



The Responsibilities of Importers & Distributors in Europe



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Introduction

Millions of products are placed on the market within Europe every year. Most of these products are compliant with the various rules, regulations and directives that govern products in the European Community, but some are not.

While national authorities generally have good visibility of manufacturers operating inside the EU and work with them where necessary to ensure the appropriate corrective action is taken, manufacturers outside the EU are less visible.

In an effort to increase the visibility of non-EU manufacturers and maximise the number of compliant products on sale within the community, the European Commission, have strengthened their conformity surveillance framework by publishing decision 768/2008/EC on 'A common framework for the marketing of products'.

The reasoning behind the decision can be summed up in 4 points from the introduction. Paragraph 19 states:

"(19) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only products which are in conformity with the applicable legislation."

Paragraph 22 adds:

"(22) It is necessary to ensure that products from third countries entering the Community market comply with all applicable Community requirements, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those products."

Paragraph 27 specifically requests the involvement of importers and distributors in these efforts and paragraph 28 highlights what is arguably the essence of the whole decision – traceability:

"(27) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by national authorities, and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the product concerned."

"(28) Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing

economic operators who made non-compliant products available on the market”

In this paper we'll outline the specific responsibilities assigned by the decision to help manufacturers, importers and distributors comply with Europe's evolving regulations.

Definitions

In the decision ANNEX 1, R1, specific definitions of Manufacturers, Importer and Distributors are given:

“3. ‘manufacturer’ shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

4. ‘authorised representative’ shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

5. ‘importer’ shall mean any natural or legal person established within the Community who places a product from a third country on the Community market;

6. ‘distributor’ shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

7. ‘economic operators’ shall mean the manufacturer, the authorized representative, the importer and the distributor;”

Obligations & Responsibilities

Article 1 paragraph 2 states:

“2. When placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation.”

Outlined in Chapter R2, Article R2 Manufacturers must:

- Design and manufacture product in accordance with regulations
- Draw up the required technical documentation for the product, conduct conformity assessment and affix conformity marking
- Keep technical documentation for the required time
- Ensure that procedures are in place for series production to remain in conformity
- When appropriate with regard to the risks presented by a product, carry out sample testing of marketed products
- Keep a register of complaints
- Keep distributors informed of any non-conformity and complaint monitoring
- Ensure that products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.
- Indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.
- Ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users
- Manufacturers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Community harmonisation legislation shall immediately take the necessary

corrective measures to bring that product into conformity, to withdraw it or recall it, if appropriate.

- Where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken.
- Further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Outlined in Chapter R2, Article R4 Importers must:

- Importers shall place only compliant products on the Community market.
- Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation that the product bears the required conformity marking or markings and is accompanied by the required documents.
- Where an importer considers or has reason to believe that a product does not conform, he shall not place the product on the market until it has been brought into conformity.
- Where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.
- Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.
- Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users
- Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance
- When deemed appropriate with regard to the risks presented by a product, importers shall carry out sample testing of marketed products, investigate,

and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of such monitoring.

- Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the Community harmonisation legislation applicable shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate.
- Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken.
- Importers shall keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
- Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

It is important to note, that where importers bring goods in from a third country and trade them under their own name or trade mark (for example retailers own brand products) the importer will be considered to be the manufacturer and have all of the manufacturer's responsibilities.

Outlined in Chapter R2, Article R5 Distributors must:

- When making a product available on the market distributors shall act with due care in relation to the requirements applicable.
- Before making a product available on the market distributors shall verify that the product bears the required conformity marking or markings, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users
- Where a distributor considers or has reason to believe that a product is not in conformity, he shall not make the product available on the market until it has been brought into conformity.

- Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.
- Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance
- Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with the Community harmonisation legislation applicable shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken.
- Furthermore, where the product presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
- Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market.

So what are the implications of these requirements?

The onus is on importers and the distributors to be sure that a product is compliant – not just in terms of safety, but also in terms of all of the regulations that apply to a product - such as, but not limited to electromagnetic compatibility, the restriction of hazardous substances used in product manufacture and compliance with the energy using products Directive. Moreover, for a product to be compliant, it must carry the correct marking (CE marking in particular, in whatever variant required by the specific regulations that govern the product – e.g. in conjunction with a notified body number if testing is mandatory) and be accompanied by the appropriate documentation. Including:

- Correct labelling including ratings and batch numbers
- Appropriate warning and safety information
- Instructions in an EU language appropriate for the country of sale
- Technical File
- Declaration of conformity
- Details of a specific point of contact to tracing purposes

Importers can also conduct product assessment if they feel it is appropriate, and should make corrective actions if they believe a product they have placed on the market does not conform.

The easiest way to both check and demonstrate compliance is to undertake a formal programme of conformity assessment, the results of which can be used as evidence to support the declaration of conformity that must accompany the product as part of the technical file. These results can also be passed to the supply chain to communicate the validated compliance of your product.

What is Conformity Assessment?

For manufacturers this falls into 3 sets of activities:

1. Internal production control

- The production of appropriate documentation that covers the assessment, the design, the manufacture and operation of the product
- Ensuring that the manufacturing process and its monitoring ensure compliance
- Making a declaration of Conformity
- Affixing CE Marking

2. Internal production control plus supervised product testing

- The production of appropriate documentation that covers the assessment, the design, the manufacture and operation of the product
- Ensuring that the manufacturing process and its monitoring ensure compliance
- Making a declaration of Conformity
- Affixing CE Marking
- Conducting product checks against the requirements for that product. These include, safety testing, EMC testing, and energy efficiency testing

3. Internal production control plus supervised product checks at random intervals

- The production of appropriate documentation that covers the assessment, the design, the manufacture and operation of the product
- Ensuring that the manufacturing process and its monitoring ensure compliance
- Making a declaration of Conformity
- Affixing CE Marking
- Conducting product checks against the requirements for that product. These include, safety testing, emc testing, and energy efficiency testing
- At the choice of the manufacturer, either an accredited in-house body or a notified body shall carry out product checks or have them carried out at random intervals determined by the body. An adequate sample of the final products, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument.

Conformity assessment may also be carried out by an Authorised Representative on behalf of the manufacturer.

The role of Notified bodies

A notified body is an independent, accredited 3rd party that is authorised to test and assess a product against a set of criteria – usually those laid out in the Standards that govern the product. They are considered technical authorities on their given product group and any of the economic operators in the supply chain can approach a notified body to assess a product on their behalf. The notified body typically offers some sort of formal certification and in many cases a certification mark that can be applied to the product to help communicate its compliant status.

Conclusion

Decision 768/2008/EC on 'A common framework for the marketing of products' is fundamentally legislation concerning the traceability of products being placed on the market in the EU. It requires importers and distributors (as well as manufacturers) to share the responsibility to only put compliant products on the market. Should a product be non-compliant and require corrective action, those responsible for making the corrective actions can be more easily identified, as all of the economic operators in the supply chain are obliged to share information with the European authorities on request about who has supplied them and whom they have supplied with goods.

As the responsibility for placing only compliant products on the market in the EU is now shared, the decision also now means that direct importers and distributors can also be held liable for damages by the EU authorities for non-complying products. For a Manufacturer, importer or distributor to maintain any degree of certainty about the compliance of a product, it is vital that conformity assessment evidence is communicated throughout the supply chain. This data should be cascaded to and requested by all of these parties, so they can demonstrate the conformity of a product on request of the authorities. It is also important to note that conformity is not just about product safety – but rather all of the rules that govern the product from labelling and marking to EMC and energy performance requirements.

It is perhaps appropriate to establish procedures now that will ensure product compliance visibility, if they don't already exist. Where compliance information is not available in the supply chain, the importer or distributor could make a provision for their own conformity assessment activity – whether conducted in-house or via a 3rd party notified body.

View the full Decision document here:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:EN:PDF>

How Intertek can help

Intertek are a notified body in dozens of product areas and we can test, assess and certify electrical, electronic and mechanical products to help manufacturers, importers and distributors demonstrate the compliance of a product. Our test reports, certificates and product certification marks can be used as the basis of a declaration of conformity in a technical file and our experts are frequently called upon by the authorities to conduct analysis on non-conforming products, so our experience in conformity assessment is extensive.

If you are targeting specific countries in Europe we have a number of safety certification marks available. National Marks include the S Mark (for Sweden) the GS Mark (for Germany) and the BEAB mark (for the UK). If you require a pan-European safety certification we can provide you with the ETLEU mark.

We also have an extensive range of EMC, Energy Efficiency and Hazardous Substances assessments available, and we also offer a 'Corrective Actions' service, helping manufacturers, retailers, distributors and importers recall products and correct non-compliances.

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

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