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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Journal in June 2009, it will be effective from July 2011 onwards, while the current Directive 88/378/EEC will be repealed (apart from chemical aspects).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 product 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:

- The requirements apply regardless of age.
- Toys within food must be contained within their own packaging that 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 that 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 means 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 that 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 20 July 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).

CMR Category	CMR Classification
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 that 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 2011. Toys that comply with the existing directive can continue to be sold providing they were first placed on the market before 20 July 2011. 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 that specify that your technical documentation must include a Declaration of Conformity in the form described in the Toy Directive and a Safety Assessment.

Will I need to re-design my toys?

Possibly. There are new requirements on hygiene, particularly requiring that textile toys for children under 36 months 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 that 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 Toy Directive?

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

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

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. Visit www.intertek.com/icomply for more information.

For more information on specific testing and certification information, please contact Intertek by emailing consumergoods.uk@intertek.com, or visit our website at 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 & 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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