

# ENSURE YOUR PRODUCTS REMAIN SAFE AND COMPLIANT

## ADVICE FOR ENTREPRENEURS INVOLVED IN MANUFACTURE OR PRODUCTION

If you have designed and manufactured and initially tested your products and services so that they comply with harmonised standards or you have used other methods to provide a similar level of safety for consumers, then your products or services are should comply with the essential safety requirement of all the applicable directives.

Most New Approach Directives allow the producer to "self-declare" compliance with Essential Health and Safety Requirements, but some directives require Notified Body intervention. For example, The Machinery Directive lists types of machines that must be submitted to a Notified Body for evaluation.

If you propose to self-certify, ensure that this method of conformity assessment is applicable to the type of product you produce. Self-certification is acceptable for a range of products covered by the Simple Pressure Vessels, Pressure Equipment, Machinery, Low Voltage, EMC and Toys Directives.

However, you still need to ensure that your production or service delivery processes are in control and produce consistent results. Can you be sure that your product complies with the requirements during its whole lifespan – from product idea to changes in construction and testing procedures? As producers you need to know and understand the product safety testing standards that apply to your particular products.

If you supply your products to importers or distributors, they will also be interested in knowing that your production processes are being checked and providing you with consistently compliant and safe products. They may wish to examine the technical files and testing records for the products that you are supplying or offering to supply.

The General Product Safety Directive defines a safe product as one that in normal or reasonably foreseeable conditions of use, including duration, it provides NO RISK OR ONLY MINIMUM RISK compatible with the products use and is an acceptable and consistent with a high level of protection for the health and safety of people.

It therefore is important that you accurately described the purpose of your product and the circumstances in which it can be safely used. You must provide clear and accurate instructions for use and assembly if required. You also need to warn about any hazards that are unavoidably present but maybe not obvious to some consumers. Take particular care with products aimed at vulnerable groups such as children and the elderly. Take care that the packaging or advertising for the product does not suggest an improper use or usage by an inappropriate class of users.

The most important points to remember are that it is the producer's responsibility to:

- place only safe products on the market
- continue to monitor their products after sale in case safety faults develop
- update warnings and instructions that are required to ensure consumers continue to use the product safely
- inform CRPC if they know or ought to know that a product they supply is unsafe
- withdraw any product from the market that they have supplied and is subsequently found to be unsafe
- issue a recall from existing users for any product that they have supplied and is subsequently found to be unsafe

## **CHECKLIST FOR PRODUCERS**

There are about 30 Directives, either adopted or under consideration, which require that products be marked with the CE mark. More than one Directive can apply to many given products. So use this checklist to ensure that you have covered all the important issues for each product.

- Identify all applicable EU Directives and national laws
- Determine the applicable standards - Harmonised, International, European or National
- Assess your product to the "essential requirements" contained in the Directives
- Ensure your production process has appropriate levels of Quality Assurance and Quality Control
- Choose the appropriate conformity assessment module for the product
- If required, choose a "competent body" to perform test on your products
- Establish the correct usage and safety parameters for the product – develop appropriate warnings and instructions
- Prepare a technical file, including a uses manual, particularly for products with high risk hazards
- Assemble the required approvals and certificates and prepare a Declaration of Conformity for each applicable Directive
- Affix the CE marking in the correct format – CE marking must be affixed visibly, legibly and indelibly.
- Ensure your marketing and advertising of the product does not mislead consumers and cause them to use the product dangerously
- Continue to monitor the compliance of your product during its production run and record the results of product testing
- Batch code the product and record any changes in design, materials, component suppliers, production process or product testing
- Continue to monitor the safety of your product whilst in use and investigate consumer complaints alleging accident or injury

## ADVICE FOR ENTREPRENEURS INVOLVED AS IMPORTERS OR AUTHORISED REPRESENTATIVES

Importers of products from countries other than member states, normally referred to as “third countries”, should be aware that you will assume many of the responsibilities of the producer. It is very important that you make detailed checks that the products are fully compliant and safe before you seek to bring them into any member state.

Be aware that whilst an Authorised Representative of a producer situated outside of the EU can undertake a number of activities that are normally carried out by the producer, a non-authorised importer only has a very limited range of options. The importer established in a member state that places a product from a third country on the Community market has a limited, but defined responsibility under the New Approach directives. In some directives the importer is referred to as the person responsible for placing on the market.

Under the New Approach directives, the importer as the person responsible for placing a product on the market must be able to provide the market surveillance authority with a copy of the EC declaration of conformity and make the technical documentation available.

The importer needs neither a mandate from the manufacturer, nor a preferential relationship with the manufacturer like the authorised representative. However, the importer must ensure, in order to fulfil his responsibilities, that a contact with the manufacturer can be established. In some situations the person referred to as an importer is able to assume the responsibilities of the manufacturer. Thus, he shall ensure that the product complies with the essential requirements and that the appropriate conformity assessment procedure has been applied.

It is particularly important to realise that the manufacturer, whether established inside or outside the Community, is the person ultimately responsible for the conformity of the product with the provisions of the directive and for the affixing of the CE marking. Importers do not normally have the knowledge or the right to apply CE marking.

Customs Services in all member states have a duty under Customs Regulation (EEC) No 339/93 to check imports from third countries for product safety conformity. They are empowered to suspend the release of products that:

- give serious concern as to the existence of a **serious and immediate** risk to health and safety under normal and foreseeable conditions of use **or**
- when a **document** required to accompany the products is missing **or**
- do not bear **conformity marking** or **labelling** required under product safety rules

The Customs Service are also under a duty to inform the relevant Market Surveillance authority when they have exercised any of the above powers. The Market Surveillance authority can then take control of the products pending further enforcement action.

## **CHECKLIST FOR IMPORTERS**

- When considering whether a new product is safe, look in particular for anything that stands out as being unusual or of poor quality when compared with products of the same type.
- Ensure that all relevant products carry CE marking, have appropriate warnings, use and assembly instructions and are accompanied by a certificate of conformity and technical file when required to do so by an appropriate directive.
- The completeness, durability and clarity of the CE marking, warnings and instructions for use are often a reasonable indication of the quality of the product.
- If your supplier provides you with test certificates that claim to show the product complies with safety requirements, make every check possible to make sure that the certificate shown to you is genuine and refers to current production of the product in question. You could for example telephone the test laboratory and ask to speak to the author of the test certificate or report.
- Check the RAPEX website frequently for notifications of unsafe products and be aware that other similar products with different brand names may have originated from the same producer.
- If you are an importer or distributor you will also be interested in knowing that the producer's production processes are being checked and providing you with consistently compliant and safe products.
- You might consider seeking to become an Authorised Representative if your main supplier produces products outside the EU as this will normally give you better access to technical details and the results of product testing. This status will allow you carry out administrative tasks on behalf of the manufacturer. To become an authorised representative you need to be established in a member state and you has to be explicitly designated by the manufacturer.

## **ADVICE FOR ENTREPRENEURS INVOLVED AS DISTRIBUTORS**

Distributors are general not included in New Approach directives but you must act with due care in order not to place clearly non-compliant products on the Community market. You must also be capable of demonstrating this to the national surveillance authority. You must store and handle the products in such a manner so as not to cause them to become non-compliant or unsafe. This requirement can normally be met by delivering the goods to your customers in the same good state as you received them.

The General Product Safety Directive has introduced a range of action that distributors must undertake:

- You now have to monitor the safety of products that you supply
- You must pass on information on product risks to your customers
- You must keep documentation necessary for tracing the origin of products
- You must co-operate in actions taken by manufacturers and government agencies to avoid the risks