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An Overview of the General Product Safety Directive 2001/95/EC



Intertek
Cleeve Road, Leatherhead, Surrey KT22 7SB UK

info.uk@intertek.com 01372 370900 www.intertek.com

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Introduction

Anyone involved in the commercial development or quality assurance of products being placed on the market in the European Union, will certainly be aware of the specific Directives that cover their products.

As the state-of-the-art develops across all sectors and new products appear, it is feasible that goods will start to fall outside the scope of specific Directives, or that goods not originally intended for consumer use, start being used by consumers. In these cases, the General Product Safety Directive (GPSD) 2001/ 95 EC applies.

The GPSD is the catch all safety net intended to protect consumer health and safety, and applies to all new and second hand goods in the region that are not covered by their own sector specific legislation but that may be used by consumers (whether they are actually intended for consumers or not). This paper is intended to provide an overview of the General Product Safety Directive 2001/95/EC

General Product Safety Directive (GPSD) 2001/95/EC

Article 1 – paragraph 1 “The purpose of this Directive is to ensure that products placed on the market are safe.”

The current version of the GPSD came into force 15th January 2004. It is intended to ensure consumer safety and to facilitate the free movement of goods across the European Union through a consistent and high level of safety of goods in the region, regardless of where they are produced.

- It applies to all manufacturers who place goods on the market in the EU, regardless of where that manufacturer is located, and covers goods that are not covered by their own sector specific legislation.
- If CE Marking legislation does not apply to a product being supplied to consumers, or only applies in part, the GPSD does apply.
- It doesn't matter how a product is sold; directly or by electronic means over a distance, the GPSD applies
- All parts of the supply chain are affected by the GPSD, from manufacturers, importers and distributors, to repairers and modifiers.

Definition of what constitutes a product

Article 2, paragraph a) of the Directive defines a product to be: “‘product’ shall mean any product – including in the context of providing a service – which is intended for consumers or likely, under reasonable foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether, new, used, or reconditioned.”

Exclusions

The GPSD does not apply to:

- Products that have their own specific EU harmonised legislation, such as for example electrical products (covered by the Low Voltage Directive 2006/95 EC) or cosmetics (covered by (EC) 1223/ 2009)
- Products for use in the workplace by employees
- Products for export outside the EU
- Antiques
- Products that need to be repaired or reconditioned prior to be used
- Products forming part of a personal transaction

Definition of what constitutes a safe product

Article 2, Paragraph b) of the Directive, defines this to be: “‘safe product’ shall mean any product which, under normal or reasonably foreseeable conditions of use including duration where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible to the product’s use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular

- i. The characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- ii. The effect of other products, where it is reasonably foreseeable that it will be issued with other products
- iii. The presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product
- iv. The categories of consumers at risk when using the product, in particular children and the elderly.”

Demonstrating compliance

When a manufacturer (producer) is working to demonstrate compliance with the GPSD, they must not only review the product with an eye to the characteristics of that product, but also with an eye on who might potentially be using those products. Paragraph 8 says “The safety of products should be assessed taking into consideration all of the relevant aspects, in particular the categories of consumers which can be vulnerable to the risks posed by products under consideration, in particular children and the elderly”

Even if formal standards and rules do not exist that cover the product in the EU, Producers can validate their products against a number of different regional codes and advice. Paragraph 16 adds “In the absence of specific regulations...the safety of products should be assessed taking into account in particular national standards transposing any other relevant European or international standards, Commission recommendations or national standards, international standards, codes of good practice, the state of the art and the safety which consumers may reasonably expect...” (These are also listed in Article 3). It is interesting to note that no one type of validating criteria is considered any more valid than any other.

So do you need to involve a 3rd party in your product validation?

No. You can choose to involve a 3rd party, but it isn't mandatory. For example, if you are validating your product against a specific national standard, you are likely to seek an appropriately accredited testing body to conduct the testing for you as (as paragraph 17 adds) "appropriate independent certification recognised by the competent authorities may facilitate proof of compliance with the applicable product safety criteria".

Equally though, you could assess the product yourself using knowledge of the state of the art and reasonable safety expectations of consumers.

So if my products conform, it won't be recalled?

It is feasible that even if a Producer has demonstrated product conformity that product may still not be safe – as indicated by customer complaints. In this circumstance sales could be restricted or the product banned or a product recall could still be forced.

Obligations of Producers

Article 2, paragraph e) defines a Producer to be:

- i. The manufacturer of the product, when he is established in the community, and any other person presenting himself as the manufacturer by affixing to the his name, trade mark or other distinctive mark, or the person who reconditions the product
- ii. The manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product
- iii. Other professionals in the supply chain insofar as their activities may affect the safety properties of a product

(Anyone outside of these criteria in the supply chain is considered to be a distributor)

Producers shoulder most of the compliance burden with the General Product Safety Directive. Their obligations are summed up in Article 3, paragraph 1 – “Producers shall be obliged to place only safe products on the market”. Within this activity they must:

- Provide consumers with relevant information that enables them to evaluate the potential risks (obvious or not) of a product during use or foreseeable use
- Be themselves informed of the risks their products may pose
- Notify the relevant authorities if a product they have supplied turns out to be dangerous.
- Take appropriate action relating to their unsafe product – including if appropriate a product recall that gives consumers appropriate compensation – such as refund or exchange.
- Provide on the product or packaging, the details of the Producer, the product reference and where applicable a batch number
- Where appropriate carry out sample testing of marketed products, keeping a register of safety complaints and the investigation of them.
- To co-operate with the competent authorities with regards to issues over dangerous products

Obligations on the Distributor

Article 2, paragraph f) defines “‘distributor’ shall mean any professional in the supply chain whose activity does not affect the safety properties of a product”

Distributors are required to:

- Act with care not to supply non-complaint goods or goods they as professionals would not consider be compliant
- Pass on any information on product risk
- Retaining documentation from their activities for tracing the origin of products
- Co-operating with Producers and the Competent authorities
- To inform the competent authorities if they have placed on the market and unsafe product with details of what actions they have taken to prevent risks to consumers.

Enforcement & Penalties

Here in the UK, enforcement of the GPSD is most often carried out by our Trading Standards Authorities and Environmental Health officers, but agencies such as MHRA that cover medical devices or VOSA that cover motor vehicles may also be involved in enforcement depending on the product type. Penalties for non-compliance can be severe – and include a £20K fine or a year in prison.

The GPSD also gives enforcement authorities broad powers to enter premises, test samples and seize product-related data from the supply chain.

As a last resort, a product recall can also be forced. This is also known as a 'corrective action', and costs can run into millions of pounds to complete. Recalls also absorb potentially thousands of man hours and can require refunds or exchanges to be made to the customer.

The Enforcement bodies will use the following tools in their enforcement activities.

- Suspension Notices to suspend product supply
- Requirements to add appropriate warnings and markings to a product.
- Withdrawal Notices to prevent product supply
- Recall Notices to recall products
- Seizure and disposal of products

At the time of writing there is also an enforcement provision that will allow the European Commission to ban a product on its own authority – it will not necessarily require a request for a ban from a member state.

RAPEX

RAPEX is the Community Rapid Information System – used by the network of competent authorities across Europe to communicate details of products that pose a risk to consumers. The GPSD requires public access to this type of information. RAPEX notices are issued every Friday and can be searched here - <http://ec.europa.eu/consumers/safety/rapex/>

Summary & Final Comments

- GPSD applies entirely if no specific CE Marking Directives apply or if they partially apply
- GPSD is applicable to products used by consumers, whether they were meant for consumers or not.
- GPSD is the concern of the whole supply chain and all parts of it have responsibilities under the legislation.
- GPSD applies to products in commercial transactions, not personal transactions.
- Unlike the CE Marking directives, the GPSD provides enforcement authorities powers to respond to any supplier within their own country, not just the manufacturer.
- The maximum penalties for non-conformity are higher than those of other Directives

In the near future, an updated version of the GPSD will be issued by the European Commission, as it has already undertaken a review of the Directive and identified areas it would like to address – such as the role and application of market surveillance, which plays a key part in market enforcement for other Directives. The GPSD needs to keep step with legislative developments in this and other areas, hence an upcoming revision.

Also, where a product falls outside the scope the CE Marking Directives, it means that there is no continuity of rules for it across the Community. These types of products are still therefore governed by various national rules. These products need to be governed in a common way, in the spirit of EU free trade.

European legislation is evolving and as such, the supply chain needs to be aware of the shifts and changes in their obligations. Your test and certification partner can tell you about the latest version of specific legislation, so if in doubt as to the current requirements for your product, seek professional advice.

For more information on specific testing and certification information, please contact Intertek at 1-800-WORLDCON, email icenter@intertek.com, or visit our website at www.intertek.com.

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