

## European Toy Safety Information Seminar 2012: FAQ

### **1. How can you determine whether a product is a toy or not? How can you distinguish a promotional product from a toy?**

The definition of a toy in the Toy Safety Directive (TSD) must always be the basis for deciding whether a product is a toy or not. Annex I enumerates examples of products that are not considered as toys but could be confused with toys. Since it would be impossible to enumerate all the products that are not considered as toys, the list is naturally not exhaustive. A contrario interpretation should not be drawn from it, that is, if a particular product is not mentioned in the list, it does not mean that it is automatically a toy. To be considered as a toy for the purpose of the Directive, the playing value has to be introduced in an intended way by the manufacturer. The declaration by the manufacturer of the intended use is a criterion to be considered since it figures in the wording itself. The reasonable expected use is considered to prevail over the declaration of intended use by the manufacturer. If the manufacturer labels the product as not being a toy, he has to be able to support this claim. [Guidance document No 4](#) gives further indicative criteria that need to be considered for the classification of a product as a toy. Furthermore, several [guidance documents](#) have been drafted for the classification of specific products.

### **2. What happens if an economic operator does not provide the required information to authorities?**

If the required information is not available and/or provided, the market surveillance authority may require the toy to be tested by a notified body at the manufacturer's own expense within a specified period in order to verify compliance with the harmonised standards and essential safety requirements. If the non-compliance persists, the authority will take all appropriate measures to restrict or prohibit the toy being made available on the market, or will ensure that it is recalled or withdrawn from the market. If toy manufacturers, importers, and distributors do not fulfil the safety requirements of the Directive, Member States can also impose penalties.

### **3. What should an economic operator do if he thinks a toy is not in conformity?**

The TSD provides that 'economic operators who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the relevant Community harmonisation legislation should immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate'. It also requires that 'when deemed appropriate with regard to the risks presented by a toy, economic operators should, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls'.

### **4. Should the manufacturer's contact details be affixed on the toy?**

The Toy Safety Directive obliges the manufacturer to indicate his name, registered trade name or registered trade mark and the address at which he can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy.

The manufacturer must indicate a single point at which he can be contacted. This is not necessarily the address where the manufacturer is actually established. This address, at which they can be contacted, can be the address of their authorised representative, if accompanied by the clarification ‘represented by’.

Nothing in this provision prevents the manufacturer from adding other addresses provided that the single contact point is clearly indicated. An address normally should consist of a street and number or post-box and number and the postal code and town. A website may be added as additional information.

**5. How can a manufacturer determine the age of the children its toys are intended for? Who controls the manufacturer’s decision?**

CEN report CR 14379 Classification of toys gives guidelines for matching toy characteristics to children’s ages. Although functions and characteristics and examples are listed in this report, some toys can give rise to discussion and [Guidance document No11](#) (Toys intended for children above and under 36 months) details the classification for children above and under 3 years of age. There is also the [CPSC’s Age Determination Guidelines](#) issued in 2002 and other European Commission’s [guidance documents](#). The market surveillance authorities use the same guidelines to ensure conformity and control the manufacturer’s decision.

**6. If someone changes a toy, is he considered a manufacturer?**

An importer or distributor, who modifies the product and by doing so alters its compliance, assumes the obligations and responsibilities of the manufacturer and is responsible for the conformity of the product. He does not have to provide details to customs unless requested but must ensure that he has the up-to-date technical documentation, which takes into consideration the changes made to the toy.

**7. How can manufacturers can provide full documentation showing all the safety assessments followed?**

The technical documentation file should consist of the following elements, which prove that the toy is in conformity with the TSD and has undergone all the necessary assessments.

Related clauses	Suggested Content
Annex IV (a)	Description of the design and manufacture; List of components and materials; Safety data sheets
Annex IV (b), Art 18	Safety data sheets
Annex IV (c) Art 4 (2) Art 6 (2) Art 19	Conformity assessment procedure
Annex III & IV (d), Art 15	EC declaration of conformity (DoC)
Annex IV (e)	Address of manufacture and storage
Annex IV (f)	Documents submitted to a Notified Body
Annex IV (g) Art 4 (4), Art 19 (2)	Test reports, conformity of series production details
Annex IV (h)	EC type examination details; Conformity of series production details



The European Commission's website provides a [template of a DoC](#) in all official European languages and Annex IV of the TSD lists all documents required for the technical documentation, so far as relevant for assessment.

**8. Is an importer who is obliged to attach instructions in the local language then considered to be the manufacturer?**

The addition of labels to the retail pack does not constitute a modified product and thus the importer would not be considered a manufacturer. The importer is considered the manufacturer if it modifies the toy in a way that affects compliance, e.g. changes in materials, colour, age grading, etc., or if it places a toy on the market under its name or trademark.

**9. What type of economic operator is an importer that sells a batch of products to a distributor in the Far East?**

According to the TSD, an importer means any natural or legal person established within the EU who places a toy from a third country on the EU market. As this action does not concern placing on the EU market, it is not subject to EU legislation.

**10. Is a grandmother that buys a toy abroad and brings it into the EU an importer?**

An importer (a person responsible for placing on the market), in the meaning of the New Approach Directives and as defined in the TSD, is any natural or legal person established in the European Union who places a product from a third country on the EU market. Therefore, a grandmother would only be considered an importer if she were to place the product bought abroad on the EU market.

**11. What are the obligations for importers of second hand toys?**

There is no text in the TSD that specifically covers second hand toys. The TSD covers toys placed on the EU market since 20 July 2011. If the second hand toy was placed on the EU market before that date, it is not covered by the TSD. However, if the toy comes from outside the EU and is introduced onto the EU market for the first time, then the TSD is applicable. Importers of second hand toys have the same obligations as importers of other toys, there is no differentiation regarding the requirements for newly produced or used toys – both must have the relevant documentation and the necessary markings.

**12. How can we ensure that Chinese players in the supply chain meet the requirements? What are the responsibilities for the importer in the case of non-compliance?**

Both the general explanatory guidance document and the guidance document on technical documentation are available in [Chinese](#), which should help Chinese players to meet the requirements. An importer who considers or has reason to believe that a toy which they have placed on the market is not in conformity with the relevant EU legislation should immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, the importer should immediately inform the competent national authorities of the Member States in which they made the toy available. They must give details, in particular, of the non-compliance and of any corrective measures taken. The European Commission and Toy Industries of Europe also carry out many educational campaigns on the Toy Safety Directive in China to ensure that local economic operators are aware of and comply with the requirements.

**13. If a company manufacturing a product abroad goes out of business, is the importer liable? What would happen under those circumstances if the importer**

**was formally requested to provide the technical documentation but had no records because its supplier no longer existed?**

The importer has a number of obligations and is therefore liable if he is not able to meet, inter alia, the following requirements.

The importer must ensure that the manufacturer has the technical documentation and that it can be made available upon request, for ten years after the last toy has been placed on the market. The importer can do this by getting a declaration from the manufacturer saying that he has the technical documentation. If the importer previously visited the manufacturer, this will be in its records and can be used to prove their relationship to the enforcement body and to possibly disclaim any liability. If the technical documentation cannot be provided, the authority would issue a formal non-compliance, which could lead to corrective actions.

The importer must, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy in a language easily understood by that authority. They must cooperate with that authority, at its request, on any action taken to eliminate the risks posed by toys which they have placed on the market.

**14. Is a company that has its own brand but also imports products that are manufactured in China under another brand name the importer/distributor of these products?**

A company that imports a toy that is not under its own brand is an importer according to the TSD. The company or person that makes the toy is the manufacturer. A legal agreement would help clarify this.

**15. Does an importer or distributor assume the responsibility for the translation of instructions?**

According to the TSD, the importer should ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned. Therefore, an importer or distributor does assume responsibility for the translation of instructions.

**16. Is a distributor expected to make sure that the commercialised products bear the CE marking or warning pictograms?**

The distributor should act with due care and have a basic knowledge of the applicable legal requirements. He should know, for instance, which products must bear the CE marking, what information has to accompany the product, what the language requirements for users' instructions or other accompanying documents are, and what would make the product non-compliant. A distributor may not supply products that he knows or should have assumed, on the basis of available information and professional knowledge, do not comply with the legislation. A distributor should cooperate in actions taken to avoid or minimise the risk of non-compliant toys reaching the market.

**17. How should the distributor ensure that the required documentation is available?**

The distributor is not required to have the DoC or the technical documentation but must be able to, following a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate conformity of the toy. The distributor must also be able to identify the manufacturer, his authorised representative (if any), the importer or the person who has provided him with the product in order to assist the



surveillance authority in its efforts to receive the DoC and the necessary parts of the technical documentation.

**18. Regarding the obligations of the distributor and specifically Article 7, paragraph 2 of the TSD, what are the ‘required documents’?**

When making a toy available on the market, the distributor must ensure that the toy bears the appropriate conformity marking(s) and is accompanied by the required documents, instructions and safety information in the appropriate language. ‘Required documents’ refers to all documents that must accompany the toy itself. According to the TSD, these documents are the safety information, instructions and the warnings. The distributor must also ensure that the manufacturer and/or importer complied with their obligations, in other words the distributor must verify the presence of the name, brand name and the address at which the manufacturer and/or importer can be contacted on the toy or its packaging and that the batch number, serial number or other elements have been affixed on the toy by the manufacturer to allow identification.

**19. What is the distributor supposed to do if the manufacturer does not affix his address? Should the distributor affix his address?**

The distributor is not obliged to affix his address but is obliged to check that the manufacturer’s address is affixed. If the distributor notices that a manufacturer has not affixed his address, he should inform the manufacturer that he has released a product that does not conform to the requirements of the TSD.

**20. Can distributors ask for the technical documentation?**

The TSD does not oblige manufacturers to provide the technical documentation to any other operator. Only Member States’ authorities have the right to request the technical documentation. Upon reasoned request from an authority, the distributor is obliged to provide this information and therefore must ask the manufacturer to provide the technical documentation to the authorities.

**21. Is the technical file related to a product or to the batch?**

The technical file is related to a product but if a company has internal production control, this should be part of the technical documentation. For example, if a company tests every batch of paint for lead, then those test reports could be included in the technical documentation.

**22. Is it correct that only part of the technical documentation is required when doubts exist about non-compliance of a toy?**

If the market surveillance authorities have doubts regarding the conformity of a toy, they may request the manufacturer’s technical documentation or a translation of relevant parts. The authority should indicate the nature of the doubt about the conformity of the toy concerned and the parts or aspects of the toy that are subject to investigation. Only the elements of the technical documentation that are necessary for the investigation should be requested, so as not to constitute a disproportionate burden for the manufacturer. The request should indicate the deadline for the receipt of the requested documents, which should be 30 days. A shorter deadline can be fixed if the national authority justifies the urgency on the basis of an immediate serious risk. These provisions have a dual purpose: on the one hand, providing the relevant elements of the technical documentation enables a manufacturer to explain the measures he has taken to deal with the risks associated with the toy in order to comply with the TSD requirements. On the other hand, the examination of these documents helps the market



surveillance authorities to complete their investigation and either dispel or confirm their doubts about the conformity of the toy concerned.

**23. Can the importer/distributor translate the technical files?**

According to the TSD, only the manufacturer should provide a translation of the relevant parts of the technical documentation into a Member State's language following a reasoned request from the market surveillance authority of that Member State.

**24. In what situations do authorities ask for the technical documentation? For each product sold in Europe? Are the test reports included? How much time does the company have to present the information?**

The authorities can ask for the technical file for each product or relevant parts. This contains the test reports. The Member State's authorities will ask to see the documentation when there is a doubt about the conformity of the product. The technical documentation must be made available to the surveillance authority within 30 days, unless a shorter deadline is justified in the case of serious and immediate risk. The time period can be extended if there are sound reasons.

**25. Who is obliged to have the declaration of conformity?**

When a toy is placed on the market, the manufacturer must draw up a DoC. By doing so, the manufacturer certifies and assumes responsibility for the compliance of the toy with the essential requirements of the TSD. The manufacturer, his authorised representative established within the EU (if applicable) and the importer must keep the DoC for ten years after the toy is put on the market. The distributor, upon reasoned request, must be able to provide the DoC to the competent authorities.

**26. Can a declaration of conformity be used for different products? Do they have to be under the umbrella of the same standards or sold at the same time?**

There cannot be a DoC for two totally different products. According to the TSD, a DoC is required for each toy that is placed on the EU market. There is nothing in the TSD that prevents a DoC from referring to more than one toy (a combined declaration). However, in this case, all the toys referenced on the DoC must conform to the same set of harmonised standards and legislation. It is not allowable to list inapplicable harmonised standards or legislation as 'applicable'. The DoC must contain the unique identification of the toy which refers to the traceability of the toy.

**27. Is there an obligation to sign the declaration of conformity?**

A manufacturer must sign the DoC as this affirms that the toy conforms to the TSD, which must be assured before the toy is placed on the market.

**28. Can an importer draw up the declaration of conformity?**

The manufacturer is obliged to draw up the DoC. However, if the manufacturer has, by written mandate, appointed an authorised representative, the authorised representative may draw up the DoC. If the importer has been nominated as the manufacturer's authorised representative, then, under these circumstances, the importer would be able to draw up the DoC.

**29. How fast would an authority expect to have the declaration of conformity delivered by a distributor?**

The DoC must be made available for the market surveillance authority immediately upon reasoned request. The technical documentation must be made available to the surveillance



authority within 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

### **30. What is a 'harmonised standard'?**

Harmonised standards are European standards, which are adopted by European standards organisations, prepared in accordance with the General Guidelines agreed between the European Commission and the European standards organisations, and follow a mandate issued by the Commission after consultation with the Member States. References to these standards are published in the Official Journal of the European Union. See: [http://ec.europa.eu/enterprise/sectors/toys/standards/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/toys/standards/index_en.htm)

### **31. If the chemical standards are not available, what should a manufacturer do?**

The chapter on chemical safety assessment in the [guidance document on the technical documentation](#) explains how to proceed when no standards are available or when such standards do not cover the chemical hazards in question.

### **32. On Chromium VI: how can we prepare our products to comply with limits when we do not know how to measure these limits?**

Chromium VI migration content determination is problematic. The final version of standard EN71-3 (migration of certain elements) includes methods for all substances except Chromium VI in liquid/sticky and dry/brittle toy materials. This was because the laboratory commissioned to develop the methods was not able to come up with a method to detect Chromium VI at the very low level required (e.g. 0.05 ppm in a liquid/sticky toy material) as the lowest achievable detection limit was 2 ppm. The laboratory has meanwhile been able to elaborate a test method for Chromium VI migration which still needs to be validated.

The limits in the old Directive continue to apply until the revised limits are implemented (20 July 2013). It is possible that it will not be feasible to measure Chromium VI migration at the level set out by the Directive for the two above toy materials categories. Manufacturers should nevertheless carry out a safety assessment to determine the likely presence of Chromium VI and this should help in determining whether a toy material is compliant with the Chromium VI limits. A combined measure of the migration of Chromium III and VI can also be helpful in determining whether a toy material complies. Other alternatives can also be used for the assessment, like total content determination.

### **33. Will relevant tests for CMRs or fragrances be ready by 2013?**

No CEN standards have been developed to this end. However, the TSD requires a bill of materials and a bill of substances listing all materials, chemical substances and their concentration in toy materials. These documents are drawn up by the manufacturer and kept in the technical file. They are used by manufacturers to carry out the chemical safety assessment and to ensure compliance with the TSD requirements with regards to assessing the presence of CMR substances and fragrances. If a manufacturer wants to ensure a toy material complies with the TSD requirements for a particular substance (for example DEHP, a banned phthalate which is a CMR substance), they can always have the material tested using methods developed by laboratories.

### **34. Will the list of substances of very high concern (SVHC) be forbidden in toys when the new Directive comes into force due to the CMR ban?**

Yes, this ban will apply to those SVHC that are CMRs, unless they are inaccessible parts, if they are contained in concentrations equal or smaller than the concentrations established by the



Classification, Labelling and Packaging Regulation (EC) No 1272/2008 (CLP), or if there is an EU decision allowing them to be present (for example, Annex II, part III, point 4 on CMRs).

**35. How can it be ensured that a toy is only notified on RAPEX if it represents a serious risk?**

RAPEX is the EU alert system for rapidly exchanging information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. It works according to the detailed procedures laid down in the Annex to the General Product Safety Directive 2001/95 (GPSD). As soon as a serious and immediate risk is detected, the national authority must consult, insofar as possible and appropriate, the producer or distributor of the product concerned. The authority should try to obtain the maximum amount of information on the products and the nature of the danger, without compromising the need for rapidity. The Member State should inform the Commission when it adopts, or decides to adopt, emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use of consumer products presenting a serious and immediate risk. A further condition for invoking RAPEX is that the effects of the risk can go beyond the territory of the Member State concerned. Member States are not required, as is the case under the safeguard clause procedure according to the New Approach Directives, to provide evidence to justify the national measure. The Commission verifies that the information complies with the provisions of the GPSD and circulates it to the other Member States.

**36. Who is responsible for market surveillance?**

Market surveillance is the responsibility of national authorities. This is, in particular, to guarantee the impartiality of market surveillance operations. Each Member State can decide on the market surveillance infrastructure. For example, there is no limitation on the allocation of responsibilities between authorities on a functional or geographical basis as long as surveillance is efficient and covers the whole territory.

**37. What happens to counterfeit toys that are seized?**

According to Article 8 of the General Product Safety Directive (GPSD), market surveillance authorities can order, coordinate or organise the recall and destruction of dangerous products. However, the actions taken by the market surveillance authorities must be proportional to the seriousness of the risk and take into account the precautionary principle. Regulation 765/2008 only foresees recalls of products presenting a 'serious risk' (Article 20) and enables authorities to destroy such products.

**38. When toys are chosen from a shop for testing, how can you determine if they were placed on the market before or after the TSD came into force?**

This is almost impossible to determine straight off the shelves. You need to contact the manufacturer or importer to obtain this information.

**39. Where can information about laboratories performing EC-type examination be found?**

The European Commission's website lists all notified bodies for the Toy Safety Directive (TSD): [http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir\\_id=140521](http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=140521)

**40. Do the warning labels have to be in the language of the country?**



Manufacturers should ensure that the toy is accompanied by warnings, instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned (national law indicates the language required for each Member State).

**41. What steps have been taken to harmonise EU and US requirements?**

New toy safety legislation has recently been introduced in both the EU and US. These two new pieces of legislation necessitated an update of the respective standards. EU standards are predominantly based on the TSD while the US standards have to be approved by the Consumer Product Safety Commission (CPSC). However, the European Commission and the CPSC as well as the respective standardisation bodies are discussing cooperation.

**42. Is there an official website that provides up-to-date information on changes in legislation?**

The European Commission website contains all the legislation as well as the relevant guidance documents and links to references to standards, etc. See:  
[http://ec.europa.eu/enterprise/sectors/toys/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/toys/index_en.htm)

**43. Should the instructions for use be visible and affixed on the packaging?**

No, this is not a requirement of the TSD.

**44. Is there legislation about warning information on plastic bags in toys?**

There are no specific EU rules about warnings for plastic bags in toys. However, there is a general consensus to voluntarily affixing a warning such as 'to avoid danger of suffocation, keep out of reach of babies and children'. This warning is not mandatory and its wording can vary if it is affixed.

**45. What is the minimum age for using a toy that has accessible batteries?**

Accessibility to batteries is not allowed in toys for children under three years old under the conditions specified in the standard EN 62115 (Electric toys – Safety). In addition, button cells and batteries designated R1 should not be accessible in all toys unless they meet conditions specified in that standard.

**Abbreviations:**

CE: Conformité Européenne (European conformity)

CEN: European Committee for Standardization

CMRs: substances that are carcinogenic, mutagenic or toxic for reproduction

CPSC: Consumer Product Safety Commission

DoC: declaration of conformity

EU: European Union

GPSD: General Product Safety Directive

SVHC: substances of very high concern

TSD: Toy Safety Directive

**Further information is available here:**

European Commission: [http://ec.europa.eu/enterprise/sectors/toys/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/toys/index_en.htm)

Toy Industries of Europe: <http://www.tietoy.org/>