



# Conformity Assessment of Products for Consumers: Electrical Products, Products Intended for Children, Textile and Apparel, and General Consumer Safety Comparative Study

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Contents		
	ummary	
	eviations	
•	ives and Methodologybjectives	
	lethodology	
	omparative Study July 2009 Revisited	
	eview of recommendations made in July 2009	
	hanges in China Regulations	
	hanges in EU Regulations	
	mity Assessment for Consumer Products in Europe and China	
	eneral Principles of the Systemeneral Principles of the System	
3.1.1	Role of Standards	
3.1.2	Voice of Consumers	
	he System in China	
3.2.1	Elements of the Law on Product Quality	
3.2.2	Conformity Assessment	
3.2.3	Import and Export Controls	
3.2.4	Standards for Consumer Products	
3.2.4	Market Access	_
	he System in Europe	
3.3.1		
3.3.1	The General Product Safety Directive GPSD	
	Conformity Assessment of Consumer Products	
3.3.3	Requirements for Products Already on the Market	
3.3.4		
3.3.5	Market Access for Consumer Products	
	onclusions and Recommendations	
	arison of the Systems for Consumer-related Electrical Products	
	eneral Principles of the Systems	
4.1.1	Other Regulations used Both in China and Europe	
4.1.2	The IECEE-CB Scheme	
4.1.3	Mutual Recognition of Marks and Testing Results	
	he System in China	
4.2.1	General Description of the CCC System	
4.2.2	Standards for Electrical Products	
4.2.3	Compulsory Energy Labelling	
4.2.4	Chinese RoHS and WEEE Regulations	
4.2.5	Assessment of Safety and Reliability of Software in Products	
4.2.6	Compulsory licensing of Information Security Products	
	he System in Europe	
4.3.1	Electromagnetic Compatibility	
4.3.2	Standards for Electrical Products	
4.3.3	LVD Conformity Assessment Requirements	
4.3.4	LVD Technical Documentation	43
4.3.5	Ecodesign of Energy Related Products	43
4.3.6	Compulsory Energy Label	46

	4.3.7	Other EU Legislation relevant to electrical equipment	46
	4.4 Cond	clusions	46
	4.4.1	Conclusions for China	46
	4.4.2	Conclusions for Europe	47
	4.4.3	Recommendations	48
5	•	on of the Systems for Products Intended for Children	
	5.1 Gen	eral Principles of the Systems	
	5.1.1	Definition of Toys	
	5.1.2	Non-Toy Products Intended for Children	51
	5.2 The	System in China	
	5.2.1	General Description	
	5.2.2	Standards for Products Intended for Children	51
	5.2.3	CCC Certification	
	5.2.4	Other Chinese Administrative Measures	52
	5.3 The	System in Europe	53
	5.3.1	Toys Safety Directive	54
	5.3.2	Standards for Products Intended for Children	
	5.3.3	Conformity Assessment for Toys	56
	5.3.4	Technical Documentation for Toys	57
	5.3.5	CE Marking of Toys	57
	5.3.6	Requirements for Products Already on the Market	58
	5.4 Cond	clusions	58
	5.4.1	Conclusions for China	59
	5.4.2	Conclusions for Europe	
	5.5 Reco	ommendations	59
6		on of the Systems for Textiles and Apparel	
		eral Principles of the Systems for Textiles and Apparel	
		System in China for Textiles and Apparel	
	6.2.1	Standards for Textiles and Apparel	
	6.2.2	Conformity Assessment of Textiles and Apparel	
	6.2.3	Marking and Labelling of Textiles and Apparel	
		System in Europe	
	6.3.1	Directives and Regulations Relevant for Textiles and Apparel	
	6.3.2	EU Regulation 1007/2011	
	6.3.3	Standards for Textiles and Apparel	
	6.3.4	Conformity Assessment Requirements	
	6.3.5	Voluntary Marking and Labelling for Textiles and Apparel	
		clusions and Recommendations	
		Harmonized under the GPSD	
		ndards related to the Compulsory Energy Label in Chinay Assessment Requirements of Toys	
		gulations for Chemical Substances	
LI.			





## **Executive Summary**

This report provides a comparison of conformity assessment measures taken in China and in Europe to ensure safety of consumer products, with special focus on electrical household appliances, children's products, and textiles. The study is designed to gain a better understanding of the differences in the Chinese and European approaches towards conformity assessment, their rationale, and their impact on trade. Since this is a follow-up study on a detailed comparison of conformity assessment systems in China and Europe compiled in July 2009 it does not delve too much into descriptions of the systems: The study focuses on areas where a distinctive different approach is chosen.

Both China and Europe rely on a basic piece of legislation aimed at protecting consumers from potentially unsafe and hazardous products. These two legislations contain the same core elements such as requirements to place only safe products on the market, obligations for producers and distributors, market surveillance activities, ban of unsafe products, etc.

In China, the execution of market surveillance activities is in principle delegated to the provincial authorities, whilst in Europe it is mostly delegated to the member states. Both China and Europe have implemented preventive measures allowing authorities to temporarily stop importation and distribution of potentially unsafe products; this includes also a rapid information system on such measures between the authorities in charge. China and Europe have agreed to inform each other about preventive measures taken against potentially unsafe products originating from the other economy.

Apart from this basic legislation the approach to conformity assessment for consumer goods is fundamentally different:

- China relies on a government pre-market approval for the majority of consumer goods; In Europe as a general principle pre-market approval is not required except for certain products considered generating high risks, which are indicated in the relevant EU-legislation. The core system for pre-market approval in China is the CCC certification, whilst Europe relies on the self-declaration of producers with affixing the CE marking on the product which is in the scope of the relevant Directive requiring the CE marking; any involvement of a second or third party prior to placing a product on the EU market is voluntary, except for the cases where intervention of a so-called notified body is required (see below).
- Europe introduced specific regulations for or related to many industry sectors or covering specific
  aspects, namely for electrical products, toys, EMC, radio and telecom terminal equipment, and
  many more. China relies on a framework of certifications based on Catalogues and compulsory
  product standards, regulating safety and compatibility aspects of many product categories;
- The principal tool for companies to manufacture compliant products in China is formed by the
  compulsory standards and in Europe by the Directives and Regulations in combination with supporting harmonised standards. In cases where the Chinese and/or the European standards include
  modifications to the applicable international standards this may result in variations in product de-





sign, configuration, and product verification requirements for the same products placed on the EU market or Chinese market;

- Whilst it is possible in Europe to have the producer carrying out compulsory product assessment under the supervision of a notified body, there is no similar procedure in China: Companies in China do not have the possibility to carry out conformity assessment tasks by themselves within a compulsory licensing scheme;
- Both China and Europe implemented additional regulations for compulsory energy labels, minimum energy use of products, use of hazardous substances in electronic products, electrical and electronic waste, and labelling of specific product categories such as textiles.

Both China and the EU require that all <u>compulsory</u> third party product conformity assessment is undertaken by a conformity assessment body which has been designated by governmental authorities. In Europe operating a conformity assessment body for non-compulsory product conformity assessment is free whilst in China this requires an accreditation and registration by governmental authorities. For the products that need to be assessed by a third party prior to placing them on the EU market these third parties need to be designated by the member state authorities<sup>1</sup>.

The crucial point is that there is no mutual acceptance of the results of compulsory product assessment in both economic areas. The different range of products in each economic area requiring compulsory product conformity assessment has the effect that market access for China is generally more costly and time consuming than for Europe; this applies to both domestic producers and importers.

As a general principle, for consumer products <u>intended for the EU market</u> – if intervention of third party product conformity assessment is required – an EC-type examination certificate can be obtained from an EU notified body of choice.

In case of voluntary second or third party product conformity assessment and certification, where the producer has chosen to outsource (verification of his) conformity assessment or only testing of his product, involvement of any conformity assessment body or testing laboratory will be satisfactory that is able to demonstrate the conformity of the product with the relevant requirements. However, contrary to EU producers and exporters Chinese producers and exporters may also be required to obtain an export license for products which implies product conformity assessment by the local CIQ before the issuing of the license.

For consumer products intended for the Chinese market application for CCC may be required depending on the product category, covering full product conformity assessment on top of any product conformity assessment undertaken by the producer beforehand. The issuance of certificates generally takes 6-10 months for imported products, time that is to be added to the normal product development process. Whilst the process may be considerable shorter for producers based in China, costs remain almost identical. The Chinese system is based on a "one fits all" approach, with CCC requirements essentially being equal for all

<sup>&</sup>lt;sup>1</sup> Designation means that these third parties are given the right to operate as a so-called notified (conformity assessment) body, charged with the tasks to type-examine certain products that are considered generating high risks as listed by the respective Directives (e.g. toys, machinery, and pressure equipment) or to approve and monitor a dedicated quality system established by the manufacturer to be able to perform tasks under the supervision of the notified body in the relevant cases indicated by the Directive(s) or Regulation(s) applicable to the product.





products covered by the CCC Catalogue. The European system allows a high level of flexibility in applying product conformity assessment requirements and even in compulsory certification requirements, adapted to the risks involved in any specific product category.

One of the most problematic aspects of the Chinese system is its reliance on compulsory standards: Whilst this creates legal clarity on how products have to be built to be in compliance with market access regulations, they obstruct innovative solutions: This system may lead to foreign manufacturers being forced to use obsolete technologies and outdated models to comply with Chinese compulsory standards.





# **List of Abbreviations**

**Table 1: Abbreviations** 

Abbreviation	Explanation
AQSIQ	General Administration for Supervision, Inspection, and Quarantine; AQSIQ is a Ministry that comes under the State Council
CAB	Conformity Assessment Body; a CAB is a body for conformity assessment of products, systems or services; Conformity assessment includes certification, testing, calibration and inspection
ссс	China Compulsory Certification
CC-IS	Chinese Certification System for Information Security Products
CE marking	Marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in the Community legislation providing for its affixing.
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CNAS	China National Accreditation Service for Conformity Assessment; CNAS is a unit that comes under CNCA
CNCA	Certification and Accreditation Administration of China; CNCA is a government unit that comes under AQSIQ, which is in charge of the enforcement of the CCC Certification scheme
CNIS	China National Institute for Standardization
CNIS	China National Institute for Standardization; CNIS is an institute supervised by AQSIQ and SAC
CSR	Corporate Social Responsibility
EMC	Electromagnetic Compatibility
EN	European Standard
EN-IEC	IEC Standard adopted in Europe under the same number as the European Standard of which the content is unchanged
ETSI	European Telecommunications Standards Institute
GB	Compulsory Chinese national standard
GB/T	Voluntary Chinese national standard
GPSD	General Product Safety Directive (2001/95/EC)





LVD	Low Voltage Directive (2006/95/EC)
MIIT	Chinese Ministry for Industry and Information Technology
NAL	Network Access License; NAL is used for equipment to be connected to the mobile phone network in China; NAL's are issued by MIIT
NANDO	"New Approach Notified and Designated Organisations"; NANDO is an information system of the European Commission listing all notified bodies: ec.europa.eu/enterprise/newapproach/nando/
NLF	New Legislative Framework; The NLF consists of the Regulations (EU) 764/2008 and (EU) 765/2008, and Decision 768/2008 <sup>2</sup>
Notified Body	Organisation designated by an EU member state to perform EC-type examinations or dedicated quality system assessment and monitoring as required by the relevant European Directive or Regulation
SAC	Standardization Administration of China; SAC is a government unit supervised by AQSIQ
SRRC	License applicable to equipment emitting radio-type signals; SRRC's are issued by MIIT
тс	Technical Committee for Standardisation

 $<sup>^2 \</sup> See \ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF$ 





# 1 Objectives and Methodology

## 1.1 **Objectives**

The study shall provide a comparison of conformity assessment measures required in China and in Europe to ensure safety of consumer products, with special focus on electrical household appliances, children's products, and textiles. This includes the following key elements:

- To prepare a comparative report on conformity assessment practices referring to framework and general requirements of both the EU and China and for each of the product sectors mentioned above;
- To identify each market structures related to rationale for the development of conformity assessment requirements and how the overall system impacts and reinforces the rationale;
- To make suggestions as to how the EU and China may be able to use the report findings in their development of technical regulations and standards.

## 1.2 Methodology

The Terms of Reference explain the methodology as follows: "Identify all compulsory documents which have to be complied with by enterprises and CABs and list these; evaluate the contents of the documents and determine which are identical (based on same standard or technical regulation), modified from the international standard, equivalent (have same title and deal with the same matters, have approaches that end on same results etc.) or do not exist in one of the markets (a list of the ones in each market that does not deal on similar matters). From the identification and familiarisation with the documentation described above, determine and summarise the gaps between each relevant document between the EU and China and explain these within the context of industry impacts.

The investigation should include the following steps:

- To investigate and list all the technical regulations and standards in place or being prepared in the EU related to conformity assessment requirements;
- To investigate and list all the compulsory and voluntary standards in place or being prepared in China related to conformity assessment requirements;
- To determine for each market the situation relating to the Conformity Assessment Bodies (CABs)
  considering the following: regulatory regimes and obligations under these, how are these appointed, how are these monitored and what are the issues of operability in each other's markets;
- To develop a comparison between the two markets in the selected sectors;
- To develop mutually agreed conclusions and recommendations.





## 2 The Comparative Study July 2009 Revisited

In August 2009 the EU-China Trade project published a detailed comparative analysis of the conformity assessment system in Europe and China<sup>3</sup>. This report is to be understood as a follow-up on that study, with focus on a few selected sectors. There is no intention to repeat the findings of that study; this chapter is focusing on the changes since that study was published

## 2.1 Review of recommendations made in July 2009

The conclusions and recommendations of the comparative analysis on conformity assessment published in August 2009 remain valid in their entirety. Whilst some regulations have been updated, there was no significant change in any of the key elements. In fact all recent updates both in Europe in China point to a strengthening and a refinement of the existing systems in Europe and China. The problem of compatibility lies more in the details of implementation of these regulations, and here we noted indeed concerns of industry on both sides.

Here a recap of the recommendations made in July 2009:

- It is recommended that in-depth comparative studies of the quality infrastructure of each economy be made on food and non-food sectors on the following:
  - Legislation: Detailed comparison of the legislations EU-China, the results of this comparison should propose if there is any need of changing legislation or can the existing legislation in the manner in which it has been written can cope with the different concepts that may be proposed
  - Standards 1: Compare mandatory Chinese standards identical to international standards and EU harmonised regional standards identical to international
  - Standards 2: Where modified identify the Chinese mandatory standards and difference with the international standards and undertake same work with the EU regional standards based on the same international standards as modified by the Chinese standards
  - Standards 3: Determine purely Chinese or EU standards which may affect trade or if based on regulations instead of standards
  - Metrology: Comparison of the legal, scientific and industrial metrology with respect to trade issues only
  - o Accreditation: A review of the systems to ensure uniformity of application on both systems, explore the possibility of bi-lateral agreement with EA under their cooperation scheme;
- Undertake a full review of all regulatory requirements and schemes involving conformity assessment in China and how these apply and compare to the EU, noted that support and involvement of relevant Chinese competent authorities are needed;
- Case studies on particular product categories under CCC and EU sectoral Directives to analyse the determinants of product risks and the correlation between product risks and the associated con-

<sup>3</sup> A comparative study report for EU-China conformity assessment systems, EU-China Trade Project, July 2009. Copies can be obtained from the project facility: www.euctp.org





formity assessment models, by taking account of respective technical, social and economic circumstances of EU and China, so as to gain an insight into the rationale of each economy on what is considered RISK and what conformity assessment should be used to mitigate this;

- Review exact methodology for designating conformity assessment bodies (CAB's) in China and Notified Bodies or equivalent in the EU, what are the conditions for accepting foreign CAB's in each country e.g. only have a legal entity in country with laboratories overseas or other;
- How is post market surveillance undertaken and what model is used in China and to explain the different models used in the EU with respect to their member states and how the new Decision will affect these requirements;
- Full comparison of technical documentation requirements both in China and the EU for the acceptance of products in each market together with all markings required.

Whilst many of these issues are system-related, the actual implementation of conformity assessment measures in the various sectors will demonstrate the weaknesses and strengths of both systems.

## 2.2 Changes in China Regulations

Several major updates were noted during the period:

- In 2009 China amended the administrative rules for compulsory product certification. This update strengthened the CCC system and introduced measures about product recall and emphasized the role of companies in conformity assessment;
- In 2011 China announced an amendment of the regulations for certification bodies operating in China: It stresses that any organization engaged in certification activities in China must be registered as certification body with CNCA. Furthermore it emphasizes that any individual engaged in certification related activities in China, including auditing and inspection, must practice in one single certification body only. It is not possible for individuals to engage in certification activities in China outside of a registered body;
- In 2012 China announced the revision of the "Administrative Measures on Controlling the Pollution of Electrical and Electronic Products (China RoHS)". The revision is reinforcing the current regime of self-declaration combined with compulsory type-testing. So far, the system does not require that conformity assessment measures for imported products must be undertaken in China;
- In 2013 CNCA announced a planned revision of the regulations governing the CCC certification process: CNCA proposes to the respective certification bodies that they may implement a system based on an assessment of the risk posed by the company and the product in question. The companies holding CCC certifications for their products may be categorised in risk classes. The system is to be implemented gradually, starting with toys and tyres.

The long pending revision of the Chinese Standardisation Law is still on-going. A next draft of the legislation has been announced for 2013; however, it is not sure whether this schedule will be followed.

# 2.3 Changes in EU Regulations

In July 2008 the European Council adopted a package of measures revising the New Approach, known as the "New Legislative Framework" NLF. The measures are designed to help the internal market for goods





work better and to strengthen and modernize the conditions for placing a wide range of industrial products on the EU market. Following new regulations were published:

- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting
  out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
- Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

In addition, the Commission started an alignment of existing regulations by adopting a "New Legislative Framework Alignment Package" consisting of ten of the oldest New Approach Directives <sup>4</sup> which are to be revised following this New Legislative Framework.

The New Legislative Framework Alignment Package builds on the existing system to reinforce the application and enforcement of internal market legislation. According to the Commission <sup>5</sup> its basic goals are to:

- Improve market surveillance rules, to better protect both consumers and professionals from unsafe products, including imports from third countries;
- Boost the quality of conformity assessment of products through clearer rules on the requirements for the notification of conformity assessment bodies including the increased use of accreditation;
- Clarify the meaning of CE marking and so enhances its credibility; and to
- Establish a common legal framework for industrial products; this includes definitions of terms commonly used in product legislation and procedures.

Civil Explosives Directive: Council Directive 93/15/EEC on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil use;

ATEX Directive: Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres;

Lifts Directive: European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts;

Pressure Equipment Directive: Directive 97/23/EC on the approximation of the laws of the Member States concerning pressure equipment;

Measuring Instruments Directive: Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments;

Electromagnetic Compatibility Directive: Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

Pyrotechnic Articles Directive: Directive 2007/23/EC on the placing on the market of pyrotechnic articles;

Non-automatic Weighing Instruments Directive: Council Directive 2009/23/EC on the harmonization of the laws of the Member States relating to non-automatic weighing instruments;

Simple Pressure Vessels Directive: Council Directive 2009/105/EC on the harmonization of the laws of the Member States relating to simple pressure vessels;

<sup>&</sup>lt;sup>4</sup> The ten Directives of the package are: Low Voltage Directive: Directive 2006/95/EC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits;

<sup>&</sup>lt;sup>5</sup> Website of the EU-Directorate General for Enterprise and Industry: http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/new-legislative-framework/





Also in 2011, the European Parliament requested a revision of the "General Product Safety Directive" GPSD. The revision aims for an alignment with the requirements for market surveillance of the "New Legislative Framework" NLF. It also requests that products handled by consumers but operated by service providers shall be included in the scope. Furthermore it calls on the Commission to include an obligation for manufacturers to carry out a risk analysis in the design phase;

Finally, on 24 October 2012 the EU published the revised legislation for standardisation: Regulation (EU) 1025/2012 on European Standardisation replacing the previous Directive 87/95/EEC and Decision 1673/2006, regulating standardisation in Europe. It reinforces the existing system for standardisation. To enable interoperability the Commission may decide to accept ICT related technical specifications that meet the requirements set out in Annex II to the Regulation on European Standardisation in public procurement.





## 3 Conformity Assessment for Consumer Products in Europe and China

## 3.1 General Principles of the System

Both China and Europe implemented basic legislation to protect consumers from potentially unsafe and hazardous products. In China this is the Law on Product Quality, first issued in 1993 and revised in the year 2000; in Europe this is the General Product Safety Directive GPSD (2001/95/EC) which was introduced in 2001 and applicable since January 2004; the GPSD is currently under revision. These two legislations contain the same core elements such as the general requirement that products supplied to consumer must be safe, specific obligations for producers and distributors to ensure safety of products, the legal basis for market surveillance activities, and a ban of unsafe products.

#### 3.1.1 Role of Standards

Both in China and in Europe this legislation applies where no other specific rules have been adopted. The EU legislation includes at least the procedures of compliance where no specific ways of verifying compliance with safety regulations have been adopted. The Chinese legislation relies mostly on the applicable compulsory standards to define the procedures of compliance. The European approach relies on a definition of consumer products, where products which do not fall under the scope of the GPSD might still be covered by vertical or horizontal directives, or in absence of such are not specifically addressed. The Chinese product safety law does not make this basic difference.

Both jurisdictions introduced a two level system of standards addressing product safety:

- Standards which are outright compulsory in China, and voluntary harmonised standards in Europe which give the presumption of conformity if fully complied with;
- Voluntary product standards which reflect good manufacturing practice and as such support the companies in achieving compliance.

Whilst in Europe market access is free, except for cases where the regulation requires the involvement of a notified body, this applies in China only for products which are not regulated by other legislation than the Law on Product Quality in China.

In China, the execution of market surveillance activities is in principle delegated to the provincial authorities, whilst in Europe it is delegated to the member states. Both China and Europe have implemented preventive measures allowing authorities to temporarily stop importation and distribution of potentially unsafe products.

For that matter, both China and Europe are implementing a system to alert the respective authorities in the Provinces in China and in the member states in Europe of potentially harmful products<sup>6</sup>. The system includes a mechanism to block such products throughout the jurisdiction from entering the markets. Furthermore, China and Europe have mutually agreed to inform each other about the findings of the mechanism

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 $<sup>^6</sup>$  The Chinese system was announced in 2012 and is now being gradually implemented; it has been nicknamed "C-RAPEX" however, this is not the official name





nism, and preventive measures undertaken, namely for products which are traded between Europe and China. China and Europe have agreed to inform each other about preventive measures taken against potentially unsafe products originating in the other economy.

Both Europe and China implemented an accreditation system based on ISO/IEC requirements. This system has led to a standard set of requirements for the accreditation of all conformity assessment bodies (which may include certification, testing, and inspection activities) and thus contributes to the credibility of the conformity assessment measures undertaken.

in Europe the system requires that each member state designates one single body in charge for accreditation; in China this single body is CNCA, which is part of the ministry AQSIQ.

Conformity assessment bodies in Europe do not require any government designation – except in the cases of third parties designated for compulsory type-examination of products or for approval and monitoring of a dedicated quality system required for carrying out tasks under the supervision of the third party as laid down in the relevant Directive or Regulation.

The system in China is quite different since any organization carrying out certifications or inspections must be accredited by CNCA. On top of this, the bodies must be appointed by the respective government agency to obtain the right to undertake assessment work for compulsory licensing schemes.

A unique feature of the Chinese system are the two government-related national certification bodies CQC and CQM: Since they come under the same ministry as the regulatory body CNCA, the separation between regulatory oversight and execution of conformity assessment is not fully implemented

#### 3.1.2 Voice of Consumers

Both Europe and China emphasize that the voice of consumers is integrated in the general system to ensure quality and safety of consumer products:

- China implemented a network of consumer complaint hotlines throughout the country where consumers can voice their concerns regarding any consumer product on the market. The hotline is monitored by the local authorities; it is also their decision whether an issue warrants further examination or not;
- In Europe there is a strong incentive for compliance due to the independent consumer organizations; These organizations have the resources to carry out independent testing of consumer-related products, including electrical products. The results are then presented in comparative lists with rankings of price, usability, and compliance with standards. These lists are widely recognized and are often used as guidance for consumer's purchasing decisions.

Both China and Europe apply the stakeholder principle in the standard development process; this includes namely also the voice of consumers. In China this voice is represented by the consumer associations on national and provincial level. Acknowledging that effective participation in standardisation requires expert





knowledge, the Commission financially supports the otherwise independent organization ANEC, dedicated to integrate consumer interest into European standardisation<sup>7</sup>.

## 3.2 The System in China

General consumer products are regulated by the Law on Product Quality; first issued on 1<sup>st</sup> September 1993; a revised version was published on 8 July 2000. It aims to strengthen supervision and inspection of product quality with focus on safety and health of consumers. It defines the obligations of producers, manufacturer and distributors, but also the obligations of supervision and inspection by government. The ministry responsible for implementation of this Law is AQSIQ; consequently, AQSIQ issued a number of follow-up regulations based on the Law of product quality, starting in 2001.

## 3.2.1 Elements of the Law on Product Quality

The scope of this legislation is defined as products which are "processed or manufactured for sale". It excludes construction projects but not the buildings itself. Some of the key elements include:

- Producers and vendors are responsible for product quality, they have to establish an internal system to control quality of products according to the applicable standards
- Prohibition of forgery, misstatement of origin, fraudulent use of authentication marks and other
  producer's names. The Law also prohibits to mix impurities or imitations into a product for sale, or
  to sell fake products as being genuine, or to pass a defective product for a product meeting quality
  standards
- Emphasis on standards based on advanced science and technology as basis for ensuring product safety: The Law includes also the principle of quality award for products surpassing the quality level of applicable national or international standards
- Right of consumers to make enquiries about product quality with producers and vendors, right of consumer organizations to bring a suit to court or to support consumers in doing so
- Obligation of the vendor to repair or refund if the product does not possess the required properties, is not conform to the standards as declared on product and packaging or the quality conditions indicated on the product
- Definition of defective product: constitutes an unreasonable threat to personal safety or to safety of other person's property, or fails to live up to safety standards
- Compensation for damage caused by defective products, including medical treatment and compensation for loss of working time for the victims, if claimed within 2 years, counting from the day the damage should have been known
- Compensation can be claimed within a maximum of 10 years from the date the product is delivered to the first consumer, unless a longer safe life span is declared for the product
- Penalties for violations of the law

Rights and obligations of producers and vendors Products shall:

<sup>&</sup>lt;sup>7</sup> ANEC = European Association for the Co-ordination of Consumer Representation in Standardisation, <u>www.anec.eu</u>





- Constitute no unreasonable threat to personal safety or safety of property
- Be conform to the standards for human health, personal safety, or safety of property
- Possess the properties as required by the applicable legislation, unless stated as being defective
- Be conform to the standards indicated on the products

#### Marks on products shall

- Be authentic
- Be accompanied by certificates showing that the product passed inspection
- Include the name of the product, and name and address of the producer in Chinese
- Contain the necessary information regarding specification and grade of the product, its ingredients, including indications on the packaging where necessary
- Include the production date and safe-use period / date of expiry where applicable
- Come with a warning mark where improper use may cause damage to the product or endanger personal safety or property

#### Obligations and rights of government

- To incorporate improvements of product quality in their development plans, and to prevent violations of the Law in the process of manufacturing and sales of products
- To implement an authentication scheme for quality systems for enterprises and for product quality, compounded by a voluntary authentication scheme. Both schemes must include a certification system declaring the product quality <sup>8</sup>.
- To supervise markets and undertake random inspection of goods in the market where indicated:
  - o Products constituting potential threats to human health, personal safety, or property
  - o Important industrial products bearing on national economy and people's well-being
  - Products with quality problems reported by consumers or relevant organisations
- To order companies to rectify deficiencies within a given time limit, order a temporary halt of production, or to revoke the producers' business license. In case of serious quality problems the company may be punished
- Right to seize products which are regarded as not being in compliance with national or sectoral standards ensuring health, personal safety, or safety of property, including packaging material and raw materials used for the manufacturing of such products

Several sector specific laws regulate, in combination with the Law on Product Quality, the safety of products on the China market. These include the Law on Food Safety (issued in 2009 by the State Council), the Law on Agriculture Product Quality Safety (issued in 2006 by the State Council), the Law on Administration of Drugs (issued in 1984, revised in 2001) and Regulation on Supervision of Cosmetics Health (issued in 1989 by the Ministry of Health).

China introduced a few years ago a notification system similar the European RAPEX notification system (see section 3.3.1) for all provinces, guided by AQSIQ, the so-called C-RAPEX. The Chinese system is linked to the European system, allowing a direct flow of information on potentially hazardous consumer goods to the

<sup>&</sup>lt;sup>8</sup> It is important to note that the Law treats the two terms "product quality" and "product safety" seemingly almost as synonyms





authorities in charge <sup>9</sup>. This exchange has proven to be highly valuable for both sides; especially when trying to identify the source of faulty goods on the markets. Currently the mechanism allows information about defective products in Europe; however, considering the systematic development of C-RAPEX a reverse flow of information might also be possible in future.

## 3.2.2 Conformity Assessment

The producer is responsible that the product complies with all regulations regarding product quality and safety as listed under the Law on Product Quality. He has to carry out the testing and inspection measures needed to achieve this goal. Where the Law requires special licenses, namely for CCC and Special Equipment, this testing must be carried out in a qualified laboratory. In such cases an official license once the conformity assessment has been completed successfully; issued on behalf of the authorities in charge for ensuring quality and safety of products. *In absence of such special requirements, the importation of general products is free*, but subject to the market surveillance measures under the Law on Product Quality

On top of these regulations, the authorities have issued also special administrative measures on supervision of product quality, regulating products of special interest; the first such regulation was issued in 2001 by AQSIQ, and revised in 2010. To support this mechanism of supervision of product quality, AQSIQ issued implementation rules on supervision of product quality (first batch) in 2010 and implementation rule on supervision of product quality (second batch) in 2011, covering in total 243 consumer products, including food, drink, cleaning products, coating products, textile, construction material, and household appliances. Production sites related to products listed under this regulation are covered by a special inspection scheme.

In addition, AQSIQ issued specific sectoral regulations relevant for consumer products:

- Administrative rules on food labelling in 2009
- Administrative rules on cosmetic labelling in 2007
- Rules on classification of product quality the "Provisional Measures for the Supervision of Industrial Product's Quality by Classification"

Conformity assessment is based on licensing and regular inspections by the authorities. There is no official certification or labelling requirement for such products other than what is described in the Law and the related instructions by AQSIQ.

All bodies undertaking certification and related inspection activities in China must comply with specific regulations, going beyond the general requirements outlined in the respective ISO Standards. The "Regulations on Certification and Accreditation" were first issued on 20<sup>th</sup> August 2002; and revised on 1<sup>st</sup> September 2011. According to these rules it is not possible to undertake any certification or inspection activities in China without proper legal setup in China, which includes among others an accreditation as certification or inspection body with CNCA. Individuals undertaking such activities must be registered with the Chinese register for auditors and inspectors CCAA; this obligation can be avoided only if the company employing the

<sup>&</sup>lt;sup>9</sup> The EU creates a special abstract of the RAPEX system that can be consulted by AQSIQ. Consultations take place on an annual basis between market surveillance representatives from the EU and China. Products from China must be attested 'defective' in the EU before any consultation can follow. China will then inform the EU on a regular basis about the actions undertaken.





individual holds the respective accreditation with CNCA. Foreign certification or inspection bodies or foreign individuals without legal setup in China are prohibited from undertaking such activities in China.

## 3.2.3 Import and Export Controls

Import and export controls are regulated by the Law on Import and Export Commodity Inspection, first issued on 1<sup>st</sup> August 1989 and revised on 28 April 2002. The Law introduces a Catalogue of products which requires inspection for imports and exports. The Law also introduces a process for products in the Catalogue which may be exempt from inspection if certain conditions are met.

Importers and exporters of products listed in the Catalogue most obtain a license before goods arrive at the port of entry/exit. This license is issued subject to satisfactory inspection results; the issuing authority is the local branch of the authority for Quality Inspection and Supervision CIQ. The classification of goods follows the internationally accepted HS-coding. The intensity of inspection and testing required is based on past experience of the authorities with the respective factory. If a company is found to be in repeated violation of the conditions for obtaining the import or export license, this license can be withdrawn.

China is one of the few countries requiring compulsory inspection of selected commodities for export, this in order to safeguard the brand name "Made in China". Export controls are based on the standards applicable in the country of destination of the goods (!). Execution of the system is through the local CIQ, giving to the local authorities much leeway in implementation and enforcement of this regulation.

#### 3.2.4 Standards for Consumer Products

China has published approximately 5000 compulsory National Standards and probably an equal amount of compulsory Industry Sector Standards. These compulsory standards are the basis of defining how conformity with the Law on Product Safety can be achieved. Building products in compliance with these standards is a pre-condition for obtaining the CCC certificate, and gives the presumption of conformity making government approval superfluous.

Chinese standards are in general based on the respective international standards, or in absence of such also on any other globally accepted standards. Chinese standards are often not identical with the respective international standards; it is thus of utmost importance that the manufacturer is aware of such differences. On top of these adopted international or globally accepted standards, China developed its own set of "home grown" standards, for which there is no international reference.

#### 3.2.5 Market Access

Market access to China for general consumer products is based on a combination of compulsory and voluntary measures for conformity assessment: Government bodies and producers have a shared responsibility to supervise product quality and with that also to ensure that products placed on the market are safe. The main elements of the system are:

1. Does the product fall under the scope of the Law on Product Quality? If yes:





- Is the product listed in the CCC Catalogue for products requiring compulsory certification (described in the chapter on electrical goods)? If so, these certificates must be obtained before products can be placed on the market;
- Is the product covered by the regulations for "Special Equipment", including pressure vessels, lifts and hoists, elevators and escalators, pipelines, outdoor amusement equipment, and others? If so, special licenses must be obtained before products can be placed on the market <sup>10</sup>;
- Are there any compulsory standards applicable for the product? If so, these standards define the minimum quality level to be achieved for the product and must be observed. Compliance with these standards gives the presumption of conformity with the Law;
- Are there any voluntary product quality certification schemes available? Such certificates, if based on Chinese standards, can be used to demonstrate compliance with the law;
- In case of absence of compulsory standards: Are there any voluntary national or international standards for the product? If so, these can be used to prove compliance with general quality and safety requirements of the Law;
- Are there any special sectoral regulations for the product based on the Law or Product Quality (see chapter 3.2.2)? If so, these rules apply in addition to the other rules under this legislation.
- 2. Is the product listed in the Catalogue of products for import and export control?
  - If the product is listed, a special import or export license must be obtained before the product can be shipped;
  - If not, the product can be imported freely as long it complies with the Law on product quality, any other sectoral regulations applicable, and any other regulations affecting market access for products.
- 3. Do other sectoral regulations apply? Such sectoral regulation apply for many areas, e.g. cosmetics, health-care equipment, pharmaceuticals, telecom equipment, radio devices, mining equipment, railway equipment, and many more:
  - If so, the respective licenses must be obtained on top of the rules applicable under the Law for product quality as a pre-condition for market access;
  - If not, there may be a need to produce evidence that such sectoral licenses are not required; and as a consequence the product must comply solely with the regulations under the Law on product quality.
- 4. Are there any other legislations affecting market access for products? Some of the more relevant regulations include:
  - Regulations related to the compulsory energy label (described in the chapter on electrical goods): Products covered by these regulations must carry the label and must be tested for compliance with energy efficiency classification and shall be registered with the authority in charge;

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 $<sup>^{10}</sup>$  These licenses are issued by the authority appointed by AQSIQ and are based on a combination of type-testing factory inspections, and in-production controls. Generally, they do not overlap with CCC regulations





- Regulations related to hazardous substances in electrical and electronic goods, the socalled "China RoHS" regulation (described in the chapter on electrical goods): Products covered by this regulation must be tested for compliance and carry the respective mark;
- Regulations related to electrical and electronic waste, the so-called "China WEEE" regulation (described in the chapter on electrical goods): Products covered by this regulation may face special requirements like fees for future disposal, etc.
- Regulations related to security of information products: Products containing cryptographic
  measures as a core element may be covered by such regulations; these must obtain the respective cryptographic licenses before being placed on the market<sup>11</sup>.

## 3.3 The System in Europe

The system in the European Union is driven by the needs of a single market, where consumers can confidently shop across borders without fearing differences in the level of safety of products in any part of the European market. It aims to harmonize the member state laws intended to protect consumer interest.

The system regulating placing safe products on the common market in Europe is dominated by the General Product Safety Directive GPSD, described below, the New Approach and Global Approach covering about 20 horizontal and sectoral Directives and Regulations and the New Legislative Framework NLF presently covering 11 horizontal and sectoral Directives.

There is no double application of both sectoral rules and GPSD. The sectoral Directives or Regulations are generally exclusive, meaning that for one product or group of products only one sectoral Directive applies. The sectoral Directives and Regulations under the New Legislative Framework NLF, New Approach and Global Approach that may be relevant for Consumer Products are:

- The Directive on Safety of Toys, 2009/48/EC (NLF);
- The Directive on Pyrotechnic Articles, 2007/23/EC (NLF);
- The Low Voltage Directive LVD, 2006/95/EC (NLF);
- The Regulation on Construction Products CPR, (EU) 305/2011 (New Approach);
- The Directive on Transportable Pressure Equipment TPED, 2010/35/EU (Global Approach);
- The Directive on Appliances Burning Gaseous Fuels GAD, 2009/142/EC (New Approach);
- The Machinery Directive MD, 2006/42/EC, amended by 2009/127/EC (New Approach);
- The Directive on Radio and Telecommunication Terminal Equipment R&TTE, 99/5/EC (New Approach);
- The Directive on Recreational Crafts, 94/25/EC, with amendment 2003/44/EC (New Approach);
- The Directive on Medical Devices MDD, 93/42/EC, with amendments until 2007/47/EC (New Approach);
- The Directive on Personal Protective Equipment PPE, 89/686/EC with amendments until 96/58/EC (New Approach);

<sup>&</sup>lt;sup>11</sup> The Law regulating Commercial Cryptography is currently under revision, under current regulations it is very difficult to obtain such licenses for imported products. The regulations for conformity assessment of such products require among others disclosure of software code and cryptographic keys.





- The Directive on Aerosol Dispensers ADD,75/324/EEC, with amendment 2008/47/EC (Global Approach);
- The Regulation on Cosmetic Products, (EC) 1223/2009 (Global Approach).

Non-exclusive are the Horizontal Directives and Regulations, the apply on top of the GPSD dealing with specific aspects of consumer products. The horizontal Directives that may be relevant for consumer products are:

- The Directive on Simple Pressure Vessels SPVD, 2009/105/EC (NLF);
- The Directive on Non-Automatic Weighing Instruments, 2009/23/EC (NLF);
- The Directive on Electromagnetic Compatibility EMC, 2004/108/EC (NLF);
- The Directive on Measuring Instruments, 2004/22/EC (NLF);
- The Directive on Pressure Equipment PED, 97/23/EC (NLF);
- The Directive on Equipment and Protective Systems intended for use in potentially Explosive Atmospheres ATEX, 94/9/EC (NLF);
- The Directive on Hazardous Substances in Electronic Equipment RoHS, 2011/65/EU (New Approach);
- The Directive on Noise Emission by Equipment for Use Outdoors, 2000/14/EC (New Approach);
- The Directive on Hot Water Boilers, 92/42/EEC, amended by 2005/32/EC (New Approach).

The two framework Directives on Eco-Design resp. Energy Labelling are:

- The Directive on Energy-Labelling, 2010/30/EC;
- The Directive on Eco-Design of Energy Related Products ERP, 2009/125/EC.

Other Directives and Regulations that may be relevant for consumer products are:

- The Directive on Waste Electric and Electronic Equipment WEEE, 2012/19/EU;
- The Regulation on Chemical Substances REACH, (EC) 1907/2006;
- The Directive on Packaging and Packaging Waste, 94/62/EC, amendmended by 2004/12/EC and 2005/20/EC.

# 3.3.1 The General Product Safety Directive GPSD

Safety of consumer products in Europe is regulated in the General Consumer Products Directive GPSD 2001/95/EC. The GPSD is intended to ensure a high level of product safety throughout the EU for <u>consumer</u> products that are not covered by any other legislation.

The General Product Safety Directive GPSD (2001/95/EC) contains next to the general requirement that products covered shall be safe, procedures to be followed by the authorities in case of products affecting health and safety. The Directive applies to all consumer products, except products covered by specific European health and safety legislation (the sectoral Directives as listed under 3.3). The Directive also deals with safety problems that are discovered after a product has been placed on the market.

The GPSD applies to any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not in-





tended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used, or reconditioned.

In the absence of more specific provisions, within the framework of Community legislation covering safety of the products concerned, all the provisions of the GPSD apply in order to ensure consumer health and safety. If specific Community legislation sets out safety requirements covering only certain risks or categories of risks, with regard to the products concerned the obligations of economic operators in respect of these risks are those determined by the provisions of the specific legislation, while the general safety requirement of the GPSD apply to the other risks. The provisions of the GPSD relating to the other obligations of producers and distributors, the obligations and powers of the member states, the exchanges of information and rapid intervention situations and dissemination of information and confidentiality apply in the case of products covered by specific rules of Community law, if those rules do not already contain such obligations.

The Directive provides a generic definition of a safe product; products must comply with this definition. If there are no specific national rules, the safety of a product is assessed in accordance with:

- European standards
- Community technical specifications
- Codes of good practice
- State of the art and expectations of consumers

The Directive includes a presumption that products that fully comply with European standards are safe (see also 3.3.5, there are some conditions). However where there is evidence that, despite conformity with such standards, a product is still considered dangerous (still posing unacceptable residual risks), action can be taken to impose restrictions on the product being placed on the market or to require its recall.

The Directive provides for an alert system (*the Community Rapid Information System RAPEX* <sup>12</sup>) between member states and the Commission. The RAPEX system ensures that the relevant authorities are rapidly informed of dangerous products. Whilst not mentioned in the GPSD, the Commission decided that this system shall also cover consumer products covered by the sectoral Directives.

The basis of the system is that a member state sends to the Commission information about a dangerous product found on its market. The Commission, in turn, forwards this information to the other member states, so that they can check whether the product is present on their markets, and implement appropriate actions. Subject to certain conditions, Rapid Alert notifications can also be exchanged with non-EU countries. In the case of serious product risks, the Directive provides for temporary Decisions to be taken on Community-wide measures.

The key provisions of the GPSD are:

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<sup>&</sup>lt;sup>12</sup> Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12, and of the notification procedure established under Article 11, of Directive 2001/95/EC (the General Product Safety Directive), OJ L 22, 26.1.2010, p. 1.





- Producers and distributors must inform consumers of the risks associated with the products they supply. They are obliged to take appropriate measures to prevent such risks and shall be able to trace dangerous products;
- Producers and distributors are obliged to inform the relevant authorities when a product in the
  market is potentially dangerous and take any action to prevent further risks to consumers. They
  must initiate a product recall if other measures are insufficient to protect consumers;
- Manufacturers and distributors are required to inform the authorities if they become aware that
  they have put a defective or dangerous product into circulation and advice of steps taken to avert
  the risk. Such notification will require standardized information;
- Distributors (within the limits of their activities) have an obligation to monitor safety of products and are required to maintain detailed traceability information for all products they supply or fit;
- Producers are obliged to take steps to enable them to be informed of the risks products may pose.
   This includes taking steps such as batch marking of products, regular testing and auditing of product safety and maintaining a register of customer complaints;
- The European Commission can ban a product outright if the product is considered to be dangerous;
   this emergency ban is valid for maximum one year. Products which are the subject of an emergency ban cannot be exported to third countries;
- Enforcement authorities will be able to order and, if necessary, organise product recalls, where all other methods of protection appear to them to be inadequate and both producers and distributors will have a positive duty to co-operate with the authorities <sup>13</sup>.

Failure to meet obligations in the GPSD will expose businesses to penalties at the hands of public authorities. Penalties will be 'effective, proportionate and dissuasive'. The current expectation is that penalties will be significant, not least because if the local authority becomes the enforcer, the cost of its involvement will be a factor.

The GPSD is currently under revision: In March 2011 the European Parliament adopted a resolution requiring a set of specific changes to the current GPSD. These include:

- An alignment of GPSD with the requirements of the New Legislative Framework NLF with the goal to have one unified set of criteria for market surveillance;
- A closure of existing loopholes in the regulation, e.g. for products handled by consumers but operated by service providers;
- Special recognition of particularly vulnerable people, such as children and the elderly, but now also people with disabilities;
- A requirement for a risk analysis during design phase for all manufacturers of consumer products;
- An emphasis on the need of better traceability of products throughout the supply chain and tracking of labels across different jurisdictions;
- A call for strengthening of the RAPEX system, including a better definition of "serious risk" which is the basis for applying the system;

<sup>&</sup>lt;sup>13</sup> This includes a provision to challenge any decision taken by the authorities to recall a product, and subject to the seriousness of the risk, parties subjected to recall measures will have the opportunity to submit their views prior to enforcement of a recall by the authorities.





- A call for the Commission to conclude cooperation agreements on traceability and alert system with all major trading partners, similar to the cooperation agreements with China;
- A call for addressing market surveillance issues related to online selling with special focus on pharmaceuticals and food products;
- Support for the planned introduction of guidance for custom controls.

In order to enhance safety of child care products the EU Commission published a series of Decisions based on the requirements of the GPSD:

- Commission Decision of 6 January 2010 on the safety requirements to be met by European standards for bath rings, bathing aids and bath tubs and stands for infants and young children;
- Commission Decision of 7 January 2010 on the safety requirements to be met by European standards for consumer-mounted childproof locking devices for windows and balcony doors;
- Commission Decision of 22 December 2008 on the compliance of standard EN 1273:2005 on baby walking frames with the general safety requirement of Directive 2001/95/EC.

## 3.3.2 Conformity Assessment of Consumer Products

Conformity assessment of consumer products is considered part of the market mechanisms; there is little government interference in the sector.

The GPSD as all other relevant EU legislation requires conformity assessment performed by the manufacturer. The GPSD does not rely on the involvement of a Notified Body (there are no Notified Bodies notified for the GPSD) or other type of conformity assessment body. A Notified Body may be involved if additionally a horizontal Directive (see 3.2) requiring intervention of a third party is applicable to the product.

A product is deemed safe,

- when, in the absence of specific Community provisions governing the safety of the product in question, it conforms to the specific rules of national law of the member state in whose territory the product is marketed;
- when it conforms to <u>Harmonised Standards</u>, the references of which have been published by the Commission in the *Official Journal of the European Union*.

In absence of specific national regulation and of harmonised standards, the conformity of a product to the general safety requirements shall be assessed by taking into account the following elements:

- Relevant European Standards other than the Harmonised Standards;
- Standards drawn up in the member state in which the product is marketed;
- Commission recommendations and guidelines on product safety assessment;
- Product safety codes of good practice generally used in the sector concerned;
- The state of the art and technology; and
- Reasonable consumer expectations concerning safety.

The authorities of each member state will undertake pre- and post-market inspections when needed. Such inspections will take place randomly or targeted if there are indications of non-compliance with regula-





tions. In case such non-compliances are detected and the goods considered posing unacceptable risks for consumers, the authority may refer to the RAPEX system (see 3.3.1) in order to block the goods across Europe with immediate effect.

The GPSD does not contain any legal marking requirements or requirements related to declaration of conformity of the product with the GPSD: Affixing the CE marking to products covered by the GPSD *only* is not allowed <sup>14</sup>. The GPSD also does not require the manufacturer to compile a technical file, however recommended <sup>15</sup>.

## 3.3.3 Requirements for Products Already on the Market

For the purposes of the GPSD, and in particular of Article 6 thereof, the competent authorities of the member states shall be entitled to take the measures listed below, where appropriate:

- for any product:
  - o to organise, even after its being placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;
  - o to require all necessary information from the parties concerned;
  - o to take samples of products and subject them to safety checks;
- for any product that could pose risks in certain conditions:
  - to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the member state in which the product is marketed, on the risks it may present;
  - o to make its marketing subject to prior conditions so as to make it safe;
- for any product that could pose risks for certain persons:
  - o to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;
- for any product that could be dangerous:
  - o for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply, the offer to supply it or its display;
- for any dangerous product:
  - o to ban its marketing and introduce the accompanying measures required to ensure the ban is complied with;
- for any dangerous product already on the market:

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<sup>&</sup>lt;sup>14</sup> An example where a product partly covered by the GPSD must bear the CE marking: A pressure cooker is covered by the PED for the pressure related requirements. If it complies with the PED the CE marking has to be affixed to the product. For other safety aspects it is covered by the GPSD. The declaration of conformity indicates for which Directive the CE marking has been affixed.

<sup>&</sup>lt;sup>15</sup> Such voluntary technical file will enable manufacturers to demonstrate the conformity of the product with the requirements of the GPSD. It also helps the market surveillance authorities to check the conformity of the product, particularly for aspects that cannot be checked by visual inspection only. A technical file usually covers design, manufacture and operation of the product. It is not necessary to include in the technical file all details of the design and construction that are not safety-related. The technical file should contain all information needed to demonstrate clearly that adequate measures have been taken to deal with all significant risks associated with the product in order to comply with the relevant product safety requirements (Comment: sometimes it will be necessary to pay attention in the technical file to relevant hazards as well, especially in case of consumer products that may be handled differently from products for professional use, e.g. regarding sharp edges).





- to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;
- o to order or coordinate or, if appropriate, to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions.

#### 3.3.4 Standards for Consumer Products

Standards play an important role in the regulation of consumer safety in Europe: Whilst standards are voluntary, they give guidance how compliance with the relevant EU product legislation can be achieved. With the recent revision of the General Product Safety Directive both the GPSD and the New Approach Directives and Regulations rely on European standards to provide the technical specifications necessary to manufacture products that are safe and do not expose their users to known risks and hazards.

European Standards that meet the essential safety requirements for the GPSD or the New Approach Directives and Regulations may be published in the *Official Journal of the European Union* and become as such "harmonised European standards". Whilst the standard itself remains voluntary, use of a harmonised European standard in the manufacturing of a product will give a legal presumption of conformity with the safety requirements of the specific EU legislation supported by that standard. Presumption of conformity requires a one-to-one relationship between product and scope of the standard is question and full application of the standard. It will then be up to the authorities to demonstrate that the product is unsafe despite the correct application of the European standard. In such case the authorities will simultaneously start actions to dispute the European standard (see the relevant safeguard clause of product Directives). Other European legislation addresses itself to specific safety issues and does not rely on European standards. For example vehicle safety directives that mandate the provision of seat belts and govern the performance of cars in crash tests. For a number of consumer products on the market European standards play a crucial role in defining the state of the art.

Presently there are 37 harmonised European Standards published in support of the GPSD, the harmonisation process for additional standards is on-going. The standards listed in the table in Annex A1 originate from a variety of Technical Committees of CEN and CENELEC.

#### 3.3.5 Market Access for Consumer Products

Market access for Europe for consumer products is in most cases free; products falling under the GPSD do not require intervention of a Notified Body. The CE marking is needed where specific Directives or Regulations based on the New Legislative Framework NLF or New Approach require so. . Some Directives require a different marking to be affixed to the product (e.g. TPED and Marine Equipment). The main elements of the system are:

- 1. Is the product covered by a "sectoral" Directive or Regulation dealing with all health and safety aspects of the products covered, e.g. the Low Voltage Directive or Regulation on Cosmetic Products? If so, the specific rules of this Directive or Regulation apply:
  - o If harmonised standards are applicable, use of such standards give the presumption of conformity with the supported Directive or Regulation. Care should be taken to investigate whether the scope of the standard forms a 1-to-1 relationship with the product in question. The risk assessment that is part of the conformity assessment procedure will give insight in





the risks emanating from the product and whether the standard covers all risks that may be determined. The technical file <sup>16</sup> must contain all safety-related information except for an underpinning of the measures taken that are provided by the harmonised standard(s).

- o If the manufacturer chooses not to apply the harmonised standard(s) or to apply only parts of the harmonised standards supporting the EU legislation(s) applicable to the product, he must include in the technical file the risk assessment performed and the steps taken to comply with the essential health and safety requirements of the EU legislation(s) applicable to the product.
- o The same applies in case the producer chooses to deviate from the harmonised standards supporting the EU legislation(s) in question. As in the afore-mentioned cases the technical file must contain the risk assessment and an underpinning of the decisions taken .
- 2. A consumer product may be covered by a combination of a "vertical Directive" (including the GPSD) and one or more "horizontal Directives" (e.g. PED, Noise Outdoors Directive, EMC Directive, REACH, RoHS Directive). If one of these "horizontal" Directives requires the CE marking, the product will need to be CE marked. The procedures to be taken into account when applying harmonised standards are the same a mentioned above; for the use of harmonised standards see the aforementioned text.

#### 3.4 Conclusions and Recommendations

China and Europe have today a longstanding and well established framework of dialogues addressing various aspects for safety of consumer goods. One of the most powerful results was the linkage between the RAPEX system and the government information system in China operated by AQSIQ. With this link it is now possible to identify the source of non-compliant products in the majority of cases. Nevertheless, both sides agree that the situation is still far from being ideal and that there still remain too many non-compliant products entering the market. Below some suggestions for future discussions are provided to help addressing this point:

- Strengthen bilateral cooperation between EU member states and China: Since market surveillance is very much the task of national authorities in Europe, they should also become the leading partner for Chinese national and provincial authorities in such discussions;
- Select model categories of products: Most issues related to conformity assessment are sectorspecific; thus it makes sense to select a few categories only for more intense discussions. These sectors should be chosen for their prospects to find common ground and if possible also to harmonize both standards and conformity assessment processes;
- Make testing more international: Chinese testing is still suffering from a lack of international influence: The rules for testing bodies participating in the CCC scheme effectively exclude foreign bodies from the Chinese market; on the other hand, Chinese testing bodies have minimal recognition only outside of China. This leads to an unhealthy split of the testing market in China: Testing for China is

<sup>&</sup>lt;sup>16</sup> Not all EU Directives and Regulations require a technical file. However drawing up a technical file is always useful to deal with product liability.





done by Chinese bodies, testing for overseas is done by foreign bodies. Whilst this system protects non-competitive Chinese bodies, it does not foster innovation. It is suggested to identify ways how to reform the testing industry;

Strengthen representation of consumers in standardisation: Especially for consumer-related electrical goods it is important to have consumers involved both in standardisation and in the conformity assessment process. It would probably be interesting both for China and Europe to have focused exchanges on how to strengthen the consumer's voice and how to better enable consumers to make informed decisions when selecting between competing products.





## 4 Comparison of the Systems for Consumer-related Electrical Products

## 4.1 General Principles of the Systems

Conformity rules for consumer-related electrical products are dominated by the CCC certification system in China and by the requirements of the Low Voltage Directive (2006/95/EC) in Europe. Whilst the Chinese system is a government-mandated certification executed by appointed laboratories, the European system is based on self-declaration by the producer. The marking is compulsory both in China (CCC) and in Europe (CE); however, the underlying processes are very different.

Standards are both in China and in Europe essential references for achieving compliance with the regulations. In China the conformity assessment is built on compulsory National and Industry Sector standards while in Europe the system is based on Directives and Regulations, supported by voluntary harmonised European standards, the latter giving the user the presumption of conformity with the regulation supported (conditional). Most standards for this sector are aligned with the respective international standards, both in China and in Europe. This applies namely for the IEC 60335 series of standards "Safety of Household and similar Electrical Appliances".

## 4.1.1 Other Regulations used Both in China and Europe

Whilst the key structure of regulating conformity assessment for consumer-related products in China is quite different from that in Europe, the structure of auxiliary regimentation has many parallels. Similar rules apply e.g. for:

- energy performance and labelling of selected consumer-related electrical products
- hazardous substances in electrical and electronic products (RoHS)
- electrical and electronic waste (WEEE)

Requirements regarding the electromagnetic compatibility of electrical products are regulated in China by the applicable compulsory standards; whilst in Europe they are defined by the EMC Directive and related harmonised standards. Because the EMC Directive is not dealing with health and safety aspects of electromagnetic radiation, some vertical Directives have their "own" requirements for electromagnetic radiation, related to health and safety, e.g. Machinery Directive and Medical Devices Directive.

Finally, both in China and Europe several voluntary safety marks for consumer-related electrical products appear on the market. However these marks shall not interfere with the compulsory marks.<sup>17</sup>

 In Europe these voluntary marks are issued by private organisations and indicate conformity with a relevant standard or specifications, e.g. the Kite-mark that is owned by BSI. The only remaining vol-

<sup>&</sup>lt;sup>17</sup> Basically all Directives and Regulations requiring the CE marking prohibit the affixing of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.





untary legal marking in the EU indicating among product quality also product safety is the German GS mark<sup>18</sup>;

• In China such voluntary marks are generally organization specific, such as the CQC Product Certificate and Mark.

Both China and Europe use additional voluntary marks demonstrating compliance with EMC regulations and standards; however these marks do not play a major role in consumer products.

Both China and Europe prohibit the use of deceptive Marks; this includes marks other than the compulsory CCC or CE marks suggesting compliance with the respective regulations<sup>19</sup>.

#### 4.1.2 The IECEE-CB Scheme

The IECEE-CB scheme plays an important role in market access for consumer-related electrical goods in China and in Europe. Whilst the system is completely voluntary, it has led to an indirect harmonization of market access regulations between China and Europe and has proven to be a highly useful tool for all economic players trading between China and Europe. Any testing laboratory being accredited to this scheme can issue CB certificates with international recognition, thus many testing labs in China and in Europe have chosen to participate in the system.

The CB-scheme can be used in all cases where Chinese and European market access regulations and standards are in compliance with the applicable IEC standards. In the area of electrical safety for consumer-related household goods, this is especially the IEC 60335 series of standards, which has been adopted in Europe under the same number as EN-IEC standards, and been transposed into the Chinese system with the GB 4706 series of compulsory national standards. In cases where there are deviations from the IEC standard, test results related to these differences can be included in the CB test reports.

Whilst the CB system creates the basis mutual recognition of test results in China and Europe, there is no guarantee for acceptance of the testing by the authorities. In fact, neither Europe nor China refer to this system in the legal framework. Restrictions in acceptance apply especially for the CCC certification system, where some specific requirements have to be addressed in the CB Testing Reports before these are admitted as part of the certification process for CCC.

# 4.1.3 Mutual Recognition of Marks and Testing Results

There is no mutual recognition of product Marks between Europe and China; this applies both for compulsory marking such as CCC or CE, but also for voluntary products marks such as the CQC-mark or CQM-mark in China or the GS-mark or Kitemark in Europe. Whilst mutual recognition of voluntary marks is not excluded, this would require a private agreement between the owners of the voluntary product marks and are not related to government intervention of any form.

<sup>18</sup> There is an on-going discussion with the EU Commission whether the GS mark is likely to mislead third parties as to the meaning or form of the CE marking or both

<sup>&</sup>lt;sup>19</sup> All New Approach Directives contain in essence the following text, e.g. Article 10(2) of the LVD: "The affixing on electrical equipment of any markings liable to deceive third parties as to the meaning and form of the CE marking shall be prohibited". In other words: "Other markings suggesting compliance with the LVD are prohibited".





Except for the IECEE scheme described und 4.1.2, there is no other agreement proposing mutual recognition of testing results between China and Europe applicable for consumer-related electrical household goods. Nevertheless, some of the testing results enjoy informal acceptance in both markets, e.g.

- Testing undertaken to prove compliance with the RoHS Directive in Europe or the respective regulations in China;
- Testing undertaken to prove stability and reliability of safety relevant software included in consumer-related household products.

As a general principle, testing results can be mutually accepted in Europe and in China, as long as the tests performed reflect the legislative requirements and standards of the destination market and there are no specific restrictions regarding the testing laboratory in the applicable legislation, such as:

- Requirement to involve a notified body in Europe;
- Compulsory licensing in China requiring testing in an appointed laboratory.

In the area of consumer-related electrical household goods this leads to an unequal acceptance regime of test results: LVD and EMC Directive do in general not require the involvement of a notified body, thus conformity assessment undertaken in China can be accepted for the majority of products in this sector. However, the Chinese CCC system does — except for the CB Test reports for electrical safety — not allow acceptance of testing and inspection undertaken in Europe by non-Chinese entities.

## 4.2 The System in China

The system regulating quality and safety of consumer-related electrical goods is based on several different government licenses issued by the appointed certification body, and where no such license applies, by the Law on Product Safety. The most prominent licensing scheme is the CCC scheme, applicable among others for a selection of: household electrical appliances, audio and video apparatus, information and communication equipment, and handheld electrical tools.

Other relevant licensing schemes are the SRRC approval for radio-related equipment, and the NAL license for telecom terminal equipment, and licenses related to information security and cryptography embedded in electronic goods <sup>20</sup>. These licensing schemes do all have their specific scope or Catalogue defined in the regulations underlying the system. Since the schemes are not exclusive it is possible that market access for specific product categories requires several compulsory licenses<sup>21</sup>.

Where such license scheme applies, type testing in a government appointed laboratory is required, often in combination with factory visits by Chinese inspectors appointed by the licensing authority. In cases where no compulsory licensing applies, the selection of testing and inspection bodies is in general free and has to comply with the requirements in the applicable compulsory standards. Where no such standards apply, the

<sup>21</sup> A typical case for such multiple licensing are mobile phones: Here CCC, NAL, and SRRC regulations apply, leading to a triple certification for market access

 $<sup>^{20}</sup>$  A variant of the CCC scheme was introduced for Information Security Products, the CC-IS scheme. However this system is compulsory for Public Procurement purposes only





producer has to ensure that the product complies with the requirements in the Product Safety Law and choose appropriate testing and inspection methods.

Outside of the scope of the CCC system, a full range of often competing voluntary product certificates exist: These certificates are both related to electrical products themselves and to some of the key components related to these products. The voluntary product certificates are owned and issued by the respective certification body in China, mostly operating on a national level. Voluntary product certificates for key components are often used to support compulsory licensing schemes for consumer-related electrical goods.

Compulsory marking requirements exist, where such product requires a license such as CCC. For products outside of the scope of these compulsory licenses it is not allowed to use such compulsory product quality marks. Any other voluntary product mark affixed to the product must be based on a certificate issued by a body licensed for doing so. The use of foreign product quality marks such as the Kitemark or the GS Mark has no legal relevance in China; nevertheless they may not be used without proper evidence supporting these claims.

China applies special restrictions on the importation of used and refurbished electrical goods. Consumer-related electrical household goods need a special approval for importation and need to undergo a pre-shipment inspection. As a general principle, used and refurbished consumer-related electrical household goods are not welcome.

Special regulations apply for electrical toys (see respective chapter) and for goods containing pressure devices (air conditioners) and ozone depleting chemicals (refrigerators).

Finally, unlike Europe, China is controlling the quality of imports and exports of selected goods with a licensing system (see section 3.2.3), this includes also a selected range of consumer-related electrical goods. The goods under this scheme are published and updated by AQSIQ on a regular basis.

# 4.2.1 General Description of the CCC System

The China Compulsory Certification, usually referred to as CCC or 3C scheme, is the only national multisector market access system for China. Its purpose is to ensure safety of products and to minimize risks for consumers, operators, the general public, and the environment. The CCC scheme is established on the basis of the Law on Product Quality, the Law on Import and Export Commodity Inspection of China, the Standardization Law of China, and the Regulations on Certification and Accreditation of China.

The CCC regulations are issued and implemented by AQSIQ and CNCA. The CCC system applies both to imported and domestic products and is compulsory for all items listed in the <u>"Catalogue of products subject to compulsory certification"</u>, generally referred to as <u>"CCC Catalogue"</u>.

The CCC system is a type-based approval system; variations in product specifications will in general require separate certifications. The CCC certificate is valid for 5 years. Whenever the underlying standards change, the certificate has to be adjusted to the new requirements, including additional testing where applicable, failure to "upgrade" the certificate will lead to an invalidation of the certificate.

There is only one certification body approved and appointed by CNCA for certification of consumer-related electrical goods falling under the CCC Catalogue: the *China Quality Certification Centre CQC*. CQC is in





charge of issuing the CCC certificates and undertaking related factory inspections. Testing of electrical goods is currently performed by 84 contracted testing labs <sup>22</sup> in China. However, the choice of testing laboratory is restricted by CQC and only a few of these testing labs have the right to accept international CB reports as basis for their test reports.

Currently, the CCC Catalogue contains 11 product categories related to electrical products: electrical wires and cables, switches for circuits, installation protective and connection devices, low-voltage electrical apparatus, small power motors, electric tools, welding machines, household and similar electrical appliances, audio and video apparatus, information technology equipment, and lighting appliances.

The following table contains the applicable CCC regulations and standards.

**Table 2: CCC Regulations and Standards** 

Category	Applicable Regulations and Compulsory Standards
Cord Set	Products with cord sets must comply with the implementation rule of CCC on electrical and elec-
Cord Set	tronic products-cord set CNCA-010-001:2011. Standards to be met: GB 15934-1996 on Cord Sets
	Products with wires and cables must comply with the implementation rule of CCC on electrical
Wires and	and electronic products-electric wire and cable categories- electric wires & cables CNCA-010-
Cables	001:2011. Standards to be met: GB 12972, GB 12528.1, GB 12528.11, JB/T 8145, GB 5013.1-
Cables	5013.7, GB/T 5013.8, JB/T 8735, GB 5023.1-GB 5023.5, GB 5023.7,GB/T 5023.6, JB/T 8734, GB/T
	2951, GB/T 3048, GB/T 18380
	Products with plugs and socket-outlets must comply with the implementation rule of CCC on elec-
Plugs and	trical and electronic products-switches for circuit, installation protective and connection devices-
Sockets	plugs, and socket-outlets for household and similar general purpose CNCA-01C-003:2011. Stan-
	dards to be met: GB 2099.1, GB 2099.2, GB 2099.4, GB 2099.5, GB 1002, GB 1003
	Products with switches and fixed electrical installations must comply with the implementation
Switches	rule of CCC on electrical and electronic products- for circuit, installation protective and connection
Switches	devices-switches for household and similar fixed-electrical installations CNCA-01C-004:2011.
	Standards to be met: GB 16915.1
Plugs and	Products with plugs and socket-outlets for industrial purpose must comply with the implementa-
Sockets for	tion rule of CCC on electrical and electronic products- for circuit, installation protective and con-
industrial	nection devices-plugs and socket- outlets for industrial purpose CNCA-01C-005:2011. Standards to
purpose	be met: GB/T 11918, GB/T 11919
Plugs and	Products with plugs and socket-outlets for household and general purpose must comply with the
Sockets for	implementation rule of CCC on electrical and electronic products-appliance couplers for house-
household use	hold and similar general purpose CNCA-01C-006:2011. Standards to be met: GB 17465.1, GB
nousenoid use	17465.2, GB 17465.3, GB 17465.4
	Products with thermal links must comply with the implementation rule of CCC on electrical and
Thermal Links	electronic products- for circuit, installation protective and connection devices-thermal links CNCA-
	01C-007:2011. Standards to be met: GB 9816.

<sup>&</sup>lt;sup>22</sup> Testing laboratories operating under the CCC system must be accredited for the type of product certification in question; and in a separate process appointed by CNCA for participating in the CCC system. Finally the testing laboratories must enter into a commercial contract with a certification body operating the CCC certification for the product category in question: for electrical household goods this is CQC.





Products with	Products with enclosures for accessories must comply with the implementation rule of CCC on
Enclosures for	electrical and electronic products- for circuit, installation protective and connection devices-
Accessories	enclosures for accessories for household and similar fixed electric installations CNCA-01C-
7.00000000	008:2011. Standards to be met: GB 17466.1, GB 17466.21, GB 17466.23, GB 17466.24
Cartridge Fuse	Products with cartridge fuse links must comply with the implementation rule of CCC on electrical
Link	and electronic products-cartridge fuse links of miniature fuses CNCA-01C-009:2011. Standards to
Link	be met: GB 9364.1, GB 9364.2, GB 9364.3
Low Voltage	Products with low voltage switchgear assembly must comply with the implementation rule of CCC
Switchgear	on electrical and electronic products-low voltage switchgear assembly CNCA-01C-010:2007. Stan-
Switchbear	dards to be met: GB7251.1, GB 7251.2, GB 7251.3, GB 7251.4, GB 7251.5, GB/T 15576
	Low voltage electrical apparatus- switch and control equipment must comply with the implemen-
Low Voltage	tation rule of CCC on electrical and electronic products-low voltage electrical apparatus-switch
Electrical	and control equipment CNCA-01C-011:2007. Standards to be met: GB 14048.2, GB 14048.3, GB
Apparatus	14048.4, JB/T 10736, GB 14048.5, GB 14048.6, GB 14048.9, GB/T 14048.10, GB/T 14048.11, GB
	17707, GB 17885
	Products related to installation of protective equipment must comply with the implementation
Protective	rule of CCC on electrical and electronic products-installation protective equipment CNCA-01C-
Equipment	012:2007. Standards to be met: GB 10963.1, GB 10963.2, GB 16916.1, GB 16916.21, GB 16916.22,
Equipment	GB 16917.1, GB 16917.21, GB 16917.22, GB 20044, GB 6829, JB 8756, GB 13539.1, GB/T 13539.2,
	GB/T 13539.6, GB 13539.3, GB/T 13539.5, GB/T 13539.4, GB/T 13539.7
Small Power	Products with small power motor must comply with the implementation rule of CCC on electrical
Motors	and electronic products-small power motor CNCA-01C-013:2007. Standards to be met: GB 12350,
WIOCOTS	GB 14711
	Electric tools must comply with the implementation rule of CCC on electrical and electronic prod-
Electric Tools	ucts-electric tools CNCA-01C-014:2011. Standards to be met: GB 3883.1, GB 3883.2, GB 3883.3,
Liectric 100is	GB 3883.4 , GB 3883.5, GB 3883.6, GB 3883.7, GB 3883.9, GB 3883.10, GB 3883.11, GB 3883.12,
	GB 3883.13, GB 3883.14, GB 3883.17, GB 3883.18, GB 4343.1, GB 17625.1
	Electric welding machines must comply with the implementation rule of CCC on electrical and
Electric Weld-	electronic products-electric welding machines CNCA-01C-015:2011. Standards to be met: GB
ing Machines	15579.1, GB 15579.11, GB 15579.12, GB 15578, GB 10235, GB 15579.6, GB/T 8118, GB/T 15579.5,
	GB/T 15579.7
	Household and similar use appliances must comply with the implementation rule of CCC on elec-
	trical and electronic products- household and similar use appliances CNCA-01C-016:2007. Stan-
Household	dards to be met: GB 4706.1, GB4706.13, GB 4343.1, GB 17625.1, GB 4706.27, GB 4706.32, GB
Appliances	4706.17, GB 4706.24, GB 4706.20, GB 4706.26, GB 4706.12, GB 4706.23, GB 4706.7, GB 4706.15,
	GB 4706.11, GB 4706.2, GB 4706.29, GB 4706.22, GB 4706.14, GB 4706.30, GB 4706.21, GB
	4706.22, GB 4706.28, GB 4706.19, GB 4706.13
Audio and	Audio and video products must comply with the implementation rule of CCC on electrical and
Video	electronic products-audio and video products CNCA-01C-017:2007. Standards to be met: GB 8898,
Products	GB 13837, GB 17625.1
Audio and	Audio and video apparatus equipment and components must comply with the implementation
Video	rule of CCC on electrical and electronic products-audio and video apparatus equipment and com-
Apparatus	ponents for cable distribution systems of sound and television signals (EMS) CNCA-01C-018:2007.
Equipment	Standards to be met: GB 13836
Satellite	Audio and video apparatus satellite television receivers must comply with the implementation
Television	rule of CCC on electrical and electronic products-audio and video apparatus satellite television
Receivers	receivers (EMC) CNCA-01C-019:2007. Standards to be met: GB 13837, GB 17625.1





Information	Information technology equipment must comply with the implementation rule of CCC on electrical
Technology	and electronic products-information technology equipment CNCA-01C-020:2007. Standards to be
Equipment	met: GB 4943, GB 9254, GB 17625.1
Finance and	Information technology equipment, finance and trade settlement equipment must comply with
Trade Settle-	the implementation rule of CCC on electrical and electronic products- information technology
ment Equip-	equipment finance and trade settlement equipment CNCA-01C-021:2007. Standards to be met:
ment	GB 9254
	Lighting appliance must comply with the implementation rule of CCC on electrical and electronic
Lighting	products-lighting appliances CNCA-01C-022:2007. Standards to be met: GB 7000.1, GB 7000.10,
Appliance	GB 7000.11, GB 7000.12, GB 19510.1, GB 19510.4, GB 19510.9, GB 19510.10, GB 17743, GB
	17625.1

#### 4.2.2 Standards for Electrical Products

China has its own comprehensive system of standards. For electrical household goods this system is based on adoption of relevant IEC standards in this field, especially the IEC 60335 series. Most of these adopted standards have been implemented in China without modifications; nevertheless for some appliances significant changes have been made, or in some cases the Chinese standard is based on an outdated version of the IEC standard. In addition, China develops standards for which there is no equivalent on international level or in the European standardisation system.

China distinguishes between compulsory and voluntary standards: Standards related to electrical safety and EMC are in general compulsory. This means that these standards become technical regulations in their own right, without any direct legal basis. Standards defining energy performance standards for consumer-related electrical goods and standards related to the energy labels are partially compulsory and partially voluntary of nature. Measurement standards are in general voluntary – giving some leeway to the way the testing is performed.

# 4.2.3 Compulsory Energy Labelling

Based on Law on Product Quality, the Law on Energy Saving and Regulation, and the Regulation on Certification and Accreditation, NDRC and AQSIQ jointly issued in 2005 the <u>Administrative Measure of Energy Efficiency Labelling</u>. This administrative measure created a national unified system on energy efficiency of energy consumption products. A regularly updated and expanded <u>Catalogue</u> defines the product categories to which this compulsory labelling system applies, and refers also to the respective compulsory standards. Products listed in the Catalogue must carry the energy efficiency label according the specific design requirements laid down in the respective standards.

For each product category in the *Catalogue*, AQSIQ in cooperation with CNIS and SAC published specific standards containing the minimum allowable values of energy efficiency, the energy efficiency grading system, and the implementation rules. Products which do not meet the minimum allowable efficiency values are not admitted to the market.

The system has many similar elements with the compulsory energy labels in Europe (see below) and the related standards are often based on similar European standards. However, the energy levels related to the





product classification are generally not equal to the European system. For office appliances the rules and standards of the American Energy Star system have been adopted, albeit with modifications.

All products listed in the Catalogue must be registered with the authority in charge, the <u>National Institute</u> <u>for Standardization CNIS</u>, before being imported or placed on the market. The producer must submit a test report based on the applicable Chinese standards, explaining the grading for the product as part of the registration process. Furthermore he has the obligation to report on an annual basis on the products sold carrying such labels. Testing laboratories participating in the system must be approved by CNIS <sup>23</sup>.

So far, 29 product categories have been listed in the Catalogue, including: micro-computers, household solar water heating systems, refrigerated display cabinets with remote condensing unit, digital television adapters (set-top boxes), printer & fax machines, microwave ovens for household and similar purposes, flat panel TVs, fans, power transformers, air conditioners, household refrigerators, automatic electric rice cookers, positive-displacement compressors, AC contactors, computer monitors, copy machines, electrical storage water heaters, multi-connected air conditioners, household induction cookers, speed controlled air conditioners, household gas instantaneous water heater and gas heating water heaters, water chillers, small & middle size three-phase asynchronous motors, high voltage sodium lamps, self-ballasted fluorescent lamps, unit type air conditioner and electric washing machines. A list of published standards related to the compulsory energy label can be found in Annex A2.

## 4.2.4 Chinese RoHS and WEEE Regulations

Using the respective European Directives as basis China introduced its own regulations for hazardous chemicals in electronic products, and regulations on electrical and electronic waste. These regulations are based on the <u>Circular Economy Law</u> and are aimed to reducing if not eliminating hazardous chemicals and waste from industry.

The <u>Administrative Measures on the Control of Pollution Caused by Electronic Information Products</u>, the so-called <u>"China RoHS"</u> regulation were first published in 2006. The regulation is currently under revision, a detailed draft was published in July 2012. China RoHS is addressing content of six hazardous inorganic chemicals in electronic products by setting maximum values and defining the methods how these have to be measured. The values are identical to the values published in the European RoHS Directive, the measurement methods are defined in six national standards. Complementing implementation rules have been announced.

The regulations are based on a self-declaration of the producer, combined with a compulsory mark, and a technical documentation demonstrating the claim made with the mark, in following variations:

 An all-free mark, declaring that the content of hazardous chemicals is below the minimum set by the regulation;

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<sup>&</sup>lt;sup>23</sup> Testing laboratories for the compulsory energy label are listed here:





• A mark for product containing hazardous chemicals within the maximum limits, declaring the years of safe use of the product (generally 10 years) <sup>24</sup>.

Alternatively, the producer may choose to affix the voluntary China RoHS product mark; this mark and the accompanying certificate have to be issued by a conformity assessment body in China approved by the government for this mark.

In a recent revision of the China RoHS regulation the scope has been redefined as follows: "electrical and electronic equipment designed for use with a voltage rating not exceeding 1000 Volt for alternating current, and 1500 Volt for direct current, and its accessory parts". This includes also electrical home appliances which were generally excluded from the previous version of this regulation.

Under the new China RoHS regulations, there will be a <u>"Target Administrative Catalogue for the Pollution Control of Electrical and Electronic Products"</u>. Various government bodies will set a timeline to prohibit the use of certain hazardous chemicals for the products listed in the Catalogue. In the future, various certification mechanisms may be available. It is possible for companies to issue a self-declaration or ask an independent third party to carry out the certification.

The <u>Chinese Regulations on Recovery Processing of Waste Electrical and Electronic Products "China WEEE"</u> were published in March 2009 and are effective since January 2009. The Regulations require that electrical and electronic products put on the Chinese market must be labelled according to the Regulation. Organizations or people responsible for sourcing products covered by the China WEEE regulations are required to purchase compliant products only.

So far there is little impact on conformity assessment by these Regulations. However, in Regulations implemented in July 2012, a recycling fee on new electronic products sold in China was introduced. The fee structure is based on the goods category; the classification of goods follows the international customs classification (HS Code).

## 4.2.5 Assessment of Safety and Reliability of Software in Products

As part of the CCC certification process, China introduced a compulsory third party assessment of the reliability of critical software in products. The manufacturer must demonstrate compliance with applicable compulsory standards, where failure of software could lead to dangers for the user, e.g. overheating, leakage, short circuits. As per today, transfer of test results from any accredited testing laboratory is accepted; however this may change in future. An example for a product requiring such compulsory software testing are household induction hubs for cooking.

<sup>&</sup>lt;sup>24</sup> If this mark is used, the producer must add information about the parts containing the hazardous substances, the concentrations, and how these parts can be safely disposed of.





### 4.2.6 Compulsory licensing of Information Security Products

Licensing for information security products has so far been restricted to ICT related products and does not yet affect market access for consumer-related electrical goods. However, it is expected that this is will change soon, especially for products linked to the internet or the cellular phone network.

According to the <u>Regulations on Commercial Cryptography</u>, compulsory testing is required for products containing cryptography as a core element, such as smart cards.

CNCA published a list of 13 information security related products which may undergo testing under the newly established CC-IS certification scheme. This scheme remains voluntary, except for products for public procurement.

### 4.3 The System in Europe

The main Directive regulating safety of consumer-related electrical products is the <u>Low Voltage Directive</u> 2006/95/EC. It applies to all electrical equipment not covered by another sectoral Directive (e.g. the Machinery Directive for electrical tools such as drilling machines), designed or adapted for use within a voltage range between 50 and 1000 Volts AC and 75 and 1500 Volts DC measured at input or output.

For products using battery chargers the following applies: The battery charger is covered by the LVD, so are products with built-in rechargeable batteries, which are charged by plugging the complete product into or connecting the complete product to a charging device. Appliances containing batteries which need to be removed and remain separated from the product to be charged are not covered by the LVD Directive.

The basic requirement of the LVD Directive is that the equipment is safe, manufactured in accordance with "Good Engineering Practice", and conforms to the principal elements of the safety objectives set out in Annex I of the Directive. The EU Commission published in 2007 a guidance document, now in its third revision (January 2012).

A variety of electrical equipment is excluded from the scope of the Directive, of which some may be placed on the market for use by consumers, e.g.:

- Plugs and socket outlets for domestic use;
- Electrical equipment for use in a potentially explosive atmosphere.

The producer or importer has the obligation to affix the CE marking on consumer-related electrical products covered by the scope of the Low Voltage Directive. To be noted: with this marking he declares conformity with <u>any</u> applicable EU regulation requiring the CE marking.

Under the Low Voltage Directive a great number of harmonised European Standards have been published, including the EN-IEC 60335 series of standards. Usage of these harmonised standards gives the producer the presumption of conformity with the Directive<sup>25</sup>. The harmonised European standards define also the

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 $<sup>^{25}</sup>$  For a complete overview, see the Commission communication in the framework of the implementation of Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits - OJ C 245 of 14/08/2012





conformity assessment requirements (referred to as 'verification requirements'). Unless the regulations require the involvement of a notified body, the manufacturer is free to decide whether he wishes to outsource parts of the conformity assessment activities or not (see also section 4.3.3).

### 4.3.1 Electromagnetic Compatibility

The EMC Directive 2004/108/EC is the applicable regulation for all electrical products causing electromagnetic disturbances or that are susceptible to such disturbances. It does not apply to radio and telecommunication terminal equipment covered by the R&TTE Directive. Unlike the Low Voltage Directive, it does cover electrical products with a voltage below 50V AC or 75V DC.

By affixing the CE marking, the manufacturer guarantees that the product placed on the market is immune or not disturbing in any way. However, there is no obligation for third party product conformity assessment. The producer and/or importer must compile and maintain for each product a technical documentation demonstrating compliance with the legislation. In most cases a collection of the data outlined in the respective *harmonised European standards* will suffice.

Conformity assessment for products covered by the EMC Directive takes the form of an internal production control procedure (see section 4.3.3.), carried out by the manufacturer and if desired with the involvement of a notified body. The EMC Directive requires the manufacturer to check that the equipment meets the electromagnetic compatibility requirements set out in Annex I of the Directive. The manufacturer is under an obligation to

• either demonstrate compliance following the procedure of internal production control as given in Annex II of the Directive,

or - at the discretion of the manufacturer, – following the procedure of internal production control completed with presenting the technical documentation to a notified body with the request for an assessment thereof as given in Annex III of the Directive. It is at the discretion of the manufacturer whether he applies harmonised standards when following either procedure <sup>26</sup>.

Products are considered "benign towards EMC requirements" <sup>27</sup> if their inherent physical characteristics are such that the product is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunications equipment and other equipment to operate as intended; and, it will operate without unacceptable degradation in the presence of the electromagnetic disturbance normally present in its intended environment.

Products considered benign towards EMC requirements do not need to be CE marked for the EMC Directive. However, these products may be covered by another Directive under the New Legislative Framework or New Approach that requires affixing of the CE marking, e.g. products covered by the Low Voltage Directive, Toys Directive, Machinery Directive, etc.

<sup>26</sup>It is also to the discretion of the manufacturer to apply the applicable harmonised European standard(s) to cover emission phenomena, and a detailed technical EMC assessment for immunity aspects

<sup>&</sup>lt;sup>27</sup> Benign electrical consumer products are e.g.: pocket lamps, cables, switches, plugs and sockets, light bulbs, simple heating devices, batteries, fuses, headphones, quartz watches, passive antennas (all without electronic circuits)





#### 4.3.2 Standards for Electrical Products

The standards used for consumer-related electrical products in Europe are almost 100% identical with the respective international (IEC/ISO) standards. Relevant for the safety of household and similar appliances are the EN 60315 series of standards for electrical safety, and EN 55014 series for electromagnetic compatibility; the latter is based on the CISPR 14 technical specification<sup>28</sup>. Most of these standards have an equivalent standard in China, in many cases identical to the respective IEC / CISPR standards. Since these standards are well-known in China we do not introduce these here.

For household and similar appliances producers and importers can rely on the standards series of EN 60335 and EN 55014 when assessing the conformity of products.

The following standards may apply for selected groups of consumer-related electrical products other than household appliances:

- For the electrical safety aspects of electric toys: EN 62115
- For the electrical safety aspects of medical electrical equipment: EN 60601.
- Standards presently harmonised under the EUP and ERP Directives are: EN 60034-30: 2009 and 60034-2-1:2007 covering electric motors, and EN 50564:2011 for standby and off-mode electric power consumption of electrical and electronic household and office equipment.
- Standards harmonised under the R&TTE-Directive:

The application of (harmonised) standards is completely voluntary. It is to be noted that a harmonised standard supporting a particular EU Directive or Regulation only provides presumption of conformity with the relevant essential requirements of that EU Directive or Regulation if the product is in its entirety covered by the scope of the standard, the standard reflects all relevant essential requirements for that product and the standard is applied in full. In absence of a harmonised standard or in case a harmonised standard is not applied, presumption of conformity may also be achieved on the basis of a conformity assessment directly with the essential requirements of the EU Directive(s) or Regulation(s) applicable to the product. All conformity assessment information related to design, manufacture and safe function of the product is part of the technical file.

Standards deal with abstract products. The real situation may not be consistent with the scope as reflected in the standard. That is the reason why producers should always perform a hazard inventory to check to which extent the available harmonised standard(s) can be applied.

The procedure to obtain the presumption of conformity is as follows:

- Make an inventory of all hazards that are intrinsic to the product (e.g. mechanical, electrical, noise, temperature);
- Identify the risks (does it affect the user and in which way?);
- Apply safeguarding measures to reduce the risk (e.g. insulation, guards, noise-reduction); and

<sup>&</sup>lt;sup>28</sup> CISPR - Comité International Spécial des Perturbations Radioélectriques; English: Special International Committee on Radio Interference) founded in 1934 to set standards for controlling electromagnetic interference in electrical and electronic devices, and is a part of the International Electrotechnical Commission (IEC)





• Inform the user of residual risks that cannot be reduced (user manual, warnings on the product).

### 4.3.3 LVD Conformity Assessment Requirements

The Low Voltage Directive LVD defines four conformity assessment procedures by which a manufacturer or his authorised representative can ensure that electrical products satisfy the essential safety requirements applicable to them. These are:

- Manufacture in conformity with the relevant <u>harmonised European standards</u> (see also 4.3.2) where these cover all relevant aspects of the safety of the electrical product and declaration that this is the case: Electrical products which are in conformity with the applicable <u>harmonised European standards</u> or parts thereof, shall be <u>presumed to be in conformity with the requirements</u> covered by those standards or parts thereof set out in Article 2 and Annex I. The manufacturer must follow the procedure of internal production control as given in Annex IV of the Directive.
- In absence of *harmonised European standards*, manufacture in conformity with the safety provisions of the *standards in force in the Member State of manufacture*, if they ensure a safety level equivalent to that required in their own territory. The manufacturer shall draw up the relevant technical documentation.
- In absence of harmonised European standards or relevant national standards as referred to above, manufacture electrical equipment which complies with the safety provisions of the International Commission on the Rules for the Approval of Electrical Equipment (CEE) or of the International Electrotechnical Commission (IEC). The safety provisions in question must have been be published before in the Official Journal of the European Union. The manufacturer must follow the procedure of internal production control as given in Annex IV of the Directive.
- In absence of *harmonised European standards*, relevant national standards, CEE documents, or IEC standards as referred to above, manufacture of electrical equipment directly in conformity with the provisions of the Directive. The manufacturer must follow the procedure of internal production control as given in Annex IV of the Directive <sup>29</sup>.

In the event of a challenge the manufacturer or importer may ask a third party designated for this task and notified to the Commission by the member state to assess the electrical equipment and draw up a report on the conformity with the provisions of the Low Voltage Directive.

Before being placed on the market, consumer-related electrical equipment must have the CE marking affixed to it, attesting its conformity to the provisions of the LVD and any other Directive(s) or Regulation(s) requiring the CE marking, which may be applicable to the product.

<sup>&</sup>lt;sup>29</sup> Whilst not required, it is recommended to include in the technical documentation <u>the full risk assessment</u> and information on risk reduction regarding all safety aspects relevant to the product.



#### 4.3.4 LVD Technical Documentation

Internal production control is the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in point 1, ensures that the electrical equipment satisfies the requirements of the Directive(s) or Regulation(s) that apply to it. An important element of the procedure to be followed is the collection of data in the technical documentation that gives a clear understanding of the design, manufacture and operation of the electrical equipment.

- 1. The manufacturer must establish the technical documentation described in point 2 and he or his authorized representative established within the Community must keep it on Community territory at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured <sup>30</sup>
- 2. The technical documentation must enable assessment of the conformity of the electrical equipment to the requirements of this Directive. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the electrical equipment. It must include:
  - o a general description of the electrical equipment
  - o conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
  - o descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment
  - o a list of the standards applied in full or in part, and descriptions of the solutions adopted to satisfy the safety aspects of this Directive where standards have not been applied
  - o results of design calculations made, examinations carried out, etc.
  - o test reports
- 3. The manufacturer or his authorized representative must keep a copy of the declaration of conformity with the technical documentation
- 4. The manufacturer must take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

# 4.3.5 Ecodesign of Energy Related Products

The framework Directive for Ecodesign of Energy Related Products (ERP) 2009/125/EC applies to any product that has an impact on energy consumption during use placed on the market and/or put into service. The Directive includes parts intended to be incorporated into energy-related products covered by this Directive placed on the market and/or put into service as individual parts for end-users and of which the environmental performance can be assessed independently. New product groups are selected for the Working

<sup>&</sup>lt;sup>30</sup> Where neither the manufacturer nor his authorized representative is established within the Community, this obligation is the responsibility of the person who places the electrical equipment on the Community market.





Plan every three years. The conformity assessment procedures the manufacturer can choose from are specified by the Implementing Measures <sup>31</sup>.

The scope of the ERP Directive covers currently more than 40 product groups (such as boilers, light bulbs, TVs and fridges), which are responsible for around 40% of all EU greenhouse gas emissions. The ultimate aim of the Ecodesign Directive is that manufacturers of energy-using products will, at the design stage, be obliged to reduce the energy consumption and other negative environmental impacts of products. While the Directive's primary aim is to reduce energy use, it is also aimed at enforcing other environmental considerations including: materials use; water use; polluting emissions; waste issues and recyclability.

The Implementing Measures leave the manufacturer the choice between internal design control and a management system for assessing conformity. The management system must conform to the product-related requirements and include the design function. The manufacturer must draw up and sign an *EC Declaration of Conformity*.

The following Implementing Measures have been published, more are under preparation:

Table 3: List of Implementing Measures (Website DG Enterprise & Industry January 2013)

<b>Product Category</b>	Description	Ecodesign	Energy Labelling
Air conditioners	Air conditioners and comfort fans	(EU) No 206/2012	(EU) No 626/2011
<u>Circulators</u>	Circulators and glandless circulators integrated in products	(EC) No 641/2009	
<u>Dishwashers</u>	Household dishwashers	(EU) No 1016/2010	(EU) No 1059/2010
Electric motors	Electric motors	(EC) No 640/2009	
<u>Fans</u>	Fans driven by motors	(EU) No 327/2011	
<u>Lamps – LED and</u> <u>directional</u>	Directional lamps, light emitting diode lamps and related equipment	(EU) No 1194/2012	(EU) No 874/2012

<sup>&</sup>lt;sup>31</sup> Implementing Measures are mandatory requirements in the form of regulations, which come into force without further transposition into national law.





<u>Lamps – house-</u> <u>hold</u>	Non-directional household lamps (including amendment on ultraviolet radiation)	(EC) No 244/2009 (EC) No 859/2009	(EU) No 874/2012
<u>Lamps – fluores-</u> <u>cent</u>	Fluorescent lamps without integrated ballast, for high intensity discharge lamps and for ballasts and luminaries able to operate such lamps	(EC) No 245/2009 (EU) No 347/2010	(EU) No 874/2012
Power supplies	External power supplies	(EC) No 278/2009	
Refrigerating appliances	Household refrigerating appliances	(EC) No 643/2009	(EC) No 1060/2010
Set-top boxes	Simple set-top boxes	(EC) No 107/2009	
Standby and off mode	Standby and -off mode losses of electrical and electronic household and office equipment	(EC) No 1275/2008	
Television	Television	(EC) No 642/2009	(EU) No 1062/2010
Tumble dryers	Household tumble dryers	(EU) No 932/2012	(EU) No 392/2012
Washing machi- nes	Household washing machines	(EU) No 1015/2010	(EU) No 1061/2010
Water pumps	Water pumps	(EU) No 547/2012	

#### **Harmonised Standards:**

• Electric Motors: EN 600034-30: 2009, EN 600034-2-1: 2007

• Standby and –off Mode: EN 50564: 2011

### **Intended Harmonised Standards:**

• Circulators: EN 16297-1: 2012, EN 16297-2: 2012, EN 16297-3: 2012

• Electric Motors: FprEN 60034-2-1: 2013, Mandates M/470-476-495

• Refrigeration: EN 62552: 2013

• Dishwashers: EN 50242: 2008, EN 50242: 2008 / A11: 2012

• Washing Machines: EN 60456: 2011 + Amendment, EN 60704-2-4: 2012

• Tumble Dryers: EN 60704-2-6: 2012, EN 61121: 2013





External Power Supplies: EN 50563: 2011

Televisions: EN 62087: 2012

Simple Set-top Boxes: EN 62087: 2012

 Air-Conditioners: FprEN 14825, prEN 13371-1, FprEN 12900, FprEN 12102, FprEN 115218, FprEN 14511-1,-2,-3,-4.

### 4.3.6 Compulsory Energy Label

Labelling and standard product information framework Directive 2010/30/EU: This is a new directive replacing various pieces of regulation related to product information for energy related products, including consumer-related (electrical) products. There are no harmonised standards supporting this Directive. The details for the energy labels are defined in the respective implementing measures (see table in section 4.3.5).

## 4.3.7 Other EU Legislation relevant to electrical equipment

Find below a list of other EU legislation that is relevant to the electrical equipment trade and industry:

- R&TTE Directive of 9 March 1999 of the European Parliament and of the Council on Radio Equipment and Telecommunications Terminal Equipment and the mutual recognition of their conformity;
- RoHS Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment;
- WEEE Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment;
- Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres;
- Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, amended by Directive 2009/127/EC.

### 4.4 Conclusions

Regulations for market access for consumer-related electrical product are fundamentally different in Europe and China, despite relying on mostly identical standards. The Chinese system emphasizes the responsibility of the government in ensuring the safety of products in the market, whilst the European system relies primarily on the responsibility of the manufacturer/producer or importer.

### 4.4.1 Conclusions for China

The Chinese system is built around one single ministry, offering all the conformity assessment related services companies need: Standardisation, testing, inspection, certification, import control, market surveillance, export control, are all part of or affiliated with AQSIQ and its local branches: Consumer-related electrical products must undergo additional testing in government appointed laboratories before they can be placed on the market in China or being exported from China – irrespective of any testing done beforehand.





Compulsory factory visits lead to a great effort in inspection, especially time consuming if the inspection takes place overseas. The system is based on one single certification body CQC representing China government, and it does not allow free choice of testing laboratory. It relies on third party testing and does not allow companies to undertake the testing and inspections themselves. The need to comply with the compulsory standards reduces flexibility in the approach towards safety to a minimum.

The Chinese system requires a systematic government approval of many consumer-related electrical products. It is supposed to assure that all products carrying rightfully the CCC mark comply with regulations. However, this comes at a heavy price for the industry: The process is time consuming and costly and adds considerably to the cost of producing in or importing in China. For domestic companies this system may affect their competitiveness in global markets.

### 4.4.2 Conclusions for Europe

The European system is built on trust in enterprises combined with post-market enforcement. There is little government control over goods placed on the market. Companies can undertake production control and testing in-house – if they deem themselves qualified to do so – or choose any second or third party for outsourcing these process steps. Only a few Directives require involvement of a notified body in incidental cases for (electrical) products that are intended for use by consumers; e.g. the Machinery Directive requires intervention of a notified body for certain types of woodworking machinery that may be placed on the EU market for use by consumers. EU Directives or Regulations cover placing on the EU market only. As a result there is no need to involve notified bodies for undertaking export activities to countries outside the EU. Europe does not have export controls for such products.

Generally it is at the discretion of the manufacturer to test or have his product tested as part of full product conformity assessment. It is not that much a matter of accepted test results or outsourcing to a qualified second or third party, but rather the possibility of a manufacturer to demonstrate that his product meets the essential requirements of the relevant Directive(s) or Regulation(s).

The European system is mainly built on trust in enterprises combined with mandatory third party involvement where required (essentially for what are considered high risk products) and post-market enforcement. There is little government control over products placed on the market. Companies can apply internal production control and testing as part of product conformity assessment, or seek for voluntary involvement of a second or third party (not a notified body) if they want to outsource certain process steps. There is no compulsory involvement of a third party/notified body for consumer-related electrical products under the Low Voltage, EMC, General Product Safety, RoHS and ERP Directive <sup>32</sup>. Results from testing by any second or third party if desired by the manufacturer may be accepted as part of the technical documentation.

The European system gives the manufacturer/producer the right to choose different approaches not necessarily in line with the applicable (harmonised) European standards; however in such cases he will have to demonstrate that the level of safety achieved is at least comparable with the safety as required by the relevant harmonised European standards.

<sup>&</sup>lt;sup>32</sup> Involvement of a Notified Body may apply for among others Toys, Medical Devices, Gas Appliances, R&TTE and Machinery, depending on the type of product.





The European system seems to work well for products made in Europe or exported from Europe; however there are some doubts whether the system fully addresses the needs for products imported from outside the borders of the EEA <sup>33</sup>. Thus, in recent efforts the surveillance activities have been strengthened throughout Europe. At the same time a close EU-China cooperation on identified potentially hazardous products is showing results, especially as it helps to identify the source of non-compliant products.

### 4.4.3 Recommendations

The following areas are probably interesting for further evaluation between the European and Chinese experts:

- Accelerate implementation of changes in international standards: Since both harmonised standards and Chinese compulsory national standards have a legal connotation, there is a need to formally adopt standards in both jurisdictions. Such adoptions can be a time-consuming exercise, especially if there is not a 100% consensus on the content of the standard in question. The European side developed a method that avoids such time gaps: The "parallel voting" process where all members of CENELEC vote in parallel with the vote on-going between the IEC members. However, for the Chinese side this poses still a formidable challenge; it is suggested to identify ways how China can accelerate this implementation; this still leaves open whether it will be possible to align Chinese standards with the harmonised EN standards supporting EU-legislation;
- Make better use of IEC-CB reports: Whilst such reports are accepted as part of the technical documentation both in Europe and China there seem to be many differences in the concrete implementation of this system: This problem affects mainly China, since there is no government approval in Europe influencing the content of these reports. However, since the CCC process is a governmental approval system, formal requirements of the process affect also the recognition of CB reports. It is suggested to find ways to eliminate these differences, since they have a major impact on the overall cost of the approval process;
- Make testing more international: Chinese testing is still suffering from a lack of international influence; The rules for testing bodies participating in the CCC scheme effectively exclude foreign bodies from the Chinese market; on the other hand, Chinese testing bodies have minimal recognition outside China. This leads to an unhealthy split of the testing market in China: Testing for China is done by Chinese bodies, testing for overseas is done by foreign bodies. Whilst this system protects noncompetitive Chinese bodies, it does not foster innovation. It is suggested to identify ways how to reform the testing industry;
- Localize inspection services: Many inspection bodies have global operations including the Chinese
  national inspection body CCIC (China Certification and Inspection Group). These international bodies ensure that inspection services are offered in similar ways globally. In fact, these bodies live by
  the promise, to implement agreed inspection requirements globally. It makes thus little sense to

 $<sup>^{33}</sup>$  The EU and the EFTA countries form together the EEA (European Economical Association). The EFTA countries (Norway, Iceland and Liechtenstein) as well as Switzerland have fully adopted the EU technical legislation. Iceland is on the brink of becoming full member of the EU.





send inspectors across the globe, facing language and cultural difficulties, and wasting considerable resources, instead of using local resources. It is suggested to develop a system for China which avoids the need for Chinese inspectors to be sent overseas;

- Increase transparency and good governance: A unique feature of the Chinese system for conformity assessment is the lack of separation between role setting, their execution, and their verification. Legislation, standardisation, accreditation, conformity assessment, testing, inspection, are all under the same roof. Whilst such a system may simplify the organization of government, it does not lead to better services to the industry. In fact the mix between these functions may inevitably lead to a self-serving system rather than a system supporting growth and innovation. It is suggested to discuss how to reform the structure of the conformity assessment system, using the strict separation in Europe as model;
- Good practice for effective representation of consumers in standardisation: Especially for consumer-related electrical products it is important to have consumers involved both in standardisation and in the conformity assessment process. It would probably be interesting to have focused exchanges on how to strengthen the consumer's voice and how to better enable consumers to make informed decisions when selecting between competing products.





### 5 Comparison of the Systems for Products Intended for Children

### 5.1 General Principles of the Systems

Safety of "Products Intended for Children" is high on the government agendas around the globe; even conformity assessment measures are – unlike in other areas – often discussed in a broader public space. As a consequence, safety of toys and other products intended for children is one of the most regulated areas within the consumer products sector. Nevertheless, the system is far from perfect, and major scandals are disrupting the industry on a regular basis.

Whilst there is global consensus, that clear standards providing thorough product conformity assessment requirements including appropriate testing where needed, and strict enforcement, are essential elements to increase safety of such products, the methods vary: Europe is mainly relying on self-control by the producer and importers, whilst China implemented an approval system covering toys and other child-related products.

Whilst all major economies rely on a comprehensive framework of standards, it is also clear that not every product and every aspect of such products can be addressed. Due to intense public pressure, regulators have often to take action before an international consensus is established – resulting in globally incoherent legislation and as a consequence also to substantially different standards, despite efforts around the globe for harmonization.

One of the more controversial issues is the definition of "Products Intended for Children": This may include a wide variety of products with "toys" at its core. What regulation applies e.g. for musical instruments, books or bicycles intended for children? How to treat food designed as toys or food-toy combinations? How to treat children's cloths or child supports such as walking supports or floating leisure articles? What is the definition of a toy? Here there are no universally accepted definitions, and also major differences between China and Europe.

# **5.1.1** Definition of Toys

The definition of toys in Europe is embedded the Toys Directive 2009/48/EC. All products falling under the scope of this Directive are considered "toys" whilst for most other categories of "Products Intended for Children" the General Product Safety Directive (GPSD) 2001/95/EC applies. The most important rule is that toys are products "for use in play of children under 14 years of age".

In China, "toys" are mostly defined by the scope of the CCC Catalogue for toys, albeit this does not include all types of toys. For most other products intended for children the Chinese Law on Product Quality applies in combination with the respective compulsory standards.

Both in Europe and China there is a potential overlap between the regulations applicable for toys and other regulations, this is namely the case with regulations on electromagnetic compatibility, hazardous substances, and waste regulations.





### 5.1.2 Non-Toy Products Intended for Children

Non toy products intended for children do fall either under specific regulations for the respective product category or in absence of these – which is often the case – under the general provisions of the Law on Product Safety in China and the regulations of the GPSD in Europe

### 5.2 The System in China

### **5.2.1** General Description

China does not have any specific legislation on products to be placed on the market intended for children or on toys: Nevertheless, by inclusion of five types of toys and child carriers in the CCC regulations there is a strong regulatory framework defining conformity assessment requirements. The same categories of toys are also included in the list of products falling under export controls.

For products placed on the market intended for children that are not covered by CCC regulations, including toys made of paper, wood, textile, glass and ceramics the General Product Safety Law applies. The basis reference for compliance with this regulation are the applicable compulsory standards (refer to chapter 3 for more details). It is thus important, that the importer / manufacturer knows exactly which standard applies to the type of product to be placed on the market. For toys in general, the compulsory standard GB 6675 applies.

The regulatory system for products intended for children is still under development: It was announced that the CCC Catalogue shall be expanded soon to cover new child seats and child restraints for cars.

#### 5.2.2 Standards for Products Intended for Children

The main standards for safety of toys are: GB 6675 Safety of toys, a not equivalent version of the international standard ISO 8124, and GB 19865 Safety of electrical toys, a not equivalent version of the international standard IEC 62115. The national toy safety standard GB 6675 is currently under revision.

Other **compulsory** standards applicable for products intended for children include:

- GB 14746, Safety requirements for children's bicycles
- GB 14747, Safety requirements for children's tricycles
- GB 14748, Safety requirements for children's carts
- GB 14749, Safety requirements for baby walking chairs

#### 5.2.3 CCC Certification

Six product categories are listed in CCC the Catalogue with reference to <u>"toy products"</u>, covering: child carriers, electric toys, plastic toys, metal toys, launching toys, and dolls:

• **Child carriers** should follow the implementation rule of CCC on child carriers CNCA-13C-068: 2010. Following standards must be met: GB 14746, GB 14747, GB 14748, GB 14749, GB 6675, GB 19865





- **Electric toys** should follow the implementation rule of CCC on electric toys CNCA-13C-069: 2010. Following standards must be met: GB 6675 and GB 19865
- Plastic toys should follow the implementation rule of CCC on plastic toys CNCA-13C-070: 2010. Following standard must be met: GB 6675
- **Metal toys** should follow the implementation rule of CCC on metal toys CNCA-13C-071:2010. Following standard must be met: GB 6675
- Launching toys should follow the implementation rule of CCC on launching toys CNCA-13C-072: 2010. Following standard must be met: GB 6675
- **Dolls** should follow the implementation rule of CCC on dolls CNCA-13C-073: 2010. Following standard must be met: GB 6675

There are two certification bodies appointed and approved by CNCA, the *Certification Centre of Light Industry Council*, and the *China Quality Certification Centre CQC*, to operate the CCC scheme <sup>34</sup> and to issue the CCC certificates for "toy products". There are currently 18 testing laboratories approved by CNCA to undertake the testing for toy products. Most of them are located in Shanghai, Jiangsu, Shenzhen, and Guangzhou areas.

#### **5.2.4** Other Chinese Administrative Measures

In 2007, AQSIQ issued the *regulation on recall management of children toys*. It defines clearly that the producer is primarily responsible for defective toys. AQSIQ has the responsibility to unify and coordinate the supervision and management of recalls of toys. The authorities in charge on provincial and local level *"local CIQ"* are responsible for the administration of recall of toys in the respective area. The regulation establishes also: an information system, the information collection, and the record of information. It not only provides procedures for judgment and evaluation of possible defective toys by the producer and the supervising authorities, but also stipulates the use of technical resources, defect identification, and risk assessment. To support the regulation on recall management of children toys, AQSIQ issued the *"Management approach on recall information and risk assessment on children toys"*. The *Defective Product Management Centre* of AQSIQ carries out the operational management of toy recalls.

In 2009, AQSIQ issued the "Administrative measures for supervision and inspection of import and export toy products". They include: procedures for import and export inspection on toys, registration procedures, requirements on administration and supervision by the inspection bodies, category management, traceability of quality records, and product recalls. The measures apply to: production enterprises engaged in import and export of toys, inspection and quarantine organizations, and related stakeholders. The regulation establishes a registration system for export of toys, including: type-based certification, classification of products, requirements of sampling, inspection criteria, audit requirements for producers, content of certification, format and expiration date of certification.

One of the special features of these revised administrative measures is the classification of both products and manufacturers in five risk categories: Based on these categories the frequency of inspections shall be

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<sup>&</sup>lt;sup>34</sup> For a detailed description of the CCC system refer to chapter 4.





adjusted by all authorities involved. So far, none of these internal regulations for risk classification have been made available to the public.

As a follow-up on these administrative measures, AQSIQ issued the "work rules for supervision and inspection of import and export of toy products", containing a description of the work of supervision and inspection organizations, and management measures of the recall system.

## 5.3 The System in Europe

The system addressing safety of products intended for children is based on several legislations:

- The General Product Safety Directive GPSD 2001/95/EC
- The Toys Safety Directive 2009/48/EC <sup>35</sup>
- Other specific Directives (e.g. medical devices, machinery, low voltage, etc., see section 5.3.2)

A special situation applies to products belonging to the category <u>"sports, playground, and other recreational facilities"</u>, as they are only covered by the GPSD if made available to consumers in a direct way. Sports, playground and other recreational equipment made available to consumers through service providers is covered by national member state legislation only. Nevertheless they play an important role within the products intended for children <sup>36</sup>.

Toys within the scope of the Toys Safety Directive have to be affixed with the CE marking; for other products intended for children it depends on the Directive or Regulation applicable. Products intended for children within the Scope of the GPSD for which no other specific Directive or Regulations applies do not get the CE marking.

Other specific Directives which may apply for products intended for to children are:

•	Regulation 1223/2009	Cosmetic Products (replacing the Cosmetics Directive 76/768/EEC as
		from 11 July 2013)
•	Directive 94/62/EC	Packaging and Packaging Waste (amended by 2004/12/EC and 2005/20/EC)
•	Directive 1999/5/EC	Radio- and Telecommunications Terminal Equipment <sup>37</sup> (R&TTE)
•	Directive 2011/65/EC	Restriction of use of certain Hazardous Substances in Electrical and Elec-
		tronic Equipment (RoHS)
•	Directive 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)
•	Directive 2004/108/EC	Electromagnetic Compatibility (EMC)
•	Directive 2006/95/EC	Low Voltage (LVD)

<sup>35</sup> As a last part of the previous Directive on Safety of Toys 88/378/EC, annex II, Part III will be repealed with effect from 20 July 2013.

<sup>36</sup> CEN/TC 136 is addressing the safety requirements of this group of products, which include relevant standards such as the EN 15649 series for floating leisure articles for use on and in the water.

<sup>&</sup>lt;sup>37</sup> The R&TTE Directive does not apply to all radio-controlled equipment. There is a range of free frequencies for short distances and limited transmitting power. This may be different for each member state. Examples of equipment that does not need a permit: radio-controlled toys, wireless baby alarm, garage door opener, car alarm. Range is between 5 and maximum of 100 m.





•	Directive 2006/66/EC	Batteries and Accumulators and Waste Batteries and Accumulators
•	Regulation 1907/2006	REACH (e.g. rules for benzene, nickel, phtalates, azocolorants, cadmium)
•	Regulation 1935/2004	Materials and Articles intended to come into Contact with Food
•	Regulation 10/2011	Plastic Materials and Articles intended to come into Contact with Food
•	Regulation 1007/2011	Textile Fibre Names and related Labelling
•	Regulation 286/2012	amending Regulation on Textile Fibre Names and related Labelling

### **5.3.1** Toys Safety Directive

The revised Toys Safety Directive 2009/48/EC was the first Directive to be fully aligned with the New Legislative Framework; its details on how compliance can be achieved are outlined in the respective harmonised standards, namely the EN 71 series of standards for safety of toys and the EN 62115: 2005 standard for safety of electrical toys.

The Toys Safety Directive applies to toys defined as "products designed or intended, whether or not exclusively, <u>for use in play by children under 14 years of age</u>". Annex I of the Toys Safety Directive lists 19 product categories which are not considered "toys" in the meaning of the Directive, whilst Art 2 of the Directive lists 5 product categories for which the Toys Safety Directive does not apply:

- · Playground equipment intended for public use
- Automatic playing machines
- Toy vehicles equipped with combustion engines
- Toy steam engines
- Slings and catapults

The revised Toys Safety Directive introduces in particular more references to chemicals by limiting the amounts of certain chemicals that may be contained in materials used for toys:

- Chemicals that are susceptible to provoke cancer, change genetic information or harm reproduction, so-called CMR (Carcinogenic, Mutagenic or toxic for Reproduction) substances, are no longer allowed in accessible parts of toys;
- For certain substances like nickel the tolerable limit values have been reduced and those heavy
  metals which are particularly toxic, like lead or mercury, may no longer be used in toys, except
  nickel as component of stainless steel, which has proven to be safe;
- Allergenic fragrances are either completely forbidden, if they have a strong allergenic potential, or have to be labelled on the toy if they are potentially allergenic for some consumers.

The Directive requires all toys made available on the EU market to:

- Satisfy the essential safety requirements set out in Annex II of the Toys Safety Directive and any other NLF or New Approach Directives or Regulations that may be applicable to toys;
- Bear the CE marking as a declaration by the manufacturer or his authorised representative that the toy satisfies the essential safety requirements;
- Carry the name and address details of the person taking responsibility for the safety of the toy and any warnings (for example, in the case of toys not suitable for children under three) on the toy or on the packaging.





When placing their toys on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Article 10 and Annex II of the Toys Safety Directive:

- Manufacturers shall draw up the required technical documentation and carry out or have carried out the applicable conformity assessment procedures;
- Where compliance of a toy with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity and affix the CE marking;
- Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been made available on the market;
- Manufacturers shall 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.

Manufacturers 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 shall 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, manufacturers shall immediately inform the competent national authorities of the member states in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

The European Commission has issued a guidance document <sup>38</sup> which should help with the question whether a product is covered by the Toys Safety Directive, whilst CEN has published a guidance on toys which are intended for children under 36 months of age <sup>39</sup>.

#### 5.3.2 Standards for Products Intended for Children

There are about 50 standards in Europe related to products intended for children, some directly linked to such products, and some just referencing children's products. The majority of these standards are harmonised with the Toys Safety Directive, the GPSD Directive and other applicable legislation. Manufacturing products in compliance with these standards helps the producer and/or importer to reach presumption of conformity with the relevant Directive or Regulation. The most important standards are:

Directly related to the Toys Safety Directive 40

- EN 71 Series of standards Safety of toys
   Published: EN 71-1 to EN 71-11 plus amendments, under preparation EN 71-12 to EN 71-14
- EN 62115 (plus amendments) Safety of electrical toys

<sup>&</sup>lt;sup>38</sup> The document can be downloaded here: http://ec.europa.eu/enterprise/sectors/toys/files/tsd explanatory guidance document en.pdf

<sup>&</sup>lt;sup>39</sup> This document is referred to as CEN-CR 14379:2002 and can be obtained from any European standards body.

<sup>&</sup>lt;sup>40</sup> Although the revised Toys Safety Directive 2009/48/EC came into force on 20 July 2009, Article 2(1) and Part 3 of Annex II of the prior Toys Directive 88/378/EEC are repealed with effect from 20 July 2013 only. The harmonised European standards presently supporting Part 3 of Annex II (chemical properties) of Directive 88/378/EEC will probably lose their status of harmonised European standards, if not published as supporting the relevant requirements of the revised Directive 2009/48/EC before 20 July 2013.





Standards for products intended for children related to other Directives:

- EN 1929 series Basket trolleys
- EN 716 Children's cots
- EN 14899 Children's high chairs
- EN 1080 Helmets for children
- EN 14878 Nightwear for children
- EN 14682 Cords and drawstrings in children's clothing
- EN 1400 Soothers
- EN 14765 Bicycles
- EN 1273 Baby walking frames
- EN 13209 Baby carriers
- EN 13138 Buoyant aids for swimming instruction
- Under development: standards for safety of children's clothing

Other standards for products intended for children are referring to food testing for baby foods, portable luminaries, child-resistant packaging, and child care articles such as: harnesses, slings, bouncers, mounted seats, drinking equipment, cutlery, and sleeping bags. CEN published a guidance document (CEN/CLC Guide 14: 2009) on how to include child-related safety issues in standards.

The Expert Group on Toy Safety <sup>41</sup> published a series of *Guidance Documents* covering various aspects of the Toys Safety Directive; some of these are even translated into Chinese. These *Guidance Documents* are non-binding documents intended to help stakeholders on interpretation issues related to the Toys Safety Directive. These documents express the views of the majority of Members in the Expert Group on Toy Safety. The images appearing in the documents constitute examples intended to facilitate the decision-making on classification. They do not presuppose the conformity of the represented products.

# **5.3.3** Conformity Assessment for Toys

There are two legally required methods by which a manufacturer or his authorised representative can ensure that toys satisfy the essential safety requirements applicable to them. These are:

- Manufacture in conformity with the relevant European harmonised toy safety standards where these cover all relevant aspects of the safety of the toy and following the internal production control procedure of Module A of Annex II to Decision 768/2008/EC; or in case of non-existing of a relevant harmonised European standard, non-application of an existing Harmonised European standard, application in part of an existing harmonised European standard, publication of the harmonised European standard with a restriction or when the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party intervention;
- Manufacture in accordance with a model which has been submitted to a <u>notified body</u> for EC- type examination together with the conformity to type procedure set out in Module C of Annex II to Decision 768/2008/EC.

<sup>&</sup>lt;sup>41</sup> See http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index\_en.htm





Before placing a toy on the market, manufacturers shall carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

### **5.3.4** Technical Documentation for Toys

The technical documentation referred to in Article 4(2) of the Toys Safety Directive shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements set out in Article 10 and Annex II. It shall, in particular, contain the documents listed in Annex IV.

The technical documentation shall be drawn up in one of the official languages of the Community, subject to the requirement set out in Article 20(5). Following a reasoned request from the market surveillance authority of a member state, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that member state.

The technical documentation required by the Toys Directive (article 21) shall contain among other the following information:

- a detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers the safety assessment(s) carried out
- test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure
- copies of documents submitted to and certificates received from a notified body, if involved
- the addresses of the locations used for manufacture and storage of the product
- The manufacturer, or his authorized representative established in the European Community, is requested to keep copies of the technical documentation for a period of 10 years after the last product of its type has been placed on the market.

When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may fix a deadline for receipt of such file or translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

# **5.3.5** CE Marking of Toys

If the producer and/or importer have concluded the required testing, compiled the technical documentation, and is convinced that the product complies with the Toys Safety Directive and/or other relevant NLF or Global or New Approach Directives and Regulations, the CE marking must be affixed to the product, before it is placed on the market <sup>42</sup>.

The CE marking shall be affixed visibly, legibly and indelibly to the toy, to an affixed label or to the packaging. In the case of small toys and toys consisting of small parts, the CE marking may alternatively be affixed

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<sup>&</sup>lt;sup>42</sup> Regulation on CE marking (EU) 765/2008.





to a label or an accompanying leaflet. Where, in the case of toys sold in counter displays, that is not technically possible, and on condition that the counter display was originally used as packaging for the toy, the CE marking may be affixed to the counter display. Where the CE marking is not visible from outside the packaging, if any, it shall as a minimum be affixed to the packaging.

It is not allowed to CE mark products intended for children outside the scope of the Toys Safety Directive or any other Directive or Regulation under the NLF or New Approach requiring the CE marking <sup>43</sup>.

### 5.3.6 Requirements for Products Already on the Market

For the purposes of this Directive, and in particular of Article 6 thereof, the competent authorities of the Member States are entitled to take appropriate measures as follows:

- for any product to organise, even after it is being placed on the market as being safe:
  - o appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;
  - o to require all necessary information from the parties concerned;
  - o to take samples of products and subject them to safety checks;
- for any product that could pose risks in certain conditions:
  - to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the Member State in which the product is marketed, on the risks it may present;
  - o to make its marketing subject to prior conditions so as to make it safe;
- for any product that could pose risks for certain persons:
  - o to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;
- for any product that could be dangerous:
  - o for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply, the offer to supply it or its display;
- for any dangerous product:
  - o to ban its marketing and introduce the accompanying measures required to ensure the ban is complied with;
- for any dangerous product already on the market:
  - to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;
  - o to order or coordinate or, if appropriate, to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions.

#### 5.4 Conclusions

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Both China and Europe rely on the thorough system for conformity assessment of many products intended for children. Whilst this system is quite complete for toys, there are still major gaps in other product ranges

 $<sup>^{43}</sup>$  An example: the Regulation for textile fibre names of clothing intended for use on behalf of and/or to be used by children does not belong to the group of Directives/Regulations requiring affixing of the CE marking.





equally relevant for children. Major efforts are made both in China and in Europe to build a framework of standards covering all aspects of safety of products intended for children. However, in many cases these standards are not identical, thus imposing additional burdens on the manufacturers.

The knowledge of the manufacturers regarding the requirements in these standards is an essential element towards toy safety: Training of manufacturers on standards, and harmonization of standards themselves are key issues in addressing safety of products intended for children.

#### **5.4.1** Conclusions for China

Six product categories are covered by the CCC regulations on "toy products", including the majority of toys. For products intended for children outside of the CCC scope, it is the obligation of the manufacturer to comply with the applicable standards. This mix of imposed certification for a few categories and mostly self-control for all other product categories related to products intended for children may send the wrong signal about the real risks involved with the individual product. There seems to be no middle ground between these two extremes.

Standardisation in China may still need some upgrading regarding products intended for children other than toys and child carriers, with special focus on chemicals used in such products. Since not all areas are properly covered by international standards, it probably makes sense to adopt the respective European or US-based standards. Lack of standards in these areas will lead also to a lack of awareness both within the home market and also for manufacturers exporting to Europe.

## **5.4.2** Conclusions for Europe

Since the system of conformity assessment is mostly based on self-control and self-declaration by producers it is very important that Europe reaches out to manufacturers around the globe. Europe has to ensure that producers globally understand its requirements. This is especially important since several key standards relating to products intended for children are not yet harmonised globally.

The majority of non-toy products intended for children are covered by other sectoral or horizontal Directives, or in absence of these by the GPSD. Whilst many products considered especially sensitive have been addressed by harmonised standards, the system is quite complex and for non-European manufacturers difficult to understand. Thus, it seems to be especially important to create a common referencing system of globally accepted and harmonised standards.

#### 5.5 **Recommendations**

The following areas may be of specific interest for European and Chinese experts in safety of products intended for children, including toys:

• List of products intended for children in China: It would probably make sense to find a common agreement on the list of products intended for children in need of special attention: Based on such





list, individual solutions for upgrading quality structures may be found for each topic individually. This list has to be revised and updated on a regular basis;

- Common understanding between Europe and China when a product has to be considered a "toy", even if manufacturers label them differently. The definition in Europe of the intended age group is very different from the definition in China based on product categories;
- Strengthen international standardisation: Whilst a full global alignment for standards related to toy
  safety is currently not feasible, it should be possible to find such common ground for non-toy products intended for children. There are also opportunities to create new ISO standards replacing current European and nascent Chinese standards in this field;
- Make product conformity assessment (including testing in the appropriate cases) more international: The rules for conformity assessment bodies participating in the CCC scheme effectively exclude foreign bodies from the Chinese market; on the other hand, Chinese conformity assessment bodies have minimal recognition outside China. This leads to an unhealthy split of the third party product conformity assessment market in China: Third party product conformity assessment for the Chinese market is done by Chinese bodies, third party product conformity assessment for Chinese exports is done by foreign bodies. Whilst this system protects non-competitive Chinese bodies, it does not foster innovation. It is suggested to identify ways how to reform the third party product conformity assessment industry;
- Increase transparency and good governance of third party product conformity assessment: A unique feature of the Chinese system for conformity assessment is the lack of separation between role setting, their execution, and their verification. Legislation, standardisation, accreditation, conformity assessment, testing, inspection, are all under the same roof. Whilst such a system may simplify the organization of government, it does not lead to better servicing the industry. In fact the mix between these functions may inevitably lead to a self-serving system rather than a system supporting growth and innovation. It is suggested to discuss how to reform the structure of the conformity assessment system, using the strict separation in Europe as model;
- New chemical regulations for toys in Europe: There seems to be a need to train European trade
  partners such as China on the new chemical regulations for toys in Europe and its impact on both
  manufacturers and third party product conformity assessment facilities. There is a need to establish
  product conformity assessment bodies in China which enjoy full trust of European toy safety experts also regarding the new chemical requirements to be implemented in July 2013.





## 6 Comparison of the Systems for Textiles and Apparel

## 6.1 General Principles of the Systems for Textiles and Apparel

Textiles and apparel is one of the least regulated fields of consumer products – this despite the global interest in the sector and continued global trade disputes. In fact, the large majority of these disputes are about pricing and quantities and not related to technical matters. There is indeed no unified global technical approval system for production and/or import of textiles; governments both in China and in Europe seem to be rather liberal in admission practices, but strict in market surveillance activities.

One of the key features of the sector is the large amount of standards available both on international level, in Europe, and also in China. Europe has approximately 500 standards dealing with textiles, China probably over 2000 standards (!). This makes it often difficult to understand the full picture of requirements for specific products: It happens even to large multinational companies that they run afoul with safety regulations in Europe and in China, leading to seizure of large amounts of textiles and apparel.

The most stringent regulations are related to the use of chemicals in textiles and apparel, and in labelling of textiles and apparel for retail. A special feature of the textile sector is the relative importance of official and privately operated certification and labelling schemes, especially related to topics like chemical safety, environment, and corporate social responsibility (CSR). The most successful and widely used label is probably the private standard and mark "OEKO-Tex 100", owned by 15 testing houses mostly in Europe, this voluntary standard defines the acceptable amount of chemicals in textiles and apparel.

# 6.2 The System in China for Textiles and Apparel

According to the Law on Import and Export Commodity Inspection, import and export commodities which are listed in the Catalogue shall be inspected by inspection authorities. Commodities listed in the Catalogue must meet the compulsory requirements of applicable technical regulations and standards issued by the authorities in charge. The original Catalogue, issued in 2008, contained 1101 product types of textile and apparel. In 2012, AQSIQ added another 301 products to the list of textile and apparel. Local CIQ and local import & export bureaux are responsible for supervision and inspection of products listed in the Catalogue.

The key standards used for testing and inspection in China are GB 18401-2010 – general safety technical code for textile products and GB 5296.4-1998 – instructions for use of products of consumer interest / instructions for use of textiles and apparel. Textile and apparel placed on the Chinese market generally have to comply with the additional labelling regulations where applicable. FZ/T 01053-2007 "Textiles – Identification of Fibre Content" is such an additional regulation, although voluntary<sup>44</sup>.

# **6.2.1** Standards for Textiles and Apparel

The Standards Administration of China SAC published several hundreds of core national standards (GB) defining safety and products in the textile and apparel sector, many of these being compulsory. All other standards for textiles and apparel are industry standards issued by the standard bodies related to the asso-

<sup>&</sup>lt;sup>44</sup> Voluntary standards are indicated with the code "/T" added after the codes





ciations of the Chinese textile industry of the Chinese light industry. These industry standards are often referenced in the national compulsory GB standards, rendering them quasi-compulsory for any company seeking compliance with regulations.

National standards use the code "GB", whilst the code "FZ" is used for textile industry standards and the code "QB" for light industry standards, which includes standards for leather, fur and feather products. Voluntary standards are indicated with the code "/T" added after the codes.

Textile and apparel products put up for sale in China must comply with GB 18401-2010 "National General Safety Technical Code for Textile Products". GB 18401 contains the principal requirements, test methods, and test rules for textile products placed on the Chinese market. Mandatory tests under GB 18401 include:

- formaldehyde content;
- pH value;
- colour fastness to water, perspiration (acid & alkaline), rubbing;
- colour fastness to saliva on baby products;
- determination of odour;
- aromatic amine releasing azo dyes.

Textile and apparel products put up for sale in China must be labelled, as required by GB 5296.4 "Instruction for Use of Products of Consumer Interest – Instructions for Use of Textiles and Apparel". According to GB 5296.4, the following information must be included, with the first three items provided on a permanent label:

- Product Specification and Size Designation size designation for apparel in accordance with GB/T 1335.1 – 1335.3;
- Fibre Content/Component and Content of Material used in accordance with FZ/T 01053;
- Care Instruction/Washing Methods symbols specified in standard GB/T 8685, and certain words to explaining graphic symbols;
- Name and Address of the Manufacturer or in the case of imports, the registered name and address in China of the agent or importer or dealer and the country of origin;
- Product Name according to the national or industrial standards whenever possible;
- Product Standard Code relevant national, industry or enterprise standards for which the product was tested:
- Product Quality Classification based on requirements of relevant product standard;
- Product Quality Certificate Product quality certificate for each product (selling unit) manufactured in the domestic market

The industry standard FZ/T 01053-2007 "Textiles – Identification of Fibre Content" stipulates the label requirements of fibre content of textiles, marking principles, marking method, tolerance and judgment of consistency of identification, and provides examples of fibre content representation.

The national standard GB 20400-2006 "Leather and Fur – Limit of Harmful Matter" is a mandatory standard for leather and fur apparel and home furnishing products. Industrial use products are excluded. GB 20400-2006 includes mandatory tests on formaldehyde content and aromatic amine releasing azo dyes.





There are numerous product-specific industry sector standards, in addition to those mentioned above, for which compliance is in general mandatory.

In many cases the adoption of international testing standards (ISO standards) in China has been modified to the extent that when the results of testing against these Chinese standards are not compatible with the results of testing against the international standards. Since the transposed but non-equivalent Chinese standards are often compulsory, it is important that the manufacturer and importers are aware of the applicable Chinese testing requirements and safety limits.

## 6.2.2 Conformity Assessment of Textiles and Apparel

More than 100 testing laboratories have been approved by CNAS for the textile and apparel sector. Whilst there is no clear requirement for testing in a domestic lab, it seems that most Chinese manufacturers are using their services. Importers have in general their product tested overseas; however this may lead to complications since the Chinese standardisation environment is not so easy to understand, even for professional international testing bodies.

One single requirement makes out for the bulk of non-compliances with Chinese regulations: The obligation to test textiles and apparel for their formaldehyde content as outlined in the respective compulsory standards and the related Chinese testing standards. If there is no evidence that products have been tested according to these standards and proven to be free of formaldehyde, the respective products may be considered as potentially hazardous in China.

Products without proper evidence such as test reports or certificates, demonstrating that they meet the requirements of mandatory national GB standards and specified professional standards, or with unsatisfactory test results, may be rejected by China customs authorities.

# 6.2.3 Marking and Labelling of Textiles and Apparel

With the exception of certain safety equipment and home furnishing textiles, there isn't any certification or marking requirement for textile and apparel in China. Nevertheless, products found to be non-compliant can be taken off the shelf or stopped at customs. Labelling has to follow the respective standards for labelling of textiles in China, e.g. Chinese language has to be used on all labels on textiles for consumers.

Unlike Europe, there is currently no widely recognized voluntary Chinese eco-label for textiles. Covering this gap, several foreign labels have become popular in China; this also because overseas buyers are asking for such certification, generally operated by non-Chinese conformity assessment bodies.<sup>45</sup>.

# 6.3 The System in Europe

The safety of consumer-related textiles and apparel is in most cases regulated in the General Product Safety Directive GPSD, unless specific Directives or Regulations apply. On top of the safety provisions in these Di-

 $<sup>^{45}</sup>$  The Swiss testing institute TESTEX seems to hold a quasi-monopoly for testing of textiles according to their own privately held voluntary "Oeko-Tex 100" standard in China.





rectives and Regulations, textiles must comply with EU Regulation 1007/2011 on labelling and marking of fibre content.

The EU regulations on the labelling and marking of fibre content of textile and apparel products have been amended several times over the years. Eventually, in 2011 the EU adopted a new legal document that encompasses the previous amendments, Regulation 1007/2011. One of its new requirements is that labels disclose non-textile animal-derived materials (e.g. fur) included in a product. Various changes to the previous regulations were also included, such as those regarding the process for adding new fibres, exemptions of certain products from mandatory labelling requirements, as well as the addition of certain products subject to compulsory labelling.

### 6.3.1 Directives and Regulations Relevant for Textiles and Apparel

The following EU-regulations are affecting textiles and apparel for use by private consumers in Europe:

- Regulation 1007/2011 relating to textile fibre names and related labelling and marking of the fibre composition of textile products, amended by Regulation 286/2012
- Directive 2001/95/EC General Product Safety Directive (GPSD)
- Regulation 1907/2006 (REACH) applicable to chemicals in textiles
- Directive 93/42/EEC Medical Devices Directive (MDD), amended by Directives 98/79/EC, 2000/70/EC, 2001/104/EC and 2007/47/EC and Regulation (EC) No 1882/2003
- Directive 89/686/EEC Personal Protective Equipment (PPE)
- Directive 2009/48/EC Toys Safety Directive <sup>46</sup>

Other EU Directives and Regulations with have an impact on certain types of textiles and apparel:

- Geotextiles: Construction Products Regulation 305/2011/EU (CPR)
- Textile ropes and slings: Machinery Directive 2006/42/EC
- Textiles for use in the automotive industry partly based on UNECE-regulations: e.g. restraint systems (also especially for child restraint systems), airbags, fire resistance
- National member state regulations on fire resistance of textiles (not being construction products)

# **6.3.2** EU Regulation 1007/2011

In 2012, a new unified system for marketing and labelling of textiles was introduced in Europe: Regulation 1007/2011 "Textile fibre names and related labelling and marking of the fibre composition of textile products", amended just one year later by Regulation 286/2012. Products on the market before 9 May 2012 that are not in compliance with the new Regulation may be kept on the market until 9 November 2014. The new Regulation lays down provisions for:

- textile fibre names with regard to their definition and use when indicating the fibre composition of textile products;
- the labelling of textile products containing non-textile parts of animal origin;

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<sup>&</sup>lt;sup>46</sup> E.g. fancy clothes for children up to 14 years old.





methods of analysis to check information indicated on labels or markings.

Textile fibre: a unit of matter characterised by its flexibility, fineness and high ratio of length to maximum transverse dimension, which render it suitable for textile applications, or a flexible strip or tube, of which the apparent width does not exceed 5 mm, including strips cut from wider strips or films, produced from the substances used for the manufacture of the fibres listed in Table 2 of Annex I of the Directive

Textile product: any raw, semi-worked, worked, semi-manufactured, manufactured, semi-made-up or made-up product which is exclusively composed of textile fibres, regardless of the mixing or assembly process employed

The regulation concerns textile products, namely:

- Products containing at least 80 % by weight of textile fibres;
- Products treated in the same way as textile products.

The Regulation does not concern textile products contracted out to persons working in their own homes or to independent firms without property being transferred, or to textile products made up by self-employed tailors.

The description of fibre composition of textile products must use the textile fibres listed in Annex I to the Regulation. The Regulation states which names shall correspond to which type of fibre. The use of these names for other fibres is prohibited. Manufacturers may ask the European Commission to include a new textile fibre name in Annex I to the Regulation. A technical file must be submitted with their application, drawn up pursuant to Annex II and containing the following information:

- the proposed name, definition and identification for the new textile fibre;
- sufficiently developed identification and quantification methods;
- additional information concerning possible allergic reactions, the production process and consumer relevance.

Indication of the composition of textile products:

- The use of the terms "100 %", "pure", or "all" is limited to products composed of a single textile fibre;
- The terms "virgin wool" or "fleece wool" (and the terms listed in Annex III) may be used on labels provided the product is composed exclusively of a wool fibre which has not previously been incorporated in a finished product, and which has not been subjected to any spinning. If wool is contained in a mixture of textile fibres, the term "virgin wool" may appear on the labelling if:
  - all the wool is composed of a single wool fibre;
  - o such wool accounts for no less than 25 % of the total weight of the mixture;
  - the wool is mixed with only one other fibre in the case of a scribbled mixture;
- Textile products composed of several fibres must be labelled with the name and percentage by weight of all constituent fibres, in descending order;
- The term "other fibres" may be used if some minor fibres could not be stated at the time of manufacture of the product, or for fibres not listed in Annex I;





- The terms "mixed fibres" or "unspecified textile composition" may be used on a textile product the composition of which is hard to state at the time of manufacture.
- The presence of non-textile parts of animal origin in textile products must be indicated by the phrase "Contains non-textile parts of animal origin" on the labelling.

Finally, the Regulation includes a list of products for which labelling or marking is not mandatory and a list of products for which inclusive labelling is sufficient

### **6.3.3** Standards for Textiles and Apparel

CEN is responsible for standardisation in the textile sector, having published around 500 standards for textiles and apparel; these standards represent good practice in Europe. Market surveillance authorities in Europe will benchmark their findings with these standards.

Under the provisions of the General Product Safety Directive GPSD a series of harmonised European standards is being developed, addressing among others cords attached to or used with children cloths, and fire resistance of night gowns for children. It is expected that more harmonised European standards will be developed under the GPSD for textiles and apparel in future.

More European standards for textile and apparel are being developed in the following Technical Committees: CEN/TC 248 "Textile and Textile Products", CEN/TC 207 "Furniture" (e.g. EN 597-1/2 flammability of mattresses), CEN/TC 309 footwear, CEN/TC 289 "Leather".

## **6.3.4** Conformity Assessment Requirements

Market access for textiles and apparel is free, provided the manufacturer ensures that the product and its labelling are in compliance with Regulations 1007/2011 and 286/2012, the General Product Safety Directive GPSD, and/or any other Directive or Regulation affecting the product.

When placed on the market, textile products shall:

- Be marked in a durable, legible, visible and accessible way, to indicate the fibre content of each composition:
  - For products not intended for the final consumer, such labelling or marking may be replaced with accompanying commercial documents. They shall then be provided by the product manufacturer;
  - Any textile product containing two or more textile components which have different textile fibre contents shall bear a label or marking stating the textile fibre content of each component;
- Labelling must not include abbreviations and must be offered in one or more of the official languages of the member state in which the product is placed on the market;

Descriptions of textile fibre composition must also appear in product related catalogues, trade literature, and on the packaging. Such information must be visible for online purchases.





The Regulation includes in Annex VIII a detailed description of testing methodology to be used for testing of textiles and fibres.

### 6.3.5 Voluntary Marking and Labelling for Textiles and Apparel

In 2009 the EU introduced the European Eco-label for Textiles, the so-called "Flower Label". The EU Eco-label is a voluntary label for selected consumer products promoting environmental excellence which can be trusted. The label is based on a life-cycle approach and can be awarded to all kind of textile clothing and accessories, interior textiles and fibres, yarn and fabric.

Whilst the Flower Label is relatively new, there are many other private based voluntary labels on the European market. Some of the most commonly used labels are:

- The SA 8000 standard and covering issues related to corporate social responsibility CSR. Whilst this
  certification is quite popular within the industry, it has little exposure to consumers
- The OEKO-Tex 100 standard, offered in Europe and Japan by 15 private conformity assessment bodies, and international through the two institutes Hohenstein in Germany and Testex in Switzerland.

#### 6.4 Conclusions and Recommendations

Due to the great variety of textiles placed on the market it is difficult to make universal recommendations: Nevertheless, for the textiles and apparel sector we would suggest that European and Chinese experts may elaborate following areas:

- Accelerated global harmonization of standards: The differences between standards in Europe and China are often more a legacy than based on cultural differences. Thus, an accelerated harmonization of standards on ISO level seems to be the obvious way forward. This would greatly support the industry both financially and in their efforts to be in compliance
- Chemicals in apparel: Based on existing labels and certification schemes it should be possible to agree on a common set of chemicals and their limitations. All future revisions of Chinese and European standards should then include references to this list of chemicals and abandon differences
- Voluntary labels: It would probably make sense to agree on a framework of credible voluntary labels applicable both in Europe and China covering aspects such as fair trade, corporate social responsibility, child protection, free of hazardous chemicals, ecologically sound production, etc.

Beijing, 3 April 2013

Klaus Ziegler, with support of Robert Huigen and Yao Xiaojing





### **ANNEX**

# A1: Standards Harmonized under the GPSD

### Table 4: Harmonized standards supporting the GPSD

Body	Title
CEN	EN 581-1:2006 Outdoor furniture — Seating and tables for camping, domestic and contract use — Part 1: General safety requirements
CEN	EN 913:1996 Gymnastic equipment — General safety requirements and test methods
CEN	EN 916:2003 Gymnastic equipment — Vaulting boxes — Requirements and test methods including safety requirements and test methods
CEN	EN 957-1:2005 Stationary training equipment — Part 1: General safety requirements and test methods
CEN	EN 957-2:2003 Stationary training equipment — Part 2: Strength training equipment, additional specific safety
CEN	EN 957-4:1996 Stationary training equipment — Part 4: Strength training benches, additional specific safety requirements and test methods
CEN	EN 957-5:1996 Stationary training equipment — Part 5: Pedal crank training equipment, additional specific safety requirements and test methods
CEN	EN 957-6:2001 Stationary training equipment — Part 6: Treadmills, additional specific safety requirements and test methods
CEN	EN 957-7:1998 Stationary training equipment — Part 7: Rowing machines, additional specific safety requirements and test methods
CEN	EN 957-8:1998 Stationary training equipment — Part 8: Steppers, stair climbers and climbers — Additional specific safety requirements and test methods
CEN	EN 957-9:2003 Stationary training equipment — Part 9: Elliptical trainers, additional specific safety requirements and test methods
CEN	EN 957-10:2005 Stationary training equipment — Part 10: Exercise bicycles with a fixed wheel or without freewheel, additional specific safety requirements and test methods
CEN	EN 1129-1:1995 Furniture — Foldaway beds — Safety requirements and testing — Part 1: Safety requirements
CEN	EN 1129-2:1995 Furniture — Foldaway beds — Safety requirements and testing — Part 2: Test methods
CEN	EN 1130-1:1996 Furniture — Cribs and cradles for domestic use — Part 1: Safety requirements





CEN	EN 1130-2:1996 Furniture — Cribs and cradles for domestic use — Part 2: Test methods
CEN	EN 1273:2005 Child use and care articles — Baby walking frames — Safety requirements and test methods
CEN	EN 1400-1:2002 Child use and care articles — Soothers for babies and young children — Part 1: General safety requirements and product information
CEN	EN 1400-2:2002 Child use and care articles — Soothers for babies and young children — Part 2: Mechanical requirements and tests
CEN	EN 1400-3:2002 Child use and care articles — Soothers for babies and young children — Part 3: Chemical requirements and tests
CEN	EN 1466:2004 Child care articles — Carry cots and stands — Safety requirements and test methods
CEN	EN 1651:1999 Paragliding equipment — Harnesses — Safety requirements and strength tests
CEN	EN 1860-1:2003 Appliances, solid fuels and firelighters for barbecuing — Part 1: Barbecues burning solid fuels — Requirements and test methods
CEN	EN ISO 9994:2006 Lighters — Safety specification (ISO 9994:2005)
CEN	EN 12196:2003 Gymnastic equipment — Horses and bucks — Functional and safety requirements, test methods
CEN	EN 12197:1997 Gymnastic equipment — Horizontal bars — Safety requirements and test methods
CEN	EN 12346:1998 Gymnastic equipment — Wall bars, lattice ladders and climbing frames — Safety requirements and test methods
CEN	EN 12432:1998 Gymnastic equipment — Balancing beams — Functional and safety requirements, test methods
CEN	EN 12491:2001 Paragliding equipment — Emergency parachutes — Safety requirements and test methods
CEN	EN 12586:1999 Child care articles — Soother holder — Safety requirements and test methods
CEN	EN 12586:1999/AC:2002
CEN	EN 12655:1998 Gymnastic equipment — Hanging rings — Functional and safety requirements, test methods
CEN	EN 13138-2:2002 Buoyant aids for swimming instruction — Part 2: Safety requirements and test methods for buoyant aids to be held
CEN	EN 13209-1:2004 Child use and care articles — Baby carriers — Safety requirements and test methods — Part 1: Framed back carriers
CEN	EN 13319:2000 Diving accessories — Depth gauges and combined depth and time measuring devices — Functional and safety requirements, test methods
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CEN	EN 13899:2003 Roller sports equipment — Roller skates — Safety requirements and test methods
CEN	EN 14059:2002 Decorative oil lamps — Safety requirements and test methods
CEN	EN 14344:2004 Child use and care articles — Child seats for cycles — Safety requirements and test methods
CEN	EN 14350-1:2004 Child use and care articles — Drinking equipment — Part 1: General and mechanical requirements and tests
CEN	EN 14682:2007 Safety of children's clothing — Cords and drawstrings on children's clothing — Specifications
CEN	EN 14764:2005 City and trekking bicycles — Safety requirements and test methods
CEN	EN 14766:2005 Mountain-bicycles — Safety requirements and test methods
CEN	EN 14781:2005 Racing bicycles — Safety requirements and test methods
CEN	EN 14872:2006 Bicycles — Accessories for bicycles — Luggage carriers
CEN	EN 16156:2010 — Cigarettes - Assessment of the ignition propensity - Safety requirements
CENELEC	EN 60065:2002/A12:2011 — Audio, video and similar electronic apparatus — Safety requirements
CENELEC	EN 60950-1:2006/A12:2011 — Information technology equipment — Safety — Part 1: General requirements





# A2: List of Standards related to the Compulsory Energy Label in China

Table 5: Standards for Compulsory Energy Label in China

Standard	Title
GB 28380-2012	Minimum allowable values of energy efficiency and energy grades for microcomputers
GB 26969-2011	Minimum allowable values of energy efficiency and energy efficiency grades for domestic solar water heating systems
GB 12021.2-2008	The maximum allowable values of the energy consumption and energy efficiency grade for household refrigerators
GB 12021.3-2010	The minimum allowable value of the energy efficiency and energy efficiency grades for room air conditioners
GB 12021.6-2008	Minimum allowable values of energy efficiency and energy efficiency grades for automatic electric rice cookers
GB 12021.9-2008	Minimum allowable values of energy efficiency and energy efficiency grades of AC electric fans
GB 18613-2012	Minimum allowable values of energy efficiency and energy efficiency grades for small and medium three-phase asynchronous motors
GB 19044-2003	Limited values of energy efficiency and rating criteria of self-ballasted fluorescent lamps for general lighting service
GB 19153-2009	Minimum allowable values of energy efficiency and energy efficiency grades for displacement air compressors
GB 19576-2004	The minimum allowable values of the energy efficiency and energy efficiency grades for unitary air conditioners
GB 19577-2004	The minimum allowable values of the energy efficiency and energy efficiency grades for water chillers
GB 19761-2009	Minimum allowable values of energy efficiency and energy efficiency grades for fan
GB 20665-2006	Minimum allowable values of energy efficiency and energy efficiency grades for domestic gas instantaneous water heater and gas fired heating and hot water combi-boilers
GB 21454-2008	The minimum allowable values of the IPLV and energy efficiency grades for multi-connected air-condition (heat pump)unit
GB 21455-2008	The minimum allowable values of the energy efficiency and energy efficiency grades for variable speed room air conditioners
GB 21456-2008	The minimum allowable values of the energy efficiency and energy efficiency grades for household induction cookers
GB 21518-2008	Minimum allowable values of energy efficiency and energy efficiency grades for AC contactors
GB 21519-2008	Minimum allowable values of energy efficiency and energy efficiency grades for electrical storage water heaters
GB 21520-2008	Minimum allowable values of energy efficiency and energy efficiency grades for computer monitors
GB 21521-2008	Minimum allowable values of energy efficiency and energy efficiency grades for copy machine
GB 24849-2010	Minimum allowable values of energy efficiency and energy efficiency grades for household and similar microwave ovens





GB 24850-2010	Minimum allowable values of energy efficiency and energy efficiency grades for flat panel televisions
GB 24956-2010	Minimum allowable values of energy efficiency and energy grade for printers and fax machines
GB 25957-2010	Minimum allowable values of energy efficiency and energy efficiency grades for digital television adapters(set-top boxes)
GB 26920.1-2011	Minimum allowable values of energy efficiency and energy efficiency grades of commercial refrigerating appliances—Part 1:Refrigerated display cabinets with remote condensing unit
GB 24790-2009	Minimum allowable values of energy efficiency and energy efficiency grades of power transformer





### A3: Conformity Assessment Requirements of Toys

#### Internal production control plus supervised product testing of Toys (Module A1)

1. Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

#### 2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the Harmonised Standards and/or other relevant technical specifications the references of
  which have been published in the Official Journal of the European Union, applied in full or in part,
  and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those Harmonised Standards have not been applied. In the event of partly applied
  Harmonised Standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

#### 3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

#### 4. Product checks

For each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument. At the choice of the manufacturer, the tests are carried out either by an accredited in-house body or under the responsibility of a notified body chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

- 5. Conformity marking and declaration of conformity
  - 5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument.
  - 5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10





years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorized representative

The manufacturer's obligations set out in point 5 may be fulfilled by his authorized representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### EC-type examination of Toys

- 1. An application for EC-type examination, performance of that examination and issue of the EC-type examination certificate shall be carried out in accordance with the procedures set out in Module B of Annex II to Decision No 768/2008/EC (Module B is given below). EC-type examination shall be carried out in the manner specified in the second indent of point 2 of that Module. In addition to those provisions, the requirements laid down in paragraphs 2 to 5 of this Article shall apply.
- 2. The application for an EC-type examination shall include a description of the toy and an indication of the place of manufacture, including the address.
- 3. When a conformity assessment body notified <sup>47</sup> under Article 22 (hereinafter referred to as a 'notified body') carries out the EC-type examination, it shall evaluate, if necessary together with the manufacturer, the analysis of the hazards that the toy may present carried out by the manufacturer in accordance with Article 18.
- 4. The EC-type examination certificate shall include a reference to this Directive, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference to the relevant test report.
  - The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.
  - The EC-type examination certificate shall be withdrawn if the toy fails to comply with the requirements set out in Article 10 and Annex II.
  - Member States shall ensure that their notified bodies do not grant an EC-type examination certificate for a toy in respect of which a certificate has been refused or withdrawn.
- 5. The technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

#### EC-type examination according to Module B

- 1. EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it.
- 2. EC-type examination may be carried out in either of the following manners:
  - examination of a specimen, representative of the production envisaged, of the complete product (production type),

<sup>47</sup> See http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir\_id=140521





- assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimen(s), representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type),
- assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).
- 3. The manufacturer shall lodge an application for EC-type examination with a single notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the following elements:
- · a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the Harmonised Standards and/or other relevant technical specifications the references of
  which have been published in the Official Journal of the European Union, applied in full or in part,
  and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those Harmonised Standards have not been applied. In the event of partly applied
  Harmonised Standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports,
- the specimen(s), representative of the production envisaged. The notified body may request further specimen(s) if needed for carrying out the test programme,
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant Harmonised Standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
- 4. The notified body shall:

For the product:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

For the specimen(s):





- 4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant Harmonised Standards and/or technical specifications, these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;
- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
- 5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
- 6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.
  - The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.
  - Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.
- 7. The notified body shall keep itself abreast of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
  - The manufacturer shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate.
- 8. Each notified body shall inform its notifying authorities concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.
  - Each notified body shall inform the other notified bodies concerning the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.
  - The Commission, the member states and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the member states may obtain a copy of the technical documentation and the results of the examinations





carried out by the notified body. The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

- 9. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.
- 10. The manufacturer's authorized representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.





### **A4: REACH Regulations for Chemical Substances**

REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances. The law entered into force on 1 June 2007.

The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. At the same time, REACH aims to enhance innovation and competitiveness of the EU chemicals industry. The benefits of the REACH system will come gradually, as more and more substances are phased into REACH.

The REACH Regulation places greater responsibility on industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database run by the <u>European Chemicals Agency (ECHA)</u> in Helsinki. The Agency acts as the central point in the REACH system: it manages the databases necessary to operate the system, co-ordinates the in-depth evaluation of suspicious chemicals and is building up a public database in which consumers and professionals can find hazard information.

The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified. For more information read: REACH in Brief.

One of the main reasons for developing and adopting the REACH Regulation was that a large number of substances have been manufactured and placed on the market in Europe for many years, sometimes in very high amounts, and yet there is insufficient information on the hazards that they pose to human health and the environment. There is a need to fill these information gaps to ensure that industry is able to assess hazards and risks of the substances, and to identify and implement the risk management measures to protect humans and the environment.

REACH provisions are being phased-in over 11 years. Companies can find explanations of REACH on the <u>ECHA website</u>, in particular in the <u>guidance documents</u>, and can contact national <u>helpdesks</u>.





# **List of Tables**

Table 1: Abbreviations	7
Table 2: CCC Regulations and Standards	34
Table 3: List of Implementing Measures (Website DG Enterprise & Industry January 2013)	44
Table 4: Harmonized standards supporting the GPSD	68
Table 5: Standards for Compulsory Energy Label in China	71





