

# Global Regulatory Compliance

## Product Liability and Corporate Organizational Obligation

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### Introduction

These days, products must meet a variety of regulatory requirements to ensure that they are legally compliant when they enter markets. The *New Approach*, which deals with the technical harmonization of regulations within the European Union (EU), is just one example. Certain product groups such as, e.g., toys, medical devices, electric and electronic devices like PCs or video recorders, machines or personal protective equipment, are all labelled with the identifying CE mark for cross-border marketing. In other countries like the United States (e.g. for EMC: FCC Part 15) or Australia (for EMC: C tick mark), other legal requirements for accessing markets apply (see Figure 1). Not being knowledgeable about these legal requirements presents an obstacle to the proper marketing of goods.

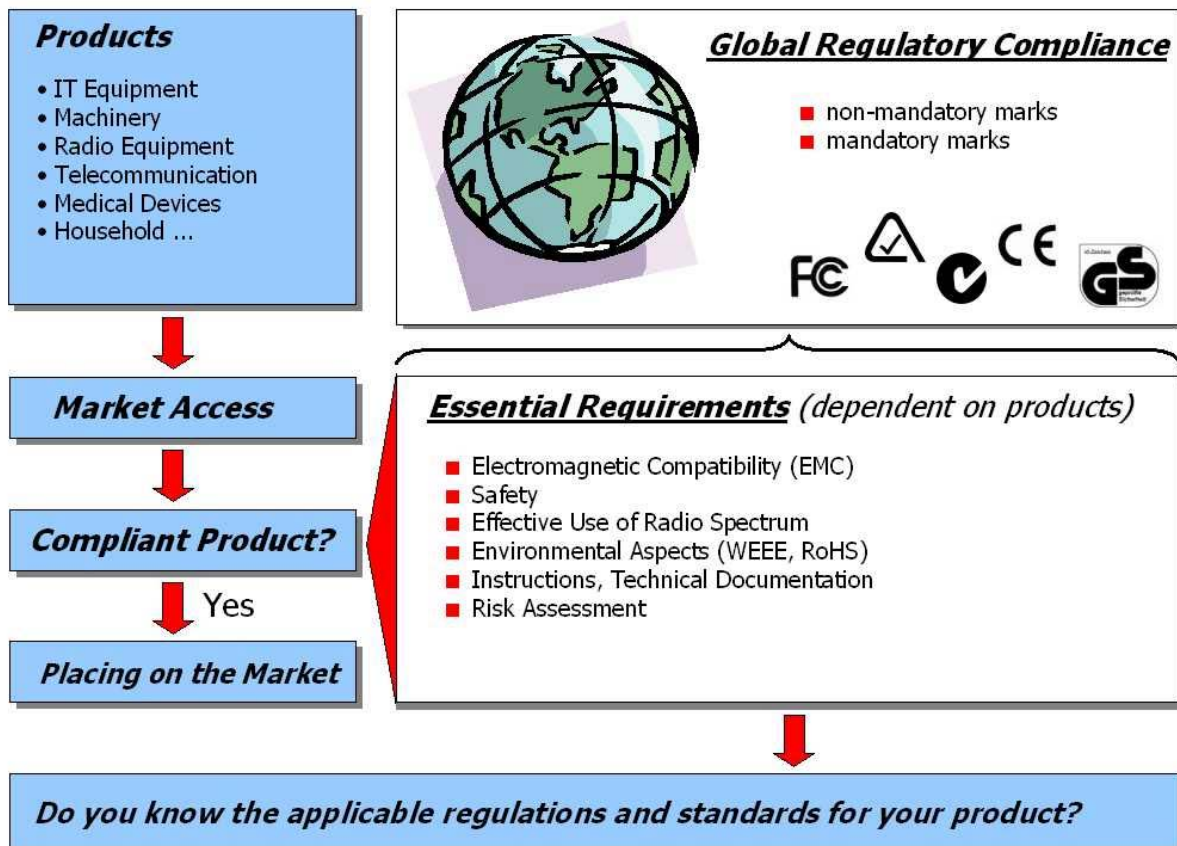


Figure 1 Market Access Conditions

## **Global Regulatory Compliance**

“Knowledge is power”. In our current environment of increasingly shorter cycles of innovation, this notion is more important than ever. In this context, however, knowledge also means maintaining a competitive edge and business security. Today, the “time to market” aspect plays an important role in the successful introduction of products. For this reason, an awareness of the applicable market access requirements is necessary during the early product development phase.

The fundamental market access requirements are:

- regulations
- standards and
- the conformity assessment procedures applicable to the product (standard concepts also include license/authorization or certification).

This, however, also includes the risk of product liability and thus the company’s liability and that of its executives.

Unfortunately, we have recently seen an increasing number of legal proceedings and product recalls (usually cross-country) dealing with major damage and conflict situations which not only have a major impact on a firm’s corporate image, but also have a very concrete effect on the corporate financial position. The questions which always arise in these instances are: How could this happen? And, who should be responsible in the final analysis? And, how can these kinds of situations be avoided in the future?

## **Legal Obligation to Maintain Safety**

Obviously, these companies did not fulfill their legal obligations to maintain the safety requirements as required by law. This concept can be divided into two areas:

1. product obligation and
2. corporate organizational obligation

Product obligation involves in particular:

- construction and planning obligation,
- manufacturing obligation (quality assurance during production, e.g. ISO 9000 QM system), e.g. Annex II no. 8 “EMC Directive 2004/108/EC”,
- duty to instruct (warning labels, instructions) and
- product monitoring obligation in all marketing regions, e.g.,

Corporate organizational obligation involves in particular:

- competent personnel and their continuing education,
- awareness of the currently state of the art (regulations, standards),
- dealing with returns and complaints,
- product monitoring (after market control) in addition to a product recall system,

- precise delegation of tasks, and monitoring their completion within the company, including their documentation.

## **Knowledge Management**

According to ISO 9001:2000-12, Paragraph 5.5.6, *Document Management* is also defined as

- d) to ensure that relevant versions of applicable documents are available at points of use, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

According to ISO 9000:2000-12, Paragraph 3.7.2, the definition of "documents" also explicitly includes regulations and standards. Thus every company has to think about Knowledge Management. In this context the topic of global regulatory compliance should be of fundamental importance.

In the past 10 years, however, many companies and agencies, whose central departments (quality and standards management) used to support Product Life Cycle Management, have either been decentralized or closed. Many companies still neglect their new responsibilities, such as organizing a possible product recall (e.g. as required under Paragraph 5 of the German Equipment and Product Safety Act for Consumer Products, GPSG). This is quite shocking – and not just in light of their industrial liability insurance.

It was often thought that the developers of new products and processes know how to determine safe specifications in terms of liability, and that they are aware of possible risks, external and internal liabilities. This, however, is not the case!

At the same time, developing new product innovations has become an integrated and therefore very complex activity which needs to become even faster and more effective. Pressure has increased not decreased. However this has not diminished the risk of potential liability. The upshot is that we have become twice as vulnerable. There is a lack of required knowledge and experience, and this in a more complex environment in which the set development period has not decreased.

Many companies have thought to themselves: Let's set up an intranet with a small search engine or a database. We can set up a library behind it containing the required documents in full-text format so that everyone can find what they need.

Based on our many years of customer service experience, especially developers and planners need additional support such as

- interpretation of legal regulations and standards,
- preparation of check lists and guidelines as results-oriented documentation,
- provision of user-specific information with notification function in case of document changes,

- fast availability (if possible in PDF or HTML format) of full-text documents and
- a hotline for urgent requests.

It is important to point out that small and medium-sized companies do not have these required internal structures in place. This presents a major drawback. When a sales ban is issued in accordance with EMC directive 89/336/EEC (replaced by: 2004/108/EC), for example, or a product recall (normally uninsured) under the directive 2001/95/EC on general product safety has to be carried out, a company quickly ends up on the brink of bankruptcy.

Therefore, entrepreneurs must be aware that product liability is an integral part of corporate culture and should also be part of a company's central knowledge base. This expert knowledge, which is changing dynamically at increasing speeds and on a global level, impacts the entire quality control system. It is also part of Business Intelligence. You only know the market if you also know the rules and the networks which affect them. You cannot expect safe products or processes from employees who do not possess this knowledge.

This should sensitize any executives in charge of development, production, purchasing, product marketing/management, etc. Additionally, internal processes should be examined as to whether they meet these corporate requirements. This is the only way in which products can be safely and successfully sold in the global marketplace in the future. The fact is that this knowledge is a key competency; one which can be successfully and competitively utilized and which should therefore not be underestimated.