

# 欧美玩具标准体系及召回案例分析

Intertek China

2013-12-19



## 欧盟

- 玩具指令 2009/48/EC （规定“基本要求”）
- 协调标准 （制定符合指令基本要求的技术规范）
- 其他与玩具相关法规
- 采用合格评定程序保证指令的实施
- 用唯一标志“CE”表示产品符合新方法指令基本要求

**Commission communication in the framework of the implementation of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys**

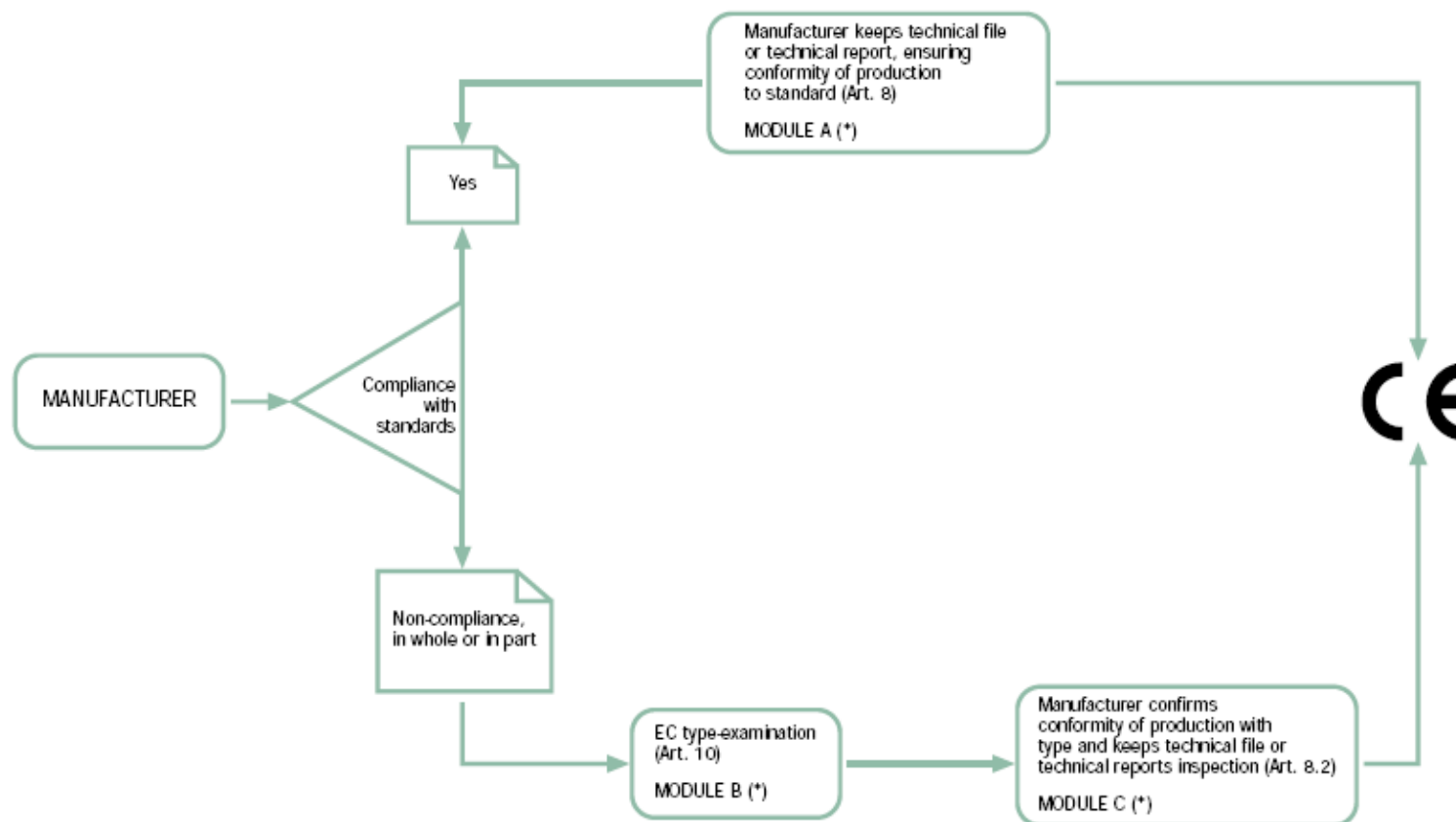
*(Publication of titles and references of harmonised standards under Union harmonisation legislation)*

**(Text with EEA relevance)**

**(2013/C 317/05)**

ISO (*)	Reference and title of the harmonised standard (and reference document)	First publication Official Journal	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 71-1:2011+A2:2013 Safety of toys — Part 1: Mechanical and physical properties	This is the first publication	EN 71-1:2011 Note 2.1	30.9.2014
CEN	EN 71-2:2011 Safety of toys — Part 2: Flammability	21.7.2011		
CEN	EN 71-3:2013 Safety of toys — Part 3: Migration of certain elements	29.6.2013		
CEN	EN 71-4:2013 Safety of toys — Part 4: Experimental tests for chemistry and related activities	28.5.2013		
CEN	EN 71-5:2013 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets	29.6.2013		
CEN	EN 71-8:2011 Safety of toys — Part 8: Activity toys for domestic use	19.10.2011		
CEN	EN 71-12:2013 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances	29.6.2013		
Cenelec	EN 62115:2005 Electric toys — Safety IEC 62115:2003 (Modified) + A1:2004	11.8.2011		
	EN 62115:2005/A2:2011 IEC 62115:2003/A2:2010 (Modified)	11.8.2011	Note 3	Date expired (11.8.2011)
	EN 62115:2005/A11:2012	15.11.2012	Note 3	Date expired (15.11.2012)
	EN 62115:2005/A11:2012/AC:2013	29.6.2013		
	EN 62115:2005/A2:2011/AC:2011	19.10.2011		


## 3. Flow chart for the conformity assessment procedures provided for in Directive 88/378/EEC on the safety of toys



(\*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

在下列情况下，应到指定机构进行EC 型式检验：

- (a) 协调标准不存在；
- (b) 协调标准存在，但是制造商并没有采用或仅部分采用
- (c) 协调标准公布时有限制；
- (d) 制造商认为玩具有需要到第三方机构认证；

	Co-ordination of the Notified Bodies NB-TOYS under the Safety of Toys Directive	NB-TOYS/2012/025 Succeeds NB-TOYS/2011/084/094 23 April 2012
<b>EC type approval protocol No. 1</b> <b>Categories of toys which have been submitted</b> <b>to an EC Type-Examination REV 3 (v2)</b>		
Agreed by: NB-Toys group on: 6 October 2011] ADCO group on Toy Safety on: 23 April 2012 Expert group on Toy Safety on: 23 April 2012 Will be available at: <a href="http://ec.europa.eu/enterprise/sectors/toys/documents/recommendations/index_en.htm">http://ec.europa.eu/enterprise/sectors/toys/documents/recommendations/index_en.htm</a>		

## 美国

- CPSIA
- 玩具标准ASTM F963
- 生产商根据测试合格结果，出具产品符合性证明
- 其他与玩具相关法规，如某些州法令

**CPSIA条款102 (a)(2)规定：**第三方检测要求—受到儿童产品安全规定制约的任何儿童产品应：

- (A)** 提出足够的儿童产品的样品予得到认可的第三方合格评估机构，检测该儿童产品是否符合安全规定；和
- (B)** 根据该检测签发证书，证明根据得到认可进行检测的第三方合格评估机构的评估结果，该儿童产品符合儿童产品安全规定。

**CPSIA条款106规定：**采用**ASTM F963**为玩具强制性标准，并且，如果标准进行修订，则应将拟议的修订通知委员会。委员会应将修订或修订的部分内容纳入消费品安全规定。

现生效的**ASTM F963-11**版

## 加拿大消费品安全法（CCPSA）

- 2011年6月20日，有害产品(玩具)法规被撤销，取而代之的是CCPSA玩具法规SOR/2011-17
- 基于《加拿大消费品安全法》其他与玩具产品相关的条例





# Middle East and GCC countries



GCC countries

## GCC Member States 海湾合作委员会的成员国

- |                                      |          |
|--------------------------------------|----------|
| 1. The Kingdom of Bahrain            | 巴林王国     |
| 2. The Kingdom of Saudi Arabia       | 沙特阿拉伯,   |
| 3. The Sultanate of Oman             | 阿曼,      |
| 4. The State of Qatar                | 卡塔尔,     |
| 5. The State of Kuwait               | 科威特      |
| 6. Yemen                             | 也门       |
| 7. State of the United Arab Emirates | 阿拉伯联合酋长国 |
| a. Abu Dhabi                         | 阿布扎比     |
| b. Ajman                             | 阿治曼,     |
| c. Dubai                             | 迪拜,      |
| d. Fujairah                          | 富查伊拉     |
| e. Ras al-Khaimah                    | 哈伊马角,    |
| f. Sharjah                           | 沙迦       |
| g. Umm al-Quwain                     | 乌姆, 盖万   |

## GCC Member States 海湾合作委员会的成员国

- Toy = Any product or material designed or clearly intended for use in play by children of less than 14 years of age.
  - Non toy: decoration, scale model, playground equipment, aquatic equipment in deep water, firework, air gun...similar to EU
- Children toys manufactured according to the Gulf standards or standards specified by GSO should **meet the essential requirement in this regulation**.
- Before placing the toys on market, manufacturers shall apply **Gulf Conformity Mark** on the toy.
- Manufacturer shall apply conformity assessment procedures
- Manufacturer issue DoC
- Manufacturer or his representative shall maintain the technical file (10 yrs)

## GCC Member States 海湾合作委员会的成员国

Gulf Standard	Others	Name of Standard/Document
577 GSO		Toys – General Safety Requirements
GSO 578		Methods of Testing Toys- Part 1: Mechanical and Chemical tests.
579 GSO		Methods of Testing Toys – Part 2: Flammability
	EN71-1	Safety of Toys – Part 1: Mechanical and Physical Properties
	EN71-2	Safety of Toys – Part 2 : Flammability
	EN71-3	Safety of Toys – Part 3 : Migration of Certain Elements
	EN71-4	Safety of Toys – Part 4 : Experimental sets for Chemistry and related activities
	EN71-5	Safety of Toys – Part 5 : Chemical Toys (sets) Other than Experimental Sets
	EN71-6	Safety of Toys – Part 6 : Graphical Symbol for Age Warning Labeling
	EN71-7	Safety of Toys – Part 7 : Fingerprints – Requirements and Testing Methods
	EN71-8	Slides of Toys – Part 8: Swings, Slides and Toys of Similar Indoor and
	EN71-9	Safety of Toys – Part 9: Organic and Chemical Compounds – Requirements
	EN71-10	Safety of Toys – Part 10: Organic and Chemical Compounds – Sample Preparation
and Extraction	EN71-11	Safety of Toys – Part 11: Organic and Chemical Compounds – Methods of Analysis
	IEC62115	Safety of electrical toys

## Latin America - Mandatory requirement overview

Argentina, Brazil, Paraguay, Uruguay	NM 300-1 Physical & Mechanical Test
	NM 300-2 Flammability Test
	NM 300-3 Toxic Elements Test
	NM 300-4 Experimental Sets
	NM 300-5 Chemical Toy Sets
	NM 300-6 Electrical Toy Test
Argentina	Resolution No. 583/2008 Phthalate Test
	Resolution No. 7/2009 Total Lead Test
Brazil	Ordinance Portaria N° 369 Phthalate Test
	Law No. 11.762 Total Lead Test
Colombia	NTC 4894 Physical & Mechanical Test
	NTC EN71-2 Flammability Test
	NTC EN71-3 Toxic Elements Test
	NTC EN71-4 Experimental Sets
	NTC EN71-5 Chemical Toy Sets
	NTC EN71-6 Graphical Symbol

## Latin America - Mandatory requirement overview

Venezuela	COVENIN 197-1 Physical & Mechanical Test
	COVENIN 197-2 Flammability Test
	COVENIN 197-3 Toxic Elements Test
	COVENIN 197-4 Experimental Sets
	COVENIN 197-5 Chemical Toy Sets
	COVENIN 197-6 Graphical Symbol
Chile	NCh1773 Physical & Mechanical Test
	NCh1775 Flammability Test
	NCh1936 Toxic Elements Test
	Decree No. 114 of 2005 Toy Safety Regulation
	No. 135 2004 Toluene Content
	No. 374 1997 Total Lead Test
Mexico	NOM-015-SCFI-2007 Toy Labeling
	NOM-015/1-SCFI/SSA-1994 Toxic Elements Test

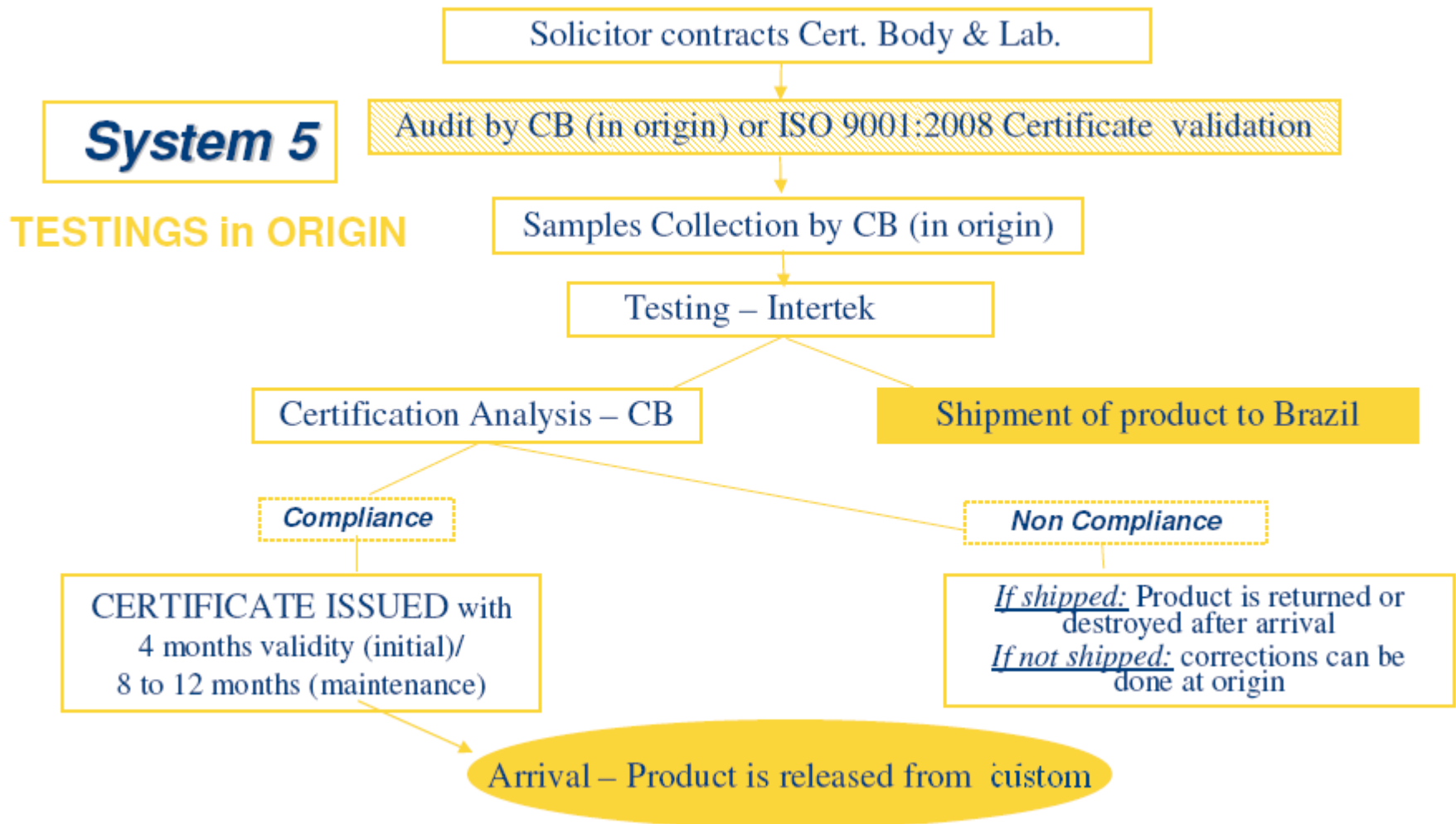
## INMETRO - Brazil

### Certification procedure





## INMETRO - Brazil





## INMETRO - Brazil

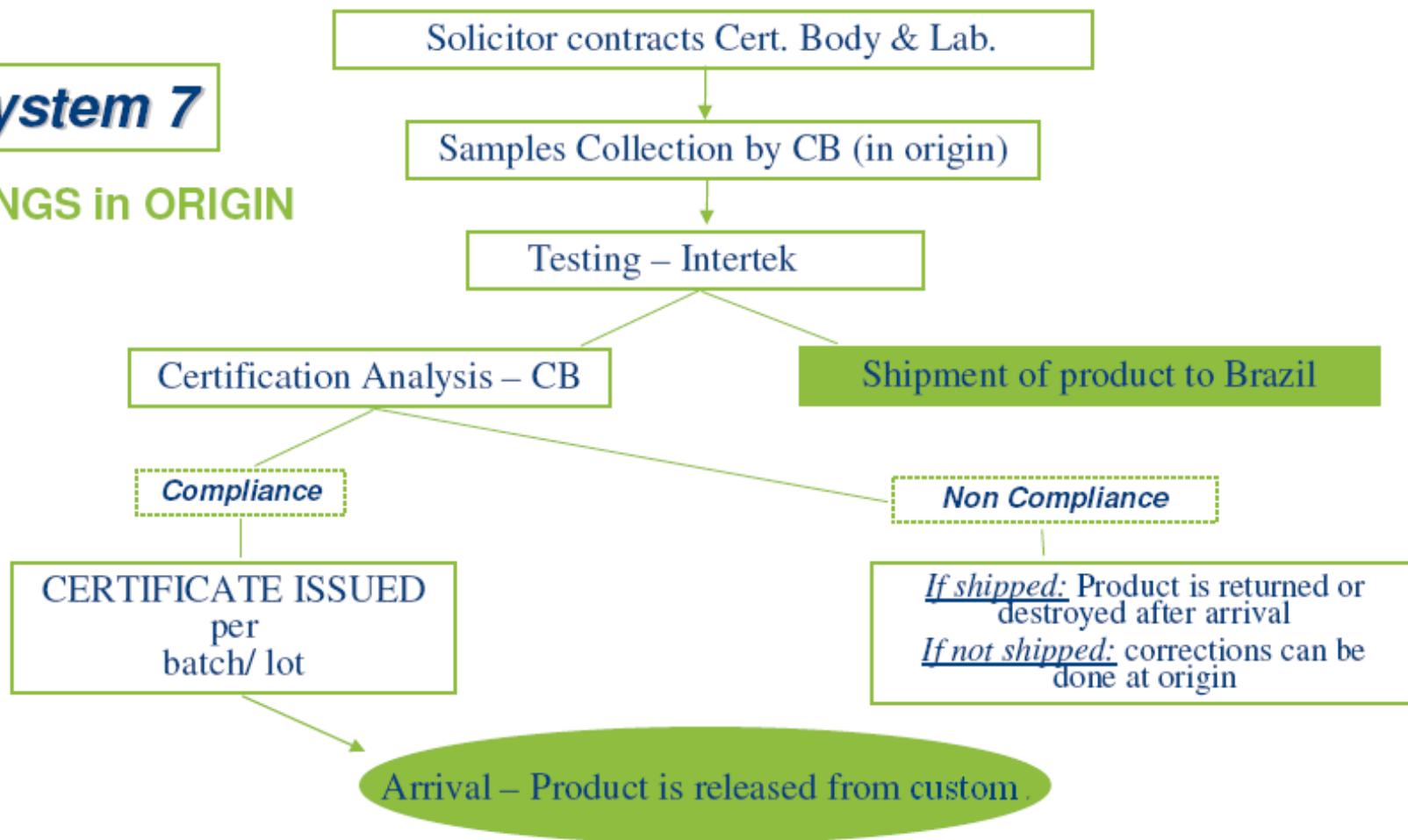
### System 5

	All Kinds of Toys		Specific Kinds of Toys				
TOTAL OF SAMPLE S *	SAMPLES FOR PHYSICAL TESTING- NM300-1	SAMPLES FOR CHEMICAL TESTINGS NM300-3	SAMPLES FOR FLAMABILIT Y NM300-2	SAMPLES FOR CHEMICAL SETS NM300-4 /5	SAMPLES FOR ELECTRICAL NM300-6	BIOLOGICAL (Port 369)	PHTHALATE S (Port 369)
4 to 9	2	2	1	1	1	1	1

## INMETRO - Brazil

### System 7

### TESTINGS in ORIGIN



## System 7

		Tests on all Toys.		Tests that depend on the type of toy.				
Lot Size, of the same Family	Total of Samples	Chemical NM 300-3	General, Mechanic and Physical Properties NM 300-1	Flammability NM 300-2	Chemical and Experimental Games NM 300-4 and 5	Electrical NM 300-6	Inmetro Resolution No. 369/2007	
							Phthalates	Biological
up to 600	3	1	2	Each one of the tests herein specified, whenever necessary, will be carried out on each lot, on the same samples that were previously subjected to the "Physical, general, and mechanical properties" NM 300-1/2002 tests.			3	3
601 TO 799	3	1	2				3	3
800 TO 999	4	1	3				3	3
1000 TO 1199	5	1	4				3	3
1200 TO 1399	6	2	4				3	3
1400 TO 1599	7	2	5				3	3
1600 TO 1799	8	3	5				3	3
1800 TO 1999	9	3	6				3	3
2000 TO 2199	10	3	7				3	3
2200 TO 2399	11	4	7				3	3
2400 TO 2599	12	4	8				3	3
2600 TO 2799	13	4	9				3	3
2800 TO 2999	14	4	10				3	3
3000 TO 3199	15	4	11				3	3
3200 TO 3399	16	4	12				3	3
3400 TO 3599	17	4	13				3	3
3600 TO 3799	18	5	13				3	3
3800 TO 3999	19	5	14				3	3
4000 TO 4199	20	5	15				3	3
4200 TO 4399	21	5	16				3	3
4400 TO 4599	22	5	17				3	3
4600 TO 4799	23	5	18				3	3
4800 TO 4999	24	5	19				3	3
5000 TO 5199	25	6	19				3	3
5200 TO 5399	26	6	20				3	3
5400 TO 5599	27	6	21				3	3
5600 TO 5799	28	6	22				3	3
5800 TO 5999	29	6	23				3	3
6000 TO 10001	30	6	24				3	3
> 10001	40	6	34				3	3

## EN 71-1:2011 + A2:2013 - clause 4.20

Close-to-the-ear toy	Hand-held toy	Rattle	Squeeze toy	Table-top toy	
					
Wind toy	Pull-along or push toy	Voice toy	Toy can be confused with a close-to-the-ear toy	Percussion toy	Cap-firing toy
					

	Close-to-the-ear toy	Hand-held toy	Rattle	Squeeze toy	Table-top toy	Pull-along or push toy
EN71-1:2011	X	X	X	X	X	Not specified but well known
A2:2013	X	X	X	X	X	X

	<b>*Voice toy</b>	<b>*Wind toy</b>	<b>*Percussion toy</b>	<b>Cap firing toy</b>	<b>LpA  Time averaged emission sound pressure level</b>	<b>Lpk  Peak emission sound pressure level</b>
EN71-1:2011				Not specified but well known	Not specified but well known	Not specified but well known
A2:2013	X	X	X	X	X	X

## EN 71-1:2011 + A2:2013 - clause 4.20

### - Exposure category 1:

- 玩具单次触发，发声时间超过30s;
- 单次触发，发声时间超过30s的近耳玩具;
- 用耳机的玩具;

### - Exposure category 2:

- 玩具单次触发，发声时间超过5s但是小于30s;
- 单次触发，发声时间超过5s但是小于30s的近耳玩具;
- 摇铃及挤压玩具;
- 模拟乐器的吹气玩具;

## EN 71-1:2011 + A2:2013 - clause 4.20

### - Exposure category 3:

- 玩具单次触发，发声时间小于5s;
- 需要持续机械力维持的声音;
- 发声时间小于5s的近耳玩具;
- 玩具火药帽;
- 吹气玩具，如哨子;



## 4.20.2 声压限值

Table 1 - A-weighted time-averaged emission sound pressure level limit,  $L_{pA}$ , assumed use distance and measurement distance

Toy Type	Exposure category (number)	Assumed use distance (cm)	Measurement distance (cm)	Limit at the measurement distance (dB)
Sub-clause 4.20.2.2 Close-to-the-ear toys	1	2,5	50	60
	2	2,5	50	65
	3	2,5	50	70
Sub-clause 4.20.2.3 Table-top or floor toys	1	25	50	80
	2	25	50	85
	3	25	50	90
Sub-clause 4.20.2.4 Hand-held toys	1	25	50	80
	2	25	50	85
	3	25	50	90
Sub-clause 4.20.2.5 Toys using headphones or earphones	1	<sup>a</sup>	<sup>a</sup>	85 <sup>a</sup>
Sub-clause 4.20.2.6 Rattles	2	25	50	85
Sub-clause 4.20.2.7 Squeeze toys	2	25	50	85
Sub-clause 4.20.2.8 Pull-along or push toys	1	25	50	80 <sup>b</sup>
	2	25	50	85 <sup>b</sup>
	3	25	50	90 <sup>b</sup>
Sub-clause 4.20.2.9 Percussion toys	2	25	50	85
Sub-clause 4.20.2.10 Wind toys	2	25	50	85
	3	25	50	90
Sub-clause 4.20.2.11 Cap-firing toys	3	25	50	90
Sub-clause 4.20.2.12 voice toys	1	25	50	80
	2	25	50	85
	3	25	50	90

<sup>a</sup> Measured using an ear simulator device and converted to a free field equivalent.

<sup>b</sup> This limit value refers to the A-weighted *maximum emission sound pressure level* using time-weighting F,  $L_{pAFmax}$ .

**Table 2 - C-weighted emission peak sound pressure level limit, worst case use distance and measurement distance**

<b>Toy Type</b>	<b>Worst case use distance (cm)</b>	<b>Measurement distance (cm)</b>	<b><math>L_{pCpeak}</math> at measurement distance (dB)</b>
Sub-clause 4.20.2.2 Close-to-the-ear toys	2,5	50	110
Sub-clause 4.20.2.3 Table-top or floor toys	2,5	50	110
Sub-clause 4.20.2.4 Hand-held toys	2,5	50	110
Sub-clause 4.20.2.5 Toys using headphones or earphones	<sup>a</sup>	<sup>a</sup>	135 <sup>a</sup>
Sub-clause 4.20.2.6 Rattles	2,5	50	110
Sub-clause 4.20.2.7 Squeeze toys	2,5	50	110
Sub-clause 4.20.2.8 Pull-along or push toys	2,5	50	110
Sub-clause 4.20.2.9 Percussion toys	25	50	130
Sub-clause 4.20.2.10 Wind toys	2,5	50	110
Sub-clause 4.20.2.11 Cap-firing toys	2,5	50	125
Sub-clause 4.20.2.12 voice toys	2,5	50	110
<sup>a</sup> Measured using an ear simulator device and converted to a free field equivalent.			

- 1 2012年伤害概况
- 2 2012年案例分析
- 3 2012年数据统计
- 4 1998-2012年数据分析

Data are from samples collected from October 1, 2012 through March 31, 2013.

**Total number of screenings – 12,435**

**Total number of products stopped – 678**

**Total number of units stopped – 6,095,106**

## **Children's Products**

**Total number of products stopped – 588 (87%)**

**Total number of units stopped – 1,201,922 (20%)**

### **Products Stopped by Primary Violation/Defect**

Lead – 335 (paint 46; content 289) (57%)

Phthalates – 56 (10%)

Certification – 48 (8%)

Tracking labels – 44 (7%)

Small parts – 32 (5%)

Art materials – 26 (4%)

Drawstrings – 11 (3%)

Durable nursery products – 13 (2%)

Battery-operated toys – 5 (1%)

The remaining 3 percent included sharp points, pacifiers, rattles, dive sticks and misbranded toys.

11 deaths

11 宗死亡事件

265,000 injuries

265,000 宗伤害事件

Note: these injuries were related to,  
not necessarily caused by toys

注：这些伤害与死亡事件与玩具有关，  
但不一定是由玩具造成的



**Table 1: Reported Toy-Related Deaths Among Children Younger Than 15 Years of Age  
2010–2012<sup>3</sup>**

Type of Toy (Hazard)	2010		2011 <sup>d</sup>		2012	
	Children 12 Years of Age or Younger	Children 13 and 14 Years of Age	Children 12 Years of Age or Younger	Children 13 and 14 Years of Age	Children 12 Years of Age or Younger	Children 13 and 14 Years of Age
<b>TOTAL</b>	<b>19</b>		<b>17</b>		<b>11</b>	
<b>Sub Total</b>	<b>19</b>	<b>0</b>	<b>16</b>	<b>1</b>	<b>11</b>	<b>0</b>
Balloons (airway obstruction, aspiration, asphyxiation)	5		5		2	
Tricycles (drowning, fall)			2		5	
Nonmotorized scooters (motor vehicle involvement)	1		1	1	2	
Stuffed toys/doll/doll accessory (choking, strangulation, suffocation)	2				1	
Balls, other (drowning)	2		1			
Toy boxes (entrapment, drowning, hanging)	2		1			
Rubber balls/other small ball (airway obstruction, choking)	3					
Inflatable toys other than balloons (drowning, fall)	1		1			
Other toys with a single reported fatality in the year (asphyxiation, drowning, choking)	3		5		1	

Source: In-Depth Investigations (INDP), Injury and Potential Injury Incidents (IPII), Death Certificates (DTHS), and the National Electronic Injury Surveillance System (NEISS) from 1/1/2010 to 12/31/2012; CPSC. Data was extracted in July 2013.

- CPSC staff received 11 reports of toy-related deaths that occurred in the 2012 calendar year among children younger than 15 years old, all 11 victims were under 12 years of age.

2012年CPSC收到11份玩具导致死亡的报告，所有11起都发生在12岁以下儿童。

- Balloons were associated with 2 (18 percent) of the 11 reported deaths in 2012.

2012年，11份报告中有2份与气球有关，占比例18%。

- In 2012, most toy-related deaths were due to drowning (5 deaths) and asphyxiation/aspiration ( 3 deaths).

2012年，有5宗意外是由于溺水死亡，有3宗意外是由于窒息死亡。

# 2012年案例分析- Tricycles 三轮车

Intertek

Valued Quality. Delivered.

Five victims—one female and four males, ages of 12 months to three years—died when falls from tricycles resulted in drowning or fatal injuries in 2012.

有5名儿童-1个女孩4个男孩，年龄由12个月到3岁，由于从三轮车上摔下而导致溺水或受伤死亡。

A 3 years old girl, and 4 2-years-old boys, fell into the pool while riding tricycle, drown.

1个3岁的女孩和4个2岁的男孩  
骑三轮车意外掉入游泳池溺水死亡。

A 12-months-old boy was riding a tricycle, the tricycle toppled over causing the victim's head struck the pavement, the victim was unconscious and pronounce dead.

一个12个月的男孩在骑三轮车时摔倒，  
头撞到人行道，昏迷之后死亡。





# 2012年案例分析- Non-motorized scooter 非机动滑板车



Valued Quality. Delivered.

There were two deaths associated with nonmotorized scooters.

2起与非机动滑板车相关的死亡案例。

A 6-year-old boy was struck by a truck while crossing a highway on a scooter.

1个6岁的男孩在骑非机动滑板车横穿马路时被一辆汽车撞死。

A 7-year-old boy rode down a hill on this scooter and passed into an intersection of roads struck a passenger car. The victim died of a traumatic brain injury.

1个7岁的男孩骑非机动滑板车从高处滑下，在十字路口撞上一辆小汽车，送医院抢救无效死于脑创伤。



There were 2 fatalities involving balloons.

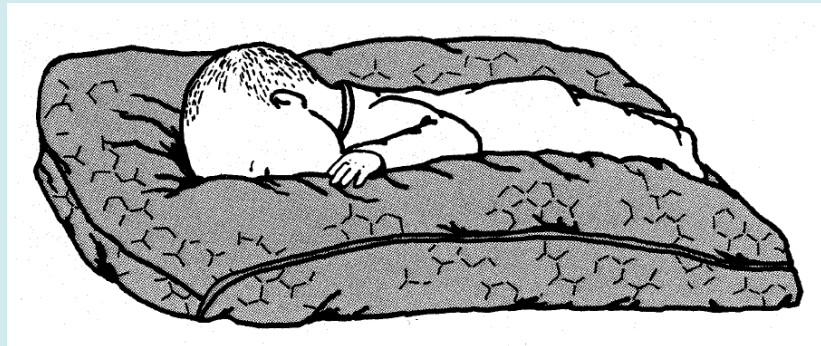
A six-month-old girl ingested a small rubber balloon and died of asphyxia due to airway obstruction. A seven-month-old girl died in a hospital 17 days after inhaling an un-inflated latex balloon at her home.

2个小孩由于吸附气球或气球碎片而窒息死亡。受害者为两个女孩，年龄为6个月和7个月。



An 7-month-old girl was found unresponsive in her crib with the right side of her face against a stuffed animal, she died of asphyxia by suffocation per the medical examiner.

1个7个月大的女孩被发现右脸贴紧一个毛绒玩具趴在童床上。受害者窒息而死。



**Table 3: Annual Toy-Related Emergency Department-Treated Injury Estimates  
2008–2012**

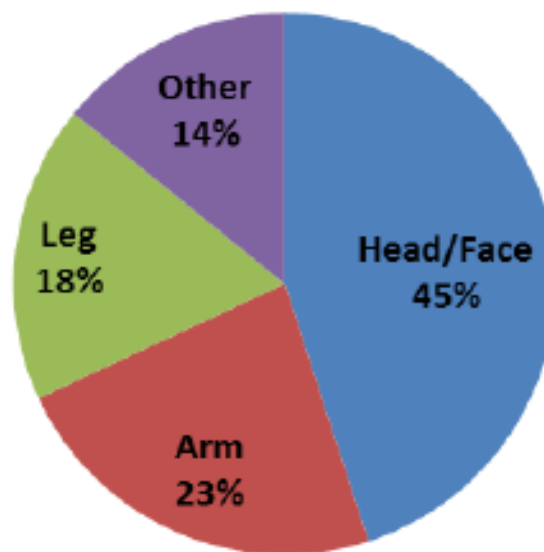
<b>Calendar Year</b>	<b>All Ages</b>	<b>Younger Than 15 Years of Age</b>	<b>12 Years of Age or Younger<sup>‡</sup></b>	<b>Younger Than 5 Years of Age</b>
2008	235,300	172,700	164,400	82,300
2009	250,100	185,900	177,800	90,600
2010	251,700	181,500	172,000	89,200
2011	262,300	193,200	184,100	92,200
2012	265,000	192,000	181,600	89,500

Source: NEISS, U.S. Consumer Product Safety Commission/EPHA. Estimates are rounded to the nearest 100.

<sup>‡</sup> Toy-related injury estimates among children 12 years of age or younger are presented to be consistent with the age definition for a children's product in the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2052 (a) (2).

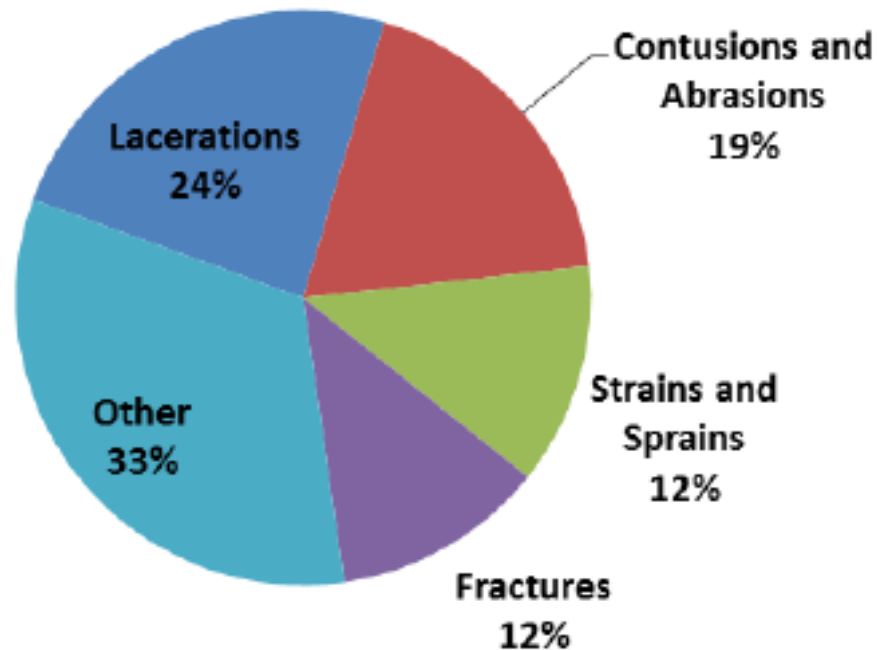
**Figure 1: Distribution of Toy-Related Injury Estimates by Body Regions Injured for All Ages**

**2012**  
(Total=265,000)



**Figure 2: Distribution of Toy-Related Injury Estimates by Type of Injuries for All Ages**

**2012**  
(Total=265,000)



**Table 4: Toy Categories Associated with the Largest Number of Estimated Emergency Department-Treated Injuries for Different Age Groups  
2012**

Toy Category	Estimated Injuries (%)			
	All Ages	Younger Than 15 Years of Age	12 Years of Age or Younger <sup>‡</sup>	Younger Than 5 Years of Age
Nonmotorized Scooters	60,100 (23)	52,400 (27)	47,500 (26)	8,300 (9)
Toys, Not Specified	57,400 (22)	33,900 (18)	33,500 (18)	24,800 (28)
Toy Balls	23,800 (9)	16,800 (9)	15,600 (9)	5,800 (6)
Toy Vehicles	13,600 (5)	9,200 (5)	9,000 (5)	6,900 (8)

Source: NEISS, U.S. Consumer Product Safety Commission/EPHA. Estimates are rounded to the nearest 100.

<sup>‡</sup> Toy-related injury estimates among children 12 years of age or younger are presented to be consistent with the age definition for a children's product in the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2052 (a) (2).



**Table 9: Toy-Related Emergency Department-Treated Injury Estimates for Different Age Groups  
1998–2012**

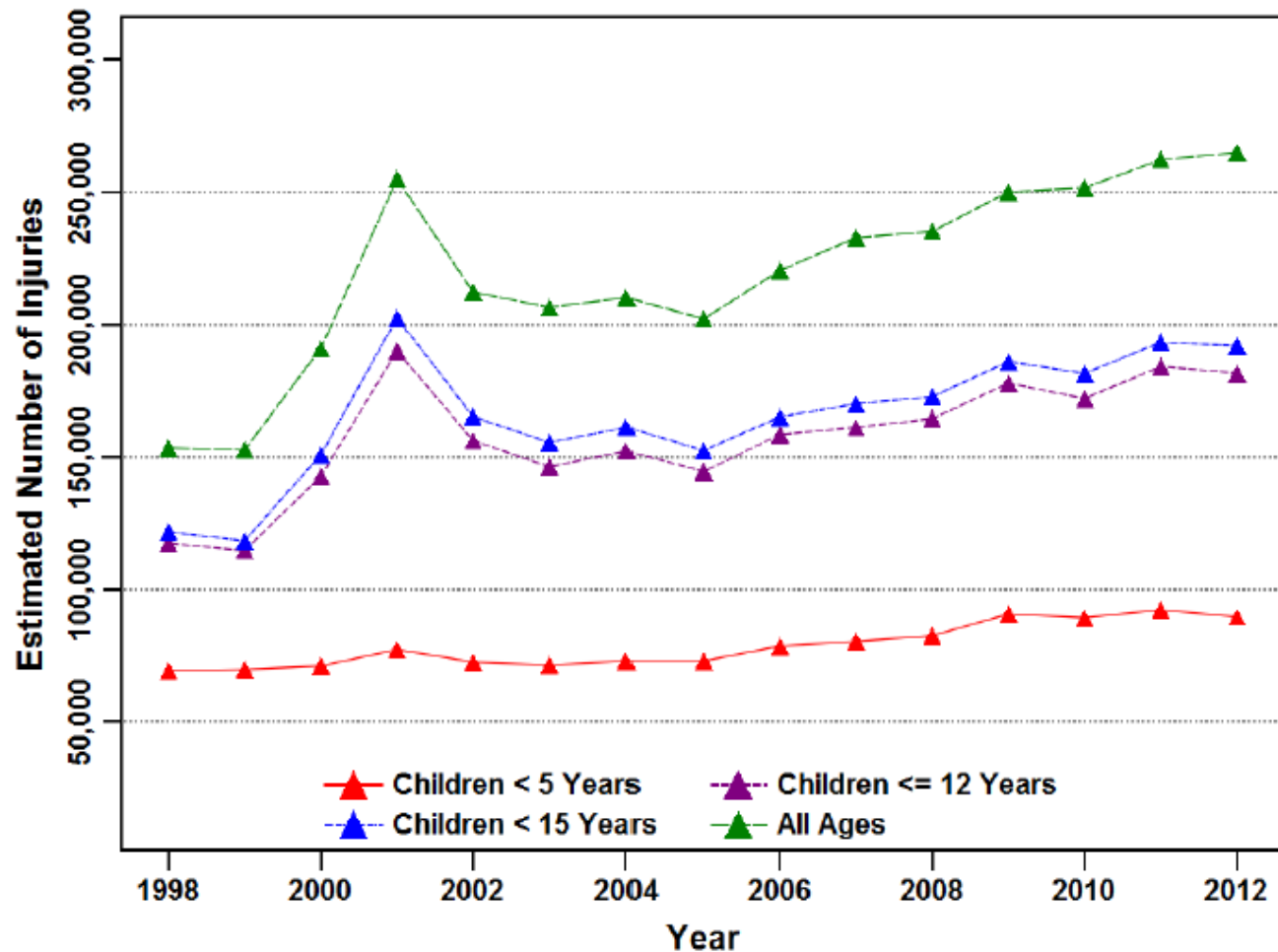
Calendar Year*	All Ages		Children Younger Than 15 Years of Age		Children 12 Years of Age or Younger		Children Younger Than 5 Years of Age	
	Injury Estimate	95% Confidence Interval	Injury Estimate	95% Confidence Interval	Injury Estimate	95% Confidence Interval	Injury Estimate	95% Confidence Interval
1998	153,400	134,400–172,500	121,600	106,000–137,200	117,300	102,100–132,400	69,100	59,400–78,900
1999	152,600	134,400–170,800	118,300	103,000–133,700	114,600	99,600–129,500	69,600	60,000–79,200
2000	191,000	161,500–220,500	150,800	125,100–176,600	142,600	118,500–166,700	70,900	60,200–81,600
2001	255,100	221,100–289,100	202,500	171,700–233,300	190,000	160,600–219,400	77,100	65,600–88,600
2002	212,400	182,800–242,100	165,200	139,600–190,800	156,100	131,900–180,200	72,400	59,900–84,800
2003	206,700	177,500–235,900	155,400	132,000–178,900	146,300	124,300–168,400	71,200	59,500–82,800
2004	210,300	179,800–240,700	161,100	135,900–186,200	152,200	128,500–176,000	72,800	61,300–84,300
2005	202,300	175,100–229,500	152,400	129,700–175,100	144,500	122,500–166,600	72,800	61,800–83,800
2006	220,500	190,300–250,800	165,100	139,900–190,200	158,400	134,300–182,600	78,400	66,500–90,300
2007	232,900	200,000–265,700	170,100	144,600–195,700	161,200	136,900–185,500	80,200	67,700–92,600
2008	235,300	202,400–268,200	172,700	146,800–198,600	164,400	139,400–189,300	82,300	69,200–95,400
2009	250,100	214,100–286,000	185,900	156,600–215,100	177,800	149,800–205,800	90,600	76,100–105,100
2010	251,700	216,100–287,200	181,500	152,400–210,500	172,000	144,400–199,500	89,200	74,000–104,500
2011	262,300	225,400–299,200	193,200	162,500–223,900	184,100	154,400–213,800	92,200	74,900–109,600
2012	265,000	228,600–301,300	192,000	161,400–222,600	181,600	152,300–210,900	89,500	73,300–105,800

Source: NEISS, U.S. Consumer Product Safety Commission/EPHA. Estimates are rounded to the nearest 100.

\*Tabulated estimates with confidence intervals for 1998–2012 were produced in July 2013.



Figure 3: Toy-Related Emergency Department-Treated Injury Estimates for Different Age Groups  
1998–2012



## Specific products & hazards analyses: 具体产品及危害分析

2007年

Rubber dart 橡皮子弹

A 9 year old boy died from aspirating a rubber dart.

1个9岁男孩因橡皮子弹而窒息死亡



## Specific products & hazards analyses:

具体产品及危害分析:

2009年

### **Battery In Toy** 玩具内的电池

**1 Death** 1起死亡事故

A two year old female died after she ingested a coin shaped battery removed by an adult from an electronic toy.

一名两岁的女孩死于吞食一个由成人从电子玩具取出的硬币型电池。



Specific products & hazards analyses:

具体产品及危害分析:

2010年

**Rubber Balls/Small Ball** 橡皮球/小球

3 Deaths 3起死亡事故

Two 2-year-old boys died of airway obstruction/ asphyxia as a result of choking on small rubber balls. The 2 rubber balls were 0.75inch and 1inch in diameter, respectively. Additionally, a 3-year-old boy choked on a toy ball and died from airway obstruction/asphyxia.

两名2岁的男孩因橡胶小球，窒息死亡。这2个橡胶球的直径分别是0.75英寸和1英寸。另外，一名3岁的男孩因勿食一个玩具球，窒息死亡。



## Pretend Toy 过家家玩具

1 Death 1起死亡事故

一名6岁男孩因误食一个烹饪玩具中形状类似于食物的塑胶玩具，窒息死亡

[illegible]

设计评估

初始产品规格分析

工厂评估

模拟样品分析

耐用性、性能和使用寿命测试

生产前检验

生产中检验

产品测试（各国法规标准）

运输前检验

产品评估和工程学分析

从产品设计到市场销售的全  
面安全保证





国际：ISO 8124

中国：GB 6675

欧盟：玩具安全标准（EN71）、电动玩具的安全标准（EN62115）、电磁兼容（EMC）、REACH法规

美国：消费品安全委员会（CPSC）、美国测试和材料协会（ASTM F963）、美国食品和药管理局（FDA）

加拿大：加拿大危险品（玩具）条例

英国：BS EN71

德国：德国标准协会（DIN EN71）、德国食品及日用品法（LFGB）

法国：NF EN71

澳大利亚：AS/NZA ISO 8124

日本：ST2002

通向全球的品质信心



深圳天祥质量技术服务有限公司

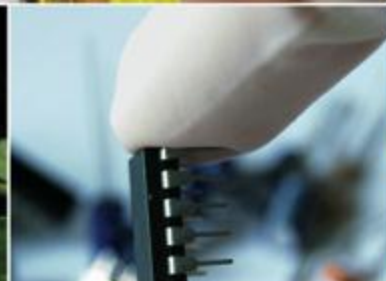
李兆新

[William.lee@intertek.com](mailto:William.lee@intertek.com)

0755-26020315



*Thank you!*



## Battery in EU (2006/66/EC) amended by 2013/56/EU



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Categories		Concentration Allowance
Batteries or accumulators	All	0.0005% (w/w) of Hg
	Portable	0.0005% (w/w) of Hg 0.002% (w/w) of Cd #
Button Cells		2% of Hg (until 1st Oct 2015), 0.0005% of Hg (from 2nd Oct 2015) 0.002% of Cd

**# :** Not apply to portable batteries and accumulators intended for use in:

- (a) emergency and alarm systems, including emergency lighting;
- (b) medical equipment; or
- (c) cordless power tools (until 31 Dec 2016).

## REACH SVHC 第10批

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**16 December 2013** – Seven new SVHCs were added to the Candidate List

[http://echa.europa.eu/view-article/-/journal\\_content/title/echa-updates-the-candidate-list-for-authorisation-with-seven-new-substances-of-very-high-concern-svhcs-](http://echa.europa.eu/view-article/-/journal_content/title/echa-updates-the-candidate-list-for-authorisation-with-seven-new-substances-of-very-high-concern-svhcs-)

英文名	中文名	CAS No.	用途
Cadmium sulphide	硫化镉	1306-23-6	用于制焰火、玻璃釉、瓷釉、发光材料，并用作油漆、纸、橡胶和玻璃等的颜料（镉黄和镉红）。高纯度的是良好的半导体。
Dihexyl phthalate	邻苯二甲酸二己酯	84-75-3	增塑剂，也用于树脂合成
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	刚果红(直接红 28)	573-58-0	主要用于纺织和纸制品的染色，也可用作指示剂用作酸碱指示剂、吸附指示剂和生物染色剂等

# REACH SVHC 第10批

**Intertek**

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英文名	中文名	CAS No.	用途
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	直接黑 38	1937-37-7	主要用于蚕丝、锦纶及其混纺织物的染色，还可用于皮革、生物和木材的染色、塑料的着色及作为赤色墨水的原料等。
Imidazolidine-2-thione; 2-imidazoline-2-thiol	乙烯硫脲	96-45-7	用作合成橡胶的促进剂，镀铜光亮剂，也用作精细化学的中间体，用于制造抗氧剂、杀虫剂、杀真菌剂、染料、药物和合成树脂。
Lead di(acetate)	醋酸铅	301-04-2	纺织品印染、制药、制造铅盐的原料、铅电镀、防水漆、分析试剂、金冶炼等。
Trixylyl phosphate	磷酸二甲酚酯	25155-23-1	用作增塑剂

## REACH Annex XVII, Entry 50, PAHs

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Articles	PAH Limit
<ul style="list-style-type: none"><li>• Toys, including activity toys</li><li>• Child care articles</li></ul>	0.5 mg/kg
<p>All other articles supplied to the general public, for example:</p> <ul style="list-style-type: none"><li>• Sport equipment such as bicycles, golf clubs, racquets</li><li>• Household utensils, trolleys, walking frames</li><li>• Tools for domestic use</li><li>• Clothing, footwear, gloves and sportswear</li><li>• Watch-straps, wrist-bands, masks, head-bands</li></ul>	1 mg/kg
<p>Polycyclic-aromatic hydrocarbons (PAH):</p> <ul style="list-style-type: none"><li>(a) Benzo[a]pyrene (BaP, CAS No 50-32-8)</li><li>(b) Benzo[e]pyrene (BeP, CAS No 192-97-2)</li><li>(c) Benzo[a]anthracene (BaA, CAS No 56-55-3)</li><li>(d) Chrysen (CHR, CAS No 218-01-9)</li><li>(e) Benzo[b]fluoranthene (BbFA, CAS No 205-99-2)</li><li>(f) Benzo[j]fluoranthene (BjFA, CAS No 205-82-3)</li><li>(g) Benzo[k]fluoranthene (BkFA, CAS No 207-08-9)</li><li>(h) Dibenzo[a,h]anthracene (DBAhA, CAS No 53-70-3)</li></ul>	

It shall apply from  
27 December 2015

# 美国加州65法例及与玩具 相关的法庭案例

**Presenter name:** Dr. S.P. Chan

**Date of presentation:** Dec 19, 2013

**Intertek Testing Services Shenzhen Ltd**



The information in this document is for reference only. For detail shall reference to the original regulations



# California Proposition 65 加州65背景介绍



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## The Safe Drinking Water and Toxic Enforcement Act, 1986

### 1986年安全饮用水和毒性物质强制执行法

No person in the course of doing business shall knowingly and intentionally exposed any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual

任何人不得在预先没有给予合理清晰警告的情况下，在从事商业活动的过程中有意或故意地暴露个别加州已知的可能引起癌症或生殖毒性的化学物质。

# Proposition 65 Today 加州65现状



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- 900 chemicals on current list 目前已有超过900种在册登记化学物质
  - 250 have Safe Harbor Limits 其中250种已有安全保护限值
  - Warning Labels 警示标签
  - Chemicals are listed and delisted by “state qualified experts” appointed by the Governor, OEHHA under EPA (office of environmental Health Hazard Assessment 美国环保署环境健康危害评估室指定的国家认可专家对在册化学物质进行增删

Chemicals are known to be either carcinogens or reproductive toxins

在册化学物质均为致癌或有生殖毒性物质

Grace period 宽限期: 12 months 12个月



# Warning Label 警示标签

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If the product contains a chemical known to the state of California to cause cancer or reproductive harm, **warning label** is needed. 若产品中含有加州明示的致癌或生殖毒性的物质时须张贴**警示标签**。

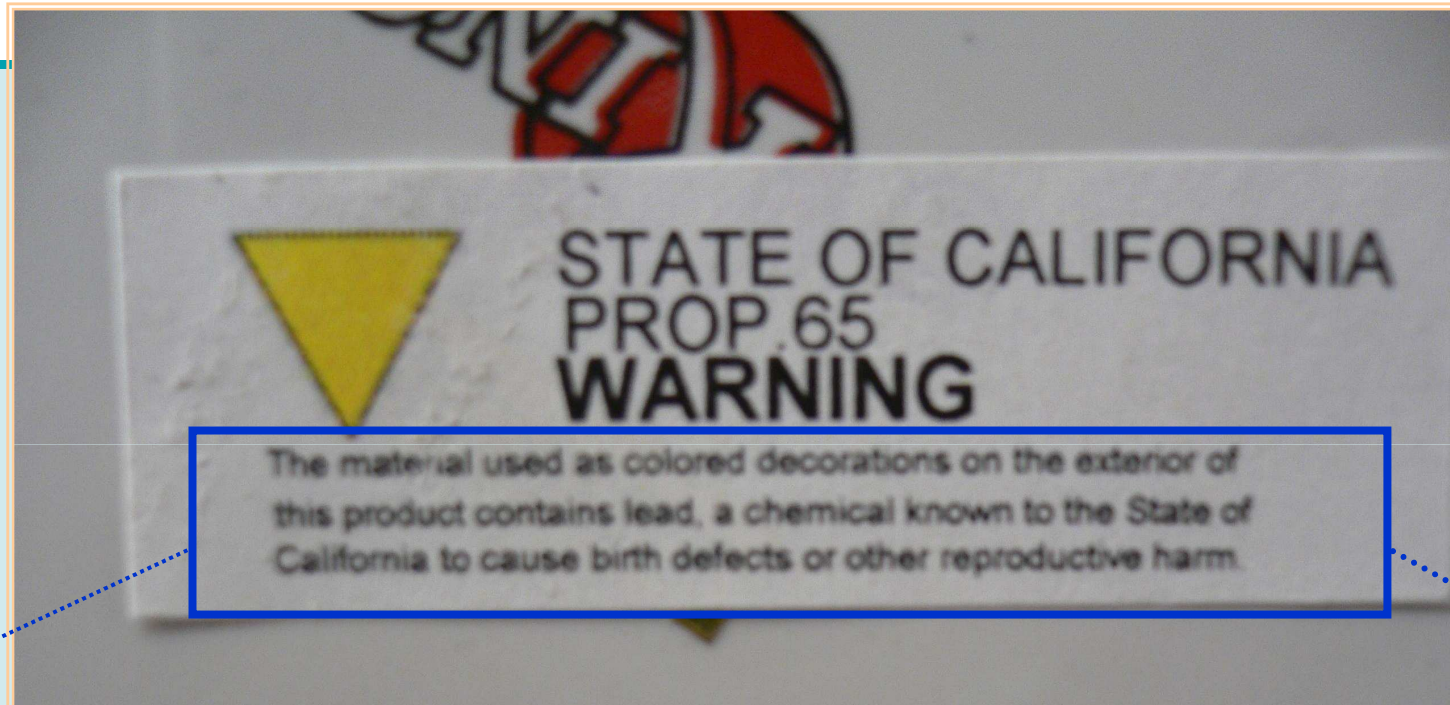
**Be printed on** the product or package label in the same section of the label that contains other safety warnings concerning the use of the subject bleach product. If the label contains no other safety warning, the prop 65 warning shall be printed on the product or package label. 加州65警示标签应与其它安全警示标签置于一一起印于产品或包装上。若无其它安全警示标签，则加州65标签要印在产品或包装上。



# Warning Label 警示标签

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**The material used as colored decorations on the exterior of this product contains lead, a chemical known to the State of California to cause birth defects or other reproductive harm**

本产品外部装饰材质中含铅,加州明示该物质会导致新生儿缺陷或其它生殖毒性

# Court Case Settlement 案例

Intertek

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## Toy 玩具

案例编号: RG-350969, RG-356892

产品: 玩具 (<6岁)

限值: 铅: 表面涂层 < 0.009% (90 ppm)

其它可接触部件 < 0.01% (100 ppm)

邻苯二甲酸盐: DEHP, BBP, DBP, DIDP & DnHP (单个)  $\leq 0.1\%$  (1000ppm)

案例编号: RG-356892

产品: 玩具 (6-12岁)

限值: 铅: 表面涂层 < 0.009% (90 ppm)

其它可接触部件 < 0.01% (100 ppm)



# 加州65案例总结



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年份	案例数量	总判决金额(美元)
2012	437	22,560,022
2011	338	16,286,728
2010	187	13,620,981
2009	321	14,608,178







## U.S. Consumer Product Safety Commission

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[▶ About CPSC](#)
[▶ Library - FOIA](#)
[▶ Business](#)

### Children's Product Certificate (CPC)

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Manufacturers and importers of [children's products](#) must certify, in a written Children's Product Certificate (CPC) based on test results from a [CPSC-accepted laboratory](#), that their children's products comply with applicable children's product safety rules. Below on this page, CPSC provides two samples of CPCs for fictitious products, showing example layouts of the CPC's required elements; one for a toy and one for an article of children's clothing. These samples are illustrative, do not capture every possible children's product safety rule that may apply to a children's product, and are subject to additional [disclaimer](#). The CPC and supporting test reports must be in English. Also see [frequently asked questions \(FAQs\)](#).

### Elements Required in a CPC

1. Identification of the product covered by this certificate:

*Describe the product(s) covered by this certification in enough detail to match the certificate to each product it covers and no others.*

2. Citation to each CPSC children's product safety rule to which this product is being certified:

*The certificate must identify separately each children's product safety rule that is applicable to the children's product.*

3. Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:

*Provide the name, full mailing address, and telephone number of the importer or U.S. domestic manufacturer certifying the product.*

4. Contact information for the individual maintaining records of test results:

*Provide the name, full mailing address, e-mail address, and telephone number of the person maintaining test records in support of the certification.*

5. Date and place where this product was manufactured:

*For the date(s) when the product was manufactured, provide at least the month and year. For the place of manufacture, provide at least the city (or administrative region), state (if applicable), and country where the product was manufactured or finally assembled. If the same manufacturer operates more than one location in the same city, provide the street address of the factory.*

6. Provide the date(s) and place when the product was tested for compliance with the consumer product safety rule(s) cited above:

*Provide the location(s) of the testing and the date(s) of the test(s) or test report(s) on which certification is being based.*

7. Identify any third party, CPSC-accepted laboratory on whose testing the certificate depends:

*Provide the name, full mailing address, and telephone number of the laboratory.*

*Registered [small batch manufacturers](#) who are not required to third party test their product to certain children's product safety requirements must include the registration number provided by the CPSC in this section of the CPC. (Products manufactured by registered [small batch manufacturers](#) must still comply with applicable children's product safety rules.).*

**Children's Product Certificate - Sample #1***(Available at [www.toystoystoys.info/3PT#34kTy](http://www.toystoystoys.info/3PT#34kTy))*

This sample is for a children's toy. Your product may require additional testing and certification.

## 1. Identification of the product covered by this certificate:

*Children's Toy Shape Sorter, Model "Show and Tell," #34kTy, Blue, Red, Yellow Models*

Color can be a source of lead. Tests of each color may be required to issue this CPC.

## 2. Citation to each CPSC product safety regulation to which this product is being certified:

In this section, you may list just citations. The titles for each children's product safety rule are provided here for educational purposes only.

[15 U.S.C. § 1278a](#) (preferred citation) or *Sec. 101 of the [Consumer Product Safety Improvement Act of 2008](#), Pub. L. No. 110-314 (August 14, 2008) (CPSIA), Ban on Total Lead Content in Excess of 100 ppm in Children's Products.*

[16 CFR Part 1303](#), *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint for Toys and Other Articles Intended for Children.*

[16 CFR Part 1501](#), *Small Parts Ban for Toys and Other Articles Intended for Children under 3 Years of Age which Present Choking, Aspiration, or Ingestion Hazards.*

This example assumes a fictional shape sorter (age graded for a child ages 18 months through 35 months) that was tested using the applicable "use and abuse testing" specified in [16 CFR § 1500.52](#). (16 CFR § 1500.52 contains additional tests like compression and flexure, which are not applicable in this situation and, therefore, testing is not required for those tests.)

For children under 6 years of age, the appropriate small parts requirement is [16 CFR Part 1501](#). (For children between the ages of 6 years and 12 years of age, the Small Objects requirement in ASTM F 963-11 Section 4.6 applies.) There may be other labeling sections that apply to the small parts requirements, such as 16 CFR §§ [1500.19](#), [1500.20](#), and [1500.121](#). While you must comply with the sections on labeling, additional certification of compliance to the labeling requirements in the CPC is not required.

-----

*Toy Safety Standard, ASTM F 963-11 [Section 4.3.5.2 Heavy Elements in Accessible Toy Substrate Materials](#).*

This example assumes that the pieces in the fictional shape sorter (age graded for a child ages 18 months through 35 months) are "accessible," as described in section 4.3.5.2. This requirement goes into effect on June 12, 2012. Testing by a CPSC-accepted laboratory is [not yet required](#) for this section.

-----

[15 U.S.C. 2057c](#) (preferred citation) or *[Sec. 108 of the Consumer Product Safety Improvement Act of 2008](#), Pub. L. No. 110-314 (August 14, 2008) (CPSIA), Permanent and Interim Ban on Phthalates in Toys and Child Care Articles Used to Facilitate Sleeping or Eating.*

This example assumes that the fictional shape sorter is plastic and testing for compliance with the ban on phthalates is required. It is not necessary to test and certify materials that are known not to contain phthalates or to certify that phthalates are absent from materials that are known not to contain phthalates. See the [FAQ](#) for more information.



3. Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:

*Toys Toys Toys Importers  
123 Toy Lane, Los Angeles, CA 56789  
(456) 789-0123*

4. Contact information for the individual maintaining records of test results:

*Lisa Lane, Compliance Manager  
Toys Toys Toys Importers  
123 Toy Lane, Los Angeles, CA 56789  
llane@toytoystoysimport.net  
(456) 789-0123, ext. 788*

5. Date and place where this product was manufactured:

*June 2011, Guangzhou, Guangdong Province, China*

6. Date and place where this product was tested for compliance with the regulation(s) cited above:

*June 2011; August 2011; Guangzhou, Guangdong Province, China*

7. Identify the third party, CPSC-accepted where this product was tested by an accredited laboratory (accepted by the CPSC) for compliance with the regulation(s) cited above:

*Guangzhou Quality Labs  
No. 023 Shi Nan Road  
Dong Zhou, Pan Zi  
Guangzhou City  
Guangdong Province, China. 511453  
+(86) 20 09 7723 5467*

*This assumes that this single lab can test for all of the requirements in Section 2 above. Multiple CPSC-accepted labs may be required in order to test for each of the requirements for your product. This particular lab is fictitious. [Search](#) for a lab.*

**Children's Product Certificate - Sample #2***(Available at [www.mamamamama.net/23](http://www.mamamamama.net/23))*

This sample is for children's clothing, considered to be a children's product. Your product may require additional testing and certification.

## 1. Identification of the product covered by this certificate:

*Baby bodysuit garment with screen printed decoration "Mommy's Little Guy." (Model 6153, and Model 6154, Blue, Yellow)*

## 2. Citation to each CPSC product safety regulation to which this product is being certified:

You may list citations only. The titles for each regulation are provided here for educational purposes only. Three examples for this fictitious article of clothing are given below.

**Example 1**

[16 CFR Part 1610](#), *Standard for the Flammability of Clothing Textiles*.

Important: If this product were children's sleepwear (including [loungewear](#)) instead of ordinary wearing apparel, the applicable standard would be 16 CFR Part [1615/1616](#), Standard for the Flammability of Children's Sleepwear.

In addition, CPSC staff [interprets](#) sleepwear as being subject to compliance with section 108 of the CPSIA, the ban on certain phthalates. The additional citation would read: Sec. 108 of the [Consumer Product Safety Improvement Act of 2008](#), Pub. L. No. 110-314 (August 14, 2008) (CPSIA), Permanent and Interim Ban on Phthalates in Toys and Child Care Articles Used to Facilitate Sleeping or Eating.

Your supplier of "blank" garments (or screen printing ink) may have performed testing with an laboratory accepted by CPSC and issued a CPC on the component part. You may be able to rely upon that CPC in issuing your own CPC. [Learn more](#).

-----

**Example 2**

[15 U.S.C. § 1278a](#) or Sec. 101 of the [Consumer Product Safety Improvement Act of 2008](#), Pub. L. No. 110-314 (CPSIA,) *Ban on Total Lead Content in Children's Products in Excess of 100 ppm in Children's Products*.

Most properly applied and cured ordinary screen printing that cannot be scraped off of the garment is considered to be part of the substrate, and not a surface coating on the clothing (textile). See our [FAQ](#) on garment decoration.

-----

**Example 3**

[16 CFR Part 1303](#), *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint for Toys and Other Articles Intended for Children*.

If the textile ink can be scraped off (e.g., it did not cure properly or it has a purposefully raised texture) or if the ink is tested by a CPSC- accepted lab in its dried state, you may certify the component to this children's product safety rule instead of Sec. 101 of the CPSIA.

3. Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:

*Mama Mama Screenprinters  
123 Derby St., Boston, MA 04598  
(617) 987-7632*

## 4. Contact information for the individual maintaining records of test results:

*Brenda Smith, Owner  
Mama Mama Screenprinters  
123 Derby St., Boston, MA 04598  
bsmith@mamamamascreenprinters.us  
(617) 987-7632*

## 5. Date and place where this product was manufactured:

*February 2012, Boston, MA*

## 6. Date and place where this product was tested for compliance with the regulation(s) cited above:

*February 2012  
Boston, MA 02854*

## 7. Identify the third party, CPSC-accepted where this product was tested by an accredited laboratory (accepted by the CPSC) for compliance with the regulation(s) cited above:

*ABC Quality Labs  
4556 South Street  
Boston, MA 02854  
(617) 859-2645*

*This assumes that this single lab can test for all of the requirements in Section 2 above. Multiple CPSC-accepted labs may be required in order to test for each of the requirements for your product. This particular lab is fictitious. [Search](#) for a lab.*

*If an exception or exemption applies that makes testing the product unnecessary, cite to that regulation for clarity in this section. (e.g., plain surface fabrics, regardless of fiber content, that weigh more than 2.6 ounces per square yard are exempt from testing. Cite to [16 CFR §1610.1\(d\)\(1\).](#))*

*Small Batch Manufacturers: If you are a registered [small batch manufacturer](#) with the CPSC and are not required to conduct third party testing on certain requirements, include your registration number in this section. Recall that registration only provides relief from third party testing requirements for [certain](#) children's product safety rules, not from every children's product safety rule, and that compliance with all children's product safety rules is always required.*

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