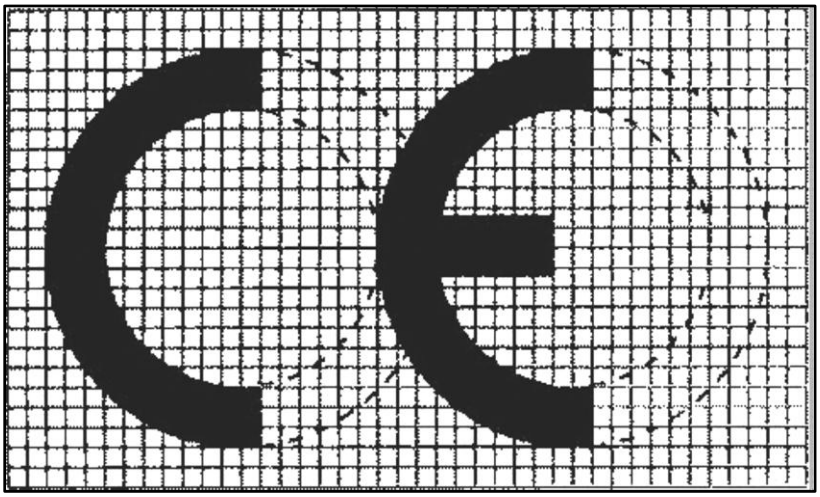
CE-marking:

Creating a model for applying the EMC, LVD and Machinery Directive



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Abstract

To further improve a single European market, the New Approach was introduced for European product safety law in 1985, indicated by CE-marking. It harmonises product safety legislation by creating mandatory fundamental legal safety requirements (directives) and voluntary technical specification standards (norms). To acquire CE-marking on a product, a manufacturer has to complete a CE-trajectory and meet the safety requirements of the applicable directives. The goal of this research was to capture the CE-trajectory in a generally usable decision making tool for manufacturers to comply with a product to the EMC, LVD and/or machinery directive.

To achieve this, first scientific literature, legal documents and practical insights were analysed to create a theoretical framework. In this report the functioning of CE legislation through directives and standardisation is discussed along with implications for manufacturers. After that an elaboration is given on the different components of acquiring CE-marking on a product, the content of the EMC, LVD and machinery directive and the exploration of decision making tools. This formed the basis for creating a well-founded decision making model. The model, a decision tree, is described in section 4.2. To evaluate the effectiveness of the design, a case study was executed as empirical method. The CE-trajectory of a high pressure water jetting gun was analysed with the decision making tool to see how the model functioned in practice and to analyse if the process of acquiring CE-marking became more efficient. The designed decision making tool was adapted on the basis of the results.

The decision making model is made up of questions. The first part consists of determining the applicable directives, leading to six options, varying from ‘all three directives apply’ to ‘none apply’. The application of each directive was analysed separately. This was done until the needed provisions to acquire CE-marking for a certain product could be determined, formulated as ‘actions manufacturer’ in the model. If two or three directives apply to a product the described paths in the model can be combined. All options and combinations of paths give 72 possible outcomes in this model.

The model was tested by means of a case study. The data analysis of this test gave the following results. First of all, the model provides clarity and overview in the complex matter of CE-marking. Applicable directives and possible outcomes (actions manufacturers) are clearly listed. Using the model can lead to efficiency and it can support implementing CE-marking into work processes. Although used definitions are distinct, they can be difficult to translate into practice. The model is limited to three directives, but other applicable directives can appear because of exclusions. A CE-trajectory is not automated by this model. Finally certain leeway can remain present within the defined paths, which subsequently is supported by supplying relevant information as outcome of the model.

The CE-trajectory is clearly captured in a decision making tool for manufacturers to comply with a product to the EMC, LVD and/or machinery directive. Based on this research and the case study, the model is generally usable, but for a better founded statement on the generalisation of the model, further testing is advisable. The model is at the junction legal and technical fields of study and could be useful for research in both fields. This research can serve as starting point for follow-up studies or further research. Furthermore could the decision making model be translated into practice. It can be developed into a web-based variant to assist manufacturers, showing one question at a time for easy navigating through the decision tree and the applicable directives can be listed as a legal groundwork for a product. After that the actions for manufacturers can be listed as outcome, based on the applicable path.

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List of abbreviations

CE	European Conformity – (*Conformité Européenne*)
CEN	European Committee for Standardisation – (*Comité Européen de Normalisation*)
CENELEC	European Committee for Electrotechnical Standardisation – (*Comité Européen de Normalisation Électrotechnique*)
DOC	Declaration of Conformity
DOI	Declaration of Incorporation
EC	European Commission
EEA	European Economic Area
EFTA	European Free Trade Association
EMC	Electromagnetic Compatibility
EN	European Norm
ESO	European Standards Organisation
ESRs	Essential Safety Requirements
ETSI	European Telecommunications Standards Institute
EU	European Union
GPSD	General Product Safety Directive
ISO	International Organisation for Standardisation
LVD	Low Voltage Directive
MD	Machinery Directive
NB	Notified Body
NEN	Dutch Norm – (Nederlandse Norm)
OJ	Official Journal – (L = law) – (C = communication)
RA	Risk Analysis
RAPEX	Rapid Exchange
RI&E	Risk Inventory and Evaluation
TCF	Technical Construction File

Chapter 1 Research Introduction

Statistics of the European Commission show that defective products cause a great amount of accidents, leading to many injuries and even deaths among citizens. This is not only caused by defective consumer products, but also by accidents in industry. This research focuses on product safety law, which is about the prevention of accidents and risks.

1.1 General Product Safety Legislation

The European Union (EU) and therefore European legislation, aims at free movement of persons (labour and professions), capital, goods and services. This European integration towards a single market resulted in a so called new European approach to product law, installed in 1985. Because of that, current European product law comprises a cluster of three parts, all consisting of directives: product liability (compensation of damage and injury), product safety (prevention of defects), and the harmonisation of normalisation. Harmonisation is achieved by installation of law on European (supranational) level. Normalisation indicates the establishment of norms (technical specifications). This research will focus on product safety. Because of several food crises, like BSE and foot-and-mouth disease, the precautionary principle was introduced for food products in 2002 by means of the General Food Law. Thereby food is extracted from the product safety directive, which is consequently about non-food. The general product safety directive contains the obligation to market only safe products with a presumption of conformity to the safety requirements (Brack, 1999; Hodges, 2001).

The new approach to product law can be clarified by the differences between positive and negative integration and between horizontal and vertical legislation. Negative integration means the mutual recognition by member states of each other's national product laws. The new approach comprises supranational legislation, to which national laws have to comply, which is positive integration. The old approach contained vertical legislation by maximal harmonisation, which was very detailed on product level. The new approach uses horizontal legislation, general requirements on product groups.

European product safety law is now limited to fundamental legal requirements. These are created for groups of products and are mandatory. Authorised European normalisation organisations translate the directives (laws) into technical specifications. They deliver standards, called norms, which are voluntary. These norms can be used to show the presumption of conformity with the general directives. This system of horizontal legislation is indicated by the CE-mark. "CE" stands for "Conformité Européenne", meaning European conformity. The CE-mark thus means conform European law and is not just a hallmark or quality mark.

Legislation discussed in this research applies to the European Economic Area (EEA), which comprises the 27 EU member states and the European Free Trade Association (EFTA) states. A full list of countries is included in appendix I. When the European market is mentioned, all those countries apply.

1.2 CE-marking

The CE-mark indicates that a product complies with the fundamental safety legislation. When a product bearing the CE-mark is used for its intended purpose or for an unintended but reasonably foreseeable purpose, it should be safe. The focus is solely on safety level. A manufacturer who markets a product on the European market is responsible for the CE-marking. The CE-mark can be seen as self-declaration of compliance with the fundamental safety requirements of the applicable directives (Twigg-Flesner, 2005).

Although sometimes other parties can be involved, CE-marking is basically a statement from a manufacturer that his product is conform safety legislation. This can be exemplified by a model created by Euronorm, an organisation that offers guidance, counselling and courses on safety requirements, that describes a so called CE-trajectory. Products put on the European market are obligated to bear the CE-mark and certain requirements have to be met to affix the CE-mark to a product. These requirements can be logically structured, which Euronorm has done in a way that clearly displays the different facets of CE-marking. To fulfil the obligations of CE-marking eight steps can be taken:

1. Define which directives / norms apply
2. Execute conformity assessment
3. Apply safety requirements
4. Execute risk analysis
5. Draw up technical construction file
6. Draw up directions for use
7. Draw up declaration of conformity
8. Affix CE-marking

Step 1; which directives / norms apply?
There are a number of directives installed for groups of products, see appendix II. The gaps that are not covered by these directives are filled by the General Product Safety directive 92/59/EEC. All the directives start with the general obligation to market only safe products. A producer, by using CE-marking, gives a promise to market safe products and provide relevant information about risks and precautions. This research focuses on the three most apparent directives in industry settings (B2B): Machinery Directive (MD) 2006/42/EC, Low Voltage Directive (LVD) 2006/95/EC, Electromagnetic Compatibility (EMC) directive 2004/108/EC. On a voluntary basis certain norms can be applied to prove conformity with these directives. There is a long list of norms.

Step 2; execute conformity assessment:
In each directive a procedure is included for a conformity assessment, often captured in a flowchart. The complete CE-process is made up of modules, from module A, internal production control, until module H, full quality assurance by a notified body. Dependent on the type of product and the safety risks, a certain module has to be followed (modules A, BC, BD, BE, BF, G, H). Along with this choice, an assessment is made whether a notified body is necessary or not, or maybe recommendable, to use.

Step 3; apply safety requirements:
In the applicable directives the minimal essential safety requirements are given.

Step 4; execute risk analysis:
To assess which risks can arise and whether the safety requirements will be met, a risk analysis can be conducted.

Step 5; draw up Technical Construction File (TCF):
Each applicable directive contains the criteria that have to be attended in the TCF.

Step 6; draw up directions for use:
Each applicable directive contains the criteria that have to be addressed in the directions for use.

Step 7; draw up declaration of conformity:
For each applicable directive the elements that have to be attended in the declaration of conformity are included. With a declaration of conformity a manufacturer states that a product is in conformity with the applicable directives and thus with European safety legislation.

Step 8; affix CE-marking:
If all steps are completed CE-marking can be affixed to a product. If a product is too small, it is allowed to place it on the packaging. The official CE-mark (mandatory shape) has to be affixed, see appendix III.

When these eight steps are carefully executed, a product should comply with the legal requirements and the CE mark can be legitimately affixed. As a result a buyer may expect that the product is conform product safety legislation. The potential risks for using a product should have been assessed and been prevented from occurring or proper warnings should have been issued with the product. So when using a product, unsafe situations must be prevented. In England recently a boy's arm has been torn off by a washing machine (Hull, 2011). He managed to open the machine and reach inside while the machine was mid-cycle. CE-marking is about preventing this kind of accidents. The risk of opening the door while it is operative should be assessed and consequently by installing a lock e.g., unsafe situations should be averted. This research focuses at acquiring CE-marking on a product and thereby preventing risks to arise and subsequently accidents to occur.

1.3 Research goal

An introduction is given into the field of European product safety law. In this research more specifically acquiring CE-marking on a product will be investigated. A product is in this case thus non-food and is very broadly defined, it includes parts of a commodity like substances and components and can even be a complete machine. The aim of this research is to reveal the decision making structure of how to acquire CE-marking on a product. When proceeding through a CE trajectory there are some aspects that always have to be completed. In accordance with the steps that have to be taken to acquire CE-marking, the aspects that have to be fulfilled can be determined on the basis of the applicable directives. Therefore determining which directives apply to a product is the first step. To keep an overview a list of the aspects that have to be attended is given:

- Assessment which directives apply
- Assessment whether a notified body is required: conformity assessment
- Safety requirements for the product of the relevant directives
- Content of the risk analysis
- Technical Construction File of the product
- Content of the directions for use
- Content of the declaration of conformity

These aspects are dependent on the applicable directives. So, once the applicable directives are defined, the other aspects are to some extent fixed. Every stage of the trajectory can be regarded metaphorically as a 'standard block' that can be filled according to the requirements in the relevant directives. This presumes there is a structure in acquiring CE-marking on a product, because the requirements in the directives are fixed for every type of product. The objective of this research is to create a decision making

tool that captures the steps of a CE-trajectory and thus of acquiring CE-marking, for all types of products that fall within the scope of the LVD, EMC and machinery directive.

This research transcends the level of one company, one product and one directive. The objective is to create a decision tree for all companies and all types of products to which the three mentioned directives apply. This research is at the crossing of legal studies and technical studies. Designing machinery or electrical products for example is combined with legislation. At this moment there is little research available on this specific topic and elaboration about creating a model for acquiring CE-marking is almost a clean sheet. Most literature is either descriptive on legislation or about technical details for designing product. This is instantly the academic relevance of this research. On the other hand this research also aims at creating a decision tree that can be used in practice. When a manufacturer wants to acquire CE-marking on a product, he can use this decision making tool. By using it he can gain insights in the requirements of CE legislation and in how he can comply with his product to the relevant directives. The decision making tool is meant for manufacturers who want to acquire CE-marking. So the designed model will be both scientifically relevant and practically usable in different situations.

Acquiring CE-marking is captured in a decision making tool in this research, covering the aspects of the CE-trajectory. Because of practical implementation, preferably the decision making tool should be a decision making tree, as long as it fits within the research goal. When a manufacturer completes the decision tree, the blocks (that correspond to the aspects that have to be fulfilled) should be filled as much as possible, adjusted to the type of product. So partial automation will be created for acquiring CE-marking for products to which the three most apparent directives in industry are applicable. Ultimately this should lead to more efficient trajectories of acquiring CE-marking.

- The goal of this research is to represent the eight steps that have to be made to acquire CE-marking for the LVD, EMC and machinery directives in a decision making tool and thereby fill the blocks that come out of the trajectory as much as possible. So it will be researched what is necessary for a product to comply with product safety (CE) legislation.

1.4 Research questions

To research whether the CE-trajectory can be captured in a decision making tool, how this can be done and how much can be standardized, the following research question is formulated:

- *In what way can the CE-trajectory be captured in a generally usable decision making tool for manufacturers to comply with a product to the EMC, LVD and / or Machinery Directive?*

To find an answer to the main question the following sub questions have been formulated:

1. Which insights can be derived from literature about CE-marking, safety requirements and the use of decision making tools for acquiring CE-marking on a product?
2. How is a CE-trajectory composed, based on the applicable directives?
3. How can different parts be captured into a decision tree or other decision making tool to fulfil the standard aspects of the CE-trajectory?
4. How does the designed decision making tool function in practice?

1.5 Research approach

This research was initiated in cooperation with Euronorm. They assist companies (their clients) and try to transfer knowledge to them about everything related to safety and associated (European) legislation. The main reason Euronorm is involved in this research, is to observe whether the CE-trajectory can be (partially) automated and thus be executed more efficient. The end goal for Euronorm is to translate the findings of this research into an online system for companies that want to acquire CE-marking. Additionally when that is realized, it could result in more interesting business for Euronorm, because standard processes could be captured in that system.

In order to reach the objective of designing a decision making tool, a qualitative research is instigated. First a literature study is conducted in combination with a study on legal documents and files from Euronorm. The thereby formed theoretical framework is used as a basis to create a model in the form of a decision making tool, preferably a decision tree. Another source of information for the model are the employees of Euronorm, with whom is collaborated during this phase. They have a wide range of knowledge about legal aspects and about practice, they have insights in lots of companies (their clients). After that the designed system is tested on a product in practice and adapted on basis of the outcomes. This leads to the conclusions and discussions at the end of this report. In chapter three a more extensive elaboration of the methodology is made.

Chapter 2 Literature Review – CE-marking & Standardisation

In order to create a clear outline and provide definitions, a theoretical framework is instigated, which is the first part of this research. An elaboration is made on the central concepts and the relationships between them to facilitate guidance in this research. First European safety law will be discussed, followed by a more specific elaboration on the CE-trajectory, directives and the practical implications. After that the step towards decision making theory will be made.

2.1 European Product Safety Law

As defined in the first chapter, European Product Safety Law comprises three parts; product liability (compensation of damage and injury), product safety (prevention of defects), and the harmonisation of normalisation (Brack, 1999). This legislation is in line with the so called New Approach. This chapter will proceed on the characteristics of this approach and discuss its implications in practice. Council Resolution 85/C 136/01 of 7 May 1985 contains in concise form the main principles of the New Approach. This legislation is subject to an ongoing modernisation process to continuously improve regulation and to obtain a practical legislative framework. In 2008 for example, the New Legislative Framework (NLF) for the marketing of products was adopted, which is regarded as such a modernising addition (OJ 2008 L 218, p. 82–128). The implementation of legislative improvements is ongoing, the basic ideas and goals however remain the same. The indication 'New Approach' remains the common name for this legislation and is therefore used in practice, in literature and in this research.

2.1.1 Objectives of the New Approach

The New Approach is established with a few intended goals. The far most mentioned objective in literature and in European Commission documents is the free circulation of products, free trade. All European legislation should contribute to a single European market, without (internal) frontiers (Brack, 1999). Free movement of persons, capital, goods and services has to be facilitated. Monetary customs barriers (e.g. tariffs) and quantitative provisions (e.g. import quota) were already prohibited, but other measures by member states under the cloak of consumer safety could still frustrate free trade within the EU. This is dissolved by the establishment of European law, supranational legislation, on product safety to which national regulations have to comply. This so called positive integration leads to harmonisation of regulations. This means that if products comply with the New Approach legislation, its trade may not be prohibited or frustrated (OJ 2002 L 11, p. 4). This will be explained in detail further on.

Another goal of product safety legislation is, as the name indicates, to secure the safety of European civilians. Consumers and professionals in industry should both be protected against unsafe products and accompanying risks. By placing a product on the market, both putting it into trade and putting it into operation are meant. The New Approach protects the public goals of health and safety by drawing attention to potential hazards, for health or the environment for instance, and by formulating procedures to comply with safety legislation. Prevention of injuries and damages is reached by the promotion of safety. Market surveillance authorities have the right to withhold unsafe products from the European market and the obligation to provide information about risks and unsafe products (Hodges, 2001).

The protection of civilians is also the reason why food is extracted from the product safety directive. A number of food crises such as foot-and-mouth disease led to a diminishing consumer confidence in the safety of food products. Therefore the precautionary principle was introduced which in concise form means that a product is unsafe, unless it strictly complies with regulation (Brack, 2009). Hereby

provisional risk-management measures by member states, such as impeding the free trade of a product, are less difficult to employ for food products if a suspicion of non-conformity arises. Although it also could be interesting to look at the distinction food-nonfood, for this research it is important to keep in mind that product safety as discussed is at the moment about non-food products.

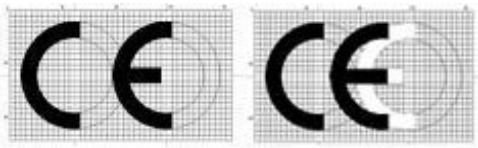
A final objective of the New Approach that is widely recognized is the stimulation of innovation. As will be discussed further on, the essential requirements for products are harmonised by this legislation. The definition of technical requirements is left to the economic actors - making the process more rapid – and the burden of control by surveillance authorities prior to a product's placing on the market is reduced. Another important aspect is that this legislation aims to prevent citizens from risks, which can enhance consumer's trust in products baring the CE-mark and in market surveillance. As a consequence consumers will have an enlarged trust in new products and are more likely to buy those products, making it more worthwhile to develop new products, thus to innovate for manufacturers (Twigg-Flesner, 2005).

These aspects are the (main) objectives of the New Approach. This is accomplished by the CE-legislation which promotes aspects like technical harmonisation. Although it is debateable whether this is a means or an end, in this research it is regarded as substance of the CE-marking process and not as an objective. A distinction is made between (higher level) objectives and all aspects included in the CE-marking process, which will attended to hereafter.

2.1.2 General safety requirements - Directives

By means of the innovative system of the New Approach, supranational law is installed for product safety. European legislation on CE-marking is limited to fundamental legal requirements written down in directives for large families of products (e.g. toys or machinery) and is mandatory for any manufacturer putting a product on the European market. The General Product Safety Directive is placed above these directives, but specific CE requirements are superior to general provisions. The focus is on the safety of (groups of) products, to avoid risks for the health of product users. The CE-directives issued by the European Commission contain general requirements that products have to meet when they are placed on the European market. These harmonised laws (on European level) have replaced diverging national laws and thereby provide leeway to ensure the free movement of products throughout the Community, keeping regard to safety requirements of general interest. This positive integration ensures that national laws are adapted to the European laws. CE-legislation indicates what has to be achieved, but does not go in to detail about technical solutions how to do that. The normalisation process, which is discussed under the next heading, is left to officially appointed normalisation organisations. This grants flexibility, the details and technical specifications can be implemented in several ways (OJ 1985 C 136, p. 1–9).

CE is the abbreviation of 'Conformité Européenne' and by placing the mark on a product, a manufacturer proclaims that it is conform the fundamental requirements of the applicable directives. CE thereby functions as pre-marketing safety and is a declaration that a product is in line with European legislation. CE-directives are about groups of products and several directives can apply to one product. A full list of the CE-directives is included in appendix II. An elaboration on the EMC, LVD and Machinery Directive is given further on. CE in Europe is not to be confused with 'China Export'. The CE-mark means compliant to European safety legislation.



2.1.3 Technical specifications – Harmonised standards

Under the New Approach, the directives constitute a coherent system with technical standardisation. Normalisation refers to the establishment of technical specifications. Such specifications are gathered in norms and are officially referred to as harmonised standards. Standardisation in this context means the establishing of those specifications concerning the essential requirements into one norm. These terms are sometimes used intermingled and not always in their purest meaning, but all refer to the creation of technical specifications in the form of harmonised standards.

Besides legislation, also standardisation is harmonised among EU member states. The technical specifications are drawn up by European Standards Organisations. Before 1985 standards were very detailed on product level and drawn up by legislators. Because of the detailed level of product requirements and a decision making process by unanimity, it took very long to develop and implement technical details. With the introduction of the New Approach, European legislators only decide on the fundamental legal safety requirements and the creation of technical specifications is left to economic actors (Hanson, 2005, p. 44–45). European standards organisations develop technical standards in consultation with industry stakeholders and consumer representatives. In the so called norm committees different actors involved are represented. In accordance with the directives, harmonised standards are about families of products, differing in that norms deal with specific aspects. For the machinery directive e.g. there is a norm that deals with safety of machinery by means of principles for determining the dimensions required for openings for whole body access into machinery (EN 547-1). It is important to bear in mind that norms are not mandatory, manufacturers can use them voluntarily. Although standards are voluntary, their transposition into national standards and the retraction of diverging national standards is obligated for member states. Norms are optional but recognized technical specification standards that can be used to show conformity with the directives. They are presumed to be conform requirements of the directives if their references are published by the Commission and by the Member States. Since harmonised standards are not legislation and therefore are voluntary, they have to be bought. There is a clear separation between European legislation and standardisation (Brack, 1999; OJ 1985 C 136, p. 1–9).

There are three European Standards Organisations: Comité Européen de Normalisation (CEN), Comité Européen de Normalisation Electrotechnique (CENELEC) and European Telecommunication Standards Institute (ETSI). They are officially appointed standardisation organisations (OJ 1998 L 204, p. 37–48). It is their responsibility to analyse, interpret and translate the abstract general safety requirements in the directives into practically useable specifications. Their work is based on consensus (OJ 1985 C 136, p. 1–9). In the Netherlands the most important organisation is the NEN (‘Nederlandse Norm’), which controls the standardisation process. It guides normalisation and maintains national norms. The NEN is a cooperation between the ‘Nederlands Normalisatie-instituut’ (NNI) and the ‘Nederlands Elektrotechnisch Comité’ (NEC). Internationally (global) there are more organisations operating in this field, like the International Organisation for Standardisation (ISO).

2.1.4 Presumption of conformity

The mandatory legal part of product law is linked to the voluntary standardisation part of the system by the concept of the presumption of conformity (Brack, 1999). This means that products manufactured in conformity with relevant harmonised standards are presumed to be conformant to the essential requirements. In line with that, standards must offer a guarantee of quality regarding the fundamental

safety requirements. So the earlier mentioned characteristics of the New Approach, positive integration with horizontal legislation, function through directives and norms:

1. *Mandatory* (binding) fundamental legal safety requirements +
2. *Voluntary* (optional) technical specification standards

Standards are not mandatory, so alternate paths are possible, but if a manufacturer markets a product, he has the obligation to be able to prove that his product is conform the fundamental requirements (OJ 2002 L 11, p. 8). This brings forward the issue of responsibility, which sometimes is also referred to as burden of proof. But before addressing that issue, notified bodies have to be discussed.

A notified body is, as the name indicates, an organisation that is notified for certain tasks. Notification in this matter is an act whereby the EC (along with other member states) is informed by a member state that an organisation (body) fulfils the relevant provisions and is designated to execute conformity assessments in accordance with a directive. The establishment and the withdrawal of a notification is a member states' responsibility and happens per directive (OJ 1985 C 136, p. 1–9). A list of notified bodies can be found at the website of the EC and is referred to as Nando Information System (New Approach Notified and Designated Organisations). Here can be seen that each notified body has an identification number and the tasks for which a body has been notified are included.

Notified bodies can help organisations with a conformity assessment, which should be executed prior to marketing a product, to demonstrate that it fulfils the legislative requirements that apply to it. These bodies are sometimes referred to as national testing organisations, however this is testing of conformity and should not be confused with market surveillance, which consists of controls after the product has been placed on the market. The precise content of a conformity assessment will be attended to further on, but it is composed of modules. Dependent on the risks of a product, for every directive a module can be chosen with certain provisions, for both the design and production phase of a product. For some modules a manufacturer can easily perform the assessment himself, but for other modules it should partly or completely be done by a notified body. They can issue a (test) certificate that proclaims conformity to the legal requirements. It is always allowed to hire a notified body, but for products with certain safety risks, consistent with certain modules, it is obligated (Blue guide, 2000, p. 31–35).

2.1.5 Issue of responsibility

The presumption of conformity brought forward the issue of responsibility. It can be said that the bottom line is that a manufacturer must show that his product is in conformity with the essential legal safety requirements. He declares that by placing the official CE-mark on his product and by drawing up a declaration of conformity. Although the manufacturer is responsible, there are ways to shift away or share that responsibility. He can use harmonised standards for certain essential safety requirements, which has the main advantage that by using them the manufacturer is presumed in conformity with law. Not using them will impose additional responsibilities to prove that a product meets the essential requirements, like an extensive technical file or hiring a notified body even when it is not obligated (Delaney & van de Zande, 2000). When a notified body is hired, it can give a test certificate on certain aspects or requirements, or even on the whole product and production process. Using harmonised standards and hiring a notified body makes a declaration of conformity very strong.

Among other authors Brack (1999), when discussing the burden of proof, brings forward producing the direct and indirect way. The direct way being the method that a manufacturer promises that his product is conform the essential requirements and has to proof that himself. The indirect way meaning producing according to harmonised norms, acquiring test certificates from a notified body and thereby claiming that a product is safe and that the notified body is responsible. However the manufacturer is responsible, he must show a legitimate and trustworthy certificate that his product is safe. In both cases someone who claims the product is not safe must proof non-compliance. However, having a notified body mark, certificate, and test report does usually shift the onus of proof in the manufacturer's favour, since the product was assessed and certified by European recognized experts (Lohbeck, 1998). Moreover harmonised standards are a recognized interpretation of specific parts of the fundamental safety requirements, to which a product must comply. But compliance to the harmonised standards also has to be demonstrated. Moreover, the use of these methods does not dismiss a manufacturer from his responsibilities.

Furthermore, the use of harmonised standards gives only a presumption of conformity. In a court case in a dispute on EMC of an electrical wheelchair, the key reference was the essential requirements and not the harmonised product standard (Leferink, 2010, p.26). In that article it is also stated that several EMC product standards have been developed under relaxed, or sometimes even no essential requirements. In addition the directive on product liability is applicable to all products covered by New Approach directives (Blue guide, 2000, p.17). So the responsibility and obligation to manufacture conform essential safety requirements remains central. Therefore a well-founded declaration of conformity is very useful for a manufacturer as will be further addressed under the next heading.

2.1.6 Market surveillance

Public authorities are responsible for the protection requirements on their territory. All directives contain safeguard clauses to withhold or withdraw unsafe or risky products from the market to protect the safety of citizens. The General Product Safety Directive (2002) encloses the safeguard in article 8, in which the measures are mentioned that competent authorities of the member states are entitled to take, like checking safety properties or even ban products from the market. Member states however may not to restrict the placing on the market and putting into service of CE marked products, unless these measures can be justified by evidence of noncompliance of the product. In article 10 of the GPSD can be found that an information sharing system is installed for the support of market surveillance on product safety: RAPEX (rapid exchange). By this system member states can cooperate, mostly by sharing knowledge. The remarkable thing is that legislation is on European level, but surveillance is done by national enforcement. It can be said that the market is unified, but surveillance is fragmented (Hodges, 2001).

Although market surveillance is not directly the scope of this research, it complements the explanation of product safety law and contains some interesting aspects to keep in mind. There are a few reasons why a company or a product can be subjected to inspection. A product may have caused damage (under prescribed use) in which case a manufacturer has to prove that the safety requirements were met. A technical construction file is a very important document in that case, possibly with test certificates. The declaration of conformity has to be proved. Another reason for inspection can be that a national inspection agency is checking a sector as a whole on the compliance to safety requirements. Furthermore a dispute may arise when there is a suspicion of non-conformity, but to go against the presumption of conformity, one must have well-founded indications. The implications can be illustrated with the so called

Finnish case where the old machinery directive 98/37/EC applied (Case C-470/03, 2007). The Finnish surveillance authorities made a report that found certain deficiencies in Italian AGM lifts, but found no sufficient evidence, so its use was not restricted or prohibited. An official of the Finnish administration however, stated on television that the lifts could be dangerous. AGM claimed that this led to a drop in its turnover and sought compensation from the Finnish State and the official in question, and applied to the Tampere District Court, which turned to the Court of Justice for an interpretation of the rules on the free movement of goods. That judgment said that no safeguard measures were employed and that the product enjoys a presumption of conformity, so the statement constituted an obstacle to the free movement of goods. Because it was an official who made the statements, the impression was given that it were official pronouncements of the State. The Court dismissed any justification on grounds of health protection outside the safeguard procedures provided for in the Directive in question, and also rejected the justification on grounds of freedom of expression, pointing out that, although Article 10 of the European Convention on Human Rights is a fundamental principle of all democratic societies, Member States cannot plead the freedom of expression of their officials to justify an obstacle to free movement.

So, to go against the presumption of conformity there must be well-founded allegations and in this case official statements of disconformities were illegitimate unless they are proven. In every directive there are safeguard clauses to keep unsafe products out of the market if safety risks do exist. It is always important that a manufacturer has a strong declaration of conformity for which he is responsible. He can use the presumption of conformity against ungrounded claims of non-compliance, but nevertheless he must be able to proof conformity to the essential safety requirements and the use of a notified body can support this to great extent (Delaney & van de Zande, 2000; Blue guide, 2000, p. 34–36). This complements the exposition of the theoretical functioning CE-marking within European product safety law.

2.2 Implications of CE-marking

Whereas the previous section elaborated on European product safety legislation, this section will focus on the implications of CE-legislation for manufacturers. The question is what companies have to do in detail in order to acquire CE-marking and how that can be structured. It will be explained how legislation functions in practice. A closer elaboration on the three separate directives of this research is included in the next section.

2.2.1 Subjects of legislation

First of all it is important to assess who is responsible for CE-marking on a product. Legislation speaks about the manufacturer. A manufacturer, in the meaning of the New Approach, is the person who is responsible for designing and manufacturing a product with a view to placing it on the Community market on his own behalf (Blue guide, 2000, p.21). This however has multiple meanings, legally manufacturer can imply the following cases. A producer if located in the EEA, an importer in the EEA of products from outside Europe, or a consumer if buying directly from a producer outside the EEA (OJ 2002 L 11, p. 8). In addition to that, if a producer uses finished products, ready-made parts or components to create a new product, he is a manufacturer. Even if all parts are marked with CE, the manufacturer is responsible for the CE-marking of the assembled product. Also by making a significant modification to a product, it is considered as a new product that has to comply with the applicable directives when placed on the market, and the responsibility shifts towards the owner of the product. Another option is the use of an authorised representative who takes over the responsibility of CE-marking from a producer outside the EEA and manages the technical documentation. Like stated before, the manufacturer has the obligation to

ensure that a product intended to be placed on the Community market is designed and manufactured in accordance with the provisions of the applicable New Approach directives and its conformity is assessed. He always must retain the overall control and take the responsibility for the product. The manufacturer or authorised representative is obliged to complete the conformity assessment, draw up the required documentation, issue a declaration of conformity and affix the CE-marking before placing any apparatus on the market (Ludwar, 2006). A buyer may then expect that a product is conform the requirements of European safety legislation (Blue guide, 2000, p. 15–26).

The manufacturer is thus responsible for CE-marking, but has opportunities to cope with this. Legal responsibility can pose big risks, so manufacturers try to decrease those risks. In practice the common unwritten rule is to shift away as much responsibility as possible. There are some practices to achieve this. When purchasing components or parts of a commodity for example, they can be bought with a declaration of conformity from the supplier. If a CE-marked component is implemented for its intended use in a product, (partial) responsibility of safe functioning of that component lies with the supplier. So purchasing specifications can be drafted. Another practise is the use of harmonised standards to show conformity with the fundamental requirements. Next to that the use of a notified body gives assistance to prove conformity. Test certificates can be included in the technical construction file (TCF). The manufacturer is responsible, but can get assistance by means of these practises and partially shift the responsibility away. Another aspect to bear in mind is that a product should cope with the state of the art and the current technology. If a significant modification is executed or a new product is developed this should be taken into account (Blue guide, 2000, p. 21; OJ 2002 L 11, p. 9).

European product safety law has been discussed, it is clear what it comprehends, how it functions in general and what different actors are involved. Now the implications for acquiring CE-marking on a product that applies to the LVD, EMC and/or machinery directive will be researched. First the steps of a CE-trajectory will be investigated. On that basis the content of the actions that manufacturers have to take, previously referred to as ‘standard blocks’, will be defined.

2.2.2 Components of acquiring CE-marking

The different steps of the CE-trajectory are analysed in detail. Completing these steps is indicated in the first chapter as the actions needed for a manufacturer to acquire CE-marking on a product.

1. *Define which directives / norms apply:*

The decision making tool will be designed for an industry setting. It could serve as a basis for other directives settings or fields, like consumer products, as will be addressed in the discussion section. But in this research the design is created for products applying to the LVD, EMC and/or machinery directive. Most products or production processes are covered by one or more of these directives. Directives are listed by their name, the year of publication and the number of publication in that year. References of directives are towards the official journal in which they are published. The three relevant directives in this research are referred to as:

- Low Voltage Directive 2006/95/EC (OJ 2006 L 374, p. 10–19)
- EMC Directive 2004/108/EC (OJ 2004 L 390, p. 24–37)
- Machinery Directive 2006/42/EC (OJ 2006 L 157, p. 24–86)

The first step is to determine which directives apply. Hereby a manufacturer knows to which legislation he has to apply, but also which directives he does not have to take into account. The scope and exceptions of each directive are clearly mentioned in article 1 of every directive, if necessary complemented by a reference to an annex. Several directives can apply to one product. It is an unwritten rule that if the LVD applies to a product, the EMC also applies, because electric equipment always shows some electromagnetic compatibility. The only exception is radio equipment and telecommunications terminal equipment covered by directive 1999/5/EC. This directive however also has requirements on electromagnetic disturbances, but uses other limits and is outside the scope of this research. A product can be subjected to only the EMC though, like USB-appliances which have electric components, but do not reach the minimal voltage limits of the LVD. It is made clear that a product is broadly defined, it can be found in the scope of the directives whether a certain product fits the definition. The relations and references between directives have to be carefully investigated when a product or hazard is covered by multiple directives. All applicable directives haven to be taken into account. The requirements have to be met, the different conformity assessments have to be executed and documentation has to be drawn up in accordance with all directives, before the CE-mark may be affixed (Blue guide, 2000, p. 15–20).

Conformity to the essential safety requirements can be proved via the path of harmonised standards which are technical specifications. Norms are a recognized interpretation of a specific aspect of a directive. They are voluntary, but when followed demonstrate compliance to the safety requirements on that specific subject. So a product shall be deemed safe if all risks categories are covered by harmonised standards (OJ 2002 L 11, p. 5–9). There is a long list of norms per directive, so practically a manufacturer can use norms for high risk categories or for aspects he has little knowledge about. This is subjective and can differ from case to case. It is a free choice for manufacturer which norms he wants to use.

To support conformity to the essential requirements, purchasing specifications to suppliers in accordance with certain directives or harmonised standards can be issued. If a product is not covered by a CE-directive or by other Community legislation, the general product safety directive (GPSD) applies (OJ 2002 L 11, p. 7). This implies CE-marking is not required, but the manufacturer remains responsible for his product. He can still be held liable and it can be advisable to complete a CE-trajectory nonetheless. Also there needs to be a regular check whether a new directive is installed that is applicable.

2. Execute conformity assessment:

Manufacturers can demonstrate a product's conformity to the requirements of the applicable directives by means of the conformity assessment. Appropriate procedures are put up, related to the type of products and accompanying hazards (OJ 1993 L 220, p. 23–39). Dependent on the risks of a product or production process, a certain module has to be followed. The modules relate to the design phase of products, their production phase or both. There are eight modules with accompanying procedures, structured in the following schematic representation.

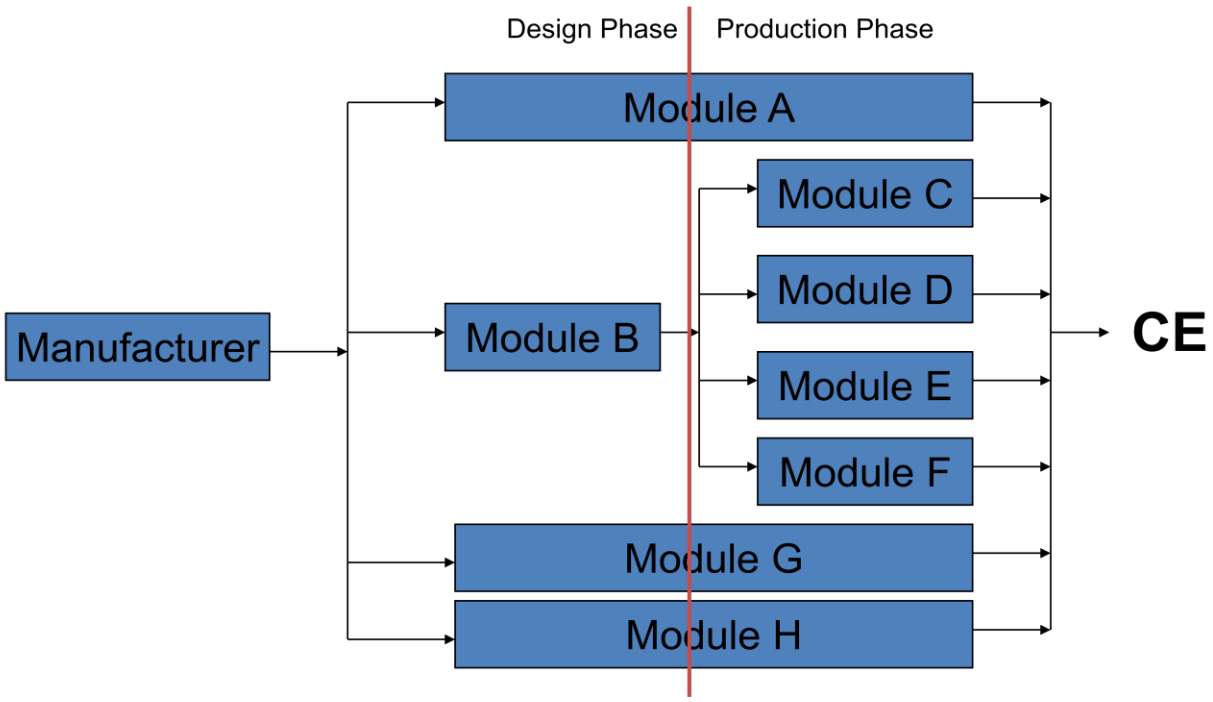


Figure 2.1: Flow chart of conformity assessment procedures (Blue guide, 2000, p.32)

The eight basic modules are applicable for a range of products, depending on the type of product and its risks and hazards. Each module has a certain safety level that has to be followed. Module B for the design phase should be followed by module C, D, E or F for the production phase. The procedures should demonstrate conformity to the safety requirements of the applicable directives.

Module A	Internal control of production	Covers internal design and production control. This module does not require a notified body to take action.
Module B	EC type-examination	Covers the design phase, and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificate is issued by a notified body.
Module C	Conformity to type	Covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B, does not require notified body to take action.
Module D	Production quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9002, with the intervention of a notified body responsible for approving and controlling the quality system for production, final product inspection and testing set up by the manufacturer.
Module E	Product quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9003, with the intervention of a notified body responsible for approving and controlling the quality system for final product inspection and testing set up by the manufacturer.

Module F	Product verification	Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.
Module G	Unit verification	Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.
Module H	Full quality assurance	Covers the design and production phase. Derives from quality assurance standard EN ISO 9001, with the intervention of a notified body responsible for approving and controlling the quality system for design, manufacture, final product inspection and testing set up by the manufacturer.

Figure 2.2: Basic modules of the conformity assessment (Blue guide, 2000, p.32)

There are some additions for specific cases, variants of the basic modules, the so called '*bis* annexes'.

Aa1 and C*bis*1	Internal production control, and one or more tests on one or more specific aspects of the finished product	Intervention of a notified body either at design or production stage regarding testing carried out by the manufacturer or on his behalf. The products concerned and the applicable tests are specified in the directive.
Aa2 and C*bis*2	Internal production control, and product checks at random intervals	Intervention of a notified body regarding product checks at production stage. The relevant aspects of the checks are specified in the directive.
D*bis*	Production quality assurance without use of module B	A technical documentation is required.
E*bis*	Product quality assurance without use of module B	A technical documentation is required.
F*bis*	Product verification without use of module B	A technical documentation is required.
H*bis*	Full quality assurance with design control	A notified body analyses the design of a product or a product and its variants, and issues an EC design examination certificate.

Figure 2.3: Variants of basic modules of the conformity assessment (Blue guide, 2000, p.33)

The modules D, E and H include the use of quality system standards, the ISO 9000 family of standards. A certified quality system is not required, it are means of establishing compliance to quality assurance modules in regard to the applicable directives. It is used to demonstrate the conformity to the requirements, which is the bottom line of the conformity assessment. Dependent on the type of products and accompanying hazards a module has to be followed to demonstrate conformity. In figure 2.3, a manufacturer may always choose a lower module than required, but may never go up. In other words, he may apply more extensive conformity procedures. Included in the conformity assessment is the possible obligation to use a notified body. It is always allowed to use a notified body, even when it is not required. This however can have high costs, but can also give a stronger declaration of conformity and more certainty for a manufacturer on the issue of safety. For some modules and thus for certain type of products the use of a notified body is mandatory (Blue guide, 2000, p. 31–34).

In the different CE-directives information about the conformity assessment is included. In annex IV of the low voltage directive for example, internal production control is discussed (OJ 2006 L 374, p. 17). To determine which module should be followed, the blue guide has to be consulted. Annex 7 deals with the contents of conformity assessments procedures and gives an overview of the tasks under the responsibility of the manufacturer and the notified body (Blue guide, 2000, p. 84–88). Annex 8 gives a flow chart presentation of conformity assessment procedures as provided for by the directives. For each directive a flowchart shows the appropriate modules and procedures dependent on the type of product (Blue guide, 2000, p. 89–112).

3. Apply safety requirements:

In the New Approach, legislative harmonisation is limited to fundamental safety requirements. These requirements are mandatory and deal in particular with the protection of health and safety of users (consumers and workers) and sometimes with other facets like protection of the environment (Blue guide, 2000, p. 27). The content of the essential safety requirements (ESRs) can be found in the annexes of the directives. In annex I of the LVD for example, the principal elements of the safety objectives are given (OJ 2006 L 374, p. 14). Products must comply to be placed on the market or put into service. Essential requirements have to be applied as a function of the hazards that accompany a certain product. To assess the hazards, a risk analysis has to be executed with the requirements as criteria and be included in the technical documentation (Blue guide, 2000, p. 27).

As mentioned before the essential requirements define what has to be achieved, but do not give technical specifications how to do that, which is done in harmonised standards. The ESRs are generally defined and can therefore be difficult to understand or interpret, especially when a manufacturer has little experience with certain requirements. For those specifications it can be advisable to use harmonised standards as a recognized interpretation of certain ESRs, apart from other considerations to use norms. For aspects where high risks occur it can also be useful to use harmonised standards (Blue guide, 2000, p. 27–30).

4. Execute risk analysis:

To apply the safety requirements a risk analysis (RA) should be performed, documented and included in the technical documentation. Hereby conformity to the ESRs from the directives can be demonstrated and the declaration of conformity can be supported. By documenting the RA, the manufacturer can show that for his product the risks that could possibly arise, are assessed and what measures have been taken. Risk analysis is the basis for risk reduction measures. So the manufacturer must ensure that a risk assessment is performed for a product that will be placed on the market or will be put into operation. Therefore he must define which health and safety requirements are applicable and what measures have to be taken.

Risk analysis can be referred to as the core of CE-marking. In this stage the safety requirements are actually assessed, analysed and possible measures are taken. The safety level of a product is investigated. Not all directives contain the obligation to perform a risk analysis, but it is a systematic way to apply the safety requirements. The machinery directive does have the obligation to carry out a risk analysis. The requirements set out in annex I can be used as criteria for it (OJ 2006 L 157, p. 35–64). This is an extensive list that also attends some electrical criteria for example, like the following two criteria: under heading 1.5. (risks due to other hazards): “1.5.1. electricity supply, 1.5.2. static electricity” (OJ 2006 L 157, p. 44). All the applicable safety requirements, also from other directives, have to be included in the risk analysis.

The norm EN-ISO 12100-1 (*Safety of machinery - Basic concepts, general principles for design*) is harmonised to the Machinery Directive 2006/42/EC and gives guidance for performing a risk assessment. Furthermore a risk graph can give guidance and overview in the RA. Several models can be used. They all use parameters that are to some extent comparable. Which risk graph is used, is not directly relevant for this research. The model of Fine & Kinney is widely used in industry and gives a distinct representation of the risk analysis (Fine & Kinney, 1971). The model has been adapted to the requirements of the new approach. The basic idea is:

- Risk = Severity x Exposure x Probability

In this formula the following meanings are used: severity of injury linked to hazard, exposure to the hazard, probability of the hazard to occur when exposed. These concepts are made operational so that it becomes a numerical method and a quantitative risk estimation can be made. For all criteria the risk has to be assessed and dependent on the outcome certain measures have to be taken, ranging from no action until large measures or directly stopping all activities. All relevant factors have to be taken into account, for example whether a product will be used (or could be used) by consumers of by professionals. The risk analysis is often referred to as risk inventory & evaluation (RI&E), because risk is assessed on basis of the consequences, possible risk reduction measures and residual risks. Different models and templates are available, so different risk graphs could be used. The model of Fine & Kinney will be used as a basis when the RA is discussed in this research, because it reflects all mentioned aspects in industry settings.

In literature about risk assessment the consideration of costs versus risk reductions is often discussed. The concept of as low as reasonably practicable (ALARP) is frequently referred to. Concisely it means that an acceptable risk level is compared to the economical and practical resources needed for risk reduction (Melchers, 2001). From the perspective of CE-marking, where safety is the core focus, other interests are of subordinate priority, but for companies other considerations like costs, could be equally or even more important, than for example the highest possible safety level.

5. Draw up Technical Construction File:

A manufacturer has the obligation to draw up a technical construction file (TCF) containing all information regarding a product and that can demonstrate conformity of that product to the applicable directives. This technical documentation has to be complete at the moment a product is marketed and must be preserved for at least ten years after fabricating the last product. It is possible to include the TCF in the quality system documentation if one of the conformity assessment modules based on a quality system is followed. In case of calamities the TCF should be handed over to the authorised inspection organisation within 72 hours.

The content of the TCF is dependent on the type of product, what has to be included is addressed in the different CE-directives. Generally, the design, production and operation of a product have to be attended. Everything that shows conformity to the essential safety requirements should be included. If harmonised standards are used, conformity to these norms has to be demonstrated and it has to be stated which safety requirements are covered by them. The level of detail depends on the complexity and safety level of the product. The language of the TCF may differ, but should at least (also) be in an official language of the member state where conformity procedures are executed. For executing a conformity assessment with the assistance of a notified body, the language should (naturally) be understandable for that notified body (Blue guide, 2000, p. 34).

6. Draw up directions for use:

The technical construction file contains all information about a product, but is an internal document for a company that only has to be shown to surveillance authorities in case of calamities. The directions for use must include information necessary for the user of a product to operate it safely like directions for installation, operating, maintenance, intended use and possibly warning or unintended use. It must be provided along with the product. The precise content is provided for in the directives, but in general it should contain the following aspects:

- Introduction
- General description product
- Intended use
- Total overview safety measures (and risks) / warnings
- Instruction for use
- Transport and storage
- Installation, assembly
- Maintenance instructions
- Technical annexes

It should provide information to use a product safely, from installation up to disposal. So no inside information from a company has to be added, if not required for a safe use. The required language differs per directive. For the machinery directive it should be in the language of the country where the machine is sold or put into operation and in the language of the country where the machine is built. For the LVD and EMC it should be in one of the official EU languages. It is always recommendable to use languages that are understandable for all actors involved (OJ 2004 L 390; OJ 2006 L 374; OJ 2006 L 157).

7. Draw up declaration of conformity:

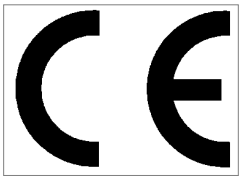
A product, when marketed, should be accompanied by directions for use and a declaration of conformity (DOC). So, along with the product a declaration of conformity must be provided, which inherently means it should be drawn up before a product is placed on the market. Subsequently it should be kept for at least ten years after fabricating the last product. The DOC sometimes does not have to physically join the product, but the user must always be able to retrieve it, possibly digitally. It must be immediately available, also if necessary for surveillance authorities. With a declaration of conformity a manufacturer states that a product is in conformity with the essential requirements of the applicable directives and has undergone all the necessary assessments (Lohbeck, 1998, p.33). The importance of a well-founded DOC has been brought forward previously.

The elements that have to be attended in the declaration of conformity are included in each directive. At least must be clear with which requirements or technical specifications conformity is declared. Naturally outdated standards (and directives) may not be used. The DOC has to be signed by a person located within the EU, who thereby takes responsibility for the declaration and the CE-marking. The following elements must at least be included:

- name / address of manufacturer (or authorised representative) issuing the declaration
- identification of product (name, type, model number, any relevant supplementary information, like lot, batch or serial number, sources and numbers of items)
- all relevant provisions complied with; referenced standards or other normative documents (like national technical standards and specifications) in precise, complete and clearly defined way
- all supplementary information that may be required (e.g. grade, category)
- date of issue of the declaration; signature and title or an equivalent marking of authorised person
- statement declaration is issued under sole responsibility manufacturer (or authorised representative)

Other aspects could be a reference to a possible notified body (name, address, identification, number) and possibly the name / address of the person who keeps the technical documentation. Basically a DOC can be issued as a single document for one product, but some directives provide a specific form. Furthermore an official Community language must be used as well as an official language of the country of use and a copy of the declaration in the original language must be supplied (Blue guide, 2000, p. 34–35).

8. Affix CE-marking:



The CE-mark must be affixed by the responsible person, the manufacturer or his authorised representative. The CE-mark has an obligated form and in case of reducing or enlarging the mark, the proportions must be respected. The official shape and proportions set in the directives is included in appendix III. It must be affixed clearly and ineradicably on the product or, if not possible, on the packaging and/or the accompanying documents. If notified bodies are involved in the production control phase, their identification number must be placed next to the mark, which means the notified body assumes the responsibility for its activities. CE-marking may only be affixed when a conformity assessment is executed. It symbolises conformity to the essential safety requirements. The CE-mark is the only marking which symbolises and is allowed to symbolise conformity to the new approach directives. A product may bear additional markings, provided that they have a different function and do not cause confusion (Blue guide, 2000, p. 45–46). If CE-marking is affixed a buyer may expect that a product is conform the legal safety requirements and it is safe for the intended use and/or relevant warnings are given.

2.2.3 Standard blocks in the CE-trajectory

When a product is placed on the market or put into operation the CE-trajectory should be completed. The previous section described what has to be done to meet the legal safety requirements. CE-legislation is about the design phase, production phase and consequently about using a product. By integrating CE-marking in the organisational processes a greater awareness for safety can arise and subsequently more efficiency can be achieved. Especially by including the design phase, possible issues are solved in an early stage. Methodologically integrating CE-trajectories in the design and production processes can prevent problems to arise and create efficient processes (van Aken et al., 1996, p. 23–27).

To conclude this section a summary of the processes that have to be fulfilled to acquire CE-marking is given. These are the steps that have to be included in the decision making tool and are previously referred to as ‘standard blocks’. The question is what manufacturers have to do to obtain (justified) CE-marking. First the applicable directives have to be determined. The use of norms is subsequently determined during throughout CE-trajectory, e.g. during the risk analysis. This however does not change the execution of the other steps, except that compliance to possible norms has to be demonstrated, but they represent certain essential requirements. When the applicable directives are determined, the other steps become to some extent fixed because of provisions in those directives. The steps that have to be completed for a CE-trajectory, independent on the type of product, can be translated into the following questions:

- Which CE-directives are applicable to a product?
- How must the conformity assessment be executed and who is involved: which module?
- Which safety requirements have to be applied in the execution of the risk analysis?
- What has to be included in the technical construction file?
- What has to be included in the directions for use?

- What has to be included in the declaration of conformity?
- ➢ Place CE-marking!

The decision making tool should answer the questions as complete as possible. The answers can be (partly) found in the provisions of the three relevant directives in this research.

2.3 LVD, EMC and Machinery Directive

Now that an elaboration is made of the CE-trajectory, a more extensive exposition of the three directives is given. The directives will be discussed in the light of acquiring CE-marking on a product applicable to them and thus in the light of the CE-trajectory. Furthermore the directives will be discussed where relevant for the functioning of (acquiring) CE-marking. Practical implications for the decision making tool will (also) be attended to in chapter 4.

Directives, as well as harmonised standards, can be subjected to renewal. For a manufacturer it is recommendable to check periodically if new applicable directives (or norms) are developed for his products. The machinery directive for example is published in 2006 and came into force at the end of 2009, thereby repealing the old machinery directive. Notably, there is a transitional period to adapt to the change (Blue guide, 2000, p 19–20). If a product has multiple applicable CE-directives, the marking indicates that a product is presumed conform to the requirements of all applicable directives. CE-marking is mandatory, but a product may not bear the mark unless it is covered by a directive providing for its affixing (Blue guide, 2000, p. 44). CE-directives are European legislation and therefore freely available.

Generally CE-directives all contain some basic elements. The scope and exceptions are given as well as the general safety requirements. The principle of free movement is brought forward and the role of member states, like for instance in the safeguard clause. The conformity assessment is addressed and the affixing of CE-marking.

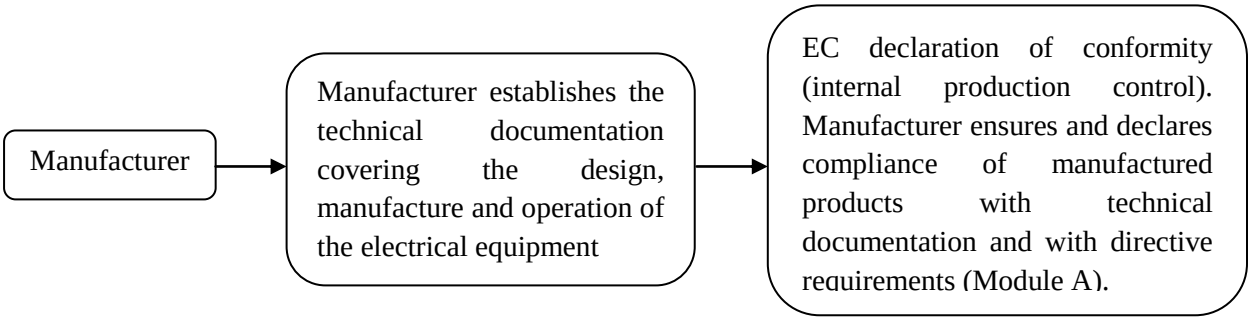
2.3.1 Low Voltage Directive

The Low Voltage Directive (LVD) was published in 2006 as directive 2006/95/EC of the European Parliament and of the Council on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (OJ 2006 L 374, p. 10–19). This section is based on texts of the directive, unless indicated otherwise.

Scope	Article 1	*Equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current.*
Exceptions	Annex II	*Electrical equipment for use in an explosive atmosphere; electrical equipment for radiology and medical purposes; electrical parts for goods and passenger lifts; electricity meters; plugs and socket outlets for domestic use; electric fence controllers; radio-electrical interference; specialised electrical equipment for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.*
Safety Requirements	Article 2	*Electrical equipment must be constructed in accordance with good engineering practice in safety matters, not endanger the safety of persons, domestic animals or property when properly installed and maintained and used in applications for which it was made.*

The principal elements of the safety objectives referred to in article 2, are fully listed in Annex I. Concisely the following elements are mentioned. The CE-mark, warnings and brand name or trade mark must be clearly placed on the product or if not possible on the packaging. Hazards by must be taken into account: by direct or indirect contact, temperatures, arcs or radiation as well as non-electrical dangers caused by the electrical equipment which are revealed by experience and insulation must be suitable for foreseeable conditions. External influences on the equipment must be assessed in relation to: the expected mechanical requirements, non-mechanical influences in expected environmental conditions and foreseeable conditions of overload.

Hereafter a mention is made that free movement may not be impeded for reasons of safety if the requirements or corresponding harmonised standards are applied. In case of non-conformity possible measures by member states are described. The manufacturer must execute a conformity assessment.



Conformity to the essential safety requirements of the LVD may be assessed according to module A, internal production control. In annex IV the procedures are given. A manufacturer must draw up a technical construction file (TCF) and produce according to that documentation. The TCF should contain:

- general description of the electrical equipment
- conceptual design, manufacturing drawings, schemes of components, sub-assemblies, circuits, etc.
- descriptions/explanations for understanding drawings, schemes and operation of electrical equipment
- list of standards applied in full or in part, and descriptions of the solutions adopted to satisfy the safety aspects of this directive where standards have not been applied
- results of design calculations made, examinations carried out, etc.
- test reports

The declaration of conformity subsequently must be drawn up in line with annex III, containing:

- name / address of manufacturer or authorised representative established within the Community
- description of the electrical equipment
- reference to the harmonised standards
- where appropriate, references to the specifications with which conformity is declared
- identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorised representative established within the Community
- last two digits of the year in which the CE marking was affixed

Finally the official CE-marking must be affixed before marketing.

2.3.2 EMC Directive

The EMC (electromagnetic compatibility) directive was published in 2004 as directive 2004/108/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ 2004 L 390, p. 24–37). This section is based on the texts of the directive, unless indicated otherwise.

Scope	Article 1	*This directive regulates the electromagnetic compatibility of equipment. It aims to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility.*
Exceptions	Article 2	*(a) equipment covered by Directive 1999/5/EC (radio equipment and telecommunications terminal equipment).* *(b) aeronautical products, parts and appliances as referred to in Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency.*
Safety Requirements	Annex I	*Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:* *(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended* *(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use* *Fixed installations must be installed with the same requirements and with applying good (documented) engineering practices.*

In the directive the free movement of equipment is addressed as well as the possible use of harmonised standards and notified bodies. Furthermore the relation with other marks and information and possible safeguarding actions are mentioned. Relevant definitions are given in article 2, where a distinction between apparatus and fixed installation is made. "*Apparatus means any finished appliance or combination, commercially available as single functional unit, intended for the end user and liable to generate electromagnetic disturbance, or liable to be affected by such disturbance. Fixed installation means a particular combination of several types of apparatus and other devices, which are assembled, installed and intended to be used permanently at a predefined location*".

The conformity assessment to show compliance of an apparatus with the essential requirements can be executed via three procedures. Firstly for (professional) radio transmitters (not covered by directive 1999/5/EC) the conformity assessment via module B-C is required: EC-type examination followed by EC declaration of conformity with type approved. For other products, apparatuses, there are two options. Annex II describes internal production control, module A, which can be applied if harmonised standards are fully used. The manufacturer must assess the electromagnetic compatibility of the apparatus to meet the mentioned safety requirements for all normal intended operating conditions and for all possible configurations the compliance to those requirements must be indicated. Measurements must be executed to check a product's electromagnetic disturbance on other equipment and its immunity against disturbance from other equipment. Technical documentation and a declaration of conformity must be drawn up and be kept for at least ten years after production, according to the provisions in annex IV. The

manufacturer must ensure production is in accordance with the technical documentation and with the requirements of this directive. The other conformity assessment procedure, in annex III, is similar but with extra provisions, suitable if none or little harmonised standards are used. The described technical documentation has to be assessed by a notified body on conformity to the safety requirements. The notified body can issue a statement of compliance, limited to the assessed aspects, which the manufacturer shall add to his technical documentation. For compliance to the EMC directive measurements have to be performed on the final product.

The technical documentation should contain:

- general description of the apparatus
- evidence of compliance with the harmonised standards, if any, applied in full or in part
- if harmonised standards are not or partly applied; description / explanation of the steps taken to meet the essential requirements, including description of electromagnetic compatibility assessment set out in Annex II, point 1, results of design calculations made, examinations carried out, test reports, etc.
- statement from notified body, when the procedure referred to in Annex III has been followed

The declaration of conformity should contain:

- reference to this directive
- identification of the apparatus to which it refers
- name / address of the manufacturer or of his authorised representative in the Community
- dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of this directive
- date of that declaration
- identity and signature of person empowered to bind the manufacturer or his authorised representative

Then the official CE-mark may be affixed. Article 13 indicates that if an apparatus is intended for incorporation into a given fixed installation and is otherwise not commercially available these provisions are not compulsory. Then, instead of the described conformity assessment, accompanying documentation shall identify the fixed installation and its electromagnetic compatibility characteristics along with precautions for the incorporation, to not harm conformity of the fixed installation. The apparatus must be identifiable by type, batch, serial number or any other information, and the name and address of the manufacturer must accompany the apparatus. The essential requirements in annex I still have to be applied. Additionally the conformity of the fixed installation can be included in the declaration of conformity. Often other directives also apply to such an installation.

2.3.3 Machinery Directive

The machinery directive was published in 2006 as directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending directive 95/16/EC (recast) (OJ 2006 L 157, p. 24–86). This section is based on the texts of the directive, unless indicated otherwise.

Scope	Article 1.1	*This directive applies to the following products:* *(a) machinery* *(b) interchangeable equipment* *(c) safety components* *(d) lifting accessories* *(e) chains, ropes and webbing*

		(f) removable mechanical transmission devices *(g) partly completed machinery*
Exceptions	Article 1.2	*The following are excluded from the scope of this directive:* *(a) safety components used as spare parts to replace identical components, supplied by manufacturer of original machinery* *(b) specific equipment for fairgrounds and/or amusement parks* *(c) machinery for nuclear purposes (risk for emission of radioactivity)* *(d) weapons, including firearms* *(e) the following means of transport (except machinery mounted on these means of transport):* – *agricultural and forestry tractors covered by Dir. 2003/37/EC* – *motor vehicles and their trailers covered by Dir. 70/156/EEC* – *vehicles covered by Dir. 2002/24/EC* – *motor vehicles exclusively intended for competition* – *means of transport by air, on water and on rail networks* *(f) seagoing vessels, mobile offshore units and machinery on it* *(g) machinery designed and constructed for military or police purposes* *(h) machinery for research purposes for temporary use in laboratories* *(i) mine winding gear* *(j) machinery intended to move performers during artistic performances* *(k) electrical and electronic products of the following areas, if covered by Dir. 2006/95/EC (LVD):* – *household appliances intended for domestic use* – *audio and video equipment* – *information technology equipment* – *ordinary office machinery* – *low-voltage switchgear and control gear* – *electric motors* *(l) the following types of high-voltage electrical equipment* – *switch gear and control gear* – *transformers*
Safety Requirements	Annex I	*Essential health and safety requirements relating to the design and construction of machinery.*

After the scope and exclusions in article 1, definitions are given in article 2. Parts of a machinery, whole machines and even assemblies of machinery can be subject of this directive as well as partly completed machinery. The procedures for the latter differ from the provisions for other machinery. Furthermore the free movement of products is addressed, placing on the market and/or putting into service of compliant products may not be prohibited, restricted or impeded. Products not conform this directive may be shown at exhibitions. Measures for potentially hazardous machinery, disputable harmonised standards, the safeguard clause and notified bodies are mentioned.

Before marketing machinery, the manufacturer or his authorised representative shall (article 5):

a) ensure that it satisfies the relevant essential health and safety requirements in annex I
b) ensure that the technical file referred to in annex VII, part A is available
c) provide, in particular, the necessary information, such as instructions
d) carry out the appropriate procedures for assessing conformity in accordance with Article 12

e) draw up the EC declaration of conformity in accordance with annex II, part 1, Section A and ensure that it accompanies the machinery
f) affix the CE marking in accordance with article 16

Article 12 gives procedures for assessing the conformity of machinery, with 3 categories:

1. If machinery is not mentioned in annex IV, the manufacturer shall apply internal checks on manufacture of machinery provided for in annex VIII. In this case the manufacturer must satisfy the relevant essential health and safety requirements and draw up technical documentation for machinery.
2. If machinery is mentioned in annex IV and manufactured in accordance with harmonised standards, provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer shall apply one of the following procedures:
   a) internal checks on manufacture of machinery, provided for in annex VIII;
   b) EC type-examination procedure provided for in annex IX (with a notified body), plus the internal checks on manufacture of machinery provided for in annex VIII, point 3.
   c) full quality assurance procedure provided for in annex X (with a notified body).
3. If machinery is mentioned in annex IV and harmonised standards are not or partly applied, or if standards do not cover all relevant essential health and safety requirements or do not exist for the machinery in question, the manufacturer shall apply one of the two latter procedures (b or c).

Before marketing partly completed machinery, the manufacturer shall ensure that:

a) relevant technical documentation described in annex VII, part B is prepared
b) assembly instructions described in annex VI are prepared
c) a declaration of incorporation described in annex II, part 1, Section B has been drawn up

To determine the health and safety requirements that apply to the machinery, a risk analysis has to be executed as described in annex I. This annex also contains the essential health and safety requirements, along with supplementary requirements for certain categories of machinery, machinery intended for underground work and supplementary requirements to offset hazards due to the mobility of machinery and lifting operations. For the risk inventory & evaluation the manufacturer shall:

- determine limits of machinery, including intended use and reasonably foreseeable misuse thereof
- identify hazards that can be generated by the machinery and associated hazardous situations
- estimate risks, using severity of possible injury or damage to health and probability of its occurrence
- evaluate risks, to determine whether risk reduction is required, according objectives of this directive
- eliminate hazards or reduce risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b) (of annex I)

To demonstrate machinery compliance with the requirements, the technical documentation must contain:

- a general description of the machinery
- overall drawing of the machinery and drawings of control circuits, as well as pertinent descriptions and explanations necessary for understanding the operation of the machinery
- full detailed drawings, any calculation notes, test results, certificates, etc., needed to check conformity
- documentation on risk assessment demonstrating the procedure followed: list of requirements which apply to the machinery, description of protective measures implemented to eliminate identified hazards or to reduce risks, possibly indication of residual risks associated with the machinery
- standards and other technical specifications used, indicating requirements covered by these standards

- any technical report giving results of tests carried out by the manufacturer or by a notified body
- copy of the instructions for the machinery
- where appropriate declaration of incorporation for included partly completed machinery and relevant assembly instructions for such machinery
- where appropriate, copies of EC declaration of conformity of machinery or other products incorporated into machinery
- copy of the EC declaration of conformity

For series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions must be included. For partly completed machinery the relevant technical documentation is set out in annex VII-B. For machinery a declaration of conformity and for partly completed machinery a declaration of incorporation has to be drawn up according to the provisions in annex II. For machinery a risk analysis is obligated. This relates to the design phase of the product, because risk reduction measures can be required. In all cases a risk inventory and evaluation has to be performed, before the product is placed on the market or put into operation.

This concludes the theoretical elaboration about the functioning of CE-legislation, the CE-trajectory and the three relevant directives for this research.

2.4 Decision making tools

For assistance in complex situations the use of decision making tools can be adopted. A decision making tool should basically provide insight in a large amount of information and give guidance in processing that data and give support in making a decision.

2.4.1 Requirements decision making model

There is much literature on decision theory, a large part is however on quantitative models which is not relevant in this research. Some literature deals with the use of decision making tools in specific fields of practice, like marketing or health care. The use of information systems is also widely addressed, e.g. with the choice for in- or outsourcing. The main principle of most models is however that guidance is given in complex situations where often much information is involved. In this cases it is difficult to find structure and to oversee the consequences of certain choices. This is where a model can offer assistance.

Hicks (2004) for example gives several approaches of dealing with large and complex problems. Decision making models deal with structuring the decision making process and connecting all aspects involved. Decision making is a choice between alternatives and the use of a model can help to tackle large complex problems. Such a model is basically a structuration of complex matters, wherein several solutions are mapped. In this way the consequences of the different actions can be overseen and thereby decision making can be supported. The use of different kinds of data is important when designing a model. A distinction can be made between soft and hard data (Hicks, 2004, p. 80). CE-marking can be mainly regarded as hard data, legislation is fixed, and although interpretation of documents can be subjective the data can be seen as factual. Hicks (2004) also addresses the use of computer and information systems, which can be used to improve structuration and clarity, and for the processing of data.

Decision tree models can be seen as testable cognitive models (Gladwin, 1989, p. 13). A model is a simplified simulation of reality, which is useful to obtain better understanding of that reality. Therefore such a model becomes meaningful if it is tested, to assess how good a representation of reality it is.

Gladwin (1989) regards decision making tools, and decision trees in particular, as a logical structuration to simplify complex situations by organising information, criteria, alternatives and outcomes. Additionally when designing a decision tree, attention should be given to the intended users of the system. The model must be tailored to the user and in the end comprehensible for them.

A decision making model is in this research regarded as a qualitative tool to structure complex situations. In can be used for clarity in great amounts of information, for mapping solutions and/or outcomes and ultimately to support decision making in acquiring CE-marking. Essentially it is a schematic representation of the possible steps and choices and can be very helpful in such complex situations where someone cannot oversee the content, the meaning or the consequences of the subject or his choices.

2.4.2 Existing tools and models

In literature decision making tools are widely addressed but actual designing or testing of such models is less common. Qualitative models on CE-marking or legislation are not present in scientific literature. In practice some models are developed by organisations, but these have some disadvantages within them. First they can be focused on one directive or even on classification within one directive. This scope is too narrow and does not support a generally usable decision making tool. Secondly they are often too simplified. They can be focused on practical ease for the user, but thereby ignore the complexity of reality. Finally those models sometimes don't function flawlessly and the reasoning is mostly not documented. Interesting of these models is that they have a tendency toward practical use and for that objective also tend to have well-developed interfaces and appearances.

An elaboration is made in this chapter on relevant literature. The goal in this research is to create a generally usable decision making tool for manufacturers to acquire CE-marking on a product that is applicable to the EMC, LVD and/or Machinery Directive. In the next chapter the methodology of this research is defined an after that the decision making tool is designed.

Chapter 3 Methodology

To find an answer to the formulated research question, a qualitative research is conducted. This chapter contains an elaboration on the used methodology.

3.1 Design research

The goal of this research is to create a decision making tool for manufacturers to acquire CE-marking on a product that applies to the EMC, LVD and/or Machinery directive. Since the objective is to develop a decision making model, the best suitable type of research is 'design research'. This is fundamentally a problem solving paradigm. Design science creates and evaluates artifacts intended to solve identified organisational problems (Hevner et al., 2004). To develop and test a decision making tool for CE-marking, such a qualitative research is instigated to obtain a better understanding of how theoretical concepts function in practice (Babbie, 2010).

Design research can be seen as a process of developing a new idea or solution, like methods or tools which are a prescriptive form of theory. Design research usually must be combined with an empirical method (e.g. action research or experiment) to validate the effectiveness of the design. This methodology is applied in this research where first a decision making model is developed, which is then tested in practice. This can be schematically represented:

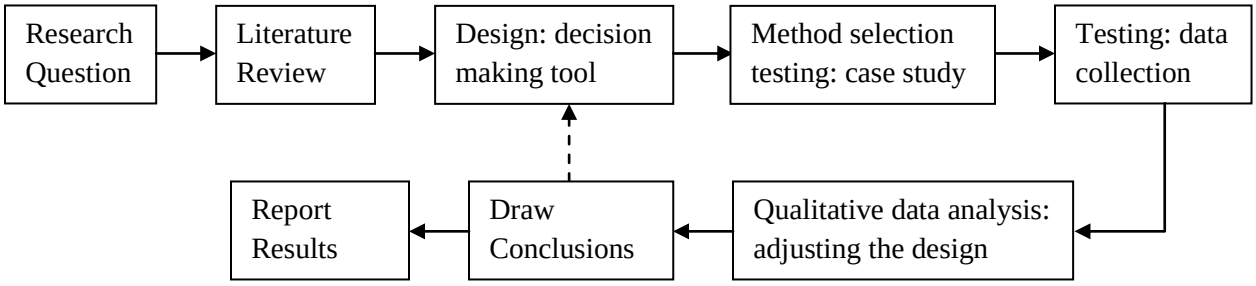


Figure 3.1: Design Research

This methodological model corresponds with the different stages of this research. The different steps, represented by the blocks, will be explained in further detail in the next paragraphs. Two main phases are distinguished: designing the decision making tool and subsequently testing that design.

3.2 Designing a decision making model

The first block in the conceptual schema above is the formulation of the research question which is the starting point of this research. After the formulation of the research goal and questions the search for the best suitable research to answer the main question led to design research. In accordance with this methodological approach shown above, the second block was conducting a literature study, which was needed to answer the first two sub questions in this research . There was searched for scientific literature, official documents from the European Commission and other legal documents. Scientific literature on this research topic posed two marginal notes. First the division between theory and practice can be somewhat vague. Legislation can be viewed as theory as well as practice at the same time. Second, research on CE-marking is scattered among different fields of study. There is literature available on European legislation, which is mainly descriptive and there is literature in specific technical fields, focused on the design and development of (new) products, e.g. in electro technical or mechanical engineering studies. This research

is at the crossing of those two fields of study. The main focus however is European product safety legislation and CE marking in particular but consequently other fields of research were also investigated, like technical study fields or decision making theory. Along with examining scientific literature also an in-depth study was conducted on relevant (legal) documents regarding CE-marking, like directives with annexes, norms and documents from Euronorm. Hereby a theoretical framework was drawn up, reported on in chapter 2.

While the literature review was conducted, several CE-trajectories in practice have been observed, to gather an understanding of how legislation functions in practice. On the basis of both the theoretical framework and the practical input, the initial design (decision making tool) is created, indicated by the third block in the schema and answering the third sub question of this research. In this phase the steps of the CE-trajectory were extensively examined by means of the CE-directives and relating documents. Furthermore, while designing the decision making tool, there has been collaborated with employees of Euronorm, who are specialized in CE-marking and work with the three relevant directives. Apart from a large amount of theoretical knowledge they have much practical experience, know how CE-marking functions in daily practice and have insights in a wide range of customers. In this way qualitative techniques were combined to improve the validity of the research, document analysis is supplemented by collaboration with experts (Cooper & Schindler, 2011). The theoretical insights functioned as a well-founded basis for the decision tree model that along with the gained practical insights also is tailored for practical use. This model, described in chapter 4, is the original design of this research.

3.3 Testing the model

To evaluate the effectiveness of the design an empirical method has to be applied. In this research a case study is selected as an empirical method to test the design. The decision making model is confronted with practice to observe its effectiveness (Verschuren & Doorewaard, 2007). The designed tool is tested on a product that applies to the relevant directives. The CE-trajectory is analysed with the decision making tool to see how it functions in practice and to analyse if the process of acquiring CE-marking becomes more efficient. The designed decision making tool was adapted on the basis of the results. Besides that also immediate action (intervention) was applied to solve minor imperfections. In this way the design is tested by confronting it with practice, which can be visually represented:

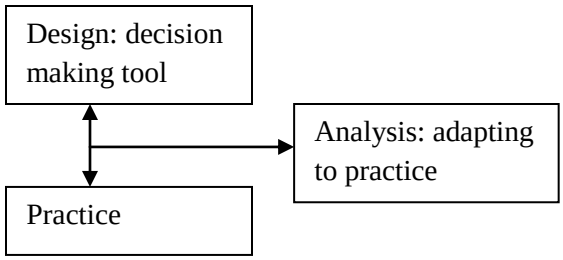


Figure 3.2: Testing design

The created decision tree model is thus tested on a product in practice. Hereby an empirical data selection was achieved. By analysing the data it is researched how the original design which was mostly based on theory and documents, functions in practice, what the advantages and disadvantages are and whether using the decision model has influence on the efficiency of a CE-trajectory. This gives an answer to the fourth sub question. The data analysis gave input to the construction of a final decision making tool in this research. After that the conclusions were drawn up, reported in chapter 6, where the main research

question is answered. The final block in the schematic representation of design research is reporting on the results, which is done through this report. This represents a single feedback loop and finalises this research. Additional feedback loops are outside the scope of this research, but can be interesting to look into. Further refinement of the design could be executed after this research. The data analysis led to adaption of the design which can then can again be tested. This is displayed by the dotted arrow in the schema. However, because of practical implications this research is limited to one case study, after which is reported on the final decision making tool and the conclusions. In the final chapter is attended to further discussion on the limits of this research.

Chapter 4 Design of a decision making tool

The theoretical framework showed that CE-marking symbolises conformity of a product to the applicable European product safety legislation. By affixing CE-marking to a product, the manufacturer declares that the product is conform the applicable safety requirements and that the appropriate conformity assessment procedures have been completed. He implies that a CE-trajectory has been correctly completed. The goal of this chapter is to capture the CE-trajectory in a decision making tool.

4.1 Designing a decision tree

The decision making tool should give a structuration in the complex field of CE-marking. It must assist manufacturers in acquiring CE-marking on a product. Therefore a practically usable tool with a clear overview is created. The CE-marking process can be complex and contains much information, including directives, guidelines and standardisation. This is even without considering information that can be found on the internet. For a manufacturer it can be difficult to oversee the content of this legislation and the different options and actions he can use including their consequences. To solve this problem, independent on the type of product, a model is created, representing the CE-trajectory with the described blocks coming out of it.

To capture the CE-trajectory all options are structured by mapping the different solutions in a decision tree. This is a straightforward and logical way to structure the complex process of CE-marking and to give guidance to manufacturers. As elaborated on in the theoretical framework, a decision making tool and in particular a decision tree processes information and lists different options, thereby giving support to manufacturers in decision making. Especially in complex situations this guidance is useful. So a logical structuration in the form of a decision tree is designed in the next sections.

The starting point of the model is the intended user, in this case a manufacturer. Therefore the first question is intended to assess whether the legal definition of a manufacturer holds and if the user is CE-responsible. For this model manufacturer is regarded as responsible for producing a product. This model is not directly tailored for importers e.g., although it could be useful for them. Manufacturers are guided through the model with a practical list of questions that together make up the decision tree. The answers give direction in the model and ultimately support acquiring CE-marking by giving substance to the standard blocks of a CE-trajectory. The aspects a manufacturer has to fulfil to comply with the requirements applicable for his product are mapped and explained as outcomes of the decision tree.

The model is designed for products subjected to the LVD, EMC and/or machinery directive. As discussed in section 2.2.2 of this research, it can be said that products subjected to the LVD are also subjected to the EMC, because electrical components always create electromagnetic fields. This relation does not hold the other way around, products can be subjected to only the EMC. In industry settings most products are subjected to one, two and often all three of these directives. Furthermore a manufacturer is responsible for the CE-marking, so the model is especially developed for use in industry settings. In the model a clear distinction is made between the application of the three separate directives. If a reference is made to an article or annex, it is to the specific directive under discussion. If other references are used it is clearly mentioned. In this way the model is grounded and the reasoning is documented, while maintaining a clear overview. In the next sections the design of the model is abundantly elaborated. The texts are mainly based on the official CE-directives. For practice Euronorm has the intention to translate this model into a

web-based tool where only one question at a time is shown and drop-down menus can be used for clarity and usability.

4.2 Decision tree design for acquiring CE-marking

The included directives are the LVD, EMC and machinery directive.

Manufacturer:

Are you located in the European Economic Area and responsible for designing and manufacturing a product with a view to placing it on the European market or putting it into operation on your own behalf (Blue guide, 2000, p. 21–22)?

Yes: CE-responsible as manufacturer

No: not directly CE-responsible, check for other responsibilities or (international) legislation

Scope – applicable directives:

LVD – Low Voltage Directive

Is the product (or equipment) designed for use with a voltage rating of between 50 and 1000 V for alternating current or between 75 and 1500 V for direct current (Article 1)?

Yes: LVD is applicable

No: product not subjected to LVD

Does the product fall within one of these categories (Annex II):

- electrical equipment for use in an explosive atmosphere
- electrical equipment for radiology and medical purposes
- electrical parts for goods and passenger lifts
- electricity meters
- plugs and socket outlets for domestic use
- electric fence controllers
- radio-electrical interference
- specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate?

  Yes: product excluded from the LVD

  No: LVD is applicable

EMC directive

Can the product cause electromagnetic disturbances to other equipment in its environment or be influenced by electromagnetic radiation from its environment (Article 1.1)? (for example if the product contains electrical components or is subject to the LVD)

Yes: EMC is applicable

No: product not subjected to EMC

Does the product fall within one of these categories (Article 1.2):

- equipment covered by Directive 1999/5/EC (radio equipment and telecommunications terminal equipment)
- aeronautical products, parts and appliances as referred to in Regulation (EC) No 1592/2002 (common rules in the field of civil aviation)

- not commercially available radio equipment used by radio amateurs (referred to in the Radio Regulations of the International Telecommunication Union). Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.

  Yes: product excluded from the EMC

  No: EMC is applicable

Machinery Directive

Does one of these definitions apply to the product (Article 1.1):

- machinery (assembly containing moving parts or components)
- interchangeable equipment
- safety components
- lifting accessories
- chains, ropes and webbing
- removable mechanical transmission devices
- partly completed machinery: assembly which is almost machinery but cannot in itself perform a specific application, intended to be incorporated into or assembled with other (partly completed) machinery or equipment, thereby forming machinery

  Yes: machinery directive is applicable

  No: product not subjected to machinery directive

Does the product fall within one of these categories (Article 1.2):

- safety components used as spare parts to replace identical components and supplied by the manufacturer of the original machinery
- specific equipment for fairgrounds and/or amusement parks
- machinery for nuclear purposes (risk for emission of radioactivity)
- weapons, including firearms
- the following means of transport (except machinery mounted on them):
  - agricultural and forestry tractors for the risks covered by Directive 2003/37/EC
  - motor vehicles and their trailers covered by Council Directive 70/156/EEC
  - vehicles covered by Directive 2002/24/EC (two or three-wheel motor vehicles)
  - motor vehicles exclusively intended for competition
  - means of transport by air, on water and on rail networks
- seagoing vessels, mobile offshore units and machinery on it
- machinery designed and constructed for military or police purposes
- machinery designed and constructed for research purposes for temporary use in laboratories
- mine winding gear
- machinery intended to move performers during artistic performances
- electrical and electronic products of the following areas, if covered by Dir. 2006/95/EC (LVD):
  - household appliances intended for domestic use
  - audio and video equipment
  - information technology equipment
  - ordinary office machinery
  - low-voltage switchgear and control gear

- electric motors

– high-voltage electrical equipment: switch gear, control gear and transformers

Yes: product excluded from machinery directive

No: machinery directive is applicable

The outcome of this assessment of applicable directives can differ between the following options:

1. *EMC directive applies: for example USB-appliances*
2. *LVD and EMC directive apply: products subjected to the LVD, are also subjected to the EMC, because electrical components always produce electromagnetic fields*
3. *Machinery directive applies*
4. *EMC and machinery directive apply*
5. *LVD, EMC and machinery directive apply*
6. *None of the three directives apply: check for other directives, (international) legislation or normalisation*

The last option is a stopping point in this model and gives an advice as outcome. This leaves the other options as starting point for the rest of the decision making tool. These five options are separate parts of the decision tree and each part has several branches within itself. If a stopping point is reached in the decision tree, an advice is formulated. To provide a systematic elaboration, the application of the different directives is attended to in different sections.

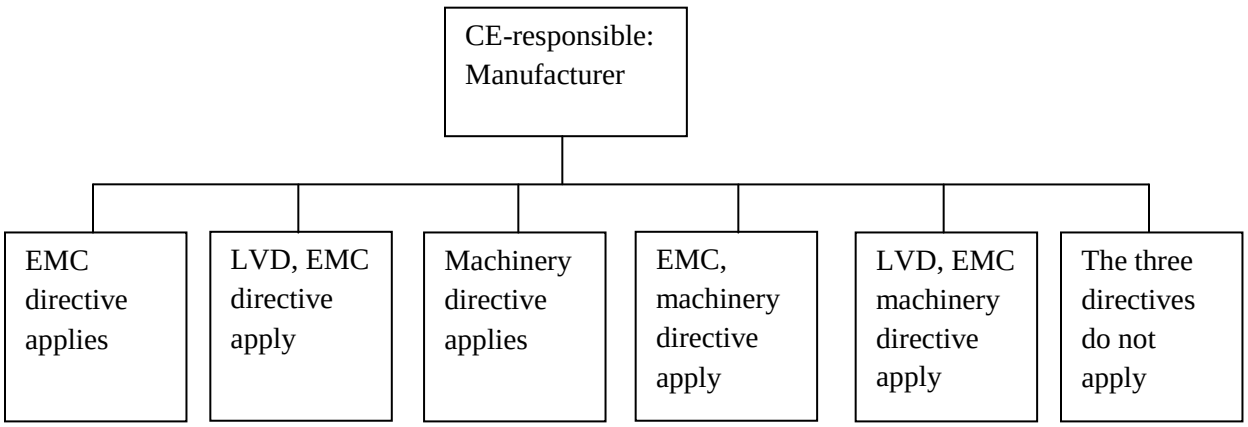


Figure 4.1: Applicable directives decision tree

4.2.1 EMC Directive

Is the product a (professional) radio transmitter (not covered by directive 1999/5/EC)?

Yes: EC-type examination followed by EC declaration of conformity with type approved

No: next question

Actions manufacturer (Blue guide, 2000, p. 93)
Apply essential safety requirements set out in Annex I.

Request for EC type-examination at a notified body of a prototype with accompanying technical documentation (covers the design phase, module B).

Provide for conformity with the type as described in the EC type-examination certificate issued. Promise to produce according the tested product (covering the production phase, module C).

Draw up technical documentation, covering the design, manufacture and operation of the product (Annex IV – 1), containing:
- general description of the product
- evidence of compliance (to EC-type examination and safety requirements in Annex I)
- test reports / certificates from notified body
- description of electromagnetic compatibility assessment, results of design calculations made, examinations carried out, test reports, etc.

Draw up directions for use: instructions for intended use of the product, possibly warnings or unintended use.

Draw up EC declaration of conformity with type approved (DOC, Annex IV – 2), containing:
- reference to EMC directive (2004/108/EC)
- identification of product: type, batch, serial number, any information allowing identification
- name and address of the manufacturer
- reference to notified body
- dated reference to the specifications (harmonised standards) under which conformity to the EMC requirements is declared
- date of that declaration
- identity and signature of the person empowered to bind the manufacturer

Keep TCF and DOC available for at least ten years after the date the last product was manufactured.

Affix official CE-marking: mandatory shape and proportions (Annex V - EMC directive).

Is the product (part of) a fixed installation and otherwise not commercially available: assembled, installed and intended to be used permanently at a predefined location?

Yes: accompanying documentation shall identify the fixed installation and its electromagnetic compatibility characteristics along with precautions for the incorporation, to not harm conformity of the fixed installation
No: next question

Actions manufacturer (Article 13)
Draw up technical documentation. It must identify the fixed installation and its electromagnetic compatibility characteristics and indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of that installation. Furthermore each product must be:
- identifiable by type, batch, serial number or any other information allowing for identification
- accompanied by the name and address of the manufacturer

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the protection requirements of the EMC

directive (Annex I). Those good engineering practices shall be documented and be held for as long as the fixed installation is in operation (Annex I – 2).

A declaration of conformity and CE-marking is not needed, but if an assessment of the electromagnetic compatibility is made, it can be useful to document that alike. If other directives apply, those requirements have to be met and CE-marking has to be affixed.

If a product is neither a radio transmitter nor part of a fixed installation, it is indicated as an apparatus. The conformity assessment procedures are given in the Blue guide (2000, p. 93).

Are harmonised standards fully applied (all of the relevant essential safety requirements covered by EMC-norms)?

Yes: module A – internal production control (if manufacturer cannot test electromagnetic compatibility himself, a test report from a notified body is required)
No: next question

Essential Safety Requirements (Annex I)
Design and manufacture equipment (having regard to the state of the art), to ensure that:

a) the electromagnetic disturbance generated does not exceed the level above which radio, telecommunications- or other equipment cannot operate as intended
b) it has a level of immunity to electromagnetic disturbance to be expected in its intended use, so that it can operate without unacceptable degradation of its intended use

Actions manufacturer (Annex II)
Perform electromagnetic compatibility assessment taking into account all normal intended operating conditions with a view of meeting harmonised standards (that cover the safety requirements). If different configurations are possible, the assessment shall evaluate compliance to the safety requirements in all possible configurations for its intended use. Possibly done by notified body.

If testing doesn't seem necessary, for example for very simple products, the opinion of a notified body can be requested. If testing is not done, include a clear explanation in the technical documentation.

Draw up technical construction file (TCF) and take all measures necessary to ensure that the products are manufactured in accordance with the TCF. Conformity of the apparatus with harmonised standards (that cover the essential requirements) must be shown, covering design, manufacture and operation of the apparatus. The TCF should at least contain (Annex IV – 1):

- general description of the apparatus
- evidence of compliance with harmonised standards (harmonised standards require testing)
- test reports, possibly from a notified body
- (if harmonised standards are not fully applied: description and explanation of the steps taken to meet the essential requirements, including description of electromagnetic compatibility assessment, results of design calculations made, examinations carried out, test reports, etc.)

Draw up directions for use: instructions for intended use of the product and possibly warnings or unintended use. E.g. a product for which compliance with safety requirements is not ensured in residential

areas shall be accompanied by a clear indication of this restriction of use, where appropriate also on the packaging.

Draw up EC declaration of conformity (DOC, Annex IV – 2), containing:
- reference to EMC directive (2004/108/EC)
- identification of apparatus: type, batch, serial number, any information allowing identification
- name and address of the manufacturer
- possible reference to notified body not mandatory but advisable
- dated reference to the specifications (harmonised standards) under which conformity to the EMC requirements is declared
- date of that declaration
- identity and signature of the person empowered to bind the manufacturer

Keep TCF and DOC available for at least ten years after the date the last product was manufactured.

Affix official CE-marking: mandatory shape and proportions: see Annex V (EMC directive).

Are harmonised standards not or partially applied?

Yes: technical construction file by manufacturer and technical report or certificate by a notified body, declaration of conformity

No: not possible – all categories covered – start over again

Essential Safety Requirements (Annex I)

Design and manufacture equipment (having regard to the state of the art), to ensure that:

a) the electromagnetic disturbance generated does not exceed the level above which radio, telecommunications- or other equipment cannot operate as intended
b) it has a level of immunity to electromagnetic disturbance to be expected in its intended use, so that it can operate without unacceptable degradation of its intended use

Actions manufacturer (Annex III)

Apply same procedures and actions as with full harmonised standards application complemented with:
- present the technical documentation to a notified body and request for an assessment thereof. Specify which aspects of the essential requirements must be assessed by the notified body.
- the notified body shall review the technical documentation and assess whether it properly demonstrates that the requirements of the EMC directive have been met. If compliance of the apparatus is confirmed, the notified body shall issue a statement to the manufacturer confirming the compliance of the apparatus. That statement shall be limited to those aspects of the essential requirements which have been assessed by the notified body.
- the manufacturer shall add the statement of the notified body to the technical documentation and add a reference to the notified body in the declaration of conformity.

The four questions in this section lead to four possible paths if only the EMC directive applies to a product. For these paths the provisions to comply to the EMC directive are given, described as actions for manufacturers.

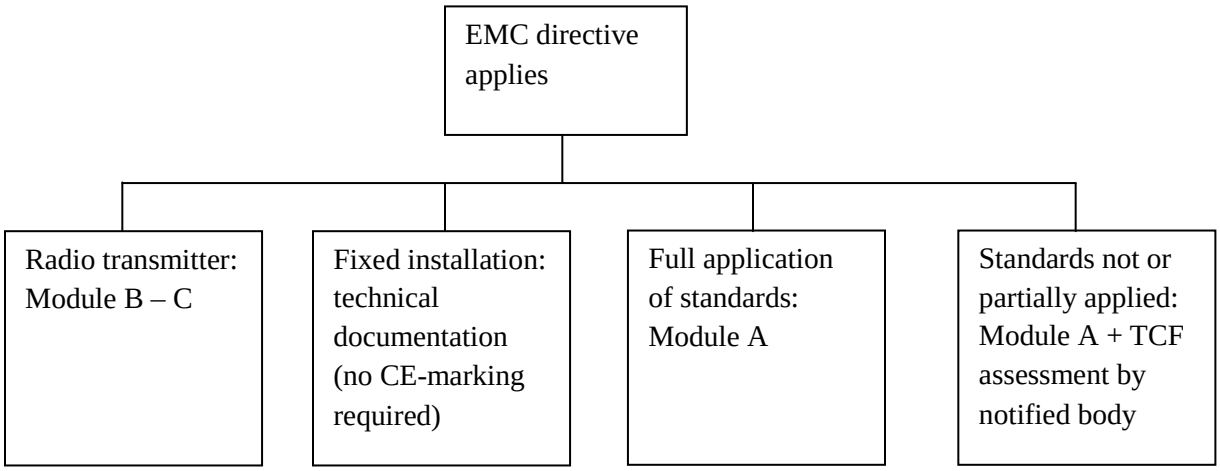


Figure 4.2: EMC directive applicable

4.2.2 LVD and EMC Directive

The EMC directive is analysed above. The LVD directive has one type of conformity assessment and therefore one path in this model. The application of the LVD directive is given singly is this part.

LVD:

Manufacturer establishes technical documentation covering design, manufacture and operation of electrical equipment. Manufacturer ensures (internal checks) and declares compliance of manufactured products with technical documentation and safety requirements (notified body not mandatory): module A.

Actions manufacturer

Apply safety requirements set out in Annex I.

Draw up technical construction file (TCF) and take all measures necessary to ensure that the products are manufactured in accordance with the TCF. Conformity of the product with the essential safety requirements (or relating harmonised standards) must be shown, covering design, manufacture and operation of the product. The TCF should at least contain (Annex IV):

- general description of the electrical equipment
- conceptual design, manufacturing drawings, schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment
- list of the harmonised standards applied in full or in part, and descriptions of the solutions adopted to satisfy the safety aspects of the LVD where standards have not been applied
- results of design calculations made, examinations carried out, etc.
- test reports

Draw up directions for use: instructions for intended use of the product and possibly warnings or unintended use.

Draw up declaration of conformity (DOC, Annex III – B), containing:

- reference to the Low Voltage Directive 2006/95/EC
- name and address of the manufacturer

- description of the electrical equipment
- reference to applied harmonised standards
- where appropriate, references to the specifications with which conformity is declared
- where appropriate, reference to a notified body (not mandatory to use notified body)
- identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer
- the last two digits of the year in which the CE marking was affixed

Keep TCF and DOC available for at least ten years after the date the last product was manufactured.

Affix official CE-marking: mandatory shape and proportions: see Annex III-A (LVD).

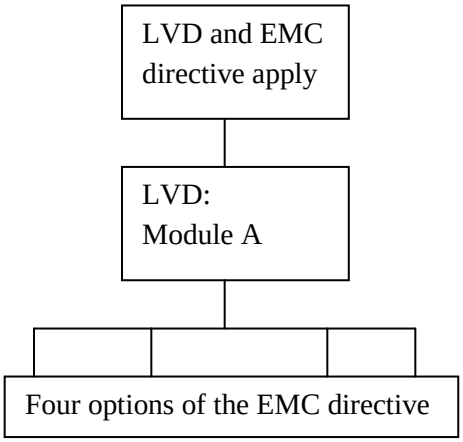


Figure 4.3: LVD and EMC directive applicable

In addition to the application of the EMC directive the application of the LVD does not bring forward new procedures. The differences are that the safety requirements of the LVD have to be used next to the ones of the EMC, and the aspects that have to be attended in the TCF and DOC must be combined. All four paths of the EMC directive application can be combined with the LVD application, they are not conflicting. The procedures and especially the actions for manufacturers of the LVD can be added to the ones of the EMC. For the application of solely the LVD there is one path, but because also the EMC is applicable in that case, it results in four paths.

4.2.3 Machinery Directive

Is the product 'partly completed machinery'?

> **'An assembly which is almost machinery but which cannot in itself perform a specific application (e.g. a drive system). Partly completed machinery is only intended to be incorporated into or assembled with other (partly completed) machinery or equipment, thereby forming machinery to which the machinery directive applies.'**
>
> *No: next question*
>
> *Yes: technical construction file, assembly instruction, declaration of incorporation*

Actions manufacturer (Article 13)
Apply health and safety requirements set out in Annex I by executing a risk analysis:

- determine limits of machinery, including intended use and any reasonably foreseeable misuse
- identify hazards that can be generated by the machinery and associated hazardous situations
- estimate risks, using severity of possible injury or damage to health and probability of occurrence
- evaluate risks, to determine if risk reduction is required, according objectives of machinery directive
- in order of priority (section 1.1.2(b) of annex I):
  1. eliminate or reduce risks as far as possible
  2. take necessary protective measures in relation to risks that cannot be eliminated
  3. inform users of residual risks due to shortcomings of the protective measures adopted, indicate whether particular training is required and specify needed personal protective equipment

Draw up technical construction file (TCF) and take all measures necessary to ensure that the products are manufactured in accordance with the TCF. Conformity of the product with the essential safety requirements (or relating harmonised standards) must be shown, covering design, manufacture and operation of the product. The TCF should at least contain (Annex VII – B):

- overall drawing of the partly completed machinery and drawings of the control circuits
- full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check conformity of the partly completed machinery with the applied essential safety requirements
- risk assessment documentation showing the procedure followed, including:
  - list of the essential health and safety requirements applied and fulfilled
  - description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks
  - standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards
  - any technical report giving the results of the tests carried out either by the manufacturer or by a (notified) body chosen by the manufacturer
  - a copy of the assembly instructions for the partly completed machinery

Draw up assembly instructions for partly completed machinery, containing a description of the conditions which must be met with a view to correct incorporation in the final machinery, to not compromise safety and health. The assembly instructions must be written in official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled (Annex VI).

Draw up declaration of incorporation (DOI, Annex II – B) of partly completed machinery in official Community language and in language of country where the machinery is to be used, at least containing:

- business name and full address of the manufacturer of the partly completed machinery
- name and address of the person authorised to compile the relevant technical documentation
- description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name
- sentence declaring which essential requirements of the machinery directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and where appropriate, a sentence declaring conformity of the partly completed machinery with other relevant directives (references to officially published texts)

- undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery: including the method of transmission and without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery
- statement that partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the machinery directive
- place and date of the declaration
- identity and signature of person empowered to draw up the declaration on behalf of manufacturer

Keep the DOI, assembly instructions and TCF available for at least ten years after the date the last product was manufactured. (The manufacturer of (final) machinery shall keep the original EC declaration of conformity for a period of at least ten years from the last date of manufacture of the machinery.)

The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.

Does the product fall into one of these categories (and is it mentioned in Annex IV of the machinery directive)?

- Sawing machinery
- Woodworking machinery
- Presses for the cold working of metals
- Injection or compression plastics- or rubber-moulding machinery
- Underground machinery: locomotives, brake-vans, hydraulic-powered roof supports
- Manually loaded trucks for collection of household refuse
- Mechanical transmission devices and guards
- Lifts: for vehicle service or for people involving a hazard of falling
- Portable cartridge-operated fixing and other impact machinery
- Protective devices designed to detect the presence of persons
- Power-operated interlocking movable guards
- Logic units to ensure safety functions
- Roll-over protective structures (ROPS) or falling-object protective structures (FOPS)

  Yes: next question

  No: technical construction file, internal checks on the manufacture of machinery, EC conformity declaration (module A – Annex VIII)

<u>Essential health and safety requirements</u> (set out in Annex I)

Some supplementary essential health and safety requirements for certain categories of machinery:

- for foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics
- to offset hazard due to the mobility of machinery
- to offset hazard due to lifting operations
- for machinery intended to work underground
- for machinery presenting particular hazards due to the lifting of persons

Actions manufacturer (Article 5+12)

Apply safety requirements set out in Annex I by executing a risk analysis:

- determine limits of machinery, including intended use and reasonably foreseeable misuse thereof
- identify hazards that can be generated by the machinery and associated hazardous situations
- estimate risks, using severity of possible injury or damage to health and probability of its occurrence
- evaluate risks, to determine if risk reduction is required, according objectives of machinery directive
- in order of priority (section 1.1.2(b) of annex I):
  1. eliminate or reduce risks as far as possible
  2. take necessary protective measures in relation to risks that cannot be eliminated
  3. inform users of residual risks due to shortcomings of the protective measures adopted, indicate whether particular training is required and specify needed personal protective equipment

Draw up technical construction file (TCF) and take all measures necessary to ensure that the products are manufactured in accordance with the TCF. Conformity of the product with the essential safety requirements (or relating harmonised standards) must be shown, covering design, manufacture and operation of the product. The TCF should at least contain (Annex VII – A):

- general description of the electrical equipment
- overall drawing of machinery, drawings of control circuits, pertinent descriptions and explanations necessary for understanding the operation of the machinery
- full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check conformity of the machinery with the essential health and safety requirements
- documentation on risk assessment demonstrating the procedure followed, including:
  - list of the essential health and safety requirements which apply to the machinery
  - description of protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery
- standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards
- any technical report giving results of tests carried out either by manufacturer or by a notified body
- copy of the instructions for the machinery
- where appropriate, declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery
- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery
- copy of the EC declaration of conformity

Draw up comprehensible instructions for use in official Community language and in language of the country where the machinery is to be used: instructions for intended use of the product, possibly warnings or unintended use, assembly, installation or disposal. (Annex I – 1.7.4.)

Draw up EC declaration of conformity (DOC, Annex II – A) in official Community language and in language of the country where the machinery is to be used, at least containing:

- business name and full address of the manufacturer
- name and address of person authorised to compile the technical file (established in Community)

- description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name
- sentence expressly declaring that the machinery fulfils all relevant provisions of the machinery directive and where appropriate, a similar sentence declaring conformity with other directives and/or relevant provisions with which the machinery complies (references to official texts)
- where appropriate, the name, address and identification number of a notified body (if used)
- where appropriate, a reference to the harmonised standards used
- where appropriate, the reference to other technical standards and specifications used
- place and date of the declaration
- identity and signature of person empowered to draw up the declaration on behalf of manufacturer

Accompany the machine with the instructions for use and DOC.

Keep TCF and DOC available for at least ten years after the date the last product was manufactured.

Affix official CE-marking: mandatory shape and proportions: see Annex III (machinery directive).

*The remaining option is that the product is mentioned in Annex IV and is not partly completed machinery***.**

Are harmonised standards fully applied (all of the relevant essential health and safety requirements covered)?

No: next question

Yes: three possible procedures (Article 12), the manufacturer may choose:

a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII, provided that a quality assurance system is installed conform EN ISO 9001 or an equal system.

b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3

c) the full quality assurance procedure provided for in Annex X

<u>a)</u> this procedure is described in the previous category, 'machinery not mentioned in Annex IV', and must be complemented by operating a quality assurance system (ISO 9001 or equal)

Globally the steps that have to be taken are: apply safety requirements set out in Annex I by executing a risk analysis, draw up TCF, operate a quality assurance system, perform internal checks on the manufacture of the machinery, draw up instructions for use, draw up DOC and affix CE-marking.

<u>b)</u> for each type of machinery (referred to in Annex IV) the procedure has to be followed separately

<u>Actions manufacturer</u> (Article 5+12)

Apply safety requirements set out in Annex I by executing a risk analysis:

- determine limits of machinery, including intended use and reasonably foreseeable misuse thereof
- identify hazards that can be generated by the machinery and associated hazardous situations
- estimate risks, using severity of possible injury or damage to health and probability of its occurrence
- evaluate risks, to determine if risk reduction is required, according objectives of machinery directive
- in order of priority (section 1.1.2(b) of annex I):
  1. eliminate or reduce risks as far as possible
  2. take necessary protective measures in relation to risks that cannot be eliminated

3. inform users of residual risks due to shortcomings of the protective measures adopted, indicate whether particular training is required and specify needed personal protective equipment

Draw up technical construction file (TCF) and take all measures necessary to ensure that the products are manufactured in accordance with the TCF. Conformity of the product with the essential safety requirements (or relating harmonised standards) must be shown, covering design, manufacture and operation of the product. The TCF should at least contain (Annex VII – A):

- general description of the electrical equipment
- overall drawing of machinery, drawings of control circuits, pertinent descriptions and explanations necessary for understanding the operation of the machinery
- full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check conformity of the machinery with the essential health and safety requirements
- documentation on risk assessment demonstrating the procedure followed, including:
  - list of the essential health and safety requirements which apply to the machinery
  - description of protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery
- standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards
- any technical report giving results of tests carried out either by manufacturer or by a notified body
- copy of the instructions for the machinery
- where appropriate, declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery
- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery
- copy of the EC declaration of conformity

Request for an EC type-examination at a notified body (Annex IX), including

- name and address of the manufacturer
- written declaration that the application has not been submitted to another notified body
- the technical file
- sample of the type at the disposal of the notified body; further samples may be required

If provision of the machinery directive are satisfied the notified body issues an EC type-examination certificate with name and address of the manufacturer, data necessary for identifying approved type, conclusions of examination and conditions to which its issue may be subject. The manufacturer and the notified body keep a copy of the certificate, technical file and all relevant documents for 15 years after the date of issue. For any modification to the approved type the notified body must be informed, which will then either confirm validity of the existing certificate or issue a new one if necessary. The manufacturer shall request the review of the validity of the certificate every five years.

Draw up comprehensible instructions for use in official Community language and in language of the country where the machinery is to be used: instructions for intended use of the product, possibly warnings or unintended use, assembly, installation or disposal. (Annex I – 1.7.4.)

Draw up EC declaration of conformity (DOC, Annex II – A) in official Community language and in language of the country where the machinery is to be used, at least containing:

- business name and full address of the manufacturer
- name and address of person authorised to compile the technical file (established in Community)
- description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name
- sentence expressly declaring that the machinery fulfils all relevant provisions of the machinery directive and where appropriate, a similar sentence declaring conformity with other directives and/or relevant provisions with which the machinery complies (references to official texts)
- name, address and identification number of the notified body
- where appropriate, a reference to the harmonised standards used
- where appropriate, the reference to other technical standards and specifications used
- place and date of the declaration
- identity and signature of person empowered to draw up the declaration on behalf of manufacturer

Accompany the machine with the instructions for use and DOC.

Keep TCF and DOC available for at least ten years after the date the last product was manufactured.

Affix official CE-marking: mandatory shape and proportions: see Annex III (machinery directive).

c) full quality assurance procedure provided for in Annex X (machinery mentioned in Annex IV)

The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing (derived from quality assurance standard EN ISO 9001), and shall be subject to the surveillance by a notified body.

Actions manufacturer (Article 5+12)

Apply safety requirements set out in Annex I by executing a risk analysis:

- determine limits of machinery, including intended use and reasonably foreseeable misuse thereof
- identify hazards that can be generated by the machinery and associated hazardous situations
- estimate risks, using severity of possible injury or damage to health and probability of its occurrence
- evaluate risks, to determine if risk reduction is required, according objectives of machinery directive
- eliminate hazards or reduce risks associated with these hazards by application of protective measures, in the order of priority (section 1.1.2(b) of annex I):
    1. eliminate or reduce risks as far as possible
    2. take necessary protective measures in relation to risks that cannot be eliminated
    3. inform users of residual risks due to shortcomings of the protective measures adopted, indicate whether particular training is required and specify needed personal protective equipment

Install and document a quality system for design, manufacture, final inspection and testing (derived from EN ISO 9001). All the requirements adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records. It must contain:

- quality objectives, organisational structure, and responsibilities and powers of the management with regard to the design and quality of the machinery
- technical design specifications, including standards applied and if standards are not applied in full, the means that will be used to ensure that the essential requirements are fulfilled
- design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery
- corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used
- inspections and tests that carried out before, during and after manufacture, and their frequency
- quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned
- means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system

Draw up technical construction file (TCF) and take all measures necessary to ensure that the products are manufactured in accordance with the TCF. Conformity of the product with the essential safety requirements (or relating harmonised standards) must be shown, covering design, manufacture and operation of the product. The TCF should at least contain (Annex VII – A):

- general description of the electrical equipment
- overall drawing of machinery, drawings of control circuits, pertinent descriptions and explanations necessary for understanding the operation of the machinery
- full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check conformity of the machinery with the essential health and safety requirements
- documentation on risk assessment demonstrating the procedure followed, including:
  - list of the essential health and safety requirements which apply to the machinery
  - description of protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery
- standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards
- any technical report giving results of tests carried out either by manufacturer or by a notified body
- copy of the instructions for the machinery
- where appropriate, declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery
- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery
- copy of the EC declaration of conformity

Request for an assessment of the quality system at a notified body, including:

- name and address of the manufacturer
- places of design, manufacture, inspection, testing and storage of the machinery
- technical construction file described, for each type or model of machinery
- documentation on the quality system
- written declaration that the application has not been submitted to another notified body
- inform notified body of any planned change to the quality system now and in the future

Draw up comprehensible instructions for use in official Community language and in language of the country where the machinery is to be used: instructions for intended use of the product, possibly warnings or unintended use, assembly, installation or disposal. (Annex I – 1.7.4.)

Draw up EC declaration of conformity (DOC, Annex II – A) in official Community language and in language of the country where the machinery is to be used, at least containing:

- business name and full address of the manufacturer
- name and address of person authorised to compile the technical file (established in Community)
- description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name
- sentence expressly declaring that the machinery fulfils all relevant provisions of the machinery directive and where appropriate, a similar sentence declaring conformity with other directives and/or relevant provisions with which the machinery complies (references to official texts)
- name, address and identification number of the notified body
- where appropriate, a reference to the harmonised standards used
- where appropriate, the reference to other technical standards and specifications used
- place and date of the declaration
- identity and signature of person empowered to draw up the declaration on behalf of manufacturer

Accompany the machine with the instructions for use and DOC.

Keep TCF, documentation on quality system and on the assessment of the quality system by a notified body and DOC available for at least ten years after the date the last product was manufactured.

Affix official CE-marking: mandatory shape and proportions: see Annex III (machinery directive). The CE-marking must be followed by the identification number of the notified body (because of the full quality assurance procedure).

Are harmonised standards not or partially applied?

No: not possible – all categories covered – start over again

Yes: two possible procedures (Article 12)

a) *the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3*
b) *the full quality assurance procedure provided for in Annex X.*

a) this procedure is described in the previous category: 'full application of harmonised standards'
Globally the steps that have to be taken are: apply safety requirements set out in Annex I by executing a risk analysis, draw up TCF, request for EC type-examination at a notified body, draw up instructions for use, draw up DOC and affix CE-marking.

b) this procedure is described in the previous category: 'full application of harmonised standards'
Globally the steps that have to be taken are: apply safety requirements set out in Annex I by executing a risk analysis, install and document a quality system for design, manufacture, final inspection and testing, draw up TCF, request for an assessment of the quality system at a notified body, draw up instructions for use, draw up DOC and affix CE-marking.

Concluding the application of the machinery directive, there are four main paths. One for partly completed machinery, one for machinery not mentioned in Annex IV, and two for machinery mentioned in Annex IV, one with full standards application and one with partly or no standards application. The latter two however have multiple options.

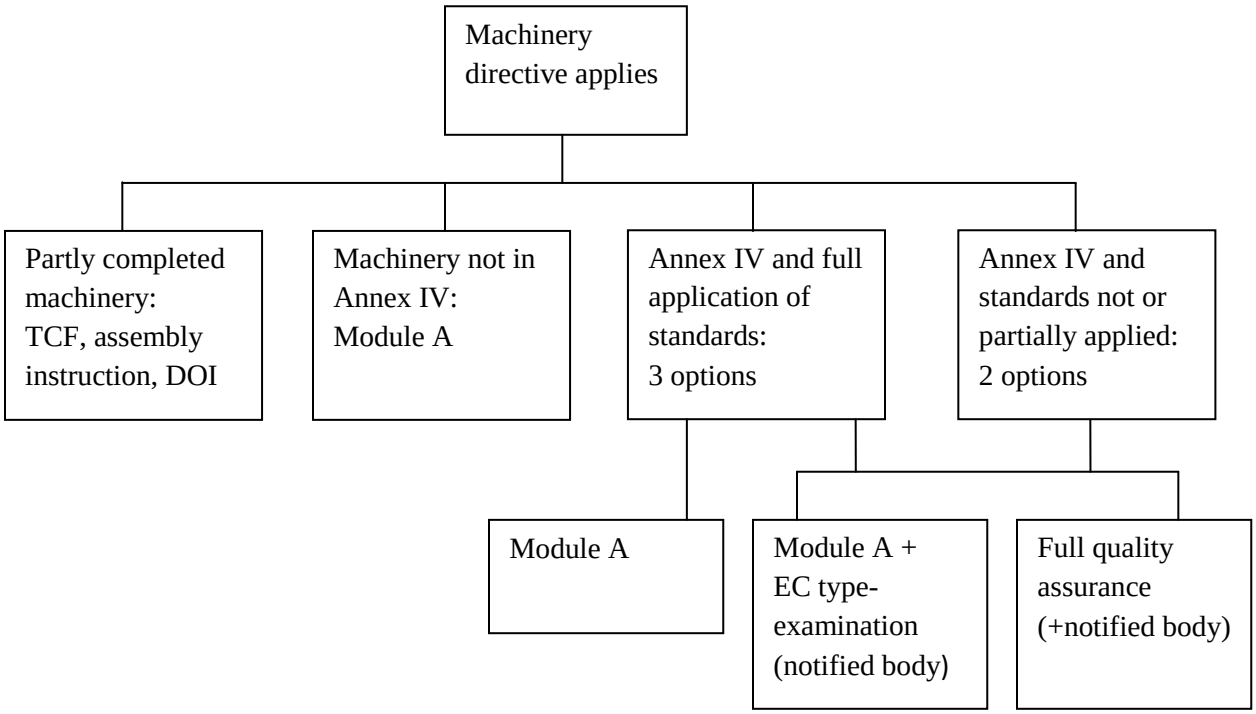


Figure 4.4: Machinery directive applicable

4.2.4 LVD, EMC and Machinery Directive application combined

When two or all three directives apply to a product the before mentioned paths have to be combined. The procedures are not conflicting, however they can be overlapping. Therefore the combining must be executed precisely. Recalling the possible outcomes of the applicable directives and combining four paths of the EMC, one path of the LVD and four paths of the machinery directive application creates the following paths:

- none of the three directive applies: 1 path
- EMC directive applies: 4 paths
- LVD and EMC directive apply: 4 paths
- Machinery directive applies: 4 paths
- EMC and machinery directive apply: 16 paths
- LVD, EMC and machinery directive apply: 16 paths

So CE-marking for the LVD, EMC and Machinery Directive consists of 45 paths, left aside the options of machinery directive. If only the machinery directive applies 1+1+3+2 = 7 options are present. If the options of the machinery directives are included they have to multiplied with the other paths giving:

1 + 4 + (1 * 4) + 7 + (4 * 7) + (1 * 4 * 7) = 72 options

For practical use they can be written out. This however is just combining the described procedures and actions and has little scientific relevance. In the next chapter a case study is conducted for a product in practice. For that objective the combined procedures of the applicable path are analysed. Elaborating on all paths and options could be done when the model is translated into an (online) system for practice. To work it out on paper however gives a great amount of text with little new insights.

If for practical purposes it is done, all actions for manufacturers have to be carefully included and sometimes actions can be eliminated because they become duplicate or redundant. Furthermore it could occur for example that a notified body has to be involved for conformity with the EMC directive, but not for conformity with the machinery directive or vice versa. Keep in mind that the requirements and procedures of all the directives that apply have to be met. The machinery directive contains the obligation to perform a risk analysis, which gives to a systematic application of the essential safety requirements, and therefore could also be applied to the LVD and EMC. As guidance, when combining the paths, the eight steps of the CE-trajectory (to acquire CE-marking) described in both the introduction and the theoretical framework, can be used.

Chapter 5 Testing the design

As empirical method to validate the effectiveness of the design, a case study is chosen. The decision making model designed in the previous chapter is tested on a product in practice. In this way an extensive elaboration on one product can be executed, thereby gaining insight in one possible path in the decision tree, including all relevant aspects. It creates leeway to discuss all interesting facets. Furthermore practical boundaries of this research do not allow for testing on a large amount of products. As described the model has 72 options as outcome, so many products have to be included to increase the validity of the results, which could be a research on its own. Instead of that an in-depth test is executed on one product.

By using a case study as testing method, the applicable path for one product can be completely described, all interesting aspects can be discussed and a link with the underlying theory can be made. It is analysed if and how the model functions in practice. At the same time can be assessed what the advantages and disadvantages of using the model are and possibly its effect on the efficiency of a CE-trajectory. In the methodology chapter it is discussed that this analysis also led to adaption of the decision making model. These minor changes are incorporated in the previous chapter. So the model as it is described, is the model after adjustment. This chapter focuses on the analysis of the case study.

5.1 High pressure water jetting gun

The product for this case study is a high pressure water jetting gun. This can be considered as a domestic high pressure cleaner, but with higher pressure and different applications. They can be used for industrial cleaning, e.g. for storage tanks or sewers. Also the bottom of a boat can be stripped from dirt and paint for example. These water jetting guns can however also be used to cut through several materials, including metal. It can slice into metal by using a jet of water at high pressure and velocity and sometimes by adding an abrasive substance to the water. The type of water jet in this research is hand held. This means that an adult can operate it using both hands. For an impression a picture of a high pressure water jetting gun is included, that shows resemblance to the analysed product.

Figure 5.1: Example of a water jetting gun

The product on which the model is tested is developed by Mourik, a multinational company where safety is a core value with the highest priority and that operates in technological and industrial fields. Among many other activities, they use and develop high pressure water jetting guns in all types, but in this case study two specific types are used. They show some resemblance to the picture above and are used for industrial cleaning. The two types are alike, only one uses a wireless module to communicate with a computer, while the other is wired. During this research the product (both types) went through a regular CE-trajectory, which facilitated comparison in using the model or not and made all information about the

product quickly available. After testing the model on the product, the results were discussed with the person responsible for acquiring CE-marking for a more thorough analysis.

The investigated product is designed to jet water with a pressure up to 2500 bar. This type is developed to be sold on the European market. A major company that is going to use this type of high pressure water jetting guns is Shell international. It is important to assess where it will be used because of work settings. The risks during operation of the product have to be assessed and risk reduction, work instructions and warnings may have to be applied. In this case study both types, wired and wireless, are analysed. In the next section the decision making model is used to determine the applicable directives and the required actions and procedures to acquire CE-marking.

5.2 CE-trajectory with decision making model

Directives that are assessed:

- LVD directive (2006/95/EC)
- EMC directive (2004/108/EC)
- Machinery directive (2006/42/EC)

Manufacturer

Are you located in the European Economic Area and responsible for designing and manufacturing a product with a view to placing it on the European market or putting it into operation on your own behalf (Blue guide, 2000, p. 21–22)?

Yes: CE-responsible as manufacturer

Scope

Is the product (or equipment) designed for use with a voltage rating of between 50 and 1000 V for alternating current or between 75 and 1500 V for direct current (Article 1)?

No: on a battery under 24 volt – product not subjected to LVD

Question on exclusions becomes redundant because LVD is not applicable (this result is discussed in the data analysis).

Can the product cause electromagnetic disturbances to other equipment in its environment or be influenced by electromagnetic radiation from its environment (Article 1.1)? (for example if the product contains electrical components or is subject to the LVD)

Yes: EMC is applicable

Does the product fall within one of the categories mentioned in Article 1.2?

No: wired type – EMC is applicable

Yes: wireless module – equipment covered by Directive 1999/5/EC (radio equipment and telecommunications terminal equipment, RTTE) – product excluded from the EMC directive. The RTTE directive however has essential requirements with respect to electromagnetic compatibility and with respect to using any voltage.

Does one of these definitions apply to the product (Article 1.1):

- machinery (assembly containing moving parts or components)
- interchangeable equipment

- safety components
- lifting accessories
- chains, ropes and webbing
- removable mechanical transmission devices
- partly completed machinery: assembly which is almost machinery but cannot in itself perform a specific application, intended to be incorporated into or assembled with other (partly completed) machinery or equipment, thereby forming machinery

    Yes: partly completed machinery – product needs to be assembled with other machinery, such as water pumping system to perform its function – machinery directive is applicable

Does the product fall within one of the categories in Article 1.2?

No: machinery directive is applicable

- *EMC and machinery directive apply.*

The wired type that is subjected to the EMC and machinery directive is further elaborated on. The wireless module type is addressed in next the section about analysis of this case study.

Application directives:

EMC directive

Is the product a (professional) radio transmitter (not covered by directive 1999/5/EC)?

No: next question

Is the product (part of) a fixed installation and otherwise not commercially available: assembled, installed and intended to be used permanently at a predefined location?

No: next question

Are harmonised standards fully applied (all of the relevant essential safety requirements covered by EMC-norms)?

Yes: module A – internal production control (if manufacturer cannot test electromagnetic compatibility himself, a test report from a notified body is required)

Harmonised standards are fully applied by suppliers and tests have been executed. The declarations of conformity of the suppliers must be included in the TCF, by which the presumption of conformity to the used standards can be declared for the assembled product, provided that instructions from those suppliers are respected. Then module A may be followed.

Machinery directive

Is the product 'partly completed machinery'?

Yes: technical construction file, assembly instruction, declaration of incorporation

Actions manufacturer

The actions that the manufacturer has to perform and the procedures he has to follow are described in chapter 4. They give a clear overview what has to be done to fulfil a CE-trajectory. For the provisions of the EMC directive an electromagnetic compatibility assessment has to be performed. In this product however all components under that directive are tested by suppliers and are used according to accompanying instructions. Those test reports and the declarations of conformity of the components have

to be included in the technical documentation, which has to prove conformity of the whole product. This fulfils the step of the EMC assessment leaving the following actions to comply with the EMC directive.

Draw up TCF, draw up directions for use, draw up EC declaration of conformity, keep TCF and DOC available for at least ten years after the date the last product was manufactured, affix official CE-marking.

These actions can be combined with the actions for the machinery directive to some extent. For example can the technical documentation be combined. But the safety requirements and provisions for technical documentation (and for all actions) from both directives have to be met. For this specific product the provisions from the machinery directive for partly completed machinery must be met, which means a declaration of incorporation must be drawn up, instead of a DOC and affixing CE-marking. The machinery directive requires the following actions.

Apply health and safety requirement by executing a risk analysis, draw up TCF, draw up assembly instructions for partly completed machinery, draw up declaration of incorporation (DOI), keep all these documentation available for at least ten years after the date the last product was manufactured, accompany the machinery with the assembly instructions and DOI.

For this product the EMC is applicable, which indicates the product as an apparatus with full application of harmonised standards. The machinery directive is applicable, which indicates the product as partly completed machinery. The full list of actions is given in chapter 4. Analysing the use of this model is done in the next section.

5.3 Data analysis testing

The use of the decision making model to determine the required actions and procedures to acquire CE-marking is analysed in detail. This brought several interesting issues forward. First of all the LVD is not applicable to this product. The model did show this correctly, but hereby the product is not subjected to all three directives in this research. The application of the LVD however only has one path, module A. The corresponding procedures and actions could be added when the LVD does apply. Besides that, this case study shows how directives can and cannot apply.

In this case study, the decision making model showed the applicable directives correctly. The outcome of the first part of the model gives a clear overview of the directives to which a product has to apply and thereby also to which it is not subjected. However there lies a risk in the interpretation of certain concepts. Some definitions can be difficult to translate towards a product in practice, meaning it is hard to determine if a definition applies to that product. Definitions in this model have to be read very carefully. If one is indecisive, the original (English) directive should be consulted for further explanation of concepts. The machinery directive for example, which introduces many concepts in article 1 that are included in the decision making model, clarifies definitions in article 2. For discussion between languages, the English version is leading, because directives are drafted in English. The decision making model is based on legal documents, so precisely defining concepts is important. Throughout the entire model careful reading is required for a correct interpretation of the concepts. This is exemplified by the product in this case study to which the option partly completed machinery applies. Although this definition seems straightforward it can be dubious, it can easily be confused with machinery that is just

not yet connected. Partly completed machinery however has a completely different path in the model, as is shown in chapter 4.

Testing the model on one product clearly showed a possible path as a whole. It can be seen that the EMC and machinery directive both apply. Additionally it is shown that the path of partly completed machinery is combined with full application of harmonised EMC standards. Defining such a path can be done for all paths and options in the decision making model. For applying the EMC, LVD and machinery directive a clear structuration is made for acquiring CE-marking by the decision making model. For the manufacturer of the (wired) high pressure water jetting gun it becomes clear what actions he has to perform to fulfil all provisions of CE legislation that apply to his product. This a distinct advantage of using the decision making model, it gives clarity and practical implications in the form of 'actions manufacturer' in the complex matter of CE-marking. Manufacturers with little or no experience in acquiring CE-marking can get insights and guidance from this model. For manufacturers that have to execute CE-trajectories on a regular basis it gives insight and overview in applicable directives and needed actions for a new (type of) product in a quick way. Moreover in such companies it could be adopted into the work processes. By doing so different departments can gain insight in the whole trajectory and responsibilities and tasks can be divided, which could lead to more efficiency. Using the decision making tool can provide efficiency for all organisations, because insights are obtained in an easy and quick way and the actions that have to be performed become clear. In the phase of examining legislation and determining what has to be done to acquire (justified) CE-marking, efficiency is achieved. Also developing new products can be assisted by facilitating overview in applicable CE-legislation. The actions still have to be executed, the trajectory is not automated, but it is listed what has to be achieved. Using the model can be a stepping stone to implement CE-marking into the work processes of an organisation.

Furthermore this case study shows an example of purchasing CE-marked parts. Several electrical components are bought with a declaration of conformity with full application of harmonised EMC standards. The parts are assembled with sound engineering into the water jetting gun according to the instructions from the suppliers. This gives a presumption of conformity to the EMC directive, because EMC norms are fully applied and the components are applied in their intended use, as discussed in the literature review chapter. An advantage is that EMC tests, which can be complex and expensive, don't have to be performed by the manufacturer in this case. It can also be useful if specialised knowledge is needed, like for example with electrical components. These parts, that are often subjected to the LVD and EMC directive, can be purchased with a declaration of conformity, which to some extent decreases the need for a manufacturer to have in-depth knowledge about those two directives or about electrical engineering.

An important part of a CE-trajectory is drawing up instructions for use. After the risks and hazards of a product are assessed, risk reduction can be applied but residual risk may still be apparent. Therefore additional actions may be required. Examples can be that only professionals may be able to have access to a product, warning stickers are attached, clear instructions are included maybe with pictures or even in comic book style, covers are placed, etc. As is elaborated on before, instructions are about intended use of a product, unintended use and warning or prescriptions. For a high pressure water jetting gun it can for example be included that only professionals may use it in certain kind of settings and wearing personal protective equipment. Just as with purchasing CE-marked components the issue of responsibility discussed in chapter 2 is present here. The manufacturer tries to reach a certain safety level and otherwise

issues warnings in any form. Besides that the manufacturer underlines the responsibility of his suppliers by including the declarations of conformity of components in the TCF.

It appeared that the applicable directives found by using the model were also the only directives that applied to the product, found in the regular CE-trajectory. So for the wired type, the EMC and the machinery directive apply. For the wireless version the EMC directive is not applicable since the RTTE directive 1999/5/EC (radio equipment and telecommunications terminal equipment) applies. This is also an outcome of the model because this is mentioned in the exclusions of the EMC directive. It is interesting so see the boundaries of the model. The RTTE is not included, although it came out of the model as applicable directive, the actions for manufacturers are not elaborated on for this scenario. As discussed the three included directives cover most of the industrial products, while the RTTE is much less apparent. Furthermore do practical implications not allow for more directives to be included in this research. However, this could be interesting to look further into as will be addressed in the discussion part of this report.

Finally it can be said that the model supports decision making by listing applicable directives and the actions that have to be executed. Sometimes there is still leeway within those actions. The model does not make choices on these available options, but it does support manufacturers on that point by supplying relevant information.

5.4 Functioning decision making model

In chapter 4 the decision making tool is described and in the previous section an extensive description of the analysis of the case study (testing the model) is given. This single case study led to the following findings about the model:

- the model gives clarity and overview in the complex matter of CE-marking
- applicable directives are listed by the model
- outcomes (actions for manufacturers) are clearly listed – all paths can be defined
- efficiency can be achieved by using the model
- the model can be a stepping stone to implement CE-marking in work processes
- the model uses clear definitions, but they can be difficult to translate into practice
- the model is limited to three directives, but other applicable directives can appear because of exclusions
- the model lists actions for manufacturers, but does not automate the trajectory
- the model supports remaining decisions by supplying relevant information

Chapter 6 Conclusions

This report showed an elaboration on CE-marking. Specifically applying the EMC, LVD and machinery directive has been attended to. This last chapter gives a description of the main findings and conclusions of this research, thereby answering the main research question. The last section attends to limitations and possible follow-up research.

6.1 Answering the research question

Throughout this research it is found that a structuration can be indicated in complying with CE-legislation for products subjected to the EMC, LVD and / or machinery directive. A design research has been systematically executed to answer the four sub questions in this research:

1. Which insights can be derived from literature about CE-marking, safety requirements and the use of decision making tools for acquiring CE-marking on a product?
2. How is a CE-trajectory composed, based on the applicable directives?
3. How can different parts be captured into a decision tree or other decision making tool to fulfil the standard aspects of the CE-trajectory?
4. How does the designed decision making tool function in practice?

The first two sub questions are answered in chapter 2. By analysing scientific literature, legal documents and practical insights, a theoretical framework was instigated, which showed how a CE-trajectory is composed in detail. This allowed for designing a well-founded decision making model in chapter 4, and answering the third sub question. After that the model was tested by means of a case study. The data analysis of the case study gave answer to the fourth sub question. The sub questions all form a part of the main question:

- *In what way can the CE-trajectory be captured in a generally usable decision making tool for manufacturers to comply with a product to the EMC, LVD and / or Machinery Directive?*

How the CE-trajectory is captured in a decision making model for these three directives is extensively described throughout this report and the result is given in chapter 4. A structuration is made, resulting in four paths for the EMC directive, one path for the LVD directive, and four paths (or seven options) for the machinery directive. The applicable directives and actions for manufacturers are clearly listed. Here conclusions are given that can be drawn on basis of the decision making model and especially the data analysis in the case study, thereby also assessing if the model is generally usable.

6.2 Findings

Based on this one case study, it can be said that the model is generally usable. It can assist manufacturers in acquiring CE-marking by listing the directives that have to be complied with and how that can be achieved. In chapter 2.4 decision tree models are described as testable cognitive models. An empirical method can be chosen to assess how good a representation of reality the model is, which is done with the case study. Further testing of the validity of the model, for example by using it on more products, is however outside the scope of this research and has not been done. For a better founded statement on the generalisation of the model, further testing is advisable.

The several paths under each directive are clearly described and the different possibilities in the model are made clear. The combining of those paths into 72 options on the other hand has not been done, because of

practical limitations in this research and the little added scientific relevance to do this on paper. In an computer based tool, however this can be done while maintaining clarity. This can help the processing of data and improve the structuration (Hicks, 2004). For practical use, such a tool can be developed in a web-based variant to assist manufacturers. One question at a time can be shown for easy navigating through the decision tree and the applicable directives can be listed as a legal groundwork for a product. After that the actions for manufacturers can be listed from the paths that apply. By means of the case study the model has proven to be practically usable and by translating it into a web-based tool it can become widely usable for manufacturers. Furthermore it has been discussed how using this model can make parts of a CE-trajectory more efficient.

This research is at the junction of legal and technical fields of study. In this specific topic there is little research available. A theoretical model for complying with a random product to CE-legislation is not yet developed, so this research has evident theoretical significance. For legislative literature it supplements theories about what the content of product safety law is and how it functions in practice. For technical fields it can be an addition for new product development theories. CE-marking addresses the design phase of a product and for a manufacturer it can be helpful to have an overview of applicable legislation and actions to achieve compliance.

So the research question has been answered and the decision making model described in chapter 4. Although the validity is only tested by means of a case study and the limitations of this research have to be kept in mind, it is discussed that the model can be regarded as generally usable within the scope of this research.

6.3 Discussion

The decision making model could serve as basis for different models. Firstly more directives could be included. When thinking about industry settings the RTTE directive found in the case study for example could be added to the model. The methodology of designing the model in this research can be followed to get a grounded elaboration on a directive, after which it could be added. It has to be defined what the possible options of the applicable directives are. Then the different paths can be captured. For this end a web-based tool seems useful to remain overview and clarity. Instead of adding directives, the methodology could be used to make a model for different directives, e.g. medically oriented directives. It is difficult to assess if the model could serve as a basis for modelling with other kinds of law besides CE-directives. Also is it hard to estimate when adding directives will make the model too complex to be practically usable. But the model could serve as basis for similar models with different content.

For this research some important limitations can be determined. As is addressed before, the model only contains three directives. The boundaries of the model in terms of applicable directives are discussed in the analysis of the case study. Furthermore the decision making model is developed for industrial manufacturers. The first question in the model addresses if a manufacturer is CE-responsible. Subsequently in the rest of the model the assumption is used that a manufacturer is located in the Netherlands (or at least in the EEA) and is CE-responsible. Importers or authorised representatives are not the focus in this research. The model could be useful to them, but it has to be carefully assessed if differences could arise. Besides that, the model does not address the changing of products to great extent. In the path of EC-type examination under the machinery directive for example, changes to the product are mentioned. However the model does not attend to the assessment of a product in the form of whether

those modifications are significant and what the meaning is for a (new) CE-trajectory. Finally the decision making model does not go into detail about the leeway within the defined paths. Sometimes choices can be made even if an applicable path is defined, often certain leeway remains present. The model gives information as support but does not elaborate on that leeway. These limitations and assumptions have to kept in mind when using the decision making model.

On basis of the data analysis, conclusion and discussion, several options for possible follow-up studies or further research can be defined. The following starting points for research can be used:

- Testing the validity of the model with a large range of products
- Testing the validity of the model with a large range of manufacturers
- Including more directives in the model
- Designing a model for different CE-directives or different legislation
- Supporting decision making inside the model and paths more extensively
- Implementing the model into organisations and their work processes
- Some limitations have been mentioned which could be addressed, such as the use of an authorized representative, the issues for importers, or the implications of making modifications to a product

The decision making model gives a clear structuration in acquiring CE-marking for the EMC, LVD and machinery directive. These points for further research give very interesting subjects to see how this model can serve as basis for other models or theories.

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Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (OJ 1985 C 136, p. 1–9).

Decision no 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ 2008 L 218, p. 82–128).

Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1998 L 204, p. 37–48).

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ 2002 L 11, p. 4–17).

Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ 2004 L 390, p. 24–37).

Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (OJ 2006 L 374, p. 10–19).

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ 2006 L 157, p. 24–86).

Recommended websites for further information

http://eur-lex.europa.eu/ – European law database

www.euronorm.net – website Euronorm

www.newapproach.org – overview New Approach

http://ec.europa.eu/ – European Commission

www.nen.nl – Dutch standardisation

www.cen.eu – www.cenelec.eu – www.etsi.org – European standardisation

Appendix I – European Economic Area (EEA) states

EU members; Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.

EFTA members; Iceland, Liechtenstein and Norway. Switzerland is not part of the EEA Agreement, but has a bilateral agreement with the EU.

Retrieved from: http://www.efta.int/eea/eea-agreement.aspx

Appendix II – CE directives

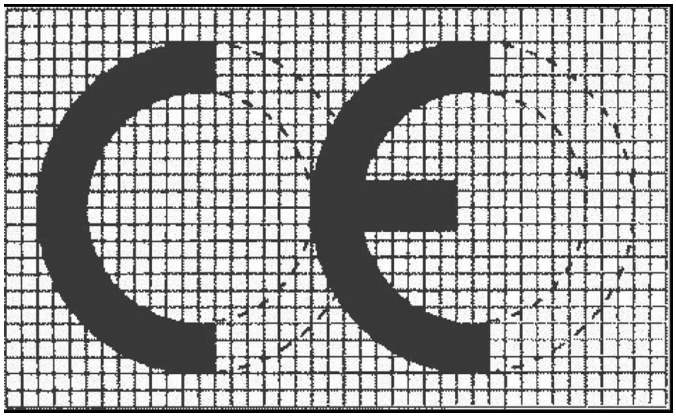
New Approach directives (directives providing for CE marking) and directives based on principles of the New Approach and the Global Approach combined:

1. Low Voltage Directive 2006/95/EC
2. Simple Pressure Vessels Directive 2009/105/EC
3. Safety of Toys Directive 2009/48/EC *(88/378/EEC)*
4. Construction Products Directive 89/106/EEC
5. Electromagnetic Compatibility Directive 2004/108/EC
6. Machinery Directive 2006/42/EC
7. Personal Protective Equipment Directive 89/686/EEC
8. Non-automatic Weighing Instruments Directive 2009/23/EC
9. Active Implantable Medical Devices Directive 90/385/EEC
10. Appliances Burning Gaseous Fuels Directive 2009/142/EC
11. Efficiency requirements hot-water boilers fired with liquid or gaseous fuels Directive 92/42/EEC
12. Explosives for civil uses Directive 93/15/EEC
13. Medical Devices Directive 93/42/EEC
14. Equipment Explosive Atmospheres (ATEX) Directive 94/9/EC
15. Recreational Craft Directive 94/25/EC
16. Lifts Directive 95/16/EC
17. Pressure Equipment Directive 97/23/EC
18. In-Vitro Diagnostic Medical Devices 98/79/EC
19. Radio Equipment and Telecommunications Terminal Equipment Directive 99/5/EC
20. Cableway Installations designed to carry persons Directive 2000/9/EC
21. Measuring Instruments Directive 2004/22/EC
22. Pyrotechnic Articles Directive 2007/23/EC
23. Energy efficiency requirements for household electric refrigerators, freezers and combinations thereof Directive 96/57/EC
24. Noise emission in the environment by equipment for use outdoors Directive 2000/14/EC
25. Energy efficiency requirements for ballasts for fluorescent lightning Directive 2000/55/EC
26. Ecodesign requirements for energy-related products Directive 2009/125/EC

Retrieved from: http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/#ch2

Appendix III – Official CE-mark

The CE conformity marking shall consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected. The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

Retrieved from: LVD (OJ 2006 L 374, p. 16)