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# *An Expert's View of the Implications of the New EU Toy Directive (2009/48/EC)*



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## Implications of the New EU Toy Directive (2009/48/EC)

With increasing consumer concerns on toys safety, a new EU Toy Directive, 2009/48/EC, has been published in order to cope with evolving safety issues and improve enforcement activities. Published in the Official Journal in June 2009, it will be effective from July 2011 onwards, while the current Directive 88/378/EEC will be repealed (apart from chemical aspects).

This document will provide an overview of the changes in the regulations.

The current EU Toy Directive, 88/378/EEC, was mandated more than 20 years ago. During the past two decades, toys have changed significantly and the current Directive can no longer provide comprehensive coverage on the safety of toys. The new chemical requirements will be effective from July 2013 onwards.

The key changes are highlighted briefly below:

- Drawing up of the EC Declaration of Conformity
- Carrying out safety assessments under Article 18
- New migration limits for 19 restricted elements
- Toys shall comply with the EU REACH regulation
- Ban on substances classified as CMR (Carcinogenic, Mutagenic or Toxic for Reproduction)
- 55 allergenic fragrances may not be used in toys. Only technically unavoidable traces are allowed up to 100 parts per million (ppm).
- Cosmetic toys shall comply with Directive 76/768/EEC
- 11 allergenic fragrances in Annex II of 76/768/EEC shall be listed on toys at concentration exceeding 0.01% by weight
- A toy intended for use by children under 36 months must be designed and manufactured in such a way that it can be cleaned
- Toys contained in food must have their own packaging
- Toys that are firmly attached to food are prohibited
- New provisions on sound-emitting toys
- Nitrosamines and Nitrosatable substances banned in toys for children under 36 months or mouth-contact toys

Other requirements include new requirements and warnings on labels and production control on manufacturing process.

### ***Cleaning of Toys Intended for Children Under 36 Months***

There will be new legal requirement for all toys intended for children under 36 months for products first placed on the European market from 20 July 2011.

A toy intended for use by children under 36 months must be designed and manufactured in such a way that it can be cleaned. A textile toy shall be washable (which means by soak washing), except if it contains a mechanism that may be damaged if soak washed. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

Guidance published by the European Commission has defined textile toys as "...toys entirely made of textile with exception for materials inside the toy and minor features or decorations sewed/adhered to the outside (e.g. eyes and nose). They can have a mechanical non textile component (mechanism) on the inside. Textile toys would therefore include soft plush toys and disguise costumes for children under 36 months. Additional examples can be found in the guidance document. Furthermore the guidance makes it clear that "Soak washing means immersing the toy in water or other liquid; this handling does not necessarily imply machine washing, it can be hand wash."

The manufacturer shall also carry out an analysis of all hazards mentioned in Article 18 after cleaning, among them hygiene hazards as well as an assessment of the potential exposure to all such hazards. For example, small parts hazards that appear after cleaning or soak washing need to be assessed.

As part of the Safety Assessment that a manufacturer is obligated to carry out under Article 18, consideration should be given as to what safety aspects may be compromised after washing. Relevant testing can then be carried out after washing to assess this if appropriate.

### ***Toys Associated with Food***

For products first placed on the European market from 20 July 2011, there will be new legal requirements for toys associated with food.

The directive states:

- 1) Toys contained within food or co-mingled with food must have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent it being swallowed and/or inhaled. Such toys shall bear the following:  
"Toy inside. Adult Supervision recommended".
- 2) Toy packaging, which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
- 3) Toys firmly attached to a food products at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, shall be prohibited. Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in (Annex II 1, 4) (c) and (d).

Guidance published by the European Commission indicates that:

- The requirements apply regardless of age.
- Toys within food must be contained within their own packaging which separates the toy from the food. That packaging must not fit within the small parts cylinder specified in EN 71-1.
- Certain shapes of packaging e.g. spherical, egg-shaped and detachable parts of it must not pass through Template E (small balls template) specified in EN 71-1. This also applies to the detachable parts of cylindrical toy packaging with rounded ends. (These requirements regarding certain shapes of packaging apply to all packaging and not only to packaging of toys associated with food.)
- Detachable parts are those which are produced following testing to EN 71-1 clause 5.1.
- Products where the food has to be consumed in order to get direct access to the whole toy are prohibited. In cases where the toy is attached to the food but is accessible without consuming the food, the toy and its parts must not fit within the small parts cylinder or pass through Template E.

### ***Other implications for product design and labelling***

As a result of new requirements of 2009/48/EC, the European toy standard EN 71-1 has been revised.

Among other changes there are implications for toys intended to be placed in the mouth which mean that there must be no small parts produced from any part of the toy, regardless of whether the toy is "mouth actuated" and whether the part is intended to be placed in the mouth.

Warnings which determine the decision to purchase must be visible at the point of sale, whether that is in store, on-line or through a catalogue. They must be preceded by the word "Warning" and even if the graphical symbol is used it must be accompanied by the word "Warning". The name and address of the manufacturer should be on the toy unless there is good reason for it not to be. In the case of the identification (e.g. batch number, SKU, model number) this must be on the toy unless it is not technically possible or it would be illegible.

### **Technical Documentation**

The manufacturer is obligated to produce and retain technical documentation for 10 years. While similar to the existing requirements under the current directive, such technical documentation must now include a Declaration of Conformity in the form specified in the directive and a Safety Assessment. The latter is basically a risk assessment which should include all hazards and an assessment of whether they are covered by the harmonised toy standards, or whether a Type Examination is required in cases where the hazards are not addressed by standards.

### **Chemicals in Toys**

The new legal requirements covering chemicals in toys will not apply on July 20, 2011, as the existing chemical requirements of Directive 88/378/EEC will not be repealed until 20 July 2013. Nevertheless, to better prepare for the several upcoming chemical challenges within a limited time frame, many manufacturers have started looking into one of the major new restrictions with regards to CMR chemicals in toys. CMRs refer to chemicals that are carcinogenic (C), mutagenic (M) and/or toxic to reproduction (R). In principle, CMRs are classified as category 1A, 1B or 2 under Regulation 1272/2008 (referred to as the CLP Regulation).

<b>CMR Category</b>	<b>CMR Classification</b>
Category 1A	Known to have carcinogenic potential for humans largely based on human evidence
Category 1B	Presumed to have carcinogenic potential for humans largely based on animal evidence
Category 2	Suspected human carcinogens with limited evidence

The new Directive 2009/48/EC requires that CMRs shall not be used in toys, components of toys or micro-structurally distinct parts of toys. The latter term is similar to the term 'homogeneous material' as applied to the ROHS directive and is intended to ensure that all areas of the toys that could be of relevance for the safety of the child are considered.

There are a huge number of CMRs classified by the EU at the moment, and the majority of them are chemicals derived from petroleum and coal. CMRs of utmost concern will be those volatile CMRs which are frequently used in solvents or as monomers of plastics, and hence may be found in residual amounts if the toy or its components contain paint coatings, plastics (especially soft plastics), adhesive, etc. Typical examples of these CMRs include benzene, toluene, phenol, dichloromethane, vinyl chloride and n-hexane. Toy manufacturers are highly advised to evaluate the possible presence of these CMRs in their products in order to address the possible impact of the new toy directive.

There are several other new chemical requirements/restrictions under the new toy directive which include allergenic fragrances, nitrosamines and nitrosatable levels, and migration limits for 19 chemicals. Please stay tuned while Intertek continues to furnish detailed information on each new requirement as well as our solution to help you get prepared well ahead.

### **The Solution**

Intertek, through our extensive global network, has a variety of services available to help you overcome the challenges related to complying with the new directive. Besides keeping you updated on any new developments, Intertek provides legal, regulatory and strategic consulting, testing, implementation programmes for compliance to the new directive, chemical testing and analysis and advice and guidance on compiling a technical file and a Declaration of Conformity. We can even provide system certification to meet your production control requirements.

## Frequently Asked Questions for the New EU Toy Directive

### When does it come into force?

Everything apart from the new chemical requirements applies to products first placed on the market from 20 July this year. Toys which comply with the existing directive can continue to be sold providing they were first placed on the market before 20 July. The chemical requirements apply to products first placed on the market from 20 July 2013.

### Has the scope changed?

A toy is now defined as a product “designed or intended, whether or not exclusively, for use in play by children under 14 years of age”. This means that a product is subject to this directive if it has an intended play function, even if that is not the primary function.

### Who is a manufacturer?

Someone who manufactures a toy or who has a toy manufactured and markets that toy under their own name/brand.

### What new documentation do I need as a manufacturer?

There are new requirements which specify that your technical documentation must include a Declaration of Conformity in the form described in the directive and a Safety Assessment.

### Will I need to re-design my toys?

Possibly. There are new requirements on e.g. hygiene, particularly requiring that textile toys for under 3's must be capable of being soaked washed. In addition, the directive has specific new requirements for toys in association with food and certain types of packaging.

### Will I need to change my labelling?

Possibly. Warnings which affect the decision to purchase must be visible at point of sale. They must be preceded by the word “Warning” (even if the graphical symbol is used). A web address is not a substitute for a name and address.

### Where can I get more guidance on the directive ?

The European Commission has published a general Guidance Document which can be found at:

[http://ec.europa.eu/enterprise/sectors/toys/files/tsd\\_explanatory\\_guidance\\_document\\_en.pdf](http://ec.europa.eu/enterprise/sectors/toys/files/tsd_explanatory_guidance_document_en.pdf)

The European Commission has published a technical Guidance Document which can be found at:

[http://ec.europa.eu/enterprise/sectors/toys/files/guidance-documents/technical\\_documentation\\_guidance\\_document\\_rev\\_1.0\\_en\\_.pdf](http://ec.europa.eu/enterprise/sectors/toys/files/guidance-documents/technical_documentation_guidance_document_rev_1.0_en_.pdf)

## iComply

As a solution to compliance with a number of regulations, Intertek developed iComply™, a user-friendly, web-based artificial intelligence application facilitating collaborative supply chain assembly of technical files. iComply™ is a simple solution built on sophisticated technology that takes a sequence of product-specific information entered by the importer or manufacturer, **PRODUCES** a production test plan, **GENERATES** necessary compliance declaration documents and **STORES** all documentation in a complete technical documentation file, all of which is available for easy access 24 hours a day, 7 days a week.

iComply™ is a one-stop-shop solution that enables you to demonstrate due diligence and guides you through the compliance process for the EU Toy Directive and proposed CPSIA Testing and Certification Rule. Additional modules are currently being developed for the Canada Consumer Product Safety Act and Proposition 65. iComply™ provides a complete solution to your record-keeping and compliance needs.

For more information on specific testing and certification information, please contact Intertek by emailing [consumergoods.uk@intertek.com](mailto:consumergoods.uk@intertek.com), or visit our website at [www.intertek.com](http://www.intertek.com).

### About the Author

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Philip graduated in analytical chemistry in 1982. He has over 30 years experience in quality control and technical support, formerly for a major UK retailer and for Intertek for the past 11 years. As a member of the Toy Industries of Europe Technical Committee, he has been involved in discussions on the new Toy Directive for many years. He is a member of various BSI committees, including CW/15 (Safety of Toys), and the BTHA Toy Interpretations Group. He attends both UK and European co-ordination meetings of Toy Notified Bodies and is also a Technical Assessor for toy and consumer products on behalf of UKAS.

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## 专家解析新欧盟玩具指令(2009/48/EC)



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## 新欧盟玩具指令(2009/48/EC)要求释意

由于人们对玩具的安全性日益关注，欧盟颁布了新的玩具指令2009/48/EC，旨在应对不断变化的玩具安全问题，并提升执法力度和有效性。该指令于2009年6月在欧盟官方公报上发布，并于2011年7月生效，届时现行指令88/378/EEC将废止(化学要求除外)。

本文将对新法规中变化的内容进行概括介绍。

现行的欧盟玩具指令88/378/EEC于20多年前开始实施。在过去的20年中，玩具产品发生了巨大变化，现行指令已不能涵盖玩具安全的方方面面。新的化学品要求将于2013年以后开始实施。

主要的变化归纳如下：

- 新的19项受限制元素迁移限值；
- 玩具应符合欧盟REACH法规；
- 对CMR类物质(致癌、诱导有机体突变或对生殖系统有毒害的物质)的禁令；
- 玩具中不能使用55种致敏性芳香物质，仅允许技术上无法避免的含量在0.01%(100ppm)以下的限量存在；
- 化妆品玩具应符合指令76/768/EEC的要求；
- 如果玩具中含有指令76/768/EEC附件II列举的11种致敏性芳香剂中的任何一种，并且含量超过重量的0.01%，则玩具上应该标注出来；
- 供36个月以下儿童使用的玩具必须被设计和制作为可以清洁的；
- 食品中的玩具必须有独立包装；
- 玩具不得牢固地粘附于食品；
- 有关发声玩具的新规定；
- 有关警告和标签的新规定；
- 36个月以下儿童使用的玩具或与嘴部接触的玩具中不得含有亚硝胺(Nitrosamines)和亚硝基胺(nitrosatable)物质。

其它要求还有 EC 合格声明，根据第 18 条进行安全评估，以及制造流程的生产控制等。

### 供 36 个月以下儿童使用的玩具清洁要求

在新玩具指令中，有一项针对 2011 年 7 月 20 日后投放欧洲市场的供 36 个月以下儿童使用的玩具的新要求。

所有供 36 个月以下儿童使用的玩具必须被设计和制作为可以清洁的。纺织品制作的玩具必须是可以洗涤的(指浸泡洗涤)，除非玩具含有浸泡后可能被损坏的机械装置。同时，玩具在依照法规和生产商的说明确清洗后，仍须满足安全要求。

欧洲委员会发布的指引将纺织品玩具定义为：“除玩具内部的材料，以及外部缝着/粘着的小构件或装饰品(如眼睛和鼻子)，完全由纺织品制成的玩具。此类玩具内部可以含有非纺织品的机械部件(机械装置)。”因此，纺织品玩具包括供 36 个月以下儿童使用的软毛绒玩具和装扮用服装。有关产品的更多示例，请参见指引文件。另外，指引文件对“浸泡洗涤”的说明是“将玩具浸入水中或其它液体中，这一处理过程不一定是机洗，也可以是手洗。”

在对玩具清洁之后，生产商应分析玩具是否存在第 18 条列举的所有危害，包括健康危害，以及对所有这些危害的潜在接触性进行评估，例如需要对清洁或浸泡洗涤后出现的小部件危害进行评估等。同时，作为第 18 条生产商必须进行的安全评估的一部分，生产商须考虑玩具在洗涤后哪些安全性能会受到影响，并且在适用的情况下，可以在洗涤后进行相关测试以进行评估。

### **与食品联系在一起的玩具**

对于2011年7月20日及以后投放欧洲市场的与食品相关的玩具，欧盟有新的法规要求。

指令规定：

- 1) 食品中包含的或与食品混合的玩具必须带有独立包装。包装的尺寸必须可以防止包装被吞入和/或吸入口中。并且，此类玩具应带有以下警示：  
“Toy inside. Adult Supervision recommended”.  
(中文释意：“内含玩具。建议成人监督。”)
- 2) 球形、蛋形或椭圆形的玩具包装，以及此类包装或带圆形顶端的圆柱形玩具包装的可拆卸的部件，其尺寸必须能够防止被吞入口中、咽部或下呼吸道入口时导致呼吸道阻塞。
- 3) 对于牢固地附着于食品，并且只有吃到食品才能直接接触到玩具是禁止的。玩具的某些部分直接附着于食品时，应符合(附件 II 1,4) (c)和(d)的要求。

欧盟委员会公布的指引规定：

- 上述要求适用于供各个年龄段儿童使用的玩具。
- 食品中的玩具必须置于独立包装中，将玩具与食品分隔开。包装不得完全容入EN 71-1规定的小部件量筒当中。
- 特定形状的包装，如球形、蛋形及其可拆卸的部件不得可以穿过EN 71-1规定的Template E (小球模板)。这一要求也适用于带圆形端部的圆柱形玩具包装上可拆卸的部件。(有关特定形状包装的上述要求适用于所有包装，而非仅适用于与食品相关的玩具的包装。)
- 可拆卸部件指根据EN 71-1第5.1条测试时所产生的部件。
- 只有吃到食品之后才能与整个玩具直接接触的产品是被禁止的。如果玩具附着于食品，但不需要吃到食品就可以接触到玩具，则玩具及其部件不得可以容纳进小部件量筒或穿过Template E(小球模板)。

### 有关产品设计和标签等其它要求的释意

由于 2009/48/EC 的新要求，EN71-1 进行了相应修订，其中包括有关可供放入口中的玩具的要求，即玩具的任何部位都不得脱离出小部件，不论该玩具是否由“嘴部驱动”，也不论该部件是否被设计为放入口中。

如果产品的警告语可能影响消费者的购买决定，则警告语必须贴示在明显位置，并且可以清晰辨识，让消费者在购买前就能看到，这项要求适用于在店铺、网络或者以产品目录形式销售的产品。警告语的最前面必须有“Warning”(警告)字样。即使产品使用年龄警告图示符号，也必须附有“Warning”(警告)字样。

除有合理原因外，生产商的名称和地址必须显示在玩具上。货品标识(如批次号、SKU、型号等)必须显示在玩具上，除非技术上不可行，或者无法辨识。

### 技术资料

生产商有责任编写技术资料，并将这些资料保存10年。与现行指令要求相似的是，此类技术资料必须包括按指令要求格式编写的合格声明和安全评估报告。后者基本上是一份风险评估报告，内容包括产品的所有潜在危害，以及评估这些危害是否有相应的协调标准，或者在某些危害没有相应的标准时是否需要进行EC型式检验(Type Examination)。

### 玩具中的化学品

新玩具指令中有关玩具中化学品的规定不会于2011年7月20日付诸实施，因为现行指令 88/378/EEC的化学要求直到2013年7月20日才废止。尽管如此，为在有限的时间内针对即将实施的化学品要求做好准备，许多生产商已经开始考虑如何应对其中的一项重要限制，即玩具中的CMR化学物质。CMR指具有致癌性、诱导有机体突变和/或生殖毒性；根据法规 1272/2008(亦称CLP法规) CMR的规定，CMR物质被分为1A, 1B和2三个类别。

CMR类别	CMR特性
类别1A	依据大量的人类证据显示，已知对人体具有潜在的致癌性
类别1B	依据动物证据显示，估计对人体具有潜在的致癌性
类别2	依据有限证据显示，猜测对人体具有潜在的致癌性

新指令2009/48/EC要求，CMR物质不得用于玩具、玩具的部件或具有不同微观结构的玩具部件中。其中最后一项与RoHS指令所指的“均质材料”相似，其目的是确保玩具中所有与儿童安全相关的区域都能顾及。

目前，已经有大量的物质被欧盟分类为**CMR**，其中大部分是从石油和煤中提取出来的化学品。最受关注的是那些可挥发的**CMR**，它们大多用于溶剂或作为塑料的单体；因此如果玩具或其部件带有涂层、塑料(尤其是软塑料)或粘合剂时可能含有这些物质的残留。典型的**CMR**包括苯、甲苯、苯酚、二氯甲烷、氯乙烯和正己烷等。建议玩具生产商评估产品中是否含有这些**CMR**，以便及时符合新玩具指令的要求，避免对生产和业务造成影响。

新的玩具指令还规定了其它几项新的化学品要求 / 限制，包括致敏的芳香物质、亚硝胺和亚硝胺化合物的含量水平，以及对**19**种化学品的迁移量限值。**Intertek**将及时提供各项新要求的具体信息，以及相关的解决方案，帮助您未雨绸缪并有效应对，希望您持续关注。

#### 解决方案：

**Intertek**拥有遍布全球的实验室网络和丰富的专业经验，可以提供全面细致的服务，帮助您符合新指令的要求。除随时传递法规的最新进展外，我们还提供有关新指令的法律、法规和策略咨询、测试和新指令符合性计划实施、化学品测试和分析，以及编写技术文件和符合性声明的顾问和指导等服务。我们还可以提供体系认证，帮助您确保满足生产控制的要求。

### 有关新欧盟玩具指令的常见问题解答

#### 何时开始实施？

2011年7月20日起新投放市场销售的产品应符合新指令中除化学品要求之外的所有规定。2011年7月20日前投放市场销售的玩具，如果符合现行指令，则可以继续销售。2013年7月20日起新投放市场销售的产品需符合化学品要求的规定。

#### 管制范围是否有变化？

现在对玩具的定义是“为14岁以下儿童设计或可供(不论是否专门)其在玩耍中使用的产品。”这意味着如果一件产品有可供玩耍的功能，即使其主要功能不是用于玩耍，也要受该指令管控。

#### 生产商指的是谁？

自己生产或让别人生产玩具，并在市场上用自己的名称/品牌销售该玩具的人。

#### 作为生产商，我需要准备哪些新的文件？

新指令规定技术资料中必须包含按指令要求的格式制作的符合性声明和安全评估。

#### 我需要修改玩具的设计吗？

可能需要。新指令在玩具的卫生方面有新要求，特别是要求供36个月以下儿童玩耍的纺织玩具必须可以浸泡洗涤。另外，新指令对与食品联系在一起的玩具和某些类别的包装有特别的新要求。

#### 我需要修改标签吗？

可能需要。如果产品的警告语可能影响消费者的购买决定，则警告语必须贴示在明显位置，并且可以清晰辨识，让消费者在购买前就能看到。警告语的最前面必须有“Warning”(警告)字样。商家名称和地址不能只用一个网址代替。

#### 在哪里获取更多有关玩具指令的说明和指引？

欧洲委员会已发布一份通用指南，详情可点击查看：

[http://ec.europa.eu/enterprise/sectors/toys/files/tsd\\_explanatory\\_guidance\\_document\\_en.pdf](http://ec.europa.eu/enterprise/sectors/toys/files/tsd_explanatory_guidance_document_en.pdf) 另外，针对技术资料的指导文件目前正在编撰当中。

### iComply™

iComply™是一项多法规符合性解决方案，是由Intertek开发的一套基于网络、使用简便的人工智能应用软件，可以促进整个供应链协作提供全面详尽的技术资料。iComply™采用领先科技，但使用起来非常简单便捷；进口商或生产商输入一系列产品信息后，它即可制定出生产测试计划，生成必要的符合性声明文件，并将所有文件储存在一个完整的技术文档里。用户可以一周7天、一天24小时全天候登录查看。

iComply™提供一站式解决方案，指导您顺利完成欧盟玩具指令和已提案的CPSIA测试和认证条例的符合性程序，并协助您充分展示为符合这些法规所采取的一切尽职措施。同时，我们目前还在研发其它新增方案，帮助您符合加拿大消费品安全法和加州65提案等法规的要求。

iComply™为您满足记录保存和符合性要求提供全面的解决方案。

有关具体的测试和认证信息，请咨询Intertek，Email：[consumergoods.uk@intertek.com](mailto:consumergoods.uk@intertek.com)，或浏览：[www.intertek.com](http://www.intertek.com)。

### 关于作者

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他于1982年毕业于分析化学专业，在质量控制和技术支持领域拥有超过30年的工作经验，曾就职于一家大型的英国零售商，其后至今在Intertek工作已有11年。他是欧洲技术委员会玩具行业组织的会员，过去多年参加了新玩具指令制定的讨论工作。他还是多个BSI委员会的成员，包括CW/15 (玩具安全) 和BTHA Toy Interpretations Group。他曾参加了玩具指定测试机构英国和欧洲协调会议，并且是UKAS授权的玩具和消费品技术评估人。

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