Directive 2009/48/EC



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30 June 2009

Directive Published in Official Journal EU

20 July 2009

Entry into force

20 Jan 2011

Latest date for introduction of legislation in member states

20 July 2011

New Directive takes effect and 88/378/EEC is repealed which were placed on the market, except for chemical requirements.

20 July 2013

Chemical requirements of current Directive are repealed.

- α 2011年7月20日起, 所有进入欧盟的玩具需符合新指令中有关非化学方面的要求
- α 2013年7月20日起, 所有进入欧盟的玩具需符合新指令中所有相关的非化学和化学方面的要求



## Summary

### **New Toy Safety Directive (2009/48/EC)**

Migration of certain heavy metals (19 heavy metals)  
金属迁移

Carcinogens, Mutagens and Reproductive Toxins (CMR)  
致癌的、致基因突变的或有生殖毒性的物质

Fragrances  
致敏性芳香物质

Nitrosamines and Nitrosable substances  
亚硝酸胺及亚硝酸胺化合物



## Summary

### General chemicals legislation

(i) Regulation (EC) No. 1907/2006 (REACH)

(ii) Regulation (EC) No. 1935/2004

- Toys or their parts and their packaging expected to be brought into contact with food

(iii) Directive 2002/95/EC & Directive 2002/96/EC

- Apply to electrical and electronic equipments

(iv) Directive 94/62/EC

- Packaging and packaging waste

(v) Directive 2006/66/EC

- Batteries and accumulators and waste Batteries and accumulators

(vi) Directive 76/768/EEC

- Cosmetic Toys



# Thank you!