

新的欧盟玩具安全指令（2009/48/EC）



为什么制定新的玩具指令？

玩具的安全性对于消费者来说极为重要，尤其是对于儿童。因此，各类旨在确保儿童安全的国际和国家玩具标准和法规越来越严格。在过去20年中，玩具的设计和生经历了巨大变化，现行的玩具指令（88/378/EEC）已经无法全面覆盖玩具的各方面性能和安全。为解决新的安全问题，欧盟于2009年6月30日公布了新的玩具安全指令（2009/48/EC），并发表在官方刊物上。

谁应该承担相应责任？

新的玩具安全指令对供应链中的各方提出了新的责任和要求，这些责任人包括欧盟内的玩具制造商、进口商和经销商，以及欧盟外希望为欧盟市场供应玩具的制造商。

何时开始生效？

新的玩具安全指令2009/48/EC已于2009年7月20日生效。该指令的一般规定（非化学品）将于2011年7月20日生效，而化学品部分将于2013年7月20日生效。在实际操作中，这意味着符合当前指令88/378/EEC的玩具只能在市场上销售到2011年7月19日，而受化学品要求管制的玩具可以销售到2013年7月19日。

挑战：

- * 玩具的新定义；
- * 对各商家的职责的界定：制造商、进口商和经销商；
- * 编撰技术文件和EC合格声明；
- * 根据第18条进行安全评估，包括物理和机械、化学、电气、放射性、可燃性和卫生等方面；
- * 建立生产流程的控制体系；
- * 19种受限元素的新的迁移限值；
- * 禁止使用CMR类（致癌、致基因突变或有生殖毒性的）物质；
- * 化妆品类的玩具应符合指令76/768/EEC的成份和标签要求；
- * 禁止生产或销售与食品密切接触的玩具，食品中包含的玩具必须有独立包装；
- * 警示和标签的新规定；
- * 为36个月以下儿童设计生产的玩具或有嘴部接触的玩具禁止使用亚硝酸胺和可亚硝化物质。

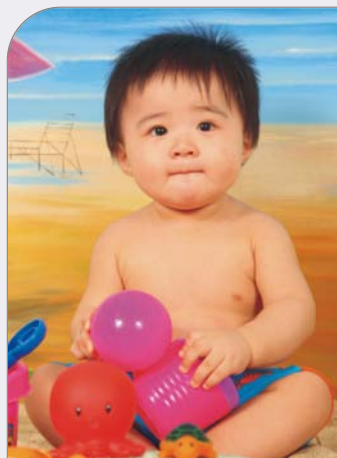
上述所列仅为部分新要求，了解更多详情，敬请咨询Intertek。

职责一览表

	制造商	授权代表	进口商	经销商
编写技术文件（TF）以及开展合格评定程序	√	X	△	X
确保投放市场的玩具符合安全要求	√	√	√	X
确保符合合格评定的批量生产程序落实到位	√	X	X	X
为产品加贴标识和CE标志	√	√	△	△
编写EC合格声明（DoC）	√	√	X	X
保管并在需要时提供技术文件和EC合格声明	√	√	√	√
在产品上标明制造商名称或制造商注册商标以及联系地址	√	√ 针对非欧盟生产商	√	△

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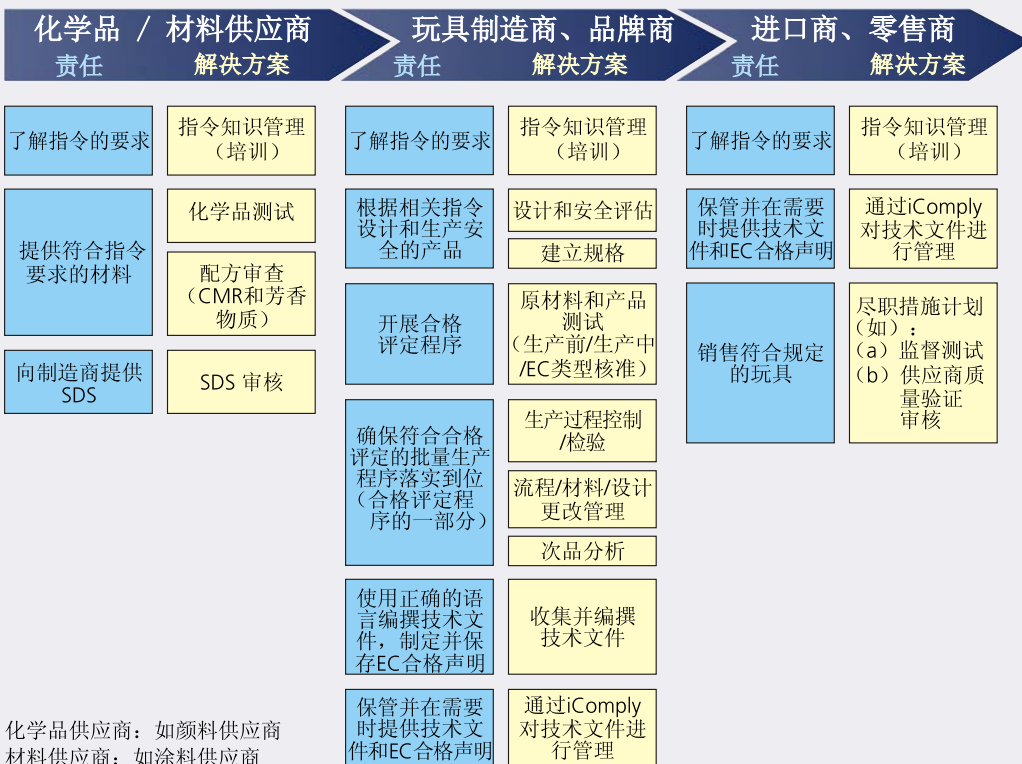
职责一览表



	制造商	授权代表	进口商	经销商
保存投诉、不合格玩具和召回的记录	√	√	√	√
确保产品在存储和运输的过程中符合性不受损害	X	X	√	√
提供相关文件，并且文件应使用主管部门和消费者理解的语言	√	√	√	√

△：确保或验证已完成

我们建议的解决方案



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Intertek已尽一切努力确保本文件信息准确可靠，但其内容不作法律顾问之用。详细内容解释和变更请参见欧盟委员会的相关文件。

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The New EU Toy Safety Directive (2009/48/EC)



Why?

Toy safety is of paramount importance to consumers, particularly for children. Therefore, local and international toy standards & regulations aiming at ensuring greater safety for children become more and more demanding. For the past 2 decades, toys have evolved tremendously and the current Toy Directive (88/378/EEC) can no longer provide comprehensive coverage on the safety of toys. In order to cope with new safety issues, a new Toy Safety Directive (2009/48/EC) was published in the EU's official journal on June 30, 2009.

Who?

The new Toy Safety Directive (TSD) affects many roles in the supply chain, from manufacturers to importers to distributors of toys within the European Union as well as manufacturers outside the European Union who want to supply toys to the EU market.

When?

The new Toy Safety Directive 2009/48/EC entered into force on July 20, 2009, and the general provisions (non-chemical) of the Directive would be effective on July 20, 2011, whereas the chemical provisions will be effective on July 20, 2013. In practice, this means that toys compliant with the current Directive 88/378/EEC will be allowed to be placed on the market until July 19, 2011 or July 19, 2013 in the case of certain chemical provisions.

The Challenge

- * New definition of Toy
- * Defines obligations of economic operators: manufacturers, importers, and distributors
- * Drawing up of Technical Documentation and EC Declaration of Conformity
- * Safety assessments under Article 18, involving physical & mechanical, chemical, electrical, radioactivity, flammability, and hygiene aspects
- * Establishing production control on manufacturing process
- * New migration limits for 19 restricted elements
- * Ban on substances classified as CMR (Carcinogenic, Mutagenic or Toxic for Reproduction)
- * Complying with the compositional and labeling requirements of Directive 76/768/EEC for cosmetic toys
- * Toys that are firmly attached to food are prohibited, while toys contained in food must have their own packaging
- * New rules on warnings and labeling
- * Ban on Nitrosamines and Nitrosatable substances in toys for children under 36 months or mouth-contact toys

The challenges listed above are not exhaustive, please contact Intertek if you wish to know more.

Roles & Obligations At A Glance

	Manufacturer	Authorized Representative	Importer	Distributor
Prepare Technical File (TF) and conduct conformity and safety assessments	√	X	△	X
Carry out safety testing of marketed toys	√	√	√	X
Ensure conformity of series production	√	X	X	X
Affix identification and CE marking to product	√	√	△	△
Prepare EC Declaration of Conformity (DoC)	√	√	X	X
Keep and make Technical File and EC DoC available	√	√	√	√
Indicate name and address on product	√	√ For non-EU manufacturer	√	△

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Roles & Obligations At A Glance



	Manufacturer	Authorized Representative	Importer	Distributor
Keep records of complaints, non-conforming toys and recalls	√	√	√	√
Ensure product compliance not jeopardized during storage and transportation	X	X	√	√
Provide documents in language understood by authority and consumer	√	√	√	√

△ : Ensure or verify it's done

Our Recommended Solution

Chemical / Material Supplier		Toys Manufacturer, Brand		Importer, Retailer	
Obligations	Our Solutions	Obligations	Our Solutions	Obligations	Our Solutions
Understand TSD requirements	TSD knowledge management (Training)	Understand TSD requirements	TSD knowledge management (Training)	Understand TSD requirements	TSD knowledge management (Training)
Supply material in compliance with TSD	Chemical testing Formulation review (CMR & fragrances)	Design and manufacture safe products according to relevant directives	Design evaluation and safety assessment Develop specification	Keep & make TF & DoC available	TF Management by iComply
Provide SDS to manufacturer	SDS Authoring	Conduct conformity assessment	Raw material & product testing (pre-production / production / EC Type approval)	Place compliant toys in the market	Due Diligence Program (eg): (a) surveillance testing (b) supplier quality validation audit
		Ensure conformity of series production (part of conformity assessment)	In process control / Inspection Process / material / design change management Failure analysis		
		Prepare TF in correct language, draw up & keep DoC	TF (collection & compilation)		
		Keep & make TF & DoC available	TF Management by iComply		

Chemical supplier: e.g. pigment suppliers
Material supplier: e.g. paint suppliers

Disclaimer

Intertek made all reasonable efforts to ensure the accuracy of the information. However, the information provided should not be relied upon as legal advice. Further changes and interpretation by the EU Commission is anticipated.

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