SPEAC

Safe non-food consumer Products in the EU and China

EU-CHINA

A SPEAC Study

EU Perspectives of Consumer Product Safety

Document control

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Executive summary

This report summarises aspects of the EU's consumer product safety, consumer protection and market surveillance arrangements. These arrangements are complex and consist of many elements, delivered at the EU level and the EU Member State level for the arrangements overall to be a success.

The arrangements can be thought of as an integrated system, all parts of which have to function in order for the system overall to work. Part of the complexity arises from the fact that the system is seeking to achieve more than one objective. In other words, it is not simply about protecting European consumers from dangerous products, it is also about facilitating the free movement of goods within the single market. Many of the requirements in EU consumer product safety legislation exist to facilitate the operation of the single market.

For the arrangements to work effectively across the 27 Member Countries of the EU, there is a shared responsibility between the EU and the individual Member Countries themselves. Put very simply, the legal framework and high-level policy is created at the EU level. Activities and services which interface more directly with consumers and businesses are delivered at the Member State level.

Inevitably, this doesn't quite hold true in all cases, and there would be examples of law making and policy development at Member State level and services being delivered at the EU level, but it is nevertheless, a useful way of thinking about the relationship.

EU responsibilities relating to the operation of the single market and consumer protection derive from several treaties. The European Single Market, originally known as the Common Market, has its foundations in the former European Economic Community (EEC) which was established by the Treaty of Rome in 1957. The first significant change to the original treaty was in 1986, with the Single European Act (SEA). In 1992, the European Union was formed, encompassing the former EEC. In relation to consumer protection, EU accountabilities are enshrined in Articles 4(2), 12, and 169 of the Treaty on the functioning of the EU Market and Articles 38 of the Charter of Fundamental Rights of the EU.

The EU has several law-making tools at its disposal, and these are more fully described in the report itself. Many, (but not all) of the requirements relating to the single market and consumer product safety are in the form of Directives.

Directives must be enacted into law in each Member State. A Directive sets out goals that each Member State must achieve. However, it is up to each Member State to create administrative arrangements that achieves those goals.

The intention is that there are consistent outcomes, including levels of safety that EU consumers are entitled to expect, but that the actual administration of for example market surveillance and consumer protection services will vary across the EU.

As a result of this, there are several coordination arrangements between the individual market surveillance and consumer protection bodies to ensure that the overall objectives set out in the Directives are indeed met and that there is consistency of outcomes and sharing of best practice.

A key Directive is the General Product Safety Directive (GPSD). The GPSD requires that only safe consumer products are placed on the European market. Some key product groups such as toys, electrical appliances and personal protective equipment are covered by their own specific legislation. These pieces of legislation provide further guidance as to what can be considered safe and take precedence over the GPSD in respect

of the hazards they describe explicitly.

In summary, if there is a specific piece of legislation relating to a product type, the product must comply with that legislation and any others that may be applicable. The legislation will however only identify 'essential requirements' that the product must comply with. Anything else relating to the product's design is up to the manufacturer.

The essential requirements are set out in general terms, but often further clarification is available in 'Harmonised Standards' or other standards referenced in the OJ EU and thus providing presumption of safety/conformity. Standards developed by the European standards bodies play an important role in the regulation of consumer safety in Europe.

The major aspects of the system are:

- EC legislation with essential requirements
- Harmonised Standards & Presumption of Conformity
- Conformity Assessment Procedures
- Declaration of Conformity – CE Marking
- Quality Assurance
- Conformity Assessment Bodies - Notified Bodies
- Accreditation Bodies
- Consumer Protection
- Market Surveillance
- European and International Co-operation

Primary responsibility for ensuring compliance with the legal requirements is with manufacturers and those who import products into the EU. This is particularly important as once products are imported into Europe (and marked with the conformity mark – the CE mark, where this is required), the products largely enjoy free circulation between the Member Countries without further checking by public authorities at the Member State borders. The single market is larger than the EU as it also includes the 3 EEA Countries and Switzerland.

The market surveillance authorities in the Member States will undertake routine checks and sampling at various points in the chain of distribution and can act if they find something wrong, but the basic principle of free movement remains. There is no pre-market inspection or certification required for most consumer products. This contrasts with the situation in many European countries before the establishment of the single market.

With the open borders that now exist between countries within the European Union it is important that national market surveillance authorities' co-ordinate their activities at the European level. There is a need to recognise that their actions have consequences far beyond their own national boundaries.

The Commission operates the system for the rapid exchange of information on dangerous non-food products (Safety Gate/RAPEX). The European Commission also funds and coordinates testing activities on the safety of products (CASP). Other forms of cooperation and cooperation exist between Member States and the Commission such as the Consumer Safety Network

We live in a period of change, where patterns of trade are also changing. As trade continues to move online – bypassing many of the traditional trading arrangements – it will be even more critical that

compliance moves further upstream to places of manufacture if European consumers are to continue to receive adequate protection.

Abbreviations

ANEC	European Association coordinating consumer standardisation representation
AQSIQ	China General Administration of Quality Supervision
B2B	Business to business (sales)
B2C	Business to consumer (sales)
BEUC	European consumer organisation
CE	Conformité Européene/ European Conformity
CEN	European Committee for Standardization
CENELEC	European Committee for Electro-technical Standardisation
CNIS	China National Institute of Standardisation
EA	European Cooperation for Accreditation
EC	European Commission
EEA	European Economic Area (EU plus Iceland, Liechtenstein and Norway)
EN	European Standard
EU	European Union
GPSD	General product Safety Directive (2001/95/EC)
IAF	International Accreditation Forum
ISO	International Standardization Organization
MOU	Memorandum of Understanding
MS	Market Surveillance
MSA	Market Surveillance Authority
NGO	Non-Governmental Organisation
NLF	New Legislative Framework
NQI	National Quality infrastructure
RAPEX	The rapid alert system for dangerous non-food products - "Safety Gate"
QI	Quality Infrastructure
SME	Small and Medium Enterprises

1. An overview of the legal framework in the EU

The European Union is an international organisation made up of 27 Member States and around 450 million people. Among other things, it is the largest tariff free trade area in the world.

The EU has a decision-making structure, the main permanent institutions being:

- the European Council, which provides the political direction of the EU
- the European Commission which proposes the legislation and oversees the functioning of the EU
- the Council and the European Parliament which together make the rules
- the Court of Justice of the EU

The laws which apply in the Member States are made at the European level by these institutions. To ensure consistency, laws made by the institutions override national laws.

EU rule making primarily comes in the form of 'Regulations' and 'Directives' although other types exist. These are legally binding on Member States. However, Regulations effectively become laws in each Member State when they are passed. For a Directive to become a law, a Member State must pass its own law making it so.

A Directive says what outcomes need to be achieved – each Member State then passes its own law to set up the administrative arrangements for achieving that outcome. This means that all Member Countries will share the same objectives but may create different organisations and arrangements for achieving those objectives.

A summary of the different types of EU law is set out in annex 1.

The EU has wide-ranging law-making powers. Single market rules require the free movement from one EU Member State to another of goods, people, services and capital.

In relation to rules which address consumer product safety matters, the rules directly address both:

a. The safety issues which need to be addressed by those putting products onto the market;
b. The issues which help facilitate the single market and give the different Member Countries the confidence that products made (or imported) in one part of the EU can be safely traded in another part of the EU without the need for further checks.

In addition, the rules indirectly support fair trade and competition between businesses by ensuring all follow the same requirements and those supplying unsafe products cannot gain an unfair competitive advantage against those who do.

The requirements relating to consumer product safety are applicable across the wider European Economic area (EEA) and not just the EU. The EEA includes EU countries and Iceland, Liechtenstein and Norway. Switzerland is not an EU or EEA member but is part of the single market.

The detailed rules relating to the operation of the single market have changed over the years and is still developing. One of the challenges for manufacturers and importers seeking to bring consumer products into the European market is keeping up to date with an evolving framework.

2. Core Aspects of the EU's product Safety requirements

The previous section set out the broad approach to law making and put the development of consumer product safety requirements into that context. The requirements have evolved over the years as a result of:

- Ongoing work to complete the internal market in products and services, i.e. continuing to reduce and remove technical barriers that inhibit consumer products from moving freely between EU Member States.
- A changing emphasis on the technical requirements which need to be controlled with a greater focus on only regulating where necessary and focusing on 'essential requirements'.
- Increasing expectations on the part of consumers as to what levels of safety are regarded as acceptable.
- New and emerging products and technologies which may present new risks to consumers.

Development of the EU's approach to product safety

The overall approach to consumer product safety is a mixture of a legal framework, supported by voluntary standards and delivered through the application of 'quality infrastructure' principles by those in the business community. Compliance/safety is supervised by market surveillance authorities, but it is emphasised that the primary responsibility lies with the business community rather than with the public sector or the state.

The evolution of the system overall has seen an increased move away from legal requirements attempting to cover all aspects of a product's design to a focus on only those aspects of a product which can be regarded as essential to its safety to consumers. There have been several steps along the way including some very recent developments.

The old approach and the new approach

The old approach to law making very much reflected the traditional way that technical legislation was drawn up. Typically, such legislation would be highly prescriptive in relation to how particular products should be made and marketed, but often lacked the flexibility to deal with safety concerns posed by novel products. This approach:

- Inhibited trade between European neighbours. Each State may address similar concerns (e.g. toy safety), but the detailed laws might impose different technical requirements. This would create trading barriers as all products would need to be checked for compliance with the rules in an individual EU Member State.
- Left gaps in the safety of consumer products as new products may be completely unregulated. Legislation was inevitably behind the latest developments

A good deal of bureaucracy was typically associated with this approach with public authorities granting permissions, licences or issuing certificates of conformity themselves before products could be traded.

Gradually, this approach was burdensome to businesses, it inhibited trade between Member States while at the same time, potentially not offer adequate safety protection for consumers.

Since 1983, there have been a sequence of legislative changes which sought to address these issues. These evolved through a process of 'mutual recognition' to the development of the concept of regulating only in relation to those safety aspects regarded as 'essential'. This latter concept emerged from a landmark case[1] which created the subsequent basis for what became known as the 'new approach' to EU legislation.

In 1985, the 'new approach' was adopted which restricted the content of legislation to 'essential requirements', leaving the technical detail to European harmonised standards. Following the case referred to above, the following principles formed the basis of the new approach:

a. Legislative harmonisation should be limited to 'essential requirements' which are written in general terms;
b. The detail for products meeting the essential requirements would be laid down in harmonised standards which could be applied alongside the legislation;
c. Products manufactured in compliance with harmonised standards would be presumed to conform with the relevant essential requirements;
d. The manufacturer may benefit from a simplified conformity assessment procedure: in many instances the manufacturer's declaration of conformity will be sufficient;
e. The application of harmonised standards remains voluntary, and the manufacturer can meet the essential requirements by other means. However, such an approach would not benefit from the automatic presumption of conformity;
f. Products which meet the essential safety requirements of the relevant pieces of legislation need to display the CE marking.

The relationship between the development of essential requirements, harmonised standards and conformity assessment procedures is at the heart of the new approach and facilitates trust between Member States. It enables products to move freely between Member States, providing protection for consumers while minimising subsequent checking of products by public authorities once placed on the market.

It should be noted that the 'Old Approach' is nevertheless still used in some areas of EU technical legislation such as cars, food and cosmetics.

The pieces of legislation which are together known as the "new approach" are listed as annex 2. They cover issues relevant to this project such as toys, electrical goods and personal protective equipment.

General Product Safety Directive

Sitting alongside the specific legislation referred to above is the General Product Safety Directive (GPSD)[2]. The GPSD introduced the principle of the "general product safety obligation" and applies to all consumer products to the extent that an aspect of their safety is not regulated by other EU sector-specific safety requirements.

The main requirement is that producers or distributors must only place safe products on the market. In general, the GPSD applies in a complementary way to products and/or risks covered by sector-specific

[1] Cassis de Dijon case
[2] 2001/95/EC

product safety legislation described above.

The GPSD itself defines what constitutes a 'safe product' which is broadly a product presenting no or only a minimum risk to consumers. The full definition is in the Directive.

It is the manufacturer or importers responsibility (referred to as the 'producer' in the GPSD) to place only safe products on the market. Producers need to provide consumers with any relevant information regarding risks inherent in the product.

If producers or distributors become aware that a product is dangerous, they must inform national authorities and cooperate with them.

It is the GPSD which established RAPEX (Rapid Exchange of Information System): this is a communication tool between market surveillance authorities and the European Commission. It enables information to be circulated relating to risks identified in products and action taken by the market surveillance authorities. The European Commission publishes on the internet overviews of dangerous products and the measures taken to eliminate the risks.

The GPSD is worded in such a way that it is flexible to address risks inherent in the development of novel products and a changing market. However, it does present challenges for producers in that it does not create the absolute certainty which would be found in highly detailed technical regulations. Producers always need to keep in mind the fundamental obligation of only putting 'safe' products onto the market.

To comply with the GPSD, a manufacturer needs to undertake and document an assessment that covers the risks and risk categories associated with the product. The recommended method of undertaking such an assessment is through the application of voluntary European Standards.

The list of referenced standards, which form part of the 'Official Journal' can be viewed on the European Commission's website. Details of applicable referenced standards are available online[3]. As of October 2019, around 120 such standards have been made by the European Standards bodies under the GPSD. These standards cover a range of consumer goods, from furniture to bicycles, from cigarette lighters to gymnastic equipment.

Finally, in emergencies, the European Commission can adopt a temporary decision requiring:

- A ban on the marketing of the product
- A recall of it from consumers
- The withdrawal of it from the market altogether

The role of standards and essential requirements

The relationship between standardisation and legislation within the EU is at the heart of the 'new approach'. The following summarises the relationship between standards and legislation:

- The EU adopts legislation that defines the essential requirements - in relation to safety and other important matters - which should be satisfied by products being sold;
- The European Commission issues standardisation requests to the European Standardisation Organizations (CEN, CENELEC and ETSI), which are responsible for preparing technical standards

[3] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

and specifications that facilitate compliance with these essential requirements;

- Public authorities must recognize that all products manufactured in accordance with harmonised standards are presumed to conform to the essential requirements;
- European Standards remain voluntary and there is no legal obligation to apply them. Any producer who chooses not to follow a harmonised standard is obliged to prove that their products nevertheless conform to the essential requirements;

There is a benefit to business therefore from making use of harmonised standards. They benefit from a 'presumption of conformity' with the essential requirements set out in the relevant piece of legislation.

New Legislative Framework (NLF)

Towards the end of the 1990s, the European Commission reviewed the new approach legislation and considered there was a strong case for an update to the approach. Ultimately, this led to revised requirements, together known as the 'New legislative framework'.

Whereas the new approach legislation described above predominantly develop the technical requirements for products, the New legislative framework concerns the operation of the system as a whole and deals with issues such as conformity assessment, accreditation and market surveillance.

The legal basis was set out in the following:

- **Regulation (EC) No 765/2008 (amended in 2019 by Regulation 2019/1020, see below)** sets out requirements for accreditation and market surveillance relating to the marketing of products
- **Decision No 768/2008/EC** creates a common framework for the marketing of products
- **Regulation (EC) No 764/2008** develops procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and

The objective of the NLF was therefore to:

- Improve market surveillance rules,
- Boost the quality of (and hence confidence in) the conformity assessment of products through stronger clearer rules on the requirements for the notification of conformity assessment bodies (testing, certification and inspection laboratories) including the increased use of accreditation;
- Clarify the meaning of CE marking

Further Developments

In June 2019, a new Regulation[4] was adopted and published in the Official Journal of the EU. Known as the Market Surveillance Regulation, this regulation is part of the 'Goods Package' and contains important provisions of relevance to Chinese manufacturers and other stakeholders in China. The Goods Package also contained proposals for a regulation on the mutual recognition of goods lawfully marketed in another EU Member State (Mutual Recognition Regulation), that it was also approved and published in the Official Journal of the EU.

[4] Regulation (EU) 2019/1020

Both regulations share the objective of reinforcing trust in the EU single market by ensuring compliance with and enforcement of product legislation while also improving and facilitating the mutual recognition of goods. Product compliance with non-food consumer products legislation will be enhanced through:

- The creation of rules and procedures for businesses
- Enhanced market surveillance of products covered by EU harmonisation legislation and,
- The creation of a framework of EU border controls

The most significant changes arising from the new requirements will be noticed in relation to online sales and this is described in further detail later in this report in the sub-section entitled 'E-commerce'

In addition, the Market Surveillance Regulation places new obligations on those involved in the chain of distribution and these are described in the sub-section below entitled 'Obligations arising from the Market Surveillance Regulation'

The Regulation itself sets out the scope of its application and lists the EU legislation to which it applies. This is the legislation referred to as 'harmonisation legislation' referred to above and includes priority sector products for the SPEAC project such as toys and electrical equipment.

The new provisions of the Market Surveillance Regulation apply from July 16, 2021, although some provisions relating to cooperation between Member States' market surveillance authorities and the European Commission will apply from January 1, 2021.

Conformity assessment

Conformity assessment is an important element in the overall approach to the free circulation within the EU. It is undertaken for products for which there is sector legislation and is the process carried out by a manufacturer to demonstrate that specific requirements relating to a product have in fact been achieved. Products which do not have their own sector legislation are covered by the General Products Safety Directive (GPSD). While the GPSD requires producers to only place safe products on the market, it does not contain the same conformity assessment processes or conformity marking requirements. A manufacturer can only place a product on the EU market when it meets all the applicable requirements. The following sections describe in general terms the requirements, the detail of which is contained within sectorial legislation.

There are different routes to assessing conformity depending on the legislation which is applicable to that product. The legislation itself will specify how conformity is assessed. Essentially, the higher the risk, the greater the need for the involvement of independent, third party organisations.

A product is subjected to conformity assessment both during the design and production phase.

EU conformity assessment procedures are composed of one or two conformity assessment modules. As products are subjected to conformity assessment both during the design and production phase, a module may cover either one of these two phases.

An EU Decision[5] identifies several conformity assessment modules. There is a total of 8 modules named with letters A to H. Each individual Directive draws from the menu of conformity assessment modules the most appropriate ones. The modules range from what are essentially self-assessment processes to much more rigorous processes involving the application of quality assurance systems and independent conformity assessment organisations.

What are known as 'Notified Bodies' may need to be involved in the conformity assessment process depending on the requirements in the Directive dealing with the product type or issue. A notified body is simply a conformity assessment body which can carry out these tasks.

A notified body is therefore an organisation, designated by an EU State to assess the conformity of certain products before they are placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.

The Commission maintains an up-to-date list of bodies notified by EU countries and this can be found on the 'New Approach Notified and Designated Organisations (NANDO) website[6].

Notified bodies are free to offer their conformity assessment services to any business inside or outside the EU and may carry out these activities in the EU or a non-EU State.

Manufacturers are free to choose any notified body that has been legally designated to carry out the conformity assessment procedure.

As part of the conformity assessment, the manufacturer must draw up a declaration of conformity. The declaration must contain details such as:

- Information to identify the product
- The legislation according to which it was issued
- The manufacturer
- The notified body (if applicable)
- A reference to the harmonised standard used

Technical file

For certain categories of products, it is the responsibility of the manufacturer to draw up a technical file, which is the written justification that all aspects of a product are safe. The technical file contains the evidence that the product conforms with relevant legislation. The technical documentation will include information on how the product was developed and how it has evolved during the production run, along with evidence of the efforts undertaken to ensure the product remains compliant.

When questions arise as to the safety of a product, a technical file must be made available when requested by market surveillance bodies. Technical files, for certain products, must be maintained for up to 10 years from the time the product was placed on the market.

Depending on the complexity of a product, the following elements should be present in a technical file:

- Design and production drawing and diagrams

[5] No 768/2008/EC
[6] https://ec.europa.eu/growth/tools-databases/nando

- A general description of the product
- A list of standards and or/solutions applied
- Detailed technical data for essential aspects of the product
- Risk assessment
- Reports of calculations and tests that have been carried out
- Certificates and inspection reports
- User's manual
- Declaration of Conformity

Traceability requirements

The traceability of the product's history is important because it makes the enforcement of corrective measures, such as withdrawals and recalls, possible. Traceability requirements also help the manufacturer maintain effective control of the production phase. Traceability requirements are set out within sectorial legislation and therefore the exact requirements are applicable only to products within the sector covered by that legislation.

A key traceability requirement is the indication of the manufacturer's name and address on the product, as well as the importer's where applicable. This allows the market surveillance authorities to contact the economic operator responsible for placing the unsafe products on the market

Accreditation

Accreditation is a means of creating confidence in the system of conformity. It is an independent and impartial evaluation of the proficiency of the personnel and the conformity bodies performing calibration, testing, and certification of products, processes, services, quality systems and surveillance. A standard[7] addresses criteria for accreditation, assessment, and the operation of conformity assessment bodies.

Those involved in the conformity system such as those undertaking testing, issuing certificates or calibration services need to demonstrate their competence. They do this by being accredited by a nationally recognized accreditation body.

Accreditation delivers confidence in certificates and reports by implementing widely accepted criteria set by the European (CEN) and/or international standardization bodies (ISO). The EN/ISO 17000 standards address issues such as impartiality, competence and reliability; leading to confidence in the comparability of certificates and reports across national borders.

The Regulation[8] establishes that each Member State may appoint one single national accreditation body. Only the national accreditation bodies can perform accreditation of conformity assessment bodies.

To create confidence in the system between Member States, the European Cooperation for Accreditation has been created as an organisation of European national accreditation bodies.

[7] ISO/EN 17000:2004
[8] 765/2008

CE marking

The CE mark is a marking on a product made by the manufacturer of a product's compliance with relevant EU product harmonisation legislation and it has been designed and manufactured to meet the essential safety requirements. The CE marking does not apply to non-harmonised products.

Responsibilities in the chain of distribution

There are different levels of responsibility for different businesses in the chain of distribution of a product. A typical distribution chain would start with a manufacturer or importer, would potentially include one or more wholesalers and a retailer or someone selling the product to the consumer.

The overall system works by placing most responsibility for ensuring products comply with the product safety requirements on the importer or manufacturer, i.e. the business at the top of the chain of distribution. The logic being that generally, if compliance takes place at this level, all other participants in the system will also supply safe products.

A European Commission Decision[9] defines the different types of economic operators as follows:

Manufacturer. This is the person or company who makes the product and places it on the market under his own name or trademark. The manufacturer is responsible for the conformity assessment of the product and is subject to a series of obligations including traceability requirements. When placing a product on the EU market, the responsibilities of a manufacturer are the same whether he is established outside the EU or in a Member State.

Importer. The importer is defined as the person or company who places a product originating in a State outside the EU on the EU market. The importer must ensure that the manufacturer's obligations have been correctly fulfilled and has the role in guaranteeing the compliance of imported products. As a rule, before placing a product on the market the importer must ensure:

a. that the appropriate conformity assessment procedure has been carried out by the manufacturer.
b. that the manufacturer has drawn up the technical documentation, affixed the relevant conformity marking (e.g., CE marking), fulfilled his traceability obligations and, where applicable, provided the product with instructions and safety information in a language easily understood by consumers and other end-users, as determined by the Member State concerned.

Distributor. The distributor is essentially anyone else in the chain of distribution other than the manufacturer or importer. They have a lesser responsibility but must still be able to demonstrate to the market surveillance authorities that they have acted with due care and that their own supplier has taken the measures required by the relevant legislation.

Authorised representative. The legislation recognises the existence of a role called authorised representative. The manufacturer may appoint an authorised representative in the Union to act on his behalf in carrying out certain tasks required by the relevant legislation. Apart from particular cases (medical devices), a manufacturer established outside the European Union is not obliged to have an authorised representative. In order to be able to act on behalf of the manufacturer, the authorised representative must be established inside the Union. The delegation of tasks from the manufacturer to the authorised

[9] 768/2008/EC

representative must be explicit and set out in writing, in particular setting out the contents and limits of the representative's tasks.

Ecommerce and the role of online marketplaces

A key element in relation to protecting consumers from unsafe consumer goods is the growth of e-commerce and the use of online market places. Online marketplaces have many benefits for consumers but carry with them additional risks. The basic rule is that whatever protections consumers enjoy do not change whether products are purchased in a shop or online. However, extra protection is afforded consumers who purchase things online to recognise the fact that they cannot examine goods prior to purchase as they would in a shop. These protections also recognise the extra risks involved with online trading.

The E-commerce Directive[10] establishes the general legal framework for electronic commerce in the EU. The obligations set out apply, inter alia, to online sellers of products and services or online advertisers, as long as they are providers of an information society service that fall within the scope of that Directive.

The E-commerce Directive also standardises the exemptions of liability for third party content that apply to those information society service providers which act as intermediaries. For that purpose it describes three different categories of services, of which hosting is the most relevant from a product safety and compliance point of view. Hosting is a service where an intermediary service provider, such as an online market place or an online platform, merely passively stores on its server — and makes it available to the public — information provided by the recipient of the service, such as an online seller of products.

Intermediary service providers carrying out hosting activities may benefit under certain conditions from an exemption of liability for illegal information provided by third parties using their networks or illegal activities initiated by third parties, such as information constituting infringements of copyright or trademark or unfair commercial practices. While the E-commerce Directive does not define the concept of illegal information or activity, based on the Union harmonisation legislation and the General Product Safety Directive, this concept can also cover the offer of unsafe and/or noncompliant products.

However, the liability exemption is subject to specific conditions. It only applies if the intermediary service providers have no actual knowledge or awareness of the illegal activity or information hosted or, upon obtaining such knowledge or awareness (for instance by a 'sufficiently precise and adequately substantiated' notice), they act expeditiously to remove or to disable access to it. If hosting service providers do not fulfil these conditions, they are not covered by the liability exemption and thus they can be held liable for the content they host.

The liability exemption set out in the E-commerce Directive does not prevent Member States from establishing procedures governing the removal or disabling of access to information.

Likewise, a court or an administrative authority, under Member States' legal systems, can require the information service provider to terminate or prevent an infringement by removing third party content and/or prevent the alleged infringements from re-occurring in future. In this sense, public authorities can establish specific monitoring requirements. However, under current legal basis, Member States cannot impose either a general obligation on online intermediaries, such as the providers of hosting services, to

[10] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (E-commerce Directive) (OJ L 178, 17.7.2000, p. 1).

monitor the content or a general obligation to actively seek the facts or circumstances indicating illegal activity. This means, for instance, that national authorities cannot establish a general obligation for such intermediaries to actively monitor their entire internet traffic and seek parts that indicate illegal activities such as offering non-compliant or dangerous products for sale. This has been further clarified by the Court of Justice of the European Union.

In the context of market surveillance, a new Directive was adopted in November 2019[11] which contained many new elements, but particularly addresses a range of issues associated with online market places. The Market surveillance regulation[12]referred to above, while not singling out online sales, will nevertheless have a significant impact on sales crossing the EU border, particularly business to consumer sales where the business is outside the EU and the consumer is within the EU. Currently, for this type of business to consumer transaction, there is no enterprise formally responsible for regulatory compliance. Consumers themselves are effectively the 'importers' and therefore responsible for compliance. They should ensure that what they buy online from sellers based outside the EU complies with EU rules. In practice, this doesn't happen for a variety of practical reasons. In addition, there is no penalty or incentive for operators to control compliance themselves.

The Market surveillance regulation changes this and requires non-EU sellers to have a representative in the EU. If there is no representative, the fulfilment service provider becomes responsible. A fulfilment service provider is a person or business which offers at least two of the following services; warehousing, packaging, addressing and dispatching (without ownership of the products involved). Note however that courier and postal companies are specifically excluded.

Product Safety Pledge

As stated above, consumer products placed on the EU market must be safe, regardless of whether they are sold online or in traditional shops. Across the EU in 2018, online sales accounted for 20% of total sales. E-commerce marketplaces may facilitate economic growth by enabling sellers to access new countries and to reach new customers.

The Product Safety Pledge, a voluntary non-legislative initiative, facilitated by the European Commission sets up areas where online intermediaries voluntarily agree to take specific actions with respect to the safety of non-food consumer products sold online by third parties on their marketplaces. The goal is to improve the detection of unsafe products marketed in the EU before they are sold to consumers. These commitments go beyond what is already established in the EU legislation on product safety.

In June 2018, four online marketplaces (AliExpress, Amazon, eBay and Rakuten France), signed the Product Safety Pledge.

The conclusion of the Pledge was facilitated by the European Commission with the objective of increasing the safety of products sold online by third-party sellers through online marketplaces.

As part of the Pledge, signatory online marketplaces have committed to report to the European Commission every six months on the actions taken to implement the Product Safety Pledge, with the

[11] Directive on better enforcement and modernisation of EU consumer protection
[12] Regulation (EU) 2019/1020

inclusion of key performance indicators.

In January 2020, two new online marketplaces, Allegro and Cdiscount, signed the Product Safety Pledge. They have been followed in July 2020 by Wish.com.

New EU award to celebrate product safety champions

In February 2019 a new Product Safety Award to reward businesses that excel in product safety was announced. The award took place in October 2019 in the following category:

- **Childcare products**: companies putting children's safety at the top of their priorities could apply for the award. That could be, for example, the way they designed a baby's cot or the creative way in which they communicate risks to their customers.

Obligations arising from the Market Surveillance Regulation.

Reference was made earlier in this report to the Market Surveillance Regulation[13]and the new tasks for operators. This Regulation prohibits the placing on the market of certain goods unless an economic operator established in the EU is identified as responsible for ensuring the availability of the conformity documentation, cooperating with market surveillance authorities and informing authorities when they have reason to believe that a product presents a risk. The economic operator established in the EU could be:

- The manufacturer of the goods
- The importer (where the manufacturer is not established in the EU
- An authorised representative (see definition above)
- A Fulfilment service provider (if none of the above are established in the EU)

Note: Products offered for sale online, or through other distance sales means, are presumed to be made available on the EU market if the offer is targeted at EU consumers.

Specific issues relating to priority product categories the most notified in the Safety Gate/RAPEX

The preceding paragraphs consider the rules generally applicable to product safety and the free movement of goods. The following takes the rules of general applicability and taking toys as an example, considers how the rule relate to a product category.

The key Directive is the Toy Safety Directive[14]. As stated elsewhere, other pieces of EU legislation may also

[13] Regulation (EU) 2019/1020

[14] 2009/48/EC

be applicable. The main requirements are that toys:

- Satisfy the essential safety requirements
- Be properly marked to ensure traceability
- Bear the CE mark
- Be accompanied by instructions for use and warnings where necessary

The Toy Safety Directive defines the roles and responsibilities of:

- Manufacturers
- Importers
- Distributors
- Authorised representatives

Toys are products designed or intended (whether or not exclusively) for use in play by children under 14 years old. A manufacturer is required to carry out a safety assessment before placing a toy on the market.

The safety assessment is 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.

There are certain types of product that fulfil the definition of toys but are excluded from the scope of the regulations.

The key requirement is that toys must not adversely affect the safety or health of users or third parties when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

Toys which conform to the relevant harmonised standards which have been published in the Official Journal of the European Union are presumed to conform to the essential safety requirements.

There are a range of EN standards such as the EN71 series that cover the essential safety requirements.

Where the toy has been shown to conform to the essential safety requirements the manufacturer must draw up an EC declaration of conformity to follow the structure set out in the Directive.

The manufacturer must affix the CE marking to the toy, to an affixed label or to the packaging. The mark must be visible at the point of sale, be easily legible and in an indelible form.

The Directive requires that a comprehensive technical file is maintained for each toy that includes:

- a detailed description of the design and manufacture including a list of components and materials
- the safety assessments
- a description of the conformity assessment procedure used
- a copy of the EC declaration of conformity
- the addresses of the places of manufacture and storage
- copies of any documents submitted to a notified body (where applicable)
- test reports or documentation demonstrating compliance to harmonised standards
- a copy of the EC type examination certificate (where applicable)
- safety assessment
- a colour image of the toy

The toy must be accompanied by instructions and relevant safety information. These may also contain details such as use instructions or information regarding ways in which hazards may be further reduced, such as the requirement for adult supervision or using additional personal protective equipment.

Traceability markings must be applied to the toy or packaging or instructions. These must include a model number type or batch number, the identification and address of the manufacturer and any importer.

Where applicable the toy or packaging must bear specific warnings and indications of precautions to be taken when using the toy. These are usually specified in safety standards.

3. Practical Application of the product safety approach

The section above entitled 'Core Aspects of the EU's Product Safety Requirements' set out in detail the legal and technical background which controls the circulation of consumer goods and consumer product safety. The purpose of this section is to take this information and present it as an approach that could be followed by those conducting business within EU Member Countries

For those looking to enter the European market, it can sometimes feel like there is much to know about laws, compliance, standards, and expectations inside the EU. Available information may appear cumbersome and unclear with various sources of information needing to be consulted to obtain the answer to what may appear a simple question.

The following section attempts to summarise as succinctly as possible the steps that could be followed in bringing a product to market and taking the consumer product safety implications into account. It would be possible to start from a range of perspectives, from the legal framework, from the technical standards or from the application of the rules by the public authorities. The route chosen is from the CE mark.

The CE mark is possibly the most visible but also misunderstood aspect of the approach to the circulation of goods within the internal market. When marked on a product, the 'CE' mark is not a mark of safety, a mark of quality, nor does it mean 'made in Europe'.

The CE mark is a symbol which indicates that a product complies with relevant EU product harmonisation legislation. If a product needs to comply with more than one piece of legislation that requires CE marking, the mark is an indication that the product complies with all the legislation requiring CE marking.

The CE mark is placed on the product by the manufacturer of the product and its purpose is to enable the free movement of those products within the internal market. The CE mark is therefore:

- An indicator that the product complies with applicable piece of legislation
- An indicator that the product is allowed free movement within the European market

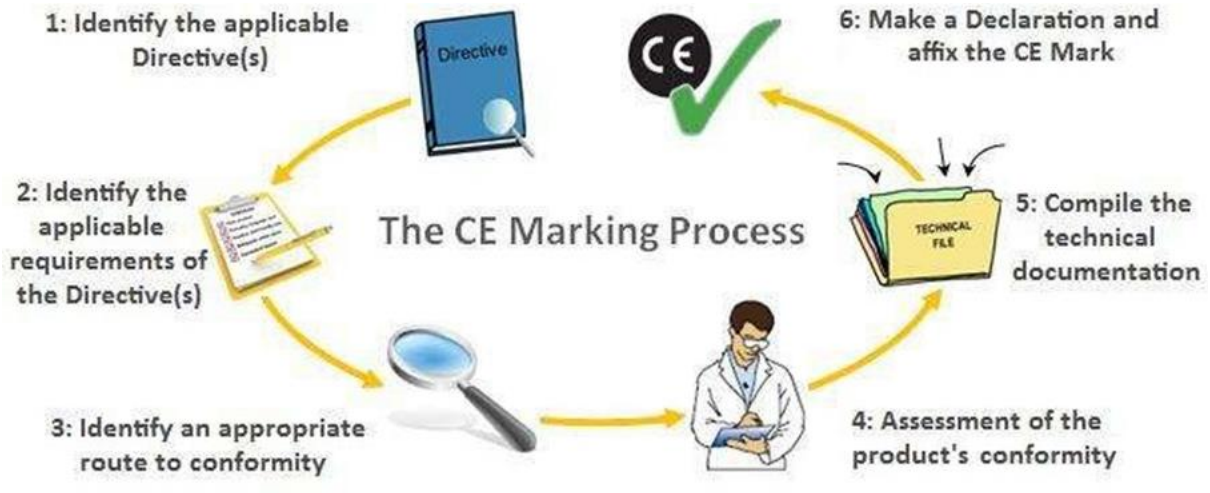
Not all products must bear the CE marking. Only those product categories subject to specific EU legislation that provide for the CE marking are required to be CE marked. A manufacturer therefore has the following responsibilities:

- carry out the conformity assessment
- set up the technical file
- issue the EC Declaration of Conformity
- place CE marking on a product where applicable

A distributor (e.g. wholesaler or retailer) must check the presence of both the CE marking and the necessary supporting documentation.

An importer importing a product from a third State (e.g. China) must check that the manufacturer outside the EU has undertaken the necessary steps. The importer must check that the documentation is available.

On the face of it, the steps to the CE marking are straightforward and are represented in the diagram below:



These steps create a system which:

- Identifies only the key safety requirements which need to be addressed
- Requires those who put products on the market ensure their products meet the safety requirements
- Requires the use of processes to confirm regular conformity of the product with the requirements – these may be undertaken by the manufacturer or a third party depending on the requirements in the applicable piece of legislation
- Requires record keeping in case something goes wrong or the information is needed by market surveillance authorities
- Requires the CE mark to be placed on the product when applicable, confirming all the above steps have been met

This section attempts to follow through the key processes that need to be followed to ensure that only products which comply with EU requirements on consumer product safety are placed on the market for free circulation within the EU. It takes a step by step approach based on the diagram above.

Identify the applicable pieces of legislation

There are over 20 separate pieces of legislation which require a CE marking and the full list is attached in annex 2. However, there are some key issues to keep in mind:

- There is no guarantee that only a single Directive is applicable in relation to any product type. Some Directives are sector specific and relate to specific product types, e.g. the Machinery Directive[15] and the Low Voltage Directive[16].
- It is also important to consider the Consumer Product Safety Directive (GPSD)[17] when considering

[15] 2006/42/EC
[16] 2014/35/EC
[17] 2001/95/EC

which is the applicable legislation. Where a product, and all the risks associated with it, are already subject to other existing regulations (for example, toys) then those regulations will apply to that product. The GPSD does not apply to the safety of a product where there are specific provisions of EU law governing all aspects of its safety.

- That there are other pieces of EU legislation which are horizontal and apply to many different product types, e.g. Electromagnetic Compatibility Directive[18] and Waste Electrical and Electronic Equipment Directive[19]. The significant point is that some research is required to ensure that all applicable rules relating to any given product have been identified.

However, the GPSD will apply where they go further than the existing regulations in terms of the specific aspects of safety covered and the extent of the obligations. Unlike sector-specific laws, the GPSD does not permit CE marking but does require that distributors only supply safe products.

The following types of consumer goods are examples of products that would be covered within the GPSD:

- children's articles such as cots, prams, high-chairs, bunk beds
- bicycles
- household goods such as crockery, cutlery, cooking utensils
- DIY tools
- furniture and soft furnishings
- clothing
- candles and other ornaments
- hobby and art materials

There will be other, generic pieces of EU legislation which will almost certainly be applicable, but also do not require the application of the CE mark. For example, the Directive on Packaging and Packaging waste[20].

These requirements are beyond the scope of the SPEAC project which focuses on consumer product safety. Nevertheless, this issue is referred to here to indicate the scope and breadth of the pieces of EU legislation which need to be considered.

Identify the applicable requirements of the legislation

The next step in the process is to identify the applicable requirements of EU legislation which relate to the specific product. For example, the Directive on the safety of toys covers all products designed or intended (whether exclusively or not) for use in play by children under 14 years of age.

Other pieces of legislation would similarly cover a wide range of product types within their scope. Manufacturers and importers need to identify which requirements specifically apply to the products in question.

'New Approach' legislation is described in the previous section of this study. These pieces of legislation only set out the essential safety requirements which a product must fulfil in order to be considered safe in

[18] 2014/30/EC
[19] 2012/19/EU
[20] 2005/20/EC

general terms. They do not contain information on how the essential requirements could or should be met, nor do they contain the technical specifications needed to manufacture a product that will comply with the essential safety requirements.

Harmonised standards provide the manufacturer with one solution for satisfying the essential requirements of EU product harmonisation legislation. Manufacturers would be recommended to use European harmonised product standards to demonstrate compliance with the essential requirements set out in each Directive. Details of applicable harmonised standards are available online[21].

However, compliance with a harmonised standard is not mandatory if it can be demonstrated that an alternative approach demonstrates the equivalent level of safety. As this is likely to be a more complex and onerous process, following harmonised standards is likely to be a simpler and more cost-effective process.

Identify an appropriate route to conformity

Conformity assessment is the responsibility of the manufacturer. Even if a specific Directive requires the involvement of a 3rd party, it is the manufacturer who remains accountable for the conformity of his products. The essential objective of a conformity assessment procedure is to enable public authorities to ensure that products placed on the market conform to the requirements. Conformity assessment processes and procedures are set out in an EU Decision[22].

The use of conformity assessment is designed to promote the removal of barriers to trade in the EU/EEA market. Further, it provides confidence for consumers that the requirements have been met. Manufacturers must verify that all stages of product manufacturing (design, construction, presentation and marketing) fulfil legal requirements for their products to provide the safety consumers expect.

The applicable Directive will be the guide to the level of risk involved and the methods of conformity assessment that may be employed. Conformity assessment modules are specified in each Directive.

If a harmonized standard is used to meet an essential requirement of a New Approach Directive, and if the risk of injury is low, no third-party conformity assessment procedure is required, regardless of the nationality of the manufacturer. Therefore, for most consumer products under the New Approach legislation, it is enough that the manufacturer (or his representative) certifies that the product complies with the Directive(s)/harmonized standards. Very risky products on the other hand require an approved quality assurance system to be put in place and reviewed by a conformity assessment body.

A conformity assessment body is known as a Notified body in the EU as it is the process of notification which enables them to perform conformity assessment tasks.

Assessment of the product's conformity

A product is subjected to conformity assessment both during the design and production phase. Conformity assessment is the responsibility of the manufacturer. Should a manufacturer subcontract design or production, he remains legally responsible for the conformity assessment.

The essential objective of a conformity assessment procedure is to demonstrate that products placed on

[21] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

[22] 768/2008/EC

the market conform to the requirements expressed in the provisions of the relevant legislation.

EU conformity assessment procedures are composed of one or two conformity assessment modules. As products are subjected to conformity assessment both during the design and production phase, a module may cover either one of these two phases.

There are eight conformity assessment modules[23]. The modules set out the responsibilities of the manufacturer (and his authorised representative) and the degree of involvement of the in-house accredited or notified conformity assessment body.

Essentially, there are three possible approaches to the assessment of a product's conformity.

1. No third-party involvement. This would be the case if the Directive itself permitted the manufacturer to effectively self-declare that the product conformed with the legal requirements.
2. In-house conformity assessment. This is the situation where the manufacturer has their own in-house facility. Rules exist[24] which mean that the in-house facility must have the same technical competence and independence as an external conformity assessment body and the accreditation process ensure this.
3. Third-party involvement. In some cases, the law requires the involvement of an external conformity assessment body.

As has been stated, whatever route is applicable, the manufacturer is always responsible for the conformity/safety of his products and it is he who is responsible for drawing up the declaration of conformity.

The declaration of conformity must contain all the relevant information to identify the applicable EU legislation. A single declaration of conformity is required whenever a product is covered by several different pieces of EU legislation.

The declaration must contain details such as:

- Information to identify the product
- The legislation according to which it was issued
- The manufacturer
- The notified body (if applicable)
- A reference to the harmonised standard used

Compile the technical documentation

It is also the responsibility of the manufacturer to draw up a technical file, which is the written justification that all aspects of a product are safe. The technical file includes information that demonstrates the technical basis for conformity of the product to the applicable requirements of relevant Directive(s).

Depending on the complexity of a product, the following elements should be present in a technical file:

- Design and production drawing and diagrams
- A general description of the product

[23] Modules A to H in Decision 768/2008/EC

[24] 768/2008/EC

- A list of standards and or/solutions applied
- Detailed technical data for essential aspects of the product
- Risk assessment
- Reports of calculations and tests that have been carried out
- Certificates and inspection reports
- User's manual
- Declaration of Conformity

Make a declaration and affix the CE mark

Affixing the CE marking to a product is a declaration by the manufacturer that the product in question has been designed and manufactured to meet the essential safety requirements and creates a presumption that the product is entitled to free circulation within the EU/EEA market.

However, it must be remembered that the CE marking is not a quality mark aimed at consumers. Its main purpose is to indicate to enforcement authorities that the products are intended for sale on the EU/EEA market and guarantees that at least the minimum/essential requirements for health and safety of the consumers have been met.

As the General Product Safety Directive imposes a general safety requirement for a wide range of consumer products and does not specify any specific safety requirements as the sectoral legislation does, there are no provisions for CE marking on products falling under the scope of the GPSD.

Creating a structured approach

The process described above represents only a summary of what needs to be done. It would be strongly recommended that manufacturers follow a structured approach which builds in a consumer product safety culture and not just a mindset which sees the processes and information requirements as a bureaucratic necessity.

An international standard creates consumer product safety guidelines for suppliers[25]. There are four basic principles within this standard:

- Promoting a product safety culture within the organisation
- Promoting a product safety culture outside the organisation (e.g. with business partners throughout the supply chain)
- Commitment to providing safe products
- Continual improvement

As an international standard, its application could assist manufacturers access other markets in addition to those in Europe. The standard could serve as inspiration to generically structure information and training development.

[25] ISO 10377

4. Consumer protection policies and legislation

Across Europe, consumers are critical to economic success and EU policy reflects this. Confident, knowledgeable and demanding consumers are being good for business.

Consumer protection and consumer policy in the EU also recognizes that consumers cannot just be left on their own. There is a need for consumer advice and education to ensure that consumers receive the information and support they need. There is a need for a legal consumer protection framework to clamp down on those businesses who put the health and safety of consumers at risk.

There is a division of responsibilities between those matters dealt with at the EU level and those matters dealt with by the individual Member States. Put simply, the legal framework and the consumer policy at a European level are dealt with by the EU. The delivery of activities and services (e.g. consumer advice and education programmes) are delivered at the individual Member State level.

Advice and education support services for consumers at the Member State level are often delivered by the public sector (which may be at the regional or State level) or by civil society NGOs (or a mix of the two). Increasingly, consumers will get their advice from searching the internet and from private rather than public advice sites.

The European Consumer agenda was adopted in 2012 and replaces the Consumer Policy Strategy of 2007-2013. The European Consumer agenda (the agenda) identifies the key measures needed to empower consumers. Empowered and confident consumers are recognized as a key part of driving the European economy. The agenda sets out four key 2020 objectives directed primarily at the European Commission:

- Improving consumer safety.
- Enhancing knowledge.
- Improving implementation, stepping up enforcement and securing redress.
- Aligning rights and key policies to economic and societal change.

In addition to the consumer agenda outlined above, there is a Consumer Programme 2014-20 – the financial framework which complements the strategy.

There is no consistent and uniform definition of 'consumer' in EU law. There are also some divergences between the Member States themselves – partly arising from when Directives are transposed into national law. Because the body of EU legislation provides for a minimum level of harmonisation, many Member States extend the scope of their own consumer protection law beyond definition of 'consumer' which might exist in the individual EU pieces of legislation.

Currently, there are over 90 EU pieces of legislation covering consumer protection issues. This legislation covers a wide range of topics many of which are not directly to consumer product safety, e.g. financial products and services. However, EU consumer protection rules cover aspects which overlap consumer product safety requirements when enacted by Member States by:

a. Giving consumers rights in civil law when purchasing items which are faulty
b. Creating rules covering transactions such as those addressing e-commerce

Raising awareness

The agencies and NGOs within individual Member States are closer to their consumers and more aware of the issues which concern them. As a result, much work on raising awareness takes place at this level. Nevertheless, this is supported at the EU level. This includes awareness raising of consumer rights, particularly targeted at new Member Countries, or on specific issues such as passenger rights or consumer credit. In addition, on-line training tools have been created. A network of European Consumer Centres has been created to help solve cross border consumer disputes.

A link exists between the provision of consumer advice and consumer product safety market surveillance. By receiving complaints from consumers, individual Member States gain valuable intelligence as to emerging consumer product safety concerns. This enables them to better target their market surveillance activities through the analysis of data.

Enforcement

An EU Regulation[26] has created a mechanism for cooperation between the national consumer protection authorities in Member States. If a problem is found within one Member State, the network allows the authority in the Member State in which the consumers' interest was harmed to call a counterpart in a Member State where the business is located to take steps to stop the violation.

Redress

There is a network (The European Judicial Network) that can be used by consumers to pursue cross border disputes. With the aim of providing information on European small claims procedures, the network adopted the Practice Guide on Small Claims[27].

[26] Regulation (EC) No. 2006/2004, on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation)

[27] Practice Guide for the application of the European Small Claims Procedure. European Commission 2013

5. Market Surveillance

EU Member States must organise and carry out market surveillance[28]. The requirements do not prescribe the exact type or structural arrangements that a Member State must put in place but focuses instead on desired outcomes. The EU requirements set out:

- Obligations for EU Countries to carry out market surveillance and to prohibit or restrict the marketing of dangerous or non-compliant products
- Provide market surveillance authorities with the necessary powers to fulfil their responsibilities such as powers to obtain the necessary documentation from manufacturers to evaluate product conformity, to take samples for testing and in extreme cases to destroy products
- Obligations for EU countries to cooperate with each other on market surveillance matters

With the primary responsibility for ensuring compliance with the safety rules falling to importers and manufacturers and others in the chain of distribution, the market surveillance function acts as an important safety net to ensure the rules are being observed and that consumers are protected.

Market surveillance is an important element in the overall quality infrastructure. In addition, the function ensures fair competition between businesses and ensures that those who take their safety responsibilities seriously are not undercut by those who do not.

Although certain functions can be delegated to others, market surveillance must be undertaken by public authorities in Member States who retain full responsibility and accountability for decisions made.

Market surveillance controls such as taking samples and inspections may be carried out at different times in the life cycle of a product, following its placing on the market, e.g. importers establishments, wholesale or retail premise etc. They will commonly apply the most cost/effective intervention based on risk to ensure the desired outcomes are achieved. A risk matrix is attached as annex 3[29].

Market surveillance activities can be most effective when undertaken at the top of the chain of distribution. Once products have reached the retail level, they are able to be sold directly to consumers and in the case of non-conforming products cause harm. In addition, it is always harder to take retrospective action than to address problems at the manufacturing or importing level.

EU legislation provides for two different tools that enable market surveillance authorities to receive information on the product: the EU declaration of conformity and the technical file. These must be made available by the manufacturer, the authorised representative established within the Union or under certain circumstances by the importer.

The implications for imports from countries such as China are that as imports have to pass by the points of entry into the EU, these are the ideal places to stop unsafe and non-compliant products before they are released for free circulation within the EU. This requires the involvement of customs and cooperation between customs and market surveillance authorities.

The legal basis for cooperation with customs authorities is to be found in a Regulation. Customs authorities have the following responsibilities:

[28] Regulation (EU) 2019/1020

[29] Guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC

- to suspend the release of products when there is a suspicion that the products present a serious risk to health, safety, environment or other public interest and/or do not fulfil documentation and marking requirements and/or the CE marking has been affixed in a false or misleading manner;
- Where the release for free circulation has been suspended, customs have to immediately notify the market surveillance authority which is given three working days to perform a preliminary investigation of the products and to decide on the follow-up.

Given the critical and strategic role of market surveillance but considering that it is a function of the Member States, high levels of coordination and cooperation between the national market surveillance authorities is important. This is designed to ensure uniform and efficient enforcement of the requirements across the Member States.

Administrative cooperation between national authorities carrying out market surveillance is taking place in the following sectors and includes low voltage equipment (LVD ADCO), electromagnetic compatibility (EMC administrative cooperation) and Toy-ADCO (The Administrative Cooperation Group of toys.

EU Member State market surveillance authorities receive enhanced powers and responsibilities under the Market Surveillance Regulation [30] described in Section 2 (Core aspects of the EU's product safety requirements) above. These include:

- Conducting product checks (including physical and laboratory checks where necessary) following a risk-based approach
- Member States ensuring market surveillance authorities have the necessary powers to do their job:
    - Requiring economic operators to provide documentation (including access to embedded software and information to ascertain website ownership)
    - Requiring economic operators to take corrective action in the event of non-compliance
    - Requiring the removal of content from websites

Coordinated Actions on the Safety of Products (CASP)

Over the last 15 years, the European Commission has co-financed coordinated market surveillance activities - the so-called Joint Actions or since 2018, Coordinated Activities on the Safety of Products (CASP) carried out by Member State authorities. These coordinated activities aim at ensuring a consistent approach towards the enforcement of product safety legislation across the internal market.

Recent joint actions typically cover the following aspects of administrative cross-border cooperation activities:

- Joint and coordinated sampling and testing of non-food products found in the EU/EEA markets;
- Assessment of risks posed by non-food consumer products and product testing;
- Market surveillance operations and cooperation with customs authorities;
- Exchange of expertise and best practices;

[30] Regulation (EU) 2019/1020

- Meetings and workshops, implementation of an effective communication strategy and collaboration

The activities include several product orientated, coordinated market surveillance actions. Based on a list of products agreed by national authorities, specialised laboratories are selected to test the products and assess if they comply with the relevant EU safety rules and are considered to be dangerous. These actions often lead to notifications to the Safety Gate/RAPEX.

Until 2018, the coordinated actions were funded and implemented by the European Commission's Consumer programme under the category of grant agreements. In 2018, the implementation modality and financing of the coordinated actions was replaced by a procurement framework funded fully by the European Commission, by which an external contractor coordinates all logistical, reporting and communication tasks involved and provided the necessary expertise for each of the activities.

Consumer Safety Network

The Consumer Safety Network is a consultative expert group chaired by the European Commission and composed of national experts from all EU countries, as well as Norway, Iceland and Liechtenstein. The safety of consumer products and data collection are the main areas of discussion.

The network meets on average 3 times a year, usually in conjunction with the General Product Safety Directive committee meetings. The experts if this network are considered important resource persons for the project.

Other stakeholders

There are a range of stakeholders in both the public and private sector with an interest in and responsibility for aspects of consumer product safety. A list of some of these is set out in annex 4. These stakeholders and others have the potential to provide important support to this project.

6. Related policies and programmes including voluntary initiatives

Better Regulation policies

One of the major agendas guiding thinking across EU Member Countries is the Commissions approach to the 'better regulation'. Better regulation sets out to ensure:

- decision-making is open and transparent
- citizens and stakeholders can contribute throughout the policy and law-making process
- EU actions are based on evidence and understanding of the impacts
- regulatory burdens on businesses, citizens or public administrations are kept to a minimum

The fourth bullet point is important as this influences the broad approach of market surveillance authorities and their interactions with the business community. There is a constant push within the EU to ensure that legal requirements secure their intended outcome while minimising impacts on the business community.

Counterfeiting and intellectual property

Counterfeiting, piracy and infringements of intellectual property rights are a constant problem and have reached a global dimension. Fake products constitute a serious threat to national economies, as well as to the health and safety of EU citizens.

In addition to economic and social consequences, counterfeiting and piracy entail considerable health and safety risks by undermining the system of consumer protection. Certain counterfeited products (such as toys and children's items) that are produced in an unregulated environment can cause serious harm. The increased use of the Internet enables pirated products to be instantly distributed around the globe.

In many EU Member States, collaboration takes place between market surveillance bodies, customs and police agencies to target aspects of both consumer product safety and counterfeiting.

7. Using information

The use of data and information is key to the success of the EU's approach to driving up consumer product safety standards. Information:

- Can be used to inform consumers and help them make better informed choices and know what to do if things go wrong.
- Help businesses comply with the law.
- Provide accurate information to the media and support the press in communicating clear messages.
- Help market surveillance authorities apply a risk-based approach to their work.
- Help policy leaders and legislators better understand the impact of the legal framework and monitor performance and make changes where necessary.

As a result, a good deal of time and investment has been dedicated to collecting and monitoring data to ensure accurate information can be passed on for the reasons set out above. At the core of this is the EU's 'Safety Gate Portal'. Safety gate is the rapid alert system for dangerous non-food products.

Every week a list of dangerous products is published on the web and this can be consulted by the general public.

In addition to Safety Gate, there is a parallel initiative called 'Business Gateway'. If a manufacturer finds that one of their products on sale is dangerous, they have a duty to inform their Member State national contact.

This gateway is reserved for producers and distributors and the Member State national contact may use the information to submit a RAPEX notification.

RAPEX and "RAPEX-China"

RAPEX (EU Rapid Alert System for non-food consumer products)[31] is a European rapid alert system for dangerous consumer products. It ensures that information about dangerous products identified by the national authorities is quickly circulated between the national authorities themselves and the European Commission, with the aim of preventing or restricting the selling of these products on the market. 30 countries currently participate in the system; all the European Union countries and the European Economic Area (EEA) countries: Iceland, Liechtenstein and Norway.

A Memorandum of Understanding (MoU) on general product safety was signed with the Chinese General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) was signed in January 2006. The MoU established a framework for better communication and collaboration between both regulators and specifically seeks to support the Chinese authorities in their efforts to ensure product safety, particularly for consumer goods exported to the EU.

One important measure in this context is that RAPEX information concerning products of Chinese origin is made available to China, thereby allowing them to directly follow up on notifications regarding unsafe products (so-called RAPEX-China). This system is allowed China to follow up the cases on their territory.

[31] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

Following the implementation of the RAPEX-China system, AQSIQ had undertaken to report on follow up actions reporting on a quarterly basis. One of the main problems AQSIQ faced when investigating the notifications is incomplete, or complete lack of, information about the manufacturer, which prevents them from following up effectively. In other cases, for example, the manufacturing of the unsafe products had already stopped, the company did no longer exist or the products had already been improved. The General Administration for China Customs (GACC) has taken over the operation of RAPEX-China after the reorganization in China.

In addition, the EU undertakes market studies and a consumer scoreboard.

We refer to the complementary SPEAC study on the China system and the reform of responsibilities in China.

Market monitoring

The EU has published a consumer scoreboard since 2008. These are intended to give an overview as to how the EU's single market is working for consumers. It is based primarily on surveys of consumers and retailers and monitors:

i. Knowledge and trust
ii. Compliance and enforcement
iii. Complaints and dispute resolution

The most recent Consumer scoreboard can be found on-line[32].

[32] https://ec.europa.eu/info/publications/consumer-conditions-scoreboard-consumers-home-single-market-2019-edition_en

8. Conclusion and Recommendations

Conclusions

The European requirements are undoubtedly complex and have many elements, designed to secure not only consumer protection objectives but also the free movement of goods within the internal market. All the information that a business in China would need is available, but it may require a good understanding to know where to look and find all the information which is relevant to a business or product type.

The project is designed to secure improved consumer protection outcomes by providing extra support upstream to the source of manufacture of products in China. If this is to work, information and training needs to be structured around their needs and answer questions from their perspective.

This part of the report is intended to provide some initial and early thinking relating to the future delivery of this project and references the objectives and results from the original terms of reference (ToR) for the project.[33]

This report is one of the agreed products from the inception phase of the project. It constitutes a mapping exercise of consumer protection and product safety from the EU perspective. Together with similar work focused on the Chinese arrangements, these two pieces of work will lead to the identification of convergences and divergences between the systems. This will lead to a list of themes and topics for training.

The original ToR already envisaged the use of multiple channels and platforms to deliver both information and training. This was always going to be key, given the sheer size of China and the number of potential recipients of training. An imaginative approach is required.

More than this, the current project is being delivered against a background of the worldwide coronavirus pandemic. It is likely that as trade and commerce emerges, there will be an even greater focus on training provided using a range of digital and online technologies. In addition, it seems likely that the trend to on-line shopping will continue to rise, possibly at an increasing rate and this too needs to be a consideration as training and learning material are developed.

From a product safety perspective, the EU requirements are the same whether a product is sold online or in a shop. The challenges and risks are faced by the consumer and the market surveillance authority. In the current climate, as the world economy emerges from the pandemic, these risks could increase if business affected by the economic downturn, seek to compromise on quality and safety as a means of cutting costs. Consequently, getting things right before products leave China assumes an even greater importance

In developing the materials for the Chinese business community, it is critical to put their needs first. Business do not consider their information needs in the same way that legislators and policy makers do. There is a lot of excellent background material available online on all aspects of the law and standards relating to product safety. It covers all the key issues relating to 'essential requirements', 'harmonised standards' and 'conformity assessment' etc.

However, businesses do not tend to look at their information needs in this way. A typical question from a business will be 'Tell me what I have to do to comply with the rules' and not 'Give me all the information

[33] EuropeAid/140027/DH/SER/CN

about, for example, the Toy Safety Directive'.

The other challenge for the business community is that all the information may exist online, however, they must know where to look for it and potentially put together several sources of information to ensure that what they have is relevant to their product range. This means they must know where to look and which of the myriad requirements may be applicable to them.

The focus therefore must be on:

- The business community and meeting their needs.
- Making it as simple and easy as possible to comply with the law.
- Recognising the different needs of the largest multinational businesses as well as small and medium sized enterprises and start-up businesses.
- Finding solutions which bring all the relevant information together.
- Creating a holistic approach which brings together sources of information and training in a complete package.
- Not providing irrelevant and unwanted material and only providing information in the amount of detail needed to comply with the European requirements.

In addition to the above, it is suggested that this project addresses the product safety culture within target businesses. It is important that the EU requirements are not seen as simply a series of bureaucratic and burdensome rules but that they are seen in their proper context with important consumer safety outcomes.

A rigorous focus on the potential benefits to business needs to be made clear throughout the information and training. Benefits include customer loyalty to the brand, repeat business, fewer returned products, fewer interventions from regulators and market surveillance agencies etc.

It is therefore recommended that the structured approach to developing information and training resources focuses first on the development of the material and secondly on the medium of delivery. This means that suitable material could be delivered through a variety of channels and platforms.

One of the challenges this project will tackle is the sheer size of China and the number of potential target businesses. A mechanism must be found to secure the highest possible penetration into the business community in China. While conferences, workshops and other forms of face to face training will have their place, it will also be important that material can be delivered online and using all forms of new technology.

The advantage of creating the structure and material first is that this facilitates a range of options in relation to its delivery. A mixed approach of both online and face to face activities would be possible. The key is that the material is integrated and allows the Chinese business to select those elements of interest and relevance to their business.

Recommendations

In order to achieve the project outcomes as they relate to results 2 and 3 in the original ToR, it is recommended that the following approach be followed by the project team:

1. Undertake further research. It is important that this project is as well informed as possible by the best possible and most accurate information and data. Information gaps at present include:

- The scale of the problem to be addressed. There is a good deal of data on RAPEX and elsewhere relating to the number of products which fail EU safety requirements which are on sale in the European market. What seems less clear is evidence as to scale. For example, it is reasonable to suppose that in the best regulated environments, a certain percentage of products will fail to meet safety requirements, for a variety of reasons. Given the volume of Chinese products on sale in Europe, is the number of failing products greater or less than the failure rate of products produced by other nation's manufacturers. In addition, amongst Chinese manufacturers, does this failure rate vary between different product types, different manufacturers (large or small), or is some other factor in play? Is there a noticeable failure rate difference between products traded online and those imported for sale in shops? This information would ensure that the project was clearly targeted on the most critical issues and would therefore have the greatest impact for European consumers.
- In addition to the EU's legal controls, there have been several initiatives which have sought to improve outcomes for consumers through voluntary means. Some of these have been referenced in this report. There may have been several similar programmes. It would be helpful to know what has been tried and to know what has succeeded, what hasn't and why. This would help ensure that this project learnt from any mistakes made in the past, did not repeat these, but potentially built on the success of others.

2. The next step would be to genuinely understand what the needs are from the Chinese business perspective. It will be particularly important to understand these both from the large multinational business as well as the small and medium sized enterprises and start-up businesses. Their needs will vary. It may be that the smaller and start-up businesses are not members of trade associations and therefore understanding their challenges and perspectives will be harder to obtain. Nevertheless, this will be critical if the project outcomes are to be delivered across all sectors of the business community. Information received from trade associations to date seems to indicate that what is needed is more 'information'. However, much further analysis is required as to what genuinely prompts such comments. All the information that could be needed is available online – it must be something more. Possibly that the information is not structured in a useful way, that it isn't written in a practical way, that it requires research across multiple sites or that language is an issue. Whatever the real issues, these need to be identified so that this project focuses on real need.
3. Once these issues are completely understood, it would be possible to develop the thinking as to the overall structure to the approach. It is recommended that some key elements would include:
    - From the start, the project seeks to create an integrated approach to the provision of information and training and that this is structured from the business perspective.
    - The overall concept would be of an integrated and modular approach. The structure would seek to provide information and training on those issues common across EU legislation(e.g. conformity, CE marking), and deal separately with issues unique to

product types.

4. As stated elsewhere, it would be possible for both the reference material and the training in the form of online training videos to be fully integrated and to mutually support one another. This approach would also ensure that as the economic climate evolves, delivery of training and learning could be supported through conferences, workshops etc, but always as part of this integrated approach. It is believed that success will come from this kind of approach and structure, the project must avoid simply providing uncoordinated information and workshops if it is to truly make a difference. The approach above envisages that a significant element of the information and training is online, but does not preclude other forms of training and in fact builds this in. However, online training would ensure material was available to the widest possible audience. In addition, the suggested approach would ensure the material was structured around the real needs of individual businesses and would be more likely to engage their interest. In addition, businesses could undertake the training and look for information at a time convenient to them – something which is difficult to achieve with face to face training.
5. From the start, thought would need to be given with any of the online material as to how it is kept up to date. This is critical. Any online material needs to be capable of being updated as and when EU requirements change.
6. A focus on an online approach would lend itself to analysis of the most recurring issues and problems and would identify areas for further development of materials in those areas.
7. The online approach would facilitate greater tailoring and targeting of material such that structured information was presented in a way relevant to the audience, e.g. the information and training needs of a CEO, quality manager, lawyer, laboratory technician etc. might be different.
8. Whether training is delivered online, or through face to face methods, it will be key to make the training as practical as possible, with trainers using real examples of real products and situations from China and Europe. Training needs to be made meaningful by:
    - Putting information into the real context of the roles undertaken by different levels of staff within the business community. It must be relevant.
    - Those involved in receiving the training need to be involved in the learning process which needs to be as interactive as possible.
    - All forms of training and development can be subjected to testing to ensure key messages have been delivered and to help the project improve.
    - All forms of training need to be short and sharp and make sure key points are made clearly and succinctly using real examples of actual products and problems found.
    - Taking above into account – the approach should be 'problem solving', in other words, supporting the business to understand how to solve the problem based on the real examples used. In other words, being able to apply what has been learnt.
9. Criteria should be developed to assess the effectiveness of the information and training so that changes can be made as the project progresses.

Potential trainers need to be carefully selected, not just on their technical knowledge, but on their ability to communicate with their business audience using real world examples.

In summary, it is suggested that there needs to be a comprehensive and structured approach to information and training which puts the needs of the business community first.

9. Appendices

Annex 1 – Types of EU laws

Annex 2 – New Approach legislation

Annex 3 – The approach to risk assessments

Annex 4 – Stakeholders

Annex 1 - Types of EU laws

Regulations

A "regulation" is a binding legislative act. It must be applied in its entirety across the EU. For example, when the EU wanted to make sure that there are common safeguards on goods imported from outside the EU, the Council adopted a regulation.

Directives

A "Directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals. One example is the EU Consumer Rights Directive which strengthens rights for consumers across the EU, for example by eliminating hidden charges and costs on the internet and extending the period under which consumers can withdraw from a sales contract.

Decisions

A "decision" is binding on those to whom it is addressed (e.g. an EU State or an individual company) and is directly applicable. The decision relates to these organisations only.

Recommendations

A "recommendation" is not binding. A recommendation allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

Opinions

An "opinion" is an instrument that allows the institutions to make a statement in a non-binding fashion, in other words without imposing any legal obligation on those to whom it is addressed. An opinion is not binding. It can be issued by the main EU institutions (Commission, Council, Parliament), the Committee of the Regions and the European Economic and Social Committee. While laws are being made, the committees give opinions from their specific regional or economic and social viewpoint.

Annex 2 – Some pieces of New Approach Legislation

Toy Safety - Directive 2009/48/EU

Transportable pressure equipment - Directive 2010/35/EU

Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU

Construction products - Regulation (EU) No 305/2011

Pyrotechnic Articles - Directive 2013/29/EU

Recreational craft and personal watercraft - Directive

2013/53/EU Civil Explosives - Directive 2014/28/EU

Simple Pressure Vessels - Directive 2014/29/EU

Electromagnetic Compatibility - Directive 2014/30/EU

Non-automatic Weighing Instruments - Directive

2014/31/EU Measuring Instruments - Directive 2014/32/EU

Lifts - Directive 2014/33/EU

ATEX - Directive 2014/34/EU

Radio equipment - Directive 2014/53/EU

Low Voltage - Directive 2014/35/EU

Pressure equipment –

Directive2014/68/EU Marine Equipment

- Directive 2014/90/EU

Cableway installations - Regulation (EU) 2016/424

Personal protective equipment - Regulation (EU)

2016/425 Gas appliances - Regulation (EU) 2016/426

Medical devices - Regulation (EU) 2017/745

In vitro diagnostic medical devices - Regulation (EU) 2017/746

EU fertilising products - Regulation (EU) 2019/1009

Annex 3 - The approach to risk assessments

Risk assessment plays a key role in the work of market surveillance authorities in planning and prioritising their work. In March 2019, the EU produced a new version of the RAPEX risk assessment guidelines[34]. The guidelines are used by Member state enforcement authorities to determine whether a product presents a "serious risk" to consumers and should be withdrawn from sale or recalled. The new version replaces the previous version published in 2010

'Serious risk' is defined in the GPSD as any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities. The table below is taken from the RAPEX risk assessment guidelines.[35]

Table 4 - Risk level from the combination of the severity of injury and probability

Probability of damage during foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
High	>50 %	HIGH RISK	SERIOUS RISK	SERIOUS RISK	SERIOUS RISK
	> 1/10	MEDIUM RISK	SERIOUS RISK	SERIOUS RISK	SERIOUS RISK
	> 1/100	MEDIUM RISK	SERIOUS RISK	SERIOUS RISK	SERIOUS RISK
	> 1/1 000	LOW RISK	HIGH RISK	SERIOUS RISK	SERIOUS RISK
	> 1/10 000	LOW RISK	MEDIUM RISK	HIGH RISK	SERIOUS RISK
	> 1/100 000	LOW RISK	LOW RISK	MEDIUM RISK	HIGH RISK
	> 1/1 000 000	LOW RISK	LOW RISK	LOW RISK	MEDIUM RISK
Low	< 1/1 000 000	LOW RISK	LOW RISK	LOW RISK	LOW RISK

Level	Severity of injury
1.	Harm or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible.
2.	Harm or consequence for which a visit to A&E may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete.
3.	Harm or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.
4.	Harm or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability.

The table correlates the severity of an injury (scale across the top) with the probability:

- Greater than 1/100 of injuries requiring a visit to a hospital's accident and emergency department
- Greater than 1/1000 of an injury requiring hospitalisation
- Greater than 1/10000 of a fatal injury or an injury leading to permanent disability

[34] Decision (EU) 2019/417

[35] Guidelines for the management of the European Union Rapid Information System 'RAPEX'

Annex 4 - Stakeholders

The following is a non-exhaustive list of organisations based in Europe who may be able to support this project with input into the development of training and information needs. It should be stressed at this stage, none of the bodies referred to have been approached to seek their willingness to cooperate

Conformity Assessment bodies (Notified bodies)

Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a Directive. It is possible to conduct a search of notified bodies on the NANDO website[32] (New approach Notified and Designated Organisation). There are substantial number of bodies able to carry out a range of conformity assessment functions.

Accreditation bodies

1. The European co-operation for Accreditation (EA) is the overall European body, appointed by the European Commission to be overall responsible for the official European accreditation arrangements.
2. Each EU Member State has its own Accreditation body for the supervision of the accreditation system in that State.

Note, unlike conformity assessment bodies which operate as private entities, accreditation is a public body function and there is only one accreditation body per Member State

Market Surveillance

Market surveillance is a function of the individual EU Member Countries. In some countries, the function is part of a wider range of consumer protection functions and may include food as well as non-food market surveillance activities. However, there are coordination mechanisms and specifically:

1. Administrative cooperation Groups (AdCos)
2. Consumer Safety Network
3. A network for coordination and cooperation between enforcement authorities (referenced above and applicable from January 1, 2021)

Consumer Protection

Consumer protection is also primarily a function of the individual Member Countries in the sense of undertaking activities. Consumer protection consists of a range of functions some of which will be delivered by public bodies and others which may be delivered by public bodies or NGOs. The enforcement of fair-trading laws are usually a function of the state. The provision of advice and education for consumers may be provided by the state and/or by NGOs.

At a European level, there are organisations which represent the interests of consumers on a wider stage:

1. BEUC is a European consumer organisation. BEUC acts as the umbrella group in Brussels for its

Members and its main task is to represent consumers bodies at a European level and defend the interests of European consumers. BEUC investigates EU decisions and developments likely to affect consumers and has a staff of around 45.

2. ANEC. ANEC provides the European consumer a voice in standardisation. It represents the European consumer interest in the creation of technical standards, especially those developed to support the implementation of European laws and public policies.
3. European Consumer Consultative Group. The European Consumer Consultative Group is the Commission's main forum to consult with national and European consumer organisations.

Standards

Standards are at the heart of consumer product safety and support the essential requirements set out in EU legislation. Standards in Europe are created by the following bodies:

1. CEN, the European Committee for Standardization, is an association that brings together the National Standardization Bodies of 34 European countries.
2. CENELEC, the European Committee for Electrotechnical Standardization
3. ETSI, the European Telecommunications Standards Institute

Trade and Business Associations

There are a range of trade associations covering the different sectors of interest in this project. They cover a wide variety of interests and provide a wide range of services. Many of these trade bodies exist at a Member State level, often with an equivalent 'umbrella' body at the European level.

Many trade associations exist to support domestic manufacturers, although some support importers too. Some work would need to be undertaken to identify whether and how these bodies might support this project. By way of example, the following describes the structure of the European toy trade association.

The body is called TIE – Toy Industries of Europe. Its Members are

- National toy trade associations from individual European countries (e.g. Germany, Sweden and Spain – 9 in total),
- Corporate Members (e.g. Lego, Hasbro etc – 16 in total)
- Affiliates – These are a mix of other businesses with some (but not exclusive) interest in toys e.g. IKEA and related trade bodies (e.g. European balloon and party Council) – 7 in total.