

CE Marking Directives – Back to Basics

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The purpose of the creation of the single market by the then EEC in 31 December 1992 was the free movement of goods. This was based on a new regulatory technique and strategy laid down in 1985 and commonly referred to as the “New Approach”. Legislation based on the New Approach would contain only the essential requirements that products, which are placed on the single market, have to meet.

Normally, the fulfilment of these requirements is indicated by the letters “CE” on the product or its associated documentation or packaging.

There are more than 20 pieces of legislation, referred to as New Approach directives, ranging from directives covering construction products through electrical/electronics goods to medical devices. This article aims to introduce the common structure to these directives and uses one example to illustrate how to comply with them.

New Approach Directives – For Whom?

In the first instance New Approach directives are addressed to the member states of the EU (presently 27 sovereign states) and, by extension, to three of the four EFTA states, i.e. Iceland, Liechtenstein and Norway. These 30 states make up the European Economic Area (EEA). They are required to transpose New Approach directives into national law. This means that, as a general rule, EEA states are not allowed to introduce or maintain more stringent measures than foreseen in these directives.

As this article will explain later, New Approach directives stipulate essential requirements a product has to meet before it can be placed on the single market. The manufacturer has the “sole and ultimate responsibility for the conformity of the product” (European Communities, 2000, p. 21). In this respect “manufacturer” means anyone who presents himself as the manufacturer regardless of whether he designs, produces or labels his goods. It is also noteworthy that for the New Approach directives it does not matter whether he is established within or outside the EEA. However, importers also have certain responsibilities under the New Approach.

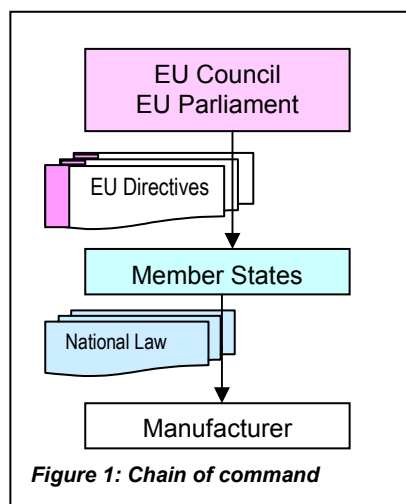
New Approach Directives – The Structure

New approach directives basically contain essential requirements a product has to comply with for it to

be placed on the single market. Ostensibly, it is up to the manufacturer to decide how to meet these requirements, but if products are manufactured in compliance with harmonised standards, then they “benefit from a resumption of conformity with the corresponding essential requirements” (European Communities, 2000, p. 7).

According to European Communities (2000, pages. 8-10) a New Approach directive contains the following standard elements:

1. The scope defines the range of products or nature of hazards covered by the directive.
2. Remarks relating to the placing on the market and putting into service of products covered.
3. The essential requirements.
4. Requirements regarding the free movement of goods.
5. Explanations indicating that the compliance with harmonised standards confers presumption of conformity with the essential requirements.
6. Safeguard clauses, requiring EEA states to police the placing of non-compliant products on the single market.
7. Conformity assessment procedure.
8. The role of conformity assessment bodies (formerly referred to as notified bodies).
9. The CE mark.
10. Provisions relating to the co-ordination of implementation.
11. Any transposition and transitional provisions.



New Approach Directives – The Application

Different parties will read directives with a different interest, e.g. governments in the member states will look at how to transpose them, enforcement agencies will look at how to police them and manufacturers look at the essential requirements; even users should be interested in them.

Let us assume a manufacturer established in one of the 27 EU member states wants to sell his new product in his home state. What should he have done in order to legally use the CE mark? As a first step he should verify whether or not his product is within the scope of one or more New Approach directives. It is worth noting any exclusions of the scope, for instance, something may be excluded because it has been designed for solely for police use.

After examining the scope of all the New Approach directives, the manufacturer concludes that his products falls within the scope of one or more directives and this (or these) directive(s) have been transposed into national law. What does the conformity assessment procedure for his product, which he intends to produce in volume, include?

Some may think that it is only going to the test house and passing tests to relevant standards - but more is involved!

According to the Decision No 768/2008/EC there are eight basic modules (plus sub-modules) from which one or more can be chosen to be incorporated in a New Approach directive. To understand the implications let us look at the Low Voltage Directive (2006/95/EC) as an example. The module chosen for this directive was module A, which covers both the design and the production phase. This requires our manufacturer to keep technical documentation which shows that his product conforms to the essential requirements of the Low Voltage Directives. It must, as far as relevant for such an assessment, cover the design, manufacturing and operation of his product (see Figure 2).

In other words the conformity assessment has to be kept in mind when starting to design a product and not only when going to a test house. Therefore the documentation must include a list of standards applied in full or in part and any design calculations made and examinations carried out. This indicates that the design phase should include some sort of risk analysis at an early stage.

Once our manufacturer is convinced that his design is safe and in compliance with the requirements of the Low Voltage Directive, he has to take all necessary steps to ensure the compliance of the manufactured products with the technical documentation referred to above. This could be an ISO 9000 certified quality system, although this is not stipulated as a requirement for this directive.

Conclusions

This article gave a brief overview of how New Approach directives work, what their general structure is and when to apply them. It also explained that the directives are only relevant for manufacturers who want to sell their products in countries where these directives have been adopted into national law.

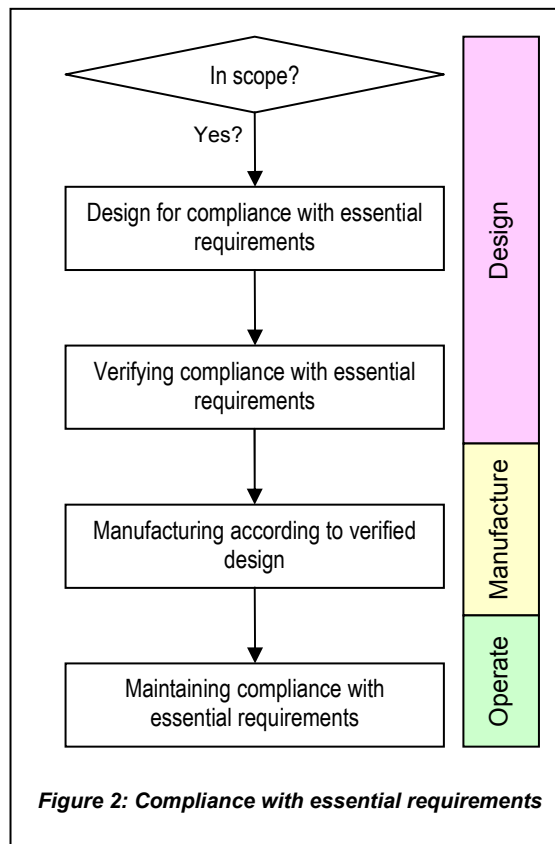
The general structure of New Approach directives includes the scope, its essential requirements and

the conformity assessment procedure(s). These sections are of particular relevance to manufacturers as they have to demonstrate compliance with the essential requirements if their products are in scope.

The example of the Low Voltage Directives shows that the conformity assessment consists not only of

tests verifying a particular design, but can also include relevant design calculations. Sufficient attention must also be given to the production control aspect to ensure that products manufactured in volume all comply with the verified design. The Low Voltage directive also requires the technical documentation to cover safe operation.

It can be seen that knowing which directive to apply and how to apply it is not always straightforward. Given the fact that they and the relevant harmonised standards change, it is easy to see that some investment in time and/or money has to be made in order to sell legally on markets in the EEA member states.



This article is based on:

- European Communities (2000). *Guide to the implementation of directives based on the New Approach and the Global Approach*, Luxembourg: office for Official Publication of the European Communities.
- European Parliament and Council (2008). *Decision No 768/2008/EC on the common framework for the marketing of products*, **L20**, pp82-127
- European Parliament and Council (2006) "Directive 2006/95/EC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits" *Official Journal of the European Union*, **L374**, pp10-19

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