Tampere University

JUHA VASARA

Managing Safety-Related Compliance of Machines in the Global Market

Tampere University Dissertations 157

Tampere University Dissertations 157

JUHA VASARA

Managing Safety-Related Compliance of Machines in the Global Market

ACADEMIC DISSERTATION
To be presented, with the permission of
the Faculty of Engineering and Natural Sciences
of Tampere University,
for public discussion in the auditorium K1702
of the Konetalo, Korkeakoulunkatu 6, Tampere,
on 22 November 2019, at 12 o'clock.

ACADEMIC DISSERTATION
Tampere University, Faculty of Engineering and Natural Sciences
Finland

Responsible supervisor and Custos
Professor
Jouni Kivistö-Rahnasto
Tampere University
Finland

Pre-examiners
Docent
Jukka Takala
International Commission of Occupational Health
Italy

Professor
Kalevi Ekman
Aalto University
Finland

Opponent
Professor
Jussi Kantola
University of Vaasa
Finland

Cover design: Roihu Inc.

ISBN 978-952-03-1314-2 (print)
ISBN 978-952-03-1315-9 (pdf)
ISSN 2489-9860 (print)
ISSN 2490-0028 (pdf)
http://urn.fi/URN:ISBN:978-952-03-1315-9

PunaMusta Oy – Yliopistopaino
Tampere 2019

PREFACE

The completing of this doctoral thesis has been a long process. A lot has occurred during these years and I have even changed the final topic after starting. However, this process has been a significant learning process for me. After graduation, I started as a researcher at former Tampere University of Technology's Institute of Occupational Safety Engineering in 2006. Back then, I did not have any idea of starting a thesis but the interesting topic and examples from the surrounding colleagues created my inspiration.

I could not have done this alone. I am very grateful to so many of all the support and advices I was given during the process. I want to thank Professor Jouni Kivistö-Rahnasto for supervising my thesis. You gave me several inputs for developing my thesis further. I am grateful to the examiners of my thesis, Dr., Docent Jukka Takala (International Commission of Occupational Health) and Professor Kalevi Ekman (Aalto University). I also want to thank all those organisations and their representatives that took part in this research and offered their time to share valuable views.

I received financial support from several sources to enable this process. I want to acknowledge the Doctoral Program of Concurrent Mechanical Engineering for all their financial and other support. Especially I respect the memory of Professor Erno Keskinen; the common foreign visits with other doctoral candidates are memorable. I also appreciate the funding I received from the Doctoral Programme in Industrial Engineering and Management and the Finnish Work Environment Fund.

I want to thank my former colleagues from Tampere University of Technology as well as my colleagues from Industrial Union. You have supported me a lot and brought other perspectives to my life.

Finally, I want to express my thanks to my relatives and friends. Especially to my parents and sister who have helped me in so many ways. My greatest thanks go to my dear wife Outi and son Elmer. I could not have finished this without you.

Tampere 17.10.2019

Juha Vasara

ABSTRACT

In global trade, a machine manufacturer must manage a large variety of safety requirements, conformity approvals and product liability issues in order to avoid the possible losses caused by undesired events related to their products. Incorrect or insufficient knowledge of regulations in different market areas may hinder business and weaken competitiveness of machine-manufacturing companies with global operations. Especially outside of European Economic Area (EEA), European manufacturing companies may face difficulties in gathering and managing all local information and anticipating new requirements.

This dissertation studies the process of managing compliance with product safety-related requirements in a global context. In here, the requirements cover external demands that an organisation has to comply. These may also be defined as external parties'/stakeholder requirements. The existing process of compliance management is studied from two perspectives: from globally operating manufacturing companies' and from external parties', such as legislators, standardisers and supervisory authorities, which have an essential role in effecting, demanding and/or supporting the management of compliance in companies as a whole. The results of the qualitative study base on prior literature and semi-structured interviews of six large machine manufacturing companies' representatives (n=37) as well as twelve Finnish (n=40) and six European (n=13) external parties' views of practices and problems in managing compliance. The results of literature review and the empirical findings of the interviews were applied in the construction of new approaches to manage compliance with safety-related requirements more systematically.

The empirical results of this study show that the European integration has clarified the companies' operations significantly within the European Union (EU). However, varying practices, requirements and their enforcement cause difficulties for companies. From the external parties' point of view, the regulatory system requires improvements in the EU. Especially market surveillance is unequal in different EU member countries. Nevertheless, the companies seem to have more difficulties related to achieving compliance in other market areas. The required information about another market is typically gathered with help of company's local units,

customers, dealers as well as by external benchmarking. Company makes a decision of whether it strives to comply with the requirements of all the market areas simultaneously or if the products are customised to different markets. The customisation may also be carried out in a local unit. However, central problems for companies are the lacking comparison of the requirements among different market areas and that the existing information does not cumulate to one place in the companies. In addition, the participating companies seem to desire more external help for official interpretations of requirements. However, this kind of advice is not easily available. Overall, according to the findings of this research, there is a need to clarify the process of managing compliance with safety-related requirements in a global context. The existing models and guidelines do not provide appropriate solutions for the identified needs.

The constructed new approaches support to structure operations around managing compliance and provide new perspectives for understanding societies' activities. These approaches consist of a model for managing compliance with safety-related requirements and safety concerns in product delivery strategies. The main part of these approaches is the model, which consists of essential issues related to the phases of managing compliance with requirements from discovering and following requirements up to evaluation and ensuring compliance of a product with the valid requirements. The model considers product-based requirements. In addition, it covers issues both from companies' and from specific external parties' perspectives.

This dissertation emphasises European legislation and practices. Nevertheless, the proposed approaches are generic and should be of interest for a wider audience. This dissertation produces scientific contribution by providing an overview of the problems and practices in managing safety-related compliance from the industrial perspective. In addition, it provides several external parties' expectations, role and possibilities in supporting and controlling companies' management of compliance. The results and constructed new approaches of this study combine several theoretical areas around compliance management, supply chain management, product liability and decision-making. Further, this study adds a novel aspect of safety in areas where it has not been covered in the earlier studies.

TIIVISTELMÄ

Globaalissa kaupassa valmistajan täytyy hallita laaja määrä erilaisia turvallisuusvaatimuksia, sääntöjen-/vaatimustenmukaisuuden hyväksymisiä ja tuotevastuuasioita välttääkseen mahdollisia, ei-toivotuttujen tapahtumien aiheuttamia, tappioita. Väärät tai riittämättömät tiedot eri markkina-alueiden vaatimuksista haittaavat liiketoimintaa ja heikentävät maailmanlaajuisesti toimivien koneenvalmistajien kilpailukykyä. Erityisesti toimittaessa laajemmin kuin Euroopan talousalueella (ETA) eurooppalaisilla yrityksillä voi olla vaikeuksia kerätä ja käsitellä kaikkia paikallisia tietoja ja/tai seurata uusia vaatimuksia.

Tässä väitöstutkimuksessa tarkastellaan tuoteturvallisuuteen liittyvien vaatimusten hallinnan prosessia maailmanlaajuisessa liiketoiminnassa. Vaatimukset käsittävät tässä ulkoiset vaatimukset, joita yrityksen täytyy noudattaa. Prosessia tutkitaan käytännön tasolla kahdesta näkökulmasta: globaalisti toimivien tuotteita valmistavien yritysten näkökulmasta sekä yritysten ulkopuolisten osapuolien, kuten lainsäätäjät, standardisointiorganisaatiot ja valvontaviranomaiset, jotka vaikuttavat olennaisesti vaatimustenhallintatyöhön yrityksissä. Laadullisen tutkimuksen tulokset perustuvat kirjallisuuskatsaukseen sekä puolistrukturoituihin haastatteluihin yrityksissä ja muissa organisaatioissa. Haasteltavina on kuuden suuren koneenvalmistajayrityksen edustajia (n=37) sekä kahdentoista suomalaisen (n=40) ja kuuden eurooppalaisen (n=13) ulkoisen osapuolen edustajaa. Heiltä selvitetään näkemyksiä käytännöistä ja mahdollisista ongelmista turvallisuuteen liittyvien vaatimusten hallinnan käytännöistä. Kirjallisuuskatsauksen ja haastatteluista kerättyjen empiirisiä tulosten avulla tutkija kehitti uusia lähestymistapoja turvallisuuteen liittyvien vaatimuksien systemaattisempaan hallintaan.

Tämän tutkimuksen perusteella Euroopan yhdentyminen on selkeyttänyt merkittävästi yritysten toimintaa Euroopan unionin (EU) sisällä. Unionin eri jäsenmaiden vaihtelevat kansalliset käytännöt, vaatimukset ja niiden toimeenpano tuottavat kuitenkin edelleen vaikeuksia yrityksille. Ulkoisten osapuolten edustajien näkökulmasta erityisesti epäyhtenäinen markkinavalvonta edellyttää kehittämistä EU:n sisällä. Tutkimukseen osallistuneet koneenvalmistajat kokevat kuitenkin enemmän vaikeuksia vaatimustenhallinnassa muilla markkina-alueilla. Tarvittavia

tietoja toisista markkinoista kerätään tyypillisesti yrityksen omien paikallisten yksiköiden, asiakkaiden ja jälleenmyyjien avulla sekä lisäksi ulkoisella vertailulla. Yritys päättää vaatimustenhallintaprosessissaan pyrkiikö se noudattamaan kaikkien markkina-alueiden vaatimuksia samanaikaisesti tai mukautetaanko tuotteita eri markkinoille itse tai esimerkiksi oman paikallisen yksikön toimesta. Keskeisenä ongelmana yrityksissä on, että vaatimuksia ei tyypillisesti ole vertailtu kattavasti ja systemaattisesti eri markkina-alueiden välillä ja olemassa olevaa tietoa ei ole tallennettu keskitetysti. Lisäksi yritykset kaipaavat enemmän ulkoista tukea virallisille tulkinnoille vaatimuksista, mutta tällaista tukea ei ole helposti saatavilla. Kaiken kaikkiaan tämän tutkimuksen tulosten perusteella on vielä tarve selventää turvallisuuteen liittyvien vaatimuksien hallintaprosessia globaalissa kontekstissa. Olemassa olevat mallit ja ohjeistukset eivät tarjoa riittäviä ratkaisuja tunnistettuihin tarpeisiin ja ongelmiin.

Tässä tutkimuksessa kehitetyt uudet menettelytavat tukevat turvallisuuteen liittyvien vaatimusten kokonaisvaltaista jäsentämistä eri osapuolten näkökulmista. Menettelytavat koostuvat mallista turvallisuuteen liittyvien vaatimusten hallintaan ja turvallisuuden huomioimisesta erilaisissa tuotteen toimitus-strategioissa. Keskeisin osa tuotoksista on vaatimustenhallinnan malli, joka koostuu olennaisista asioista liittyen vaatimustenhallinnan vaiheisiin aina vaatimuksien löytämisestä ja seuraamisesta vaatimustenmukaisuuden arviointiin ja varmistamiseen. Mallin avulla turvallisuuteen liittyviä vaatimuksia voi tarkastella tuoteperusteisesti. Lisäksi mallissa huomioidaan yrityksen ulkopuolisten osapuolien rooli vaatimustenhallintaprosessin eri vaiheissa.

Väitöskirjassa painottuvat eurooppalainen lainsäädäntö ja käytännöt, mutta ehdotetut lähestymistavat ovat monelta osin yleispäteviä ja kiinnostavia myös laajemmalle yleisölle. Väitöskirja tuottaa uusia tieteellisiä tuloksia ongelmista ja toimintavoista turvallisuuteen liittyvien vaatimusten hallinnassa sekä kokoaa kattavasti tietoa eri osapuolien odotuksista, roolista ja mahdollisuuksista yritysten vaatimustenhallintatyön tukemisessa. Väitöskirjan tulokset yhdistävät useita tieteellisiä tutkimusalueita liittyen vaatimustenhallintaan, toimitusketjujen hallintaan, tuotevastuuseen ja päätöksentekoon. Turvallisuusnäkökulmaa tarkastellaan sellaisilla tutkimusalueilla, joissa sitä ei ole aiemmissa tutkimuksissa kattavasti huomioitu.

CONTENTS

List of Figures

List of Tables

KEY DEFINITIONS

Benchmarking	Systematic process of finding best practices, innovative ideas and highly effective operating procedures that lead to superior performance (Bogan & English 1994).
CE marking/CE mark	Denotes products sold in the European Economic Area assessed to meet high safety, health and environmental protection requirements; the CE marking is part of the European Union's harmonisation legislation (European Commission 2018).
Compliance with requirements	Conforming to the stated and applicable external requirements set for e.g. companies and their products and/or services (Carroll & McGregor-Lowndes 2002).
Compliance management	Ensuring that business processes, operations and practices are in line with a set of prescribed and/or agreed-upon requirements (Sadiq & Governatori 2010); non-compliance may lead to penalties such as fines, indemnities, bans on business operations or loss of licenses (Ratsula 2017; 2016).
Declaration of Conformity	Formal declaration by a product manufacturer or a manufacturer's representative that a product meets all relevant requirements under the EU's product safety legislation; see Health and Safety Executive (2017).

Enforcement	Actions that intend to ensure law abidance (Gray & Scholtz, 1993; Ryan 1996); a well-known model showing enforcement options is the so-called 'enforcement pyramid', which presents authorities' actions ranging from persuasion to comply to permanent revocation of a company's licences (Ayres & Braithwaite 1992; Bluff 2011; 2004; Tala 2005).
European Commission	Politically independent executive arm of the European Union (EU) that promotes the general interests of the EU by proposing and enforcing legislation as well as implementing policies and EU budgets (European Union 2018a).
European Union	Union of European nations formed in 1993 to achieve political and economic integration; the EU comprises 28 member countries (European Union 2018b).
Global market	This dissertation uses the term 'global market' to describe market areas across the world.
Implementation	This dissertation uses implementation in a regulatory context. It refers to the different measures by actors (e.g. public organisation) or the procedures to enforce the legal institution and foster the created interaction between the public organisation and regulatees (Tala 2008).
Machinery, machine	An assembly fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which

	are joined together for a specific application (ISO 12100:2010).
Management	Coordinated activities to direct and control an organisation (ISO 9000:2015).
Manufacturing company, manufacturer	This dissertation uses manufacturing company/manufacturer to describe a legal person who designs and manufactures machinery or partly completed machinery (modified from 2006/42/EC).
Market area	This dissertation uses market area to describe a geographic zone with specific legislative requirements and processes to enforce these requirements.
Market surveillance for products	Ensuring that market products do not endanger consumers and workers; EU member countries must ensure effective market surveillance (European Commission 2017a).
Mass customisation	Combination of mass production and customisation, though the combination level of these production styles may vary (Ahoniemi et al. 2007).
Notified body	Organisation designated by an EU country to assess conformity of certain products prior to market placement; notified bodies perform conformity assessment procedures outlined under the applicable legislation, when a third party is required (European Commission 2017b).

Order penetration point	Supply-chain point at which customer-specific and varying requirements are added to more general standard requirements and decoupled to product structures or a specific customer order (Brun & Zorzini 2009; Gosling & Naim 2009; Wikner & Rudberg 2005; Olhager 2003). This may also be called as decoupling point.
Organisation	A group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives (ISO 19600:2014).
Postponement	Delays in supply chain activities until a demand, such as customer order, is realised (van Hoek 2001); it may result from changes in the manufacturing-distribution process or product architecture (Swaminathan & Lee 2003).
Product delivery strategy	Strategy to manufacture and deliver products to customer; product delivery strategies may be divided into make-to-stock, assemble-to-order, make-to-order and engineering-to-order (Olhager 2003).
Product liability	Producer's responsibility (liability) for damages to persons and/or property caused by a defect in its product (Mononen 2004).
Product safety	Application of engineering and management principles, criteria and techniques to achieve acceptable level of risks within the constraints of operational effectiveness, time, and cost throughout

	all phases of the system's lifecycle (New England Chapter of the System Safety Society 2002).
Regulatory compliance	To comply with external regulations set by e.g. governments (Hale et al. 2011).
Requirement	Need or expectation that is stated, generally implied or obligatory (ISO 9000:2015); in this dissertation, requirement is applied to describe external (stakeholder) demand that organisations must comply with. This may also be called as compliance requirement (ISO 19600:2014).
Responsibility	A key concept with several aspects in our moral, social and political thinking (Lucas 1993); in this dissertation, responsibility is used to describe person(s)/organisation(s) in charge.
Risk	Combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51:2014).
Risk management	Coordinated activities to direct and control an organisation with regard to risk (ISO 31000:2009).
Safety	Freedom from risk, which is not tolerable (ISO/IEC Guide 51:2014); in this dissertation the term safety includes both safety and health.

Standard	A technical document designed to be used as a rule, guideline or definition. It is a consensus-built, repeatable way of doing something. Standards are created by bringing together all interested parties. (CEN 2018)
Supply chain management	Framework for modelling and managing flows of products, services, information and financing (Mentzer et al. 2001; Tan 2001).

LIST OF ABBREVIATIONS

ADCO	Administrative Cooperation Group (in the EU)
ANSI	American National Standards Institute
BREXIT	British exit (from the European Union)
CE	Conformité Européenne/European Conformity
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
DG	Directorate General, Department of the European Commission
EC	European Commission or European Communities
EEC	European Economic Community
EEA	European Economic Area
ETSI	European Telecommunications Standards Institute
EU	European Union
IEC	International Electrotechnical Commission
ILO	International Labour Organization
ISO	International Organization for Standardization
MACHEX	Committee mandated by SLIC to examine machinery issues (in the EU)
OSHA	Occupational Safety and Health Administration (in the US)

REFIT	Regulatory Fitness and Performance programme (in the EU)
SLIC	Senior Labour Inspectors Committee (in the EU)
SME	Small- and medium-sized enterprises
TTIP/T-TIP	Transatlantic Trade and Investment Partnership between the EU and US
UK	United Kingdom
US	United States (of America)

1 INTRODUCTION

Today, machine-manufacturing companies operate in several global markets, complying with safety and health regulations of varying levels of importance. This dissertation is interested in the functionality of regulatory systems in different market areas, external requirements and the need for an in-depth understanding of compliance management, which has key implications for such companies. Specifically, it focuses on compliance in the field of work machines and specifically in business-to-business products. According to ISO 19600:2014, compliance is an outcome of an organisation meeting its obligations, which in this study mainly refer to regulatory obligations. Compliance with requirements indicates that a company conforms to the stated and applicable external requirements for itself and its products and/or services (e.g. Carroll & McGregor-Lowndes 2002). Compliance management is defined as ensuring that business processes, operations and practices are in line with a set of prescribed and/or agreed-upon requirements (Sadiq & Governatori 2010). However, to ensure that the products meet these uniform safety and health demands, compliance must be secured throughout the supply chain.

To avoid possible losses caused by undesired events, and/or external inspections, companies must pay attention to existing and pending regulations that have direct and indirect effects on their designed products (Vasara & Kivistö-Rahnasto 2015). Within the European Union (EU), the Directive 2006/42/EC on machinery (later termed Machinery Directive) and the supplemented harmonised standards lay down quite clear requirements and guidelines for taking safety and health into consideration in the design processes of most machines (Baram 2007; Rausand & Utne 2009). The Directive promotes free movement of machinery within the European single/internal market (European Commission 2017c). However, outside of European market area, EU-based companies may face difficulties in gathering and managing all local information and anticipating new stakeholder requirements. Typically, companies are expected to be aware of various product safety requirements, conformity declarations and product liability issues within all their market areas. In addition, they must understand and comply with the local or regional legislation and jurisdiction, operating conditions, duty types and customers' fields of operation. (Vasara & Kivistö-Rahnasto 2015) Furthermore, companies must choose between having similar products worldwide and having products with

different specifications for customers worldwide. They should also determine the designer and manufacturer of their products and the production locations for both processes (Stark 2011; Sadiq & Governatori 2010; Drahos & Braithwaite 2001).

Mechanical engineering companies are characterised by a relatively high manufacturing intensity. Typically, these companies produce single products or small batches; have high qualification requirements for manufacturing personnel; and effectively communicate these requirements among their manufacturing, engineering and design departments (European Commission 2016c). Coordinating several operations mandated by the various safety requirements of foreign markets induces greater costs for the companies. Further, incorrect or insufficient knowledge of regulations weakens the competitiveness of manufacturing companies with global operations. Further, lack of external help, such as that from authorities, may increase the difficulties in compliance management. (Vasara & Kivistö-Rahnasto 2015)

This dissertation examines the existing solutions to determine and manage product safety-related requirements and compliance with the requirements globally as part of product design and throughout their supply chains. There are guidelines and models around compliance management process (ISO 19600:2014; Henson & Heasman 1998; French & Neighbors 1991) but these do not explore the process in global context and pay attention to suppliers' and external parties' role. The expectations and roles of several external parties and their ability to support as well as control companies are widely discussed in this dissertation. Specifically, actors such as legislators, standardisers and supervisory authorities play essential roles in influencing companies' compliance management as a whole. Bluff (2011; 2010) highlighted the effect of these external actors (referred to as 'external parties' later) on work health and safety context around plants and the need to better understand the influence of these external parties in regulatory processes. Thus, this research contributes to scientific literature by

1) providing an overview of the problems and practices in managing compliance with safety-related requirements from several perspectives and
2) constructing new approaches to manage compliance with safety-related requirements in a global context.

The author constructs new approaches to compliance management by drawing on literature and the responses of representatives from participating companies and external parties. The research specifically sheds light on the more systematic management of safety-related compliance when operating in several market areas. Apart from highlighting the significance of structuring operations around compliance management, the new approaches will offer new perspectives for external parties. A key part of the approaches is a model to manage compliance with safety-related requirements (see Figure 4), which comprises compliance management phases ranging from discovering and following requirements to evaluating and ensuring product compliance. Importantly, while this research emphasises European legislative framework, the proposed approaches are generic and should be of interest to a wider audience.

From practical point of view, the topic addressed in this dissertation is significant because the mechanical engineering sector plays a critical role in the EU and thus, it is highly important to secure its competitiveness in the future (European Commission 2016a). According to ISO (2014) and Ratsula (2016), compliance is one of the biggest challenges faced by businesses today. The changing political situation enhances the topicality of this dissertation. For example, Brexit (the United Kingdom's (UK's) exit from the EU) will have repercussions for the European internal market. Similarly, the political situation in the United States (US) affect European companies' potential to export and operate there as well as the global trade relations as a whole. The negotiations of the Transatlantic Trade and Investment Partnership (TTIP/T-TIP) agreement between the EU and US ended without conclusion. In 2019 was stated that even the negotiating directives are obsolete and they are no longer relevant (European Commission 2019a).

2 LITERATURE REVIEW

2.1 Safety considerations for product design and development

2.1.1 Product safety and design

According to Marucheck et al. (2011), the concept of product safety refers to decreasing the probability of illness, injury, death or other negative consequences to people, property or equipment resulting from the use of a product. Adopting a lifecycle perspective, Rausand and Utne (2009) state that a safe design is one that meets product safety requirements from the front-end phase to post-production. Further, these requirements should be integrated early on in product performance specifications and treated along with other product-related aspects.

Legislation has both direct and indirect effects on product design. Companies must, therefore pay attention to existing and anticipated regulations that can influence designed products. In Europe, safety requirements for machines are based on generic criteria, listed in various standards. (Baram 2007) To indicate that a product complies with legislation objectives, companies must first identify and refine legal requirements into product-based ones and then integrate them into their product design and testing processes (Travis 2008). Safety-based information technology also allows the simultaneous incorporation of safety and other requirements into product design (Dowlatshahi 2001).

The key reasons for manufacturers to increase product safety are to enhance their competitiveness, reduce warranty cost and prevent product liability claims and recalls. However, complying with safety requirements may lead to additional costs in the design process. (Rausand & Utne 2009) Thus, the decision to comply with requirements is made on the basis of a cost–benefit analysis of safety design. In addition, competitors may have, for example, less safe and cheaper designs (Hale et al. 2007). Safety problems in a product can have a significant impact on a global scale in form of varying recall fees, litigation fees and image losses, among others (Marucheck et al. 2011). Understanding a product's nature, such as longitudinal

product performance data, and predicting possible safety problems are essential to establish a liability-free status for products in the long-term (Dowlatshahi 2001).

It is important that organisations' design and development processes follow a corporate safety policy or a general safety plan to ensure product safety. Safety policies include risk acceptance considerations related to, for example, product liability and warranties, while safety plans cover valid safety requirements and the application of these requirements. In addition, organisations are recommended to have a product-specific safety plan, comprising safety and health requirements, product liability issues and necessary actions for product development. (Rausand & Utne 2009) Such a plan helps create awareness of the wide range of safety and health requirements presented in legislations and standards and realise at which stage of product development these requirements should be addressed (Dowlatshahi 2001; Rausand & Utne 2009).

In terms of safety, manufacturers usually focus on design, manufacturing, and the provision of sufficient warnings against unsafe or hazardous conditions. Even though design is considered the most important phase of a product's lifecycle, all stages should be equally regarded in the context of safety. To establish and maintain a liability-free status for the product in the long-term, the following are necessary: a basic understanding of a product's nature, longitudinal product performance data and ability to predict safety problems. (Dowlatshahi 2001)

2.1.2 Decision-making in product safety

Organisational decision-making takes place at many levels and under various circumstances. While there is no simple decision-making approach for safety issues, the methods should be rational and logical. According to rational choice theory, which explains economic behaviour in the marketplace and was later used in behavioural studies in various disciplines, optimal decisions are made through rational decision-making. (Sten 2011)

Human decision-making is largely concerned with the discovery and selection of satisfactory, not optimal, alternatives (March & Simon 1993). In terms of safety, satisfactory alternatives are generally fulfilled through safety management since the

given solutions must meet specified requirements (Sten 2011). Designers play a key role in decision-making about product safety. Detailed knowledge about design objects is critical for safety-related decisions; however, it often is problematic to consider safety at the initial stages of the design process. Thus, it is necessary to outline a generic design process that defines checkpoints to determine whether designers' obligations are fulfilled (Hale et al. 2007). Next, the results of safety assessments should to be updated at every step of the product development process and finally, organisations should determine whether the level of safety is adequate to proceed with manufacturing. Manufacturers should also estimate the adequacy of the safety level. (Rausand & Utne 2009) In addition, the decision-making should be supported at all levels of the supply chain by adequate information systems (Lummus & Vokurka 1999).

Product risks are composed of product hazards that are the potential sources of harm and the probabilities of harms' occurrence. The manufacturer needs first identify all possible hazards related to the product during its lifecycle. Ideally, the identified hazards should be eliminated, and where this is not possible, the risks should be mitigated through various barriers and safety functions. (Rausand & Utne 2009; ISO 12100:2010) Harm caused by unsafe products may lead to settlements for injury or death, property damage not covered by insurance, warranty claims, liability and recall costs and loss of prestige or market share (Rausand & Utne 2009).

During the developmental phase of a new product, it is important to focus on ways to eliminate hazardous features from design and testing prototypes as well as define procedures for safe use, at least to the extent required by regulations (Baram 2007). In addition, the risks should be assessed throughout supply chains (Christopher & Peck 2004). However, it is difficult to arrive at an acceptable level of risk or decide that the risk-mitigation process can be stopped (Rausand & Utne 2009). These decisions are challenging possibly because of the lack of feasible instructions. Product standards can offer hints about the adequacy of solutions. However, the EU's Machinery Directive and related standards, for example, are insufficient for manufacturers to evaluate the adequacy of safety measures suggested in the directive. (Kivistö-Rahnasto 2000; McRoberts 2005) Other concerns for manufacturers include whether the product will be used in ways other than originally intended and if it will be consumed intentionally or unintentionally (Rausand & Utne 2009).

2.2 Product safety in global businesses

2.2.1 Global market

The global market can be both a challenge and an opportunity for organisations. Accordingly, a company is required to make several decisions: geographical markets in which it will offer its products, whether their products should be the same or have different specifications for customers worldwide, and the locations for product development and manufacturing. Companies are expected not only to understand customer requirements but also to comply with legislative requirements along with other market specifications. For this, the intended target country or market must be sufficiently known. (Stark 2011; Sadiq & Governatori 2010; Drahos & Braithwaite 2001; Äijö et al. 2005) Companies must also be aware of the strategies and styles of regulatory agencies/ authorities to satisfy the requirements in various market areas in addition to the compliance environment (Tallberg 2002; Sutinen & Kuperan 1999). Localisation that refers to adaptation of a product to meet the requirements of a specific target market is another aspect that companies need to consider (Rau 2013).

Another internationalisation challenge for companies, particularly the small-scaled ones, is knowledge acquisition. A case study of 10 small-scale Scottish internationalising companies showed that the companies lacked relevant experience or useful networks to acquire the needed technological, market and internationalisation knowledge. Nevertheless, small-scale organisations can acquire experience indirectly, for example, through recruitment, government advisors and consultants. (Fletcher & Harris 2012)

A company's growth and internationalisation process can be grouped into three distinct, simplified pathways: organic, collaborative and born global. A company following the organic pathway will begin its international operations by exporting to few countries and may have sales representatives in these markets. A company following a collaborative approach will form partnerships and alliances with others to expand their business. Finally, under a born-global approach, a company will proactively seek growth in international markets with rapid internationalisation; in addition, such a company may have regional offices in the main markets. However, in reality, pathways tend to be hybrid in nature. (Äijö et al. 2005)

2.2.2 Product safety requirements

External product safety requirements may be outlined in governmental regulations, standards, codes of practice, guidelines, past outcomes of legal processes, court decisions or by customers (e.g. customer interest groups). Such requirements depend on product type and application and may be qualitative and/or quantitative in nature. (Murthy et al. 2008; Rausand &Utne 2009) Various inputs that shape manufacturers' perception of a safe product may also be presented as product liability litigations, internal safety efforts and marketing requirements (Dowlatshahi 2001; Eads & Reuter 1983). Baram (2007) addressed this issue by discussing the four aspects of social control aimed at reducing product risks: marketplace, governmental regulations, self-regulation and tort law. For example, feedback from the marketplace, such as industrial consumers, can force a company to revisit its understanding of safety design (Baram 2007).

Governmental regulations are typically considered mandatory input for a product design process, whereas product liability litigations offer solutions to the process of rectifying products. While internal safety efforts serve as manufacturers' solutions to safe production, marketing requirements present customers' perceptions of safety (Dowlatshahi 2001). In developed nations, governmental regulations are the bases for creating safe products (Baram 2007). In addition, the International Labour Organization (ILO) has an essential role in effecting safety-related legislation and standardisation. The ILO has established conventions, recommendations, resolutions, codes of practices and guidelines that have been put in practice in a large number of countries globally. For example, code of practise about Safety and health in the use of machinery sets out principles to designers and manufacturers of machinery as well. (ILO 2019)

Regulations are enforceable by nature, and non-compliance is considered a violation of the law. Importantly, companies are expected to pay attention to both existing and future legislations that may have direct or indirect implications on the design of their products and processes. (Baram 2007) Regulations established by government agencies or state regulatory bodies aim at ensuring that companies meet basic safety rules. In addition, agencies may possess the authority to, for example, impose sanctions or fines when they discover violations or non-compliance (Marucheck et

al. 2011). Companies and professional associations may also develop self-regulatory measures – a tradition that has prevailed in Germany for a long time in the context of industrial safety. Some of these self-regulations have even been adopted by government regulatory programmes. (Baram 2007) In addition, the regulatory requirements may be divided into outcome-based and action-based requirements (Hale et al. 2011).

Another aspect of product safety requirements is various legal traditions. Major traditions may be categorised into civil law, common law, theocratic/religious law or a combination of these. At present, most countries follow one of the two major legal traditions: civil or common law. (University of California at Berkeley 2016) However, there are several other legal traditions within the historical context (Glenn 2014). The civil law tradition originates in continental Europe and was originally applied in the colonies of European imperial powers. In comparison, the common law tradition originates in England and was initially applied in British colonies across its continents. Systems based on civil law have comprehensive legal codes that are continuously updated. These codes specify all matters liable to be presented in a court of law as well as the procedures and punishments for each offence. In contrast, in common law systems, there is no comprehensive compilation of legal rules and statutes, and the law is largely based on precedents such as judicial decisions made in similar cases. (University of California at Berkeley 2016) Finally, the traditions of religious law emanate from the sacred texts of religious traditions, for example Islamic, Jewish or Canon law (Raisch 2006).

Standards are an essential component of product requirements and may be developed by private or public organisations, industrial associations or regulatory agencies. Many industry standards are voluntary, and in such cases, compliance with the standards is governed by independent boards. Naturally, there are no legal sanctions for non-compliance. (Marucheck et al. 2011) However, in certain markets, product requirement standards enjoy a status similar to that of legislations. Standards may be prescriptive or non-prescriptive, depending on their usage (Holloway & Johnson 2014). Prescriptive standards impose specific requirements, while non-prescriptive standards require arguments that justify the confidence of satisfying a standard's principles (Holloway & Johnson 2014).

Manufactured products have become more complex, and there are an increasing number of standards that must be considered. However, the benefits of standards have remained rather controversial. Standards promote better product quality and signify good management, although it has been argued that certain companies undertake the necessary measures solely to meet these standards. (Baram 2007; Marucheck et al. 2011) Further, some studies argue that standards are merely tariffs. For small-scale companies, the costs of implementation and accreditation of a standard act as barriers rather than enablers (Trienekens & Zuurbier 2008). At an international level, a key challenge is harmonising regulations and standards within and across countries, towards consistent application of safety management practices throughout the supply chain (Aruoma 2006). The international harmonisation of regulations and standards can decrease bureaucratic intervention for companies and thus allow them to market their products in different countries. However, first, standards must be internally harmonised within a country. (Marucheck et al. 2011)

In the EU, standardisation and standards have a specific role and the new approach has radically changed the European legislation. The EU's essential requirements for product health and safety are specified in directives and in standardisation that complements the legislation. European standardisation bodies – European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunications Standards Institute (ETSI) – are responsible for compiling their respective standards and technical specifications to meet the above essential requirements. Standards that are linked to directives are harmonised standards, and the European Commission (EC) requests and approves of them. (European Commission 2017e) The application of these harmonised standards is voluntary for manufacturers, although they are obligated to prove that a product conforms to the essential requirements (Europedia 2011; Occupational Safety and Health Administration 2008). Several European harmonised standards have been replaced by international ones such as those by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). These standards have a similar role in the EU as that of the European harmonised standards. (Murthy et al. 2008) An important area in international standardisation is also the generic management system approaches such as standards ISO 45001 for occupational health and safety, ISO 9001 for quality and ISO 14001 for environmental issues. ISO 45001 from 2018 is

the latest standard of these and it will take into account other international and national standards in this area as well as the ILO's publications. (ISO 2019) ILO has also published guidelines (ILO-OSH 2001) on occupational safety and health management systems earlier (ILO 2001).

In the European internal market, free movement of products is a fundamental freedom and is secured through the elimination of customs duties and quantitative restrictions and the prohibition of other measures that have similar effects. It is further supported by principles of mutual recognition, elimination of physical and technical barriers and the promotion of standardisation in the EU member countries. (European Parliament 2017) In addition to the EU in Europe there is European Free Trade Association (EFTA) that supports the free trade in Europe. EFTA is an intergovernmental organisation of Iceland, Liechtenstein, Norway and Switzerland. EU and EFTA, except for Switzerland, form the EEA. EEA EFTA countries share the same basic rules of the internal market than the EU member countries. (EFTA 2017)

Overall, the essential requirements for product health and safety in the EU are specified in the directives compiled by the EC (European Commission 2017e). The Machinery Directive, for example, promotes the free movement of machinery in the European single market (European Commission 2017c; Rausand & Utne 2009). The harmonisation of machine safety requirements in the EU member countries allows the marketing of machines in all member countries (Kivistö-Rahnasto 2000).

The Machinery Directive, supplemented by harmonised standards, is the main instrument to regulate the safety of most machines in the EU member countries (Rausand and Utne 2009; Baram 2007). The Directive is is a full harmonisation directive that needs to be transposed to national legislations. Member countries may not introduce or maintain that exceed the level of protection offered by the directive. It defines not only the essential health and safety requirements that machinery must satisfy to be placed on the market but also the conformity assessment procedures that demonstrate the fulfilment of these requirements. To indicate compliance with the Directive, companies must apply a CE conformity marking to their products. (European Commission 2018) However, EU member countries can set additional requirements consistent with the Machinery Directive, provided doing so does not hinder the freedom of product movement (Baram 2007).

The Machinery Directive applies to machinery not only made or supplied in the EU but also imported from outside the EU (Macdonald 2004). The Directive aims to help machine manufacturers ensure product safety. In 2016, an evaluation of the Machinery Directive was initiated to assess the performance of the directive (European Commission 2016c). The report of the evaluation by Technopolis Group was published in 2017 and the work has continued (European Commission 2019; Technopolis Group 2017) The revision may lead into new Regulation (European Commission 2019b). The EU has also set up a Better Regulation Agenda and through its Regulatory Fitness and Performance (REFIT) programme, the EC strives to ease the EU law by making it simpler and less costly (European Commission 2017f).

In contrast, the US market is not as uniform as the EU. In the United States, Congress is the legislative branch of the federal government that defines laws for the nation. In addition, federal agencies, federal courts and the state and local governments issue regulations, decisions and laws. (United States Government 2017) The Occupational Safety and Health Administration (OSHA) is an important regulatory agency under the United States Department of Labor (Occupational Safety and Health Administration 2017). General conformity markings, like the CE conformity mark in the EU, are not applied, although the products must display warnings (Cemarking 2017). In addition to complying with technical regulations, a product must comply with the private sector standards. The United States has several standard development organisations (American National Standards Institute 2017). However, many of these operate under the umbrella of the American National Standards Institute (ANSI), which coordinates the development of standards in the United States (American National Standards Institute 2017; ISO 2017). These standards may require the application of various conformity assessment measures to demonstrate compliance. In addition, while these standards are voluntary, failure to meet them could attract lawsuits. (American National Standards Institute 2017) From an exports perspective, the Transatlantic Trade and Investment Partnership agreement between the United States and EU aimed to foster greater compatibility and transparency in trade and investment legislations (European Commission 2017g; Office of the United States Trade Representative 2017). However, these negotiations ended without conclusion (European Commission 2019a).

In Australia, each state and territory government regulates occupational safety and health in its own jurisdiction. Importantly, there is variation in the responsibilities and duties undertaken to ensure that a machine is designed and manufactured with no risks to safety or health. Nevertheless, the Commonwealth government has been pursuing the processes of harmonisation. (Australian Government 2017; ILO 2017a; National Research Centre for Occupational Health and Safety Regulation 2002) Efforts have been made to compare and integrate Australia's machinery safety regulations with those of the EU. Australia's regulations and codes of practice rely on general duty requirements, performance standards and process and documentation criteria. The performance standards do not specify the measure companies must undertake to achieve compliance; instead, they define companies' obligations in the form of objectives or problems they must solve. (Bluff & Johnstone 2004) Both the Australian Occupational Health and Safety (OHS) regulatory regime for plants and the EU's Machinery Directive have a risk management approach, they require the provision of information, they utilize technical standards and they mandate the self-assessment of machinery. In addition, both conduct third-party verifications for specific machinery types. However, there are also certain differences, especially in the components of performance outcome as well as the systematic process and specification provisions. The Australian regime is mainly process-based, whereas the EU focuses on achieving performance outcomes. (National Research Centre for Occupational Health and Safety Regulation 2002; Bluff 2004)

2.2.3 Product liability issues

An important legislative aspect in designing and manufacturing safe products is liability issues (Baram 2007; Marucheck et al. 2011). Product liability is commonly considered a consumer protection phenomenon, although it is also a significant judicial phenomenon in the case of companies, at least from the perspective of tort and contract remedies. Product liability issues are related to producers' responsibility (liability) for damages caused to persons and/or property as a result of a defect in the product. (Mononen 2004; Reimann 2003a) Damages to the product itself are not included in this responsibility. However, product liability risks often go beyond mere compensation risks such as in the case of product recalls or reputation loss. Companies are also subject to this risk when exporting and thus, should be aware of

product liability systems in the respective market areas (Mononen 2004). By principal, if a company's product complies with relevant safety requirements, it is highly likely to avoid product liability claims for defective products (Mondaq 2017).

Producers are subject to tort liabilities, and the tort law establishes the right to legally seek compensation for damages if, for example, an unreasonably dangerous product harms a person. While product safety regulations prescribe in technical detail measures for safe design and use, tort law or liability doctrines present qualitative criteria that a court interprets and applies in a given context. (Baram 2007) In a business activity, it is important to act carefully without causing damages (a prudence principle), and entrepreneurs must prepare for possible operational risks (a precautionary principle). The central issues related to a product are quality control and assurance, which also concern the operations of subcontractors (Mononen 2004).

In several countries, product liability is a subfield of private law, and as in common law jurisdictions, it is firmly established in theory and practice. The American and European approaches lead product liability regimes, and typically, either or a combination of the two are followed worldwide. (Reimann 2003a; Reimann 2003b) The concept of product liability is central in the United States, which is also considered a pioneering nation in dealing with product liability problematics (Mondaq 2017; Mononen 2004). However, there is no federal product liability law; rather, the law of each state determines liability (Mondaq 2017). By contrast, in the EU, the product liability of defective products is mainly regulated by the Product Liability Directive 85/374/EEC, which was under evaluation in 2017 (European Commission 2017d; European Commission 2016b, Rausand and Utne 2009). In addition, product-specific directives such as the Machinery Directive affect liability issues in the EU.

The EU's general Product Liability Directive is based on the principle of liability without fault, according to which, a producer is typically responsible for the death, personal injuries or damages to private property caused by a defective product (Baram 2007; Mononen 2004; Rausand & Utne 2009). Here, a producer is either a manufacturer of a finished product or a component of the finished product, producer of a raw material or any person who presents him-/herself as a manufacturer (European Commission 2016b). According to the Product Liability

Directive (85/374/EEC), a product is defective when it does not provide the safety, which a person is entitled to expect, taking all circumstances into account.. Nevertheless, there are national-level differences in negligence, nuisance and strict liability pathways to recovery (Baram 2007). Typically, the evaluation of safety deficiency accounts for the time when product is manufactured, foreseeable product use, product marketing and given instructions (Mononen 2004).

The Product Liability Directive is mainly concerned with damages to consumers or their property caused by defective products marketed in the EEA (European Commission 2017d; Mononen 2004). In the case of capital goods, product liability is broadly covered under inter-company contracts and insurances (Reimann 2003a). Further, the Directive does not cover any damage caused by a product to the source of livelihood or property. However, if the product causes personal injury, the legislation may be applicable to capital goods (Mononen 2004). The freedom of contract between parties is emphasised in inter-company relationships, wherein companies may agree on, for example, restrictions on liabilities. Nevertheless, valid and efficient contracts remain focal to the companies' actions. The liability for damages may also be formed on an extra-contractual basis. Another essential aspect of risk management in the case of product liability is the transfer of risks to, for example, an affiliated company or insurance company. More specifically, companies must ensure sufficient insurance protection in the case of liabilities (Mononen 2004; Reimann 2003a).

2.2.4 Legislation implementation and enforcement

Implementation is a key stage in the lifecycle of a law and may be examined, for example, from a legislator's, regulatory agency's or an executive authority's viewpoint (Tala 2005). The implementation phase ensures compliance with the law and fulfilment of its planned objectives (Tala 2001). In this study, 'implementation' refers to the various measures taken by an actor form a public organisation, a legal institution's enforcement and application procedures and the created interaction between public organisations and regulatees (Tala 2008). From an authority's perspective, the implementation includes inspection, judicial decisions, resource allocation, participation in decision-making regarding jurisdiction and other forms

of interactions with a regulatee such as instruction, guidance and communication (Tala 2001).

The implementation and related enforcement play a significant role when a law requires regulatees to perform, what they consider, as unfavourable actions. While legislation needs to structures its implementation, enforcement ensures that people follow the law. (Gray &Scholtz, 1993; Ryan 1996) When drafting a new legislation, it is important to define justifiable conceptions of functions, problems and risks that are critical in directing attention towards implementation and enforcement as well as the types of methods that need to be followed (Tala 2008). This also relates to the legal and institutional resources available to enforce defined objectives (Ryan 1996). The supervisory authority must have adequate resources, effective resource allocation, committed personnel and hierarchical integration (Ryan 1996; Tala 2005). On an international level, the ILO's Labour Inspection Convention (No. 81) defines principles for inspections related to enforcement. It is ratified in 146 countries. (ILO 2017b)

The inspection and enforcement of law can be distinguished as a cooperative/ persuasive approach and a coercive/sanctioning approach. In a cooperative or persuasive approach, authority representatives advise, persuade or negotiate with the regulatee, whereas in the coercive or sanctioning approach, they use or initiate a form of sanction. (Bluff 2011) The two approaches can also be combined to suit a given situation (Ayres & Braithwaite 1992; Bluff 2011; Braithwaite 2002; Braithwaite 1985). The so-called 'enforcement pyramid' highlights enforcement options ranging from persuasion to comply to the permanent revocation of a company's licences (Ayres and Braithwaite 1992; Bluff 2011; Bluff 2004; Tala 2005). Overall, the global market makes it increasingly difficult to ensure and enforce product safety (Marucheck et al. 2011). The underlying issues with compliance management also intensify the regulatory burden and complexity of requirements. Thus, is it natural for the number of legislations to increase over time. (Hale et al. 2011)

In addition, there are several other external actors (third parties) that influence an organisation's responses to requirements. These include customers, clients, suppliers, contractors, insurers, industry associations, unions and various other professionals. (Black 2001; Bluff 2011; Bluff 2010) According to Bluff (2011), an organisation's interactions with and position in relation to these external actors as well as the

distribution of responsibilities, resources and power among them can affect its willingness and capacity to comply with health and safety regulations. Thus, external actors can have both positive and negative effects on an organisation's efforts towards compliance management (Bluff 2011; 2010).

From a regulatee's perspective, an important task is to interpret prevailing or upcoming legislation. However, this interpretation should be consistent for both the regulatee and various authorities on different occasions. Inconsistent interpretations may constitute negative motivations. (May 2004) In addition, the regulatee's position on the authority may be problematic when the same authority has power over both occupational and consumer safety and when the authority's style differs by circumstance (Ayres & Braithwaite 1992; May 2004). Challenges for authorities include insufficient resources to cooperate with regulatees. On the one hand, authorities may not have sufficient regulatory power, which highlights the lack of repertoire and severity of enforcement methods. On the other hand, authorities may enforce themselves beyond their assigned powers. (Ayres & Braithwaite 1992)

Successfully harmonising the safety legislation of products and services has played an important role in building the EU's common internal market. The EU has accelerated the development of internal markets by favouring immediately enforceable regulations instead of directives that need to be transposed into national law. However, the implementation, enforcement and surveillance of the EU legislation are mainly performed by the individual member states. (European Commission 2017h) The surveillance of products (market surveillance) in the EU is based on subsequent risk assessment and random checks. Authorities do not scrutinise individual products or authorise/approve products or services; rather, companies are responsible for the safety of their products (and services). (European Commission 2017a) An advantage of subsequent surveillance is that that authorities focus on defects or risks that emerge in practice. Compared to proactive supervision, this reduces costs for the authorities and entrepreneurs, although it raises problems regarding functions that can cause wide or serious damages. (Tala 2008)

In the EU, the surveillance of machinery entails national authorities checking the conformity of products subject to the Machinery Directive. These checks are executed once the machines are in the market or in service and accordingly, actions are taken to tackle non-compliant products. (Fraser 2010) If a product is considered

dangerous, a national authority undertakes various measures to eliminate the risks, such as withdrawals, recalls or warnings. In addition, the national authority provides information about the dangerous machine to the EC, whose task is to inform other EU member countries (European Commission 2017a). At the EU level, the objective is to ease the process of restricting or removing unsafe products from the European markets through the proposed Product Safety and Market Surveillance Package. The Package comprises two legislative proposals accompanied by non-legislative measures. If these proposals are approved, it will create a new framework for the market surveillance of products in the EU (European Council 2017). Unfortunately, the adoption of the Package has been delayed owing to disagreements among the member countries (Ministry of Economic Affairs and Employment 2017).

The EU member countries are free to determine the organisation responsible for their market surveillance. There are, however, certain unified criteria that need to be fulfilled, for example, adequate resources in terms of staff and budget to perform tasks must be nationally ensured for the market surveillance authorities. Market surveillance can be effective if it is based on risk assessment. Further, in addition to national surveillance, there should be more cooperation and coordination among the market surveillance authorities of the EU member countries. (Fraser 2010) However, a recognised problem is the differing competence levels among the authorities of EU member countries (Johnson 2012).

2.3 Compliance management

Compliance management can be defined as ensuring business processes, operations and practices in accordance with a set of prescribed and/or agreed-upon requirements as well as general ethical and moral principles. Compliance management should be considered part of business practices and management processes and not a distinct activity. (ISO 19600:2014; Sadiq & Governatori 2010) According to ISO 19600:2014, a comprehensive compliance management system allows organisations to demonstrate their commitment to compliance, which should be embedded in every employee's behaviour. Non-compliance could lead compliance risks such as fines, indemnities, bans on business operations and loss of

licences. By definition, compliance risks denote the failure to fulfil various expectations directed towards a company (Ratsula 2017; Ratsula 2016).

Compliance with requirements indicates that a company conforms to the stated and applicable external requirements concerning itself and its products and/or services (Ratsula 2016; Carroll & McGregor-Lowndes, 2002). A company may also follow a regulated model to prove this type of compliance; for example, in the EU and its extended Single Market, the European Economic Area, CE markings signify product compliance with safety, health and environmental protection requirements set forth by the EU directives. A product can be marked with CE marking and is offered for sale in the EEA market when its manufacturer or authorised representatives issue a conformity declaration. Machines may not be offered for sale in the EEA without a CE marking (European Commission 2018; TÜV SÜD United Kingdom 2017).

In the EU, the compliance of regular machines may be internally evaluated by the company (Murthy et al. 2008). On the other hand, machines classified as dangerous require a compliance assessment by an external body, called as a Notified Body (Macdonald 2004; Murthy et al. 2008). Notified Body is designated by an EU member country to conduct assessments as per the Machinery Directive, prior to the product's placement on the market (European Commission 2017b). The EU also has mutual recognition agreements with Australia, Canada, Japan, New Zealand, the United States, Israel and Switzerland. These agreements state what each country considers an acceptable conformity assessment result as per the EU's designated conformity assessment body. European companies wanting to export to these regions should be aware of these agreements (European Commission 2017i).

Compliance management requires a company to cooperate internally and stay abreast of changes in the business environment (Ratsula 2017; 2016). ISO 19600:2014 offers general guidance on compliance management systems and recommended practices for all organisation types. More specifically, it covers organisational issues, definition of roles and responsibilities, compliance obligations (compliance requirements and compliance commitments), compliance risks, compliance policies and operative issues. The standard may be combined with other management system standards and generic guidelines, although it is not directly intended for certification. (ISO 19600:2014) Parties such as the Austrian Standard, on the other hand, offer a certification, the Fair Business Compliance Certificate, corresponding to ISO

19600:2014 (Austrian Standards 2018, Idox 2018). The standard ISO 15288: 2015 complements processes required in compliance management of systems created by humans. It defines general processes for e.g. requirements definition, requirements analysis and requirements implementation. (ISO 15288:2015)

Compliance management should rather have a preventive focus, aiming to achieve compliance by design and reduce compliance risk (Ratsula 2016; Sadiq & Governatori 2010; Lu et al. 2008). This way, companies can attempt to influence future requirements (i.e. regulation and standards) and enforce requirements in advance. In practice, this can even be done by associations representing the companies. (Tala 2001; Henson & Heasman 1998) Companies tend to adopt different strategies to respond to new or previously unknown regulations: opportunism, full compliance, partial compliance, non-compliance or influencing the regulator/enforcer (Henson & Heasman 1998). The choice of compliance may be based on, for example, the possible consequence of non-compliance (Bluff 2011; Tala, 2001). Non-compliance can have both short- and long-term consequences as well as positive and negative ones for a company (El Kharbili et al. 2008). By choosing noncompliance as a strategic option, companies fail to utilise resources and as a result, face the greatest risk of enforcement actions (Henson & Heasman 1998). However, as mentioned in the previous subsection, several external actors affect a company's compliance management process, and these actors may have a positive or negative impact on compliance management (Bluff 2011; 2010).

The process of achieving compliance in the case of new regulatory requirements has the following distinct and sequentially ordered stages: identifying regulation, interpreting requlation, identifying changes required and attempt to influence regulation, compliance decision, specifying method of compliance, communication, implementation, and evaluation and monitoring compliance. This process is continuous, that is, even after a company evaluates and monitors the outcome of its compliance process, it may need to return to previous stages. The compliance process was originally constructed for food safety regulation and for conformity by a single company to one regulatory requirement at a time. (Henson & Heasman 1998; French & Neighbors 1991). However, compliance must be secured throughout a supply chain to ensure that products meet uniform safety demands (ISO 19600:2014).

Legislation monitoring should be a permanent and continuous activity. After learning of the legislation, which is generally during the during the identification stage, a company must interpret it, clarify whether it concerns their operations and products and then assess possible changes to establish compliance. (Henson & Heasman 1998) In ISO 19600:2014, requirements are termed as 'compliance obligations', which include both compliance requirements and commitments, such as agreements with public authorities and customers, and organisational requirements, for example, policies and procedures. The ISO standard further stipulates that a company should identify and evaluate its compliance risks to determine a risk-prevention plan. In the next stage, a company decides how it will (or not) comply with the legislation (Henson & Heasman 1998). Once a company has decided to comply with the legislation, it must specify a method to achieve its objectives and communicate it to all actors involved to ensure the implementation of changes, if any (Henson & Heasman 1998). Determining applicable requirements may be difficult when common, global requirements must be forged from disparate, and potentially conflicting, local needs and priorities. In this case, project teams deploying common systems are faced with the challenge of understanding local business processes and information needs and at the same time, developing common global requirements that can be adapted to local business units (Kirsch & Haney 2014). Further, designing complex products requires considerable data throughout the process and computational resources for its analysis (Dowlatshahi 2001). The decided actions are executed during the implementation stage. Companies may implement changes in advance before certain regulations are enforced. This stage may also be combined with compliance evaluation and monitoring, which is the final stage of compliance management process. A company may also make changes to their products according to, for example, comments from enforcement officials. (Henson & Heasman 1998) ISO 19600:2014 provides the general details of the monitoring and evaluation of compliance management systems. Important issues in achieving compliance are possible feedback sources and data collection methods (ISO 19600:2014).

In addition to compliance management and related information flows, companies must be able to react to changes in customer requirements and accordingly, execute the design, manufacturing and distribution of products and services. The reduced time to market, shorter product lifecycles and move towards mass customisation

have increased the need for flexibility, which is the ability to effectively respond to customers' changing and increasing needs. (Kara & Kayis 2004; Kara et al. 2002) The concepts of robustness and agility are also used similarly to flexibility (Kara et al. 2002). A company must identify the potential advantages of flexibility to enhance its performance and assess ways to achieve flexibility (Kara & Kayis 2004). In their literature review, Kara et al. (2002) introduced three basic forms of flexibility that companies should work towards: external, inter- and intra-flexibility, which are then further divided into more detailed subgroups. External flexibilities, similar to quick design changes and fluctuating order sizes, are beyond a company's control. In comparison, inter-flexibilities (i.e. organisational structure flexibility) can be used to promote external flexibility, and intra-flexibilities are used to manipulate the internal flexibility of operations and are generally controlled by the management (Kara et al. 2002).

2.4 Supply chain management and related strategies

Maintaining product safety is more difficult when a company has shifted their manufacturing overseas (Marucheck et al. 2011). This changed situation also requires novel methods of managing the operations. A commonly used framework to model and manage flows of products, services, information and financing is defined as supply chain management (Mentzer et al. 2001; Tan 2001). However, there are variety of different definitions for supply chain management (Burgess et al. 2006; Lummus & Vokurka 1999). Supply chain management can be represented e.g. from following two perspectives: (i) purchase and supply perspective and (ii) transportation and logistics. The purchase and supply perspective is synonymous with supplier base integration, which evolves from traditional purchase and supply management functions. In comparison, the transportation and logistics perspective highlights the need to focus on logistics in the strategic decisions (Tan 2001). The success of a supply chain is associated with, for example, product innovativeness, stable supply processes and proactive information sharing with strategic customers and suppliers (Lee 2002; Roh et al. 2014).

One of the risks related to supply chains is the failure of suppliers to meet product specifications (Khan et al. 2008). Important question is how to coordinate and

monitor suppliers' approaches to product safety. One way of ensuring product safety and that suppliers' meet uniform safety demands is for companies to invest in education and training to develop skills and abilities in the supplier network. (Marucheck et al. 2011) The supplier network covers all the suppliers' suppliers as well (Lummus & Vokurka 1999). In addition, in order to build a resilient supply chain, which is able to cover from disturbances, the risk awareness of suppliers need to be noticed (Sheffi & Rice Jr. 2005; Christopher & Peck 2004).

Next, mass customisation is a combination of mass production and customisation, wherein the combination level of both production styles may vary (Ahoniemi et al. 2007). More specifically, mass customisation denotes serial and cost-effective production of products or services as per individual needs. The mass customisation literature widely discusses the management of variations in customer needs (Fogliatto et al. 2012) and variations according to different market area (Ahoniemi et al. 2007).

The typical strategies of supply chain management and mass customisation to tackle variation-related problems are postponement, modularisation and order penetration point (Brun & Zorzini 2009). Modularisation is based on product design, while postponement is related to process design (Ernst & Kamrad 2000). In postponement, a company aims to delay product customisation, for example, until it receives a customer's order (Boone 2007); in other words, activities in a supply chain are delayed until demand is realised (van Hoek 2001). Postponement may be realised through changes in the manufacturing–distribution process or product architecture (Swaminathan & Lee 2003). Possible strategies are postponement in product design, purchase, production, logistics, price and product. The concept of postponement may be seen as a potential tool to reconfigure the entire supply chain (Boone 2007).

Modularisation, on the other hand, helps a company manage varying customer needs using a set of predefined modules and their combinations. In this product design-based approach, products are assembled from a set of standardised constituent units. Assembly combinations of a given set of standardised units can produce different end-product models. (Ernst & Kamrad 2000) In modularisation, variation in customer needs is managed by pre-defined modules and their combinations that are based on customer preferences and selections. In addition, modularisation helps

companies outsource the manufacturing of the product's constituent components (Ernst & Kamrad 2000).

At the order penetration point (or decoupling point) in the supply chain, customer-specific and varying requirements are added to more general standard requirements and applied to product structures or a specific customer order (Brun & Zorzini 2009; Gosling & Naim 2009; Wikner & Rudberg 2005; Olhager 2003). In postponement, a customer's needs and product customisation specifications are typically located and implemented during the later phases of the supply chain. However, with changes in business scenarios, modelling the supply chain with single-strategic order penetration points is insufficient (Wang et al. 2010). Rather, multiple points help create flexibility and responsiveness by partitioning the product value chain into multiple lean and agile systems (Banerjee 2012).

Depending on the location of the order penetration point, a manufacturer may apply postponement and modularisation to design different product delivery strategies. These strategies can be divided into make-to-stock, assemble-to-order, make-to-order and engineering-to-order. (Olhager 2003) In make-to-stock, products are designed and made to stock on the basis of forecasts and assumptions about customer demand. Standard products are provided from defined range. In assemble-to-order, customisation is postponed as late as possible. The strategy is typically applied in the case of varying customer needs and can be satisfied by configuring a set of pre-designed standard modules. A company can either base the standard product platform on the safety requirements of a single (e.g. European) market or may account for all main market requirements (Stark 2011; Naylor et al. 1999). A make-to-order strategy is applicable when customer orders include a new or special feature that must be considered during the fabrication and procurement phase or when the order requires new design work. In the engineering-to-order strategy, when standard or modified products do not fulfil customer needs, an extensive new design is warranted. (Olhager 2003) The most typical delivery strategies for capital goods characterised as unique or customisable products, such as heavy machinery, are the engineering-to-order and make-to-stock strategies (Sanchis et al. 2012). Global markets with diverse needs and drastically reducing product lifecycles place a significant premium on the management of effective product variety (Swaminathan & Lee 2003).

In addition to the product delivery strategies another classification in manufacturing are international strategies for manufacturing products. The may be divided into export, multi-domestic, global and transnational strategy. Each international strategy makes certain assumptions about product development priorities, logistical requirements and organisational design. In an export strategy, companies attempt their best to locate the maximum of their value chain in their home countries. Nevertheless, they may have overseas locations where downstream activities, such as marketing, occur. (St. John et al. 1999) A multinational company operating in more than one country may view the following strategies as applicable (Ketchen & Short 2012).

First, in a multi-domestic strategy, a company reproduces its operations in several countries around the world (St. John et al. 1999). Thus, the approach emphasises responsiveness to local requirements in each company's market (Ketchen & Short 2012). Second, in a global strategy, each value activity is located in one or two countries best suited for that activity. The strategy focuses on minimising duplication and costs (St. John et al. 1999). To elaborate, a company offers the same products or services in each market although it may introduce minor modifications in various locations (Ketchen & Short 2012). Finally, a transnational strategy aims to account for both local responsiveness and global efficiencies (St. John et al. 1999). This strategy may also be defined as a middle ground between the multi-domestic and global strategies. In general, a company attempts to balance efficiency-based desires with the need to adjust to local demands in various countries. (Ketchen & Short 2012) Moreover, the company will develop its products to adapt to both specific local requirements and those standardised across markets. In this case, they must be skilled at detecting country-based variations to address conflicting requirements. To do so, they may employ a 'sprinkler' or 'waterfall' strategy to deploy new products. A sprinkler strategy describes the simultaneous development of products for multiple markets, while a waterfall strategy indicates that a company first develops a product for a single market and then its variations for other locations. (Subramaniam & Venkatraman 2001)

2.5 Summary of the literature and theoretical framework

Managing compliance is defined as ensuring that business processes, operations, and practices are in accordance with a set of prescribed and/or agreed requirements and fulfil general ethical and moral principles (ISO 19600:2014; Sadiq & Governatori 2010). The concept is wide-ranging but this dissertation focuses mainly on fulfilling requirements related to product safety. The topic is important for manufacturing companies since a safety problem can have significant impact on a global scale in form of varying recall fees, litigation fees and image losses, among others (Marucheck et al. 2011). Hence, the intended target country or market must be sufficiently known (Stark 2011; Sadiq & Governatori 2010; Drahos & Braithwaite 2001; Äijö et al. 2005).

There are guidelines and models about compliance management process. ISO has published standard on compliance management systems (ISO 19600:2014) that deals with compliance management in its entirety but not exactly from global business perspective. The standard does not stipulate specific requirements but offers guidance on compliance management systems and recommended practices. In proportion, Henson & Heasman (1998) and French & Neighbors (1991) present a process on how to comply with new regulations. However, their process examines a different industrial sector. In addition, it is not targeted for globally operating companies and external parties' and supplier network's views are excluded.

Compliance management is associated with several different fields of research. It is strongly attached to (empirical) jurisprudence, implementation research and theories of decision-making. In addition, it relates to supply chain management's point of view. In the EU, the legislative foundation for safety of products is uniform (European Commission 2017e). However, other possible market areas for products have differing legal traditions, requirements and legal practices (University of California at Berkeley 2016). In addition, the role of standardisation and standards is differing in market areas (Marucheck 2011). The legislative requirements and standards relate to decision-making of compliance and when a product is safe (Baram 2007; Rausand and Utne 2009). Manufacturers should themselves estimate adequacy of safety level and decision-making should be supported at all levels of

supply chain by adequate information systems (Lummus & Vokurka 1999; Rausand & Utne 2009).

Compliance must be secured throughout a supply chain to ensure that products meet uniform safety demands (ISO 19600:2014). This relates to the concept of supply chain management that is a commonly used framework to model and manage flows of products, services, information and financing (Mentzer et al. 2001; Tan 2001). In the context of this research, coordinating and monitoring suppliers' approaches to product safety is critical. In addition, in a globally operating company supply arrangements are to be global as well (Khan et al. 2014).

Prior publications indicates that there are several phases in order to achieve compliance with requirements (ISO 19600:2014; Henson & Heasman 1998; French & Neighbors 1991). The emphasis in this dissertation is to understand existing problems and solutions of compliance management in global context and to develop further the process of compliance management paying attention to associated fields of research and identified deficiencies of prior publications. While previous studies on managing compliance with safety-related requirements have focused more on requirement-based compliance processes, this dissertation pays attention to product-based compliance management. Further, it offers a new empirical viewpoint on the standard ISO 19600:2014 on compliance management systems.

Theoretical framework of this dissertation is based on outlined processes of achieving compliance and managing supply chains from manufacturing companies' perspective. Furthermore, the compliance management process is studied from juridical risk management's point of view. The focus is on product's compliance with external safety requirements instead of safety and health issues in general. An essential question is comprehensive management of relevant information. Manufacturing companies may even exceed safety level of regulatory requirements but this study focuses on necessary/obligatory requirements to be complied. Overall, the management of compliance is much wider topic that includes consideration of corporate social responsibility and general ethical and moral principles as well. In addition, ensuring adequate level of safety at work requires specific measures both in manufacturer and user organisations' of machines. The generic management system approaches such as standard ISO 45001 for occupational health and safety support both of the parties and the guidelines on compliance management systems

(ISO 19600) may be combined with it (ISO 45001:2018; ISO 19600:2014). This dissertation is focused on companies' point of view. However, there are several different parties (stakeholders) effecting on compliance management processes. Network of different parties of a machine-manufacturing company in compliance management process on national, European and global level is illustrated in Figure 1. Most of these parties are external but local units are typically company's own operations. All the parties are situated in the essential locations and presented only once in the figure. However, several parties may exist even in all the levels of the network.

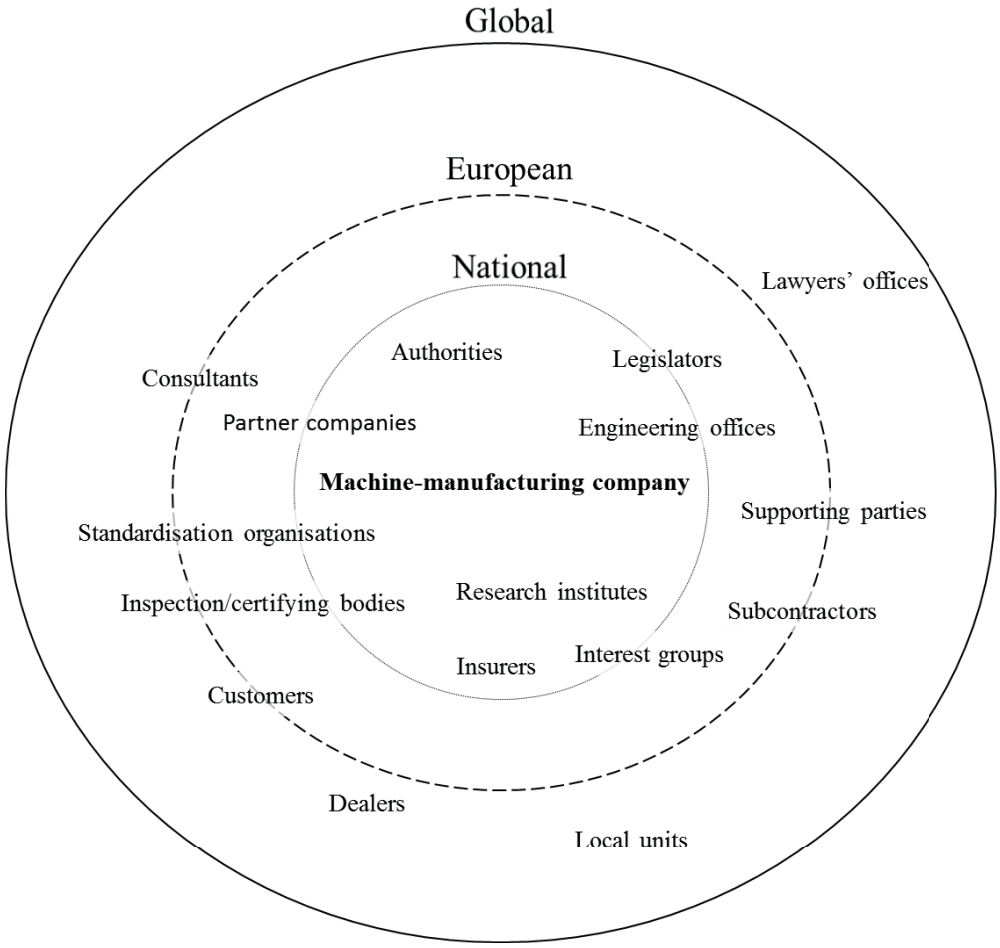

Figure 1. Network of a machine-manufacturing company in compliance management process

3 STUDY DESIGN

3.1 Research gap

Manufacturing companies must be aware of existing and pending regulations that have direct and indirect effects on their products in order to avoid possible losses caused by adverse events and/or external inspections. In the EU region, the Machinery Directive and supplementary harmonised standards define clear requirements and guidelines for safety considerations in the design process of most machines (Baram 2007; Rausand & Utne 2009). In market areas outside of the EU, information requirements increase, and there are possible difficulties in gathering and managing existing local information. Another issue is proper following of forthcoming requirements and standards. Companies attempt to predict requirements so that they can influence their enforcement as part of the compliance process (Tala 2001). However, changes in political situations, such as within the EU and United States, may impede such predictability. The EU has entered into trade and/or mutual recognition agreements with several countries but future of new negotiations is open.

The concept of compliance widely discussed in scientific literature and it is a critical issue in today's business as well. The literature review in Chapter 2 of this dissertation reviews tangential aspects related to compliance management along with safety-related requirements when operating in several market areas. However, this literature review did not provide relevant research on comprehensive safety-related compliance management in global a context. Several studies (e.g. Rausand & Utne 2009; Hale et al. 2007) are available on the integration of safe design and ergonomic products in engineering design processes. Further, the concepts of supply chain management of products and services and related strategies have been widely published (e.g. Fogliatto et al. 2012; Marucheck et al. 2011; Mentzer et al. 2001). However, from the perspectives of global compliance and supply chain management, safety design of machines remains scarce in the literature. The processes of comprehensive global compliance management process that also considers aspects of outsourcing was missing in the literature. For example, the product delivery strategies (e.g. Olhager 2003) do not originally consider safety perspectives.

To ensure successful compliance of products, a globally operating company must be aware of differing product safety requirements, conformity declarations and product liability issues in all its market areas. In addition, it is necessary to understand local or regional legislations and jurisdictions as well as local operating conditions and duty types. (Vasara & Kivistö-Rahnasto 2015) ISO has published guidelines on compliance management systems (ISO 19600:2014) that deals with the compliance management in its entirety. In addition, ISO 15288:2015 defines a system life cycle processes like requirements' definition and requirements' analysis of systems created by humans. Earlier studies (Henson & Heasman 1998; French & Neighbors 1991) present a process on how to comply with new regulations. The process examines a different industrial sector, food industry, and it does not concern operations in several market areas. In addition, other parties play an essential role in effecting compliance management. Thus, to understand compliance management process in its entirety it is necessary to study the role of external parties from company's perspective as well. Bluff (2011 and 2010) highlighted the effects of external parties (actors) in the context of work health and safety in plants and stated that it would be useful to better understand the exploitation of external parties in the regulatory process. Studies have also focused on problems faced by parties implementing and enforcing legislations (see e.g. Tala 2008; Tala 2005; Tala2001). However, these aspects are excluded from the earlier compliance management processes presented in literature.

In sum, there is a gap in understanding the compliance management processes in a global business context and in available solutions for managing compliance with safety-related requirements in a global supply chain. The scientific literature does not provide relevant research around these subjects. The recognised research gap is summarised in Figure 2.

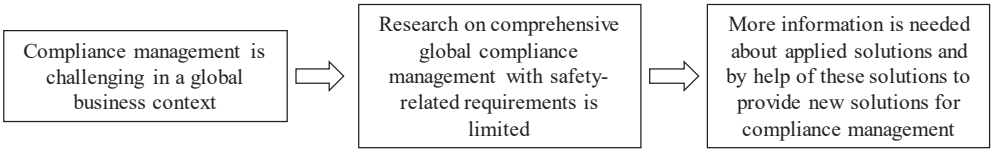

Figure 2. Summary of the research gap

3.2 Research scope and objectives

This dissertation is motivated by the interest in understanding the functionality of regulatory systems in different market areas and by a more in-depth understanding of globally operating companies in managing compliance with product safety-related requirements. More specifically, it discusses compliance management as part of machine design and supply chain management in global businesses. The discussion also expands to the role of external parties such as legislators, authorities and standardisation organisations.

This dissertation aims to provide new information on compliance management in a global context from the viewpoint of both manufacturing companies and external parties' representatives, and in doing so, it constructs new solutions to structure compliance management processes. The constructed solutions have both practical and scientific contributions. The solutions will complement significantly earlier research and publications of compliance and supply chain management from viewpoint of safety. Even though this research focuses on machine manufacturing, the results can be applied to other disciplines as well.

The objectives of this study are as follows:

1) To present solutions in managing compliance with product safety-related requirements in a global business context
2) To present problems confronted in compliance management

and by analysis of the results of these objectives

3) To construct solutions to effectively managing compliance with safety-related requirements

To meet the abovementioned objectives, the following research questions are posed:

1. How do globally operating companies manage compliance with product safety-related requirements? (Objective 1)
2. What kind of problems do companies confront in managing compliance with safety-related requirements? (Objective 2)

3. What are external parties' expectations, roles and potential effects in supporting and controlling companies to manage compliance with safety-related requirements? (Objectives 1 and 2)
4. What aspect needs revision to more systematically manage compliance with safety-related requirements in a global context? (Objective 3)
5. What kind of model suits managing compliance with safety-related requirements? (Objective 3)

3.3 Research strategy

The key objective of science is information: the greater the information regarding reality, the better are the chances of operating, explaining and understanding a phenomenon (Niiniluoto 2002). This research focuses on compliance management with safety-related requirements in a global context and in doing so, attempts to provide new information about related practices and problems for globally operating companies and solutions for more effective compliance management.

This dissertation adopted qualitative and constructive approaches. A qualitative research approach is suitable for studies attempting to describe, explain and/or interpret phenomena and practices (Eskola & Suoranta 2014). In addition, it describes the significances of our social reality and people, groups or organisations as producers of these phenomena (Eskola & Suoranta 2014). In comparison, constructive research aims to resolve practical problems while producing academically appreciated theoretical contributions. Constructs are suggested solutions to research problems based on real life. Construct designs need to be well grounded in defined problems and comprehensive knowledge gathered through the research (Kasanen et al. 1991; 1993; Olkkonen 1994).

This dissertation applies the triangulation of data sources and theories to obtain an in-depth understanding of the studied topic (Denzin & Lincoln 2011). It is based on various tangential background theories, study subjects and qualitative research questions. In doing so, it provides wide-ranging knowledge related to managing compliance with safety-related requirements of machines in the global market. The qualitative approach is applied to gather information about problems and practices

related to compliance management in a global context. The researcher gathered information from different companies, groups and other parties using semi-structured individual and group interviews, and using these data, the study answers research questions 1, 2 and 3.

The constructive approach is used to compile new approaches. In this stage, the researcher answers research questions 4 and 5. There are several methods across different disciplines that classify constructive research phases. According to Kasanen et al. (1991) and Kasanen et al. (1993), this process may be divided into the following phases: find a practically relevant problem which also has research potential, obtain a general and comprehensive understanding of the topic, construct a solution idea, demonstrate the working of the solution, show theoretical connections and research contribution of the solution concept and finally, examine the scope of the solution's applicability. Examining engineering design, Pahl & Beitz (1992) presented similar steps in system approaches: problem analysis, problem formulation, system synthesis, system analysis, system evaluation, system decision and system implementation. In the present research, the construction process of new approaches is executed in accordance with the previously presented phases of constructive approaches. Table 1 presents the objectives, research questions and research tasks of this research.

Table 1. Research tasks related to objectives and research questions

Objective	Research question	Research task
1	1	Interview machine manufacturers Literature review
2	2	Interview machine manufacturers Literature review
1 and 2	3	Interview legislators, standardisation organisations and authorities Interview other external parties Literature review
3	4	Analyse interview results and compare with the literature Identify development needs
3	5	Construct new approaches for identified needs Verify and validate new approaches

4 RESEARCH SUBJECTS AND PHASES

4.1 Research subjects

The main data for this research were collected between 2011 and 2016 as an independent research project financed by the Academy of Finland's Doctoral Programme for Concurrent Mechanical Engineering (DPCME) and Doctoral Programme in Business and Technology Management of Tampere University of Technology. The project was conducted at the Tampere University of Technology (later Tampere University) in cooperation with six companies manufacturing machines intended for use at work (Table 2), twelve national external parties (Table 3) and six European external parties (Table 4). A total of 90 organisational representatives participated in the study. The external interviewees are here called as parties that refers to judicial meaning of the word. These parties may have administrative or contractual relations to the companies.

A conjunctive factor for finding suitable participating companies is the application of the Machinery Directive of the EU. The Directive has a key role in promoting free movement of machinery within the European single market (European Commission 2017c). In addition, the mechanical engineering sector that fall under the purview of the Directive has a critical role in the EU also in the future. This sectors competitiveness has to be secured. (European Commission 2016a). The participating companies manufacture large-scale machines intended for use at work in the national, European and global markets. In addition, essential criterions for participation to this research are that a company is truly globally operating, conducting businesses also in Finland and there is understanding and experience in managing safety-related compliance of products in the Global Market. The researcher charted the field of machine-manufacturing companies by help of earlier experience on globally operating companies in Finland. All the companies were willing to participate this study. Five of the companies (A–E) are large-scale companies operating globally, and one is large-scale company (F) whose products are resold in the global market. Company A has around 44 000 employees and global market share for the studied products around 40 %, Company B around 12 000 employees and global market share around 20 %, Company C around 15 000

employees and global market share around 20 %, Company D around 56 000 employees and global market share around 30 %, Company E around 11 000 employees and global market share around 20 % and Company F around 500 employees with significant market shares in several market areas. Outside Europe, important market areas for these companies are especially United States, South America, Australia, Canada, China and India.

Five companies (A–D and F) manufacture business-to-business products covered under the Machinery Directive of the EU. Company E's products do not fall under the purview of the Directive, although they apply it for design support. Pure consumer products are excluded from the examination but part of Company D' and F's products are both business-to-business and consumer products. However, this research focuses on compliance from a business-to-business perspective. Two manufacturing companies (A and B) are the main subjects of the study and are subjected to broader examinations. These companies operations have the most similarities with each other, which enables broader comparison of the results.

Before contacting suitable external parties, the researcher charted the field of compliance management with safety-related requirements at the national and European level. The interviewees also had the opportunity to propose other suitable interviewees from their own organisation or other organisations during the interviews. In addition, all of the participating external parties have operations that are connected with machine manufacturing companies. External parties are represented by a standardisation organisation, inspection body and engineering office as well as national ministries, authorities, insurance companies and a group of organisations supporting companies and companies' interest groups. The researcher carried out a more detailed interview study with one national authority's representatives during 2011–2013. The researcher complemented the national material with data on external parties from the EU level in Brussels; the data were collected from legislators, standardiser and interest groups. These parties were also formally or administratively related to corresponding nationally operating parties.

Table 2. Information on the participating companies

Company	**Size**	**Number of participants**
A (main case)	Large	14
B (main case)	Large	15
C	Large	1
D	Large	1
E	Large	5
F	Large, smaller than A-E	1
		37

Table 3. Information on the national external parties

Party	**Number of participants**
Legislators (two ministries)	4
Authorities (two)	27
Standardisation organisation	2
Inspection body	1
Insurers (two)	2
Engineering office	1
Organisations supporting companies' export (two)	2
Compliance consultancy	1
	40

Table 4. Information on the European external parties

Party	**Number of participants**
Legislators (two)	8
Standardisation organisation	2
Organisations supporting companies (three)	3
	13

4.2 Interviews

Data collection is based on semi-structured interviews including pre-prepared, open-ended questions (see Hirsjärvi and Hurme 2009). A total of 90 participants were interviewed. Each interview covered its themes in a similar sequence, but the exact form of questions varied. The participating companies and external parties have differing questions. The researcher formulated the themes and related interview questions by studying earlier research publications and public discourse around compliance management. The researcher applied data source triangulation using several targets of data. The participant group expanded during the interviews as the researcher asked the interviewees to suggest other interviewees or suitable organisations that could be valuable to the study. This approach can be described as so-called 'snowball sampling'. In other words, certain key persons/informants will first be examined in line with the subject and then be asked to propose supplementing parties. This facilitates the identification of persons central to the viewpoint of the research problem (Hirsjärvi & Hurme 2009).

The contact persons at companies A and B were met first in pre-interviews to review the chosen themes and execution of interviews. The researcher chose the interviewees by help of contact persons from participating companies and other organisations. The researcher presented interview topics to contact persons in order to find appropriate experts. The interviewees were selected to represent knowledge of product safety-related issues around compliance management in global context. All interviewees provided informed consent to participate in the research.

Both individual and group interviews were conducted. The group interviews resembled discussions including mutual discussions among interviewees. The duration of each interview event was 1.5–2 hours. The respondents were also given the opportunity to discuss other issues that were not covered by the interview questions. The researcher interviewed all participants and drafted notes since the interviews were not tape-recorded given the interviewees request for confidentiality. Interviewees were also allowed to confirm the correctness of the results, which were presented to them in subsequent visits.

4.2.1 Machine manufacturers

The interview framework was based on tentative discussions with companies' representatives and a literature review of compliance management, varying requirements, regulatory strategies and authorities' role. The pre-prepared interview questions addressed the following topics:

- follow-up on requirements
- determination/detection of requirements
- management of requirements (compliance)
- liability issues
- authorities' role in different markets

In the two companies (A and B) that were the main subjects of this research, the interviewees represented groups of product safety team, product line and design. The product safety team representatives represented product safety managers, products safety experts and product safety specialists. The product line representatives were product line managers and a product safety manager. The

design representatives were designers and engineering managers. In company C was interviewed a research manager and in companies D and F a product safety manager. In one company (E), five persons were interviewed individually representing experts from product safety, design, product line and sales departments. Each interviewee had at least five years' work experience around the subject.

In companies A and B, the product safety team determines requirements, follows them, participates in related drafting and supports design in line with safety issues. The product line owns products, identifies technical requirements, liaisons with customers and local units and determines whether the final products comply with the necessary requirements (Declaration of Conformity). The design team applies technical requirements identified by the product line, and the product safety team supports the interpretation of the requirements. Representatives of the product safety teams were interviewed individually, while those from design and product line management were interviewed in groups of 2–5 persons. A total of 11 interview events were conducted with 29 interviewees in companies A and B. There were four representatives from the product safety teams, 16 from design and 9 from product line management. The product safety managers of these two companies were later re-interviewed to complete the findings from the first round of interviews. The topics covered by these interviews are problems and practices related to the following:

- management of product safety-related requirements
- decision making
- supply chain management
- mass customisation
- modularisation
- postponement

4.2.2 Legislators, standardisation organisations and authorities

Representatives of legislators, standardisation organisations, authorities and inspection/certifying body were interviewed to gain insights into their practices and roles in controlling and supporting manufacturing companies. The chosen interviewees had several years' experience and thorough expertise around the

research topic. They were interviewed in an expert role. The interviews also focused on systems to draft regulations on machine safety and implement and enforce regulations. Interviewees included both representatives of national organisations and European parties in Brussels. The interviews' framework was based on interviews of companies' representatives and a literature review on regulatory frameworks, machine safety regulations, activities of supervising authorities and standardisation systems. The following topics were covered in each interview:

- drafting and implementation of requirements for machinery safety
- companies' participation in drafting
- functionality of European internal market and comparison with those of other markets regulatory systems
- helping and guiding companies

Most of the representatives were individually interviewed. In addition, the researcher conducted in one national authority a more detailed study with similar topics. The aim was to develop simultaneously their own processes of surveillance. This enabled the researcher to interview their representatives more broadly than organisations of other external parties were interviewed. The interviewees represented persons carrying out supervision, group managers and lawyers. The authority's representatives were interviewed in groups of 4–11 persons. A total of four interview events were conducted with 24 interviewees participating in the group interviews.

4.2.3 Other external parties

Representatives from national organisations supporting exports, insurance companies, an engineering office and a consultancy office were interviewed to explore how they support and help companies. To contribute to the completion of this approach, three representatives from European supporting parties were interviewed in Brussels. The chosen interviewees had several years' experience and thorough expertise around the research topic. They were interviewed in an expert role. The interviewees' positions included constant connections with manufacturing companies. The interview frameworks were based on interviews of representatives from companies and national parties. The topics covered in each interview were the following:

- influencing and participating in requirements drafting
- following up on requirements
- functionality of European internal market and comparing it with those of other markets regulatory systems
- helping and guiding companies

4.3 Interviews analysis

Qualitative data analyses can be applied to create new knowledge regarding a studied phenomenon (Patton 2001). In this research, the qualitative data from interviews were analysed and thematically classified by the researcher after the interviews. The researcher gained an overview of the data by thoroughly reviewing the interview responses. Since the data were large and diversified, the researcher was required to read them several times. Then, the researcher classified the interview results under different thematic categories on the basis of the participating organisations.

The participating companies' practices and problems in managing product safety-related requirements were analysed by counting and tabulating company-specific answers. The researcher investigated the meaning and significance of specific practices and problems mentioned by studying the frequencies of similar views. Open-ended answers were classified under six phases of compliance management by applying stages defined in the existing compliance literature (see Henson & Heasman 1998; French & Neighbors 1991). Although headlining of the original stages are modified. These phases were identifying and discovering requirements, interpreting requirements and identifying possible changes in products or operations, decision of compliance and specifying method of compliance, communicating, implementing requirements, and evaluating and monitoring compliance. The product safety managers of companies A and B were later re-interviewed to complete the findings from the first interviews. The results of these interviews were utilised to complement earlier open-ended answers. The external parties' open-ended answers were classified under six phases similar to those for the participating companies' representatives. The researcher investigated interview data specifically from a company's viewpoint. To safeguard the parties' anonymity, their answers are not presented individually for each organisation.

Following tabulation and classification, the researcher looked for similarities and differences between the companies using cross-company comparison. The opinions of legislators, standardisation organisations, authorities and other external parties' representatives complemented the data collected from the companies. The original data from these parties were structured according to the research questions and the defined themes of the companies' interviews. Based on empirical results and literature review, the researcher recommends compliance management aspects that need revisions to more systematically manage compliance with safety-related requirements in the global market. Further, the researcher aims to solve the needed revisions by constructing new approaches to manage compliance with product safety-related requirements (see Chapter 4.4.).

4.4 Constructing new approaches to manage compliance with product safety-related requirements

New approaches are constructed for practical and scientific application. For practical application, primary target group is globally operating machine-manufacturing companies to avoid typical compliance management problems. In addition, the approaches strive to clarify the overall compliance management process for stakeholders such as legislators/regulators, authorities and companies of other interest groups. However, the approaches join safety research with other areas research in a new ways and provide major contributions for scientific communities.

In this research the new approaches were constructed in accordance with previously presented phases of constructive approaches (see Kasanen et al. 1991; 1993, Pahl & Beitz 1992). The followed phases were here divided into identifying development needs, constructing new approaches as per identified needs and evaluating the constructed approaches. The researcher deepened the initial understanding of regulatory frameworks through the literature review and identified development needs from the results of the interviews and the literature. Following the identification, the researcher constructed new approaches by applying phases defined in earlier studies on achieving compliance, standard ISO 19600:2014 on compliance management and other literature around safety and supply chain

management. The new approaches comprise model for managing compliance with safety-related requirements and safety concerns in product delivery strategies.

In the final stage of construction, the author evaluates the new approaches by verification and validation process. The verification ensures that the approaches meets the requirements. In here, this includes comparison of the approaches contents with the identified needs. The validation includes theoretical and practical validation. Theoretical validation was executed by ensuring the approaches coherency with earlier researches. Meetings and discussions with key representatives of case companies and external parties carried out practical validation. The author presented the identified needs and approaches for the representatives and got feedback to elaborate the approaches' contents. Once the verification and validation process was complete, the author finalised the contents of the approaches.

5 RESULTS

5.1 Perceptions of compliance management

The qualitative results in Chapters 5.1.1 and 5.1.2 are based on the interviews of representatives from the six case companies. A total of 37 persons were interviewed from these companies. In addition, the product safety managers of companies A and B were interviewed twice. The duration of each interview was 1.5–2 hours. The interviews produced 160 pages of data in the form of written notes.

Chapter 5.1.3 describes qualitative results gathered from interviews administered to the representatives of national and European legislators, standardisation organisations, authorities and other external parties. A total of 53 persons were interviewed, of whom 40 represented national parties and 13 were from the European parties. Each interview was approximately 2 hours long and produced 215 pages of data in the form of written notes.

5.1.1 Performing compliance management in globally operating companies

The results of this chapter are based on interviews with representatives from six case companies about applied compliance management practices. Tables 5 and 6 summarise the results. The interviews were semi-structured, and the crosses in the tables denote issues independently raised by the interviewees. In addition, as presented in Table 2 (Chapter 4.1), the number of representatives in participating companies varies. This also explains the higher number of crosses for companies A and B, and thus, a comparison of the results between all the companies is not sufficiently reliable. The coding of the companies (A–F) in this chapter's tables is similar to that in Chapter 4.1. Table 5 presents key compliance management solutions applied by the participating companies. Table 6 orders these solutions in line with the number of companies that cite them (N = 1–6). The most frequent practices (N = 6) were utilisation of external bodies in interpretation and compliance checks in projects. It is noteworthy that some of the solutions mentioned in the

tables are clearly connected to a company's internal operations, while certain practices lean on external parties or internal systems.

The participating companies' solutions to achieve and manage compliance are presented and titled in the following chapters under phases of compliance management process, as defined by earlier studies on achieving regulatory compliance (Henson & Heasman 1998; French & Neighbors 1991) and ISO 19600:2014 on compliance management systems. However, in this study, interpreting regulations, identifying changes and attempting to influence regulations are combined into one phase to simplify the process. Henson and Heasman's (1998) process of achieving compliance was originally constructed with a focus on one regulatory requirement; however, here, the model has been subjected to a more generic application. The companies' solutions may, however, vary by new product design or current product engineering. One case company's representatives listed the following phases of compliance management:

> 'Our process of compliance management consist of identifying requirements, gathering requirements, specifying requirements, maintaining requirements and verification and validation of requirements.'

Table 5. Key solutions applied in managing compliance

SOLUTIONS	COMPANY					
	A	B	C	D	E	F
Utilisation of external bodies in interpretation	x	x	x	x	x	x
Compliance checks in projects	x	x	x	x	x	x
Follow-up of requirements by product safety personnel	x	x	x	x		x
Participation in requirements drafting	x	x	x	x	x	
Participation in standards drafting	x	x	x		x	x
Collection of local information from local unit	x	x	x		x	
Help from customers in tracing and verifying local requirements		x	x		x	
Maintenance has a central role in sharing information	x	x	x		x	
Definition of common minimum requirements and specific local regulatory requirements	x		x			x
Assistance from sales companies and dealers in identifying requirements	x	x		x		
Benchmarking from other companies to help interpretation	x	x			x	
Standard product platform based on European markets requirements	x	x				x
Products are based on standards	x	x	x			
Products are modified to meet local requirements by local units	x	x		x		
Documentation of design stages	x		x	x		
Determination of general requirements by product safety personnel	x	x				
Compilation of project safety plan by product safety personnel	x			x		
International networking meetings to gain information	x			x		
Comparison between different market standards	x		x			
Simultaneous consideration of main markets' requirements in standard products		x	x			
Global safety design file				x	x	
Global product council/committee to share information		x		x		
Request of permission by local unit for modification to designing and manufacturing unit		x				
Requirements' management system	x					
Product data management system		x				
System to reach all customers		x				

Table 6. Weighting of mentioned solutions

SOLUTIONS	N
Utilisation of external bodies in interpretation	6
Compliance checks in projects	6
Follow-up of requirements by product safety personnel	5
Participation in requirements drafting	5
Participation in standards drafting	5
Collection of local information from local unit	4
Help from customers in tracing and verifying local requirements	4
Maintenance has a central role in sharing information	4
Definition of common minimum requirements and specific local regulatory requirements	3
Assistance from sales companies and dealers in identifying requirements	3
Benchmarking from other companies to help interpretation	3
Standard product platform based on European markets requirements	3
Products are based on standards	3
Products are modified to meet local requirements by local units	3
Documentation of design stages	3
Determination of general requirements by product safety personnel	2
Compilation of project safety plan by product safety personnel	2
International networking meetings to gain information	2
Comparison between different market standards	2
Simultaneous consideration of main markets' requirements in standard products	2
Global safety design file	2
Global product council/committee to share information	2
Request of permission by local unit for modification to designing and manufacturing unit	1
Requirements' management system	1
Product data management system	1
System to reach all customers	1

Identifying and discovering requirements

The requirements discussed in this section cover regulation, standards and customer requirements. Standards are often considered instructions to fulfil requirements. Five companies' representatives expressed compliance with the Machinery Directive and related the European CE marking ordinarily, which assures the wide exportation of products to different markets. However, when a company operates globally, meeting EU requirements alone is insufficient. More specifically, interviewees mentioned that product development personnel should be aware of both local and universal requirements. However, as a group of product line managers stated:

> 'The Machinery Directive influences in a much larger area than where it is valid.'

The basis of compliance is the comprehensive acquisition and management of required information. According to the interviews, five companies' product safety personnel follow general requirements and in certain cases, designed specifications for a project or product and shared this information between product lines. In many of the companies, the requirements were gathered by compiling country-specific entireties for the project or product from personnel of local units and/or customers. Representatives from two companies mentioned the usefulness of a safety plan in structuring requirements. In one of the case companies the responsibilities were as follows:

> 'The product lines are responsible for identifying technical requirements and the product safety team for safety requirements. On the other hand, the identification of safety demands also is concentrated on product lines.'

The interviewees stated that new local information may emerge from different sources: customers and new orders, suppliers, maintenance personnel, local unit personnel and dealers. It is important to have right kind people as contact persons:

> 'It would be good to have a safety oriented contact person in a local unit so that the right issues will be found out.'

Several representatives mentioned that projects for customised products offer new information for standard product design. Representatives from four companies highlighted the role of maintenance in information sharing. Maintenance representatives act as a direct point of contact for customers. If they also maintain other companies' products, it enables benchmarking on the basis of these products.

Interpreting requirements and identifying possible changes in products or operations

All participating companies reported that they utilise an external body for interpretation. The companies utilise research institutes, industrial associations, consultants and/or inspection bodies for the interpretation of requirements. Two companies' representatives highlighted the usefulness of a global safety design document in comparing requirements. In addition, as one product safety manager highlighted:

> 'Versatile product safety personnel and international networking between our different units promote interpretation.'

Most companies' representatives mentioned that authorities are typically unwilling to interpret requirements, and market surveillance is subsequent process:

> 'The authorities are interested only when something occurs.'

In certain countries, such as Australia, the authorities were described as particularly proactive in helping companies and educating companies' representatives. However, certain companies stated that asking authorities can be a problem if they disagree on a subject.

In addition, the participation of companies' representatives in the drafting process of legislation and standards enhances interpretation. While most participating companies follow this process, the level of participation tends to vary. Legislation is possibly affected through unions and associations. With regard to standards, companies' participation may be direct, which covers national, European and international drafting committees for standardisation. However, typical practices involve participation by national standardisation committees. In addition to potential

influences, the representatives mentioned that committees allow for inter-company benchmarking and interpretation.

Decision of compliance and specifying method of compliance

The decision to comply is contingent on several issues. An important aspect is to decide requirements that are to be incorporated in standard products or modules. In the case of global products, companies must decide whether to simultaneously comply with the requirements of all market areas or customise products to different markets:

> 'The products are made according to the most important requirements and the local unit takes care of the modification.'

> 'We attempt to that the mass-produced products fit on global market nearly as such. In totally tailored products, local demands have to be rummaged a lot.'

Three companies' representatives mentioned that their standard product platform is based on the European market's requirements and accounts for all main markets. However, as one designer stated:

> 'If the product is made according to the EU requirements it goes over in many countries.'

Three companies' representatives stressed that their products are based on standards. In Europe, even though they exist, standards are not mandatory. However, it is advisable to design a product in accordance with the standards, as it is a practice favoured by authorities as well. On the other hand as one product safety manager mentioned:

> 'If customer wants to have a certain kind of machine, it will tell us what must be done.'

Compliance management also depends on the organisation of a company, for example, by geographical region or product. Three companies' representatives considered it important to formulate a product liability program, which is a guideline

highlighting the meaning of product liability for different parties; this also helps with sales and marketing. In addition, contracts play an important role in the compliance management of work-related products. Finally, the limitation of responsibilities must be clearly presented, for example, in resale agreements.

Communicating

The information related to requirements must be stored, be made available to and be understandable by all necessary groups and persons. The representatives mentioned a system to manage requirements and product data as well as documentation of design stages to aid information flow. For example, in one of the companies, a product line representative compiles market-specific packages of requirements. These are typically information packages applied to make-to-order and engineering-to-order product delivery strategies. The representatives also admitted that participation in the drafting of standards allows for information sharing with other companies:

> 'Other acute issues are also discussed at committee meetings.'

In a globally operating company, information must be shared between design units. The representatives mentioned the use of, for example, global safety design files and global product councils to share information. One of the companies' representatives highlighted the necessity for a system to reach all customers. Such a system is needed, for instance, to gather feedback, inform customers of detected hazards/deficiencies or arrange the smooth recall of products. Another important element was the ability to trace all parties in a company's supply chain and manufacturing dates of all components. In addition, as one company's product line managers highlighted:

> 'In communication, it must be noticed that all the customers are not highly educated westerns.'

Implementing requirements

The clear distribution of responsibilities among design, product line, product safety, local unit and subcontracting personnel is important in implementing requirements. The companies' representatives mentioned that the product safety personnel

typically support those in design and product line to fulfil safety requirements, although their roles may vary. In one company the designers highlighted:

> 'Every requirement has a person responsible, in other words one who owns the requirement.'

Three companies' representatives highlighted that manufactured products can be localised by meeting the requirements of local units. Another option is identifying and accounting for local requirements during the initial design and manufacturing of the machine. For the first option, it was mentioned that local units' personnel or local dealers should communicate and understand the boundaries of local modifications and possibly seek permission from parent companies to ensure conformity to modifications. In the second option, the company's design and manufacturing units must seek help from local units' personnel and customers. However, in practice the operations may be more simple:

> 'An old machine is often as the basis for design and totally new are seldom made.'

> 'The standard products are made according to the Machinery Directive.'

Most representatives stated that product quality must be equal, irrespective of location and manufacturer. This is particularly important in the US market. Some representatives expressed that the court accounts for company's safety-related solutions for products intended for other markets in, for example, proceedings for an accident in the US market.

Evaluating and monitoring compliance

Few representatives highlighted that early risk analysis during the early stages of product development are key in compliance management. All participating companies perform compliance checks during their projects, and three companies mentioned documentation of the stages in design. The companies have different milestones or project gates, like prototype, pre-series and series, in projects when the compliance with requirements are controlled and safety issues are discussed:

> 'At the most critical stage of the project milestones will be every week. The project will not go forward before certain matters are executed.'

The evaluation is important to do with due to care before freeing product to the production. In addition, as one design manager highlighted:

> 'There are no resources for making changes; safety must be succeed at once.'

Companies confirm information validity with help from, for example, local units, local contacts in market areas, suppliers and customers. If a product is publicly shown beforehand for example on exhibition, then feedback will also be obtained before access to the market. Most representatives also expressed that participation on different committees, such as those for standardisation, allows for the possibility to benchmark their interpretations and practices with those of other companies.

Four companies' representatives mentioned the essential role of maintenance personnel in product engineering. Maintenance personnel are most likely to experience consequences of problems and accidents during their work, and thus, their feedback is considered increasingly valuable:

> 'The maintenance will inform designers if something has occurred.'

Few of the participating companies also maintain other manufacturers' products, and this gives them the opportunity to learn about the faults and solutions of various types of machines.

However, the final solution for validity is possible once a court decision has been passed. Sometimes it is also agreed on beforehand where the litigation occurs and/or are the cases covered by contracting.

5.1.2 Types of compliance management problems confronting companies

The results of this chapter are based on interviews with representatives from six companies on problems experienced in compliance management. The participating

companies' practices to achieve and manage compliance are presented and titled under compliance management phases, as defined by earlier studies on achieving regulatory compliance (Henson & Heasman 1998; French & Neighbors 1991) and ISO 19600:2014 on compliance management systems.

Tables 7 and 8 summarise the results. The interviews were semi-structured, and the crosses in the tables denote issues independently raised by the interviewees. In addition, as presented in Table 2 (Chapter 4.1), the number of representatives in participating companies varies. This also explains the higher number of crosses for companies A and B, and thus, a comparison of the results between all the companies is not sufficiently reliable. Chapter 5.1 presents the companies' problems in achieving and managing compliance under similar phases. Table 7 discusses participating companies' key problems in compliance management. Table 8 orders these problems according to their frequency of mention by the companies (N = 1–6). The most frequently mentioned practices (N = 5) include lack of documentation; insufficient help from national authorities; and varying practices, requirements and enforcement in EU member countries.

Table 7. Key problems in managing compliance

PROBLEMS	COMPANY					
	A	B	C	D	E	F
Lack of documentation	x	x	x	x	x	
Insufficient help from national authorities	x	x	x		x	x
Varying practices, requirements and enforcement in EU member countries	x	x	x	x		x
Occasionally coincidental information about requirements	x	x	x		x	
No requirements' management system	x		x	x	x	
Apprehension and interpretation of standards	x	x			x	x
Inadequate information flow within unit	x	x	x		x	
Inadequate information flow among units	x		x	x	x	
Unknown operations in local units		x	x	x	x	
No information about local modifications	x		x	x		x
Lacking comparison of requirements among different market areas	x		x		x	
Non-uniform market surveillance in the EU	x	x				x
Lack of type-C standards		x		x		x
Unclear responsibilities	x		x		x	
No centralised list of safety-related requirements	x				x	
No code of design practice		x			x	
Modification of ready-made products	x		x			
Lacking competence in local unit	x		x			
Lacking competence in sales and marketing	x	x				
No interpretation guidelines	x					
Insufficient global alignments for safety		x				
Non-uniform practices in projects	x					
Differing operations by notified bodies						x

Table 8. Weighting of mentioned problems

PROBLEMS	N
Lack of documentation	5
Insufficient help from national authorities	5
Varying practices, requirements and enforcement in EU member countries	5
Occasionally coincidental information about requirements	4
No requirements' management system	4
Apprehension and interpretation of standards	4
Inadequate information flow within unit	4
Inadequate information flow among units	4
Unknown operations in local units	4
No information about local modifications	4
Lacking comparison of the requirements among different market areas	3
Non-uniform market surveillance in the EU	3
Lack of type-C standards	3
Unclear responsibilities	3
No centralised list of safety-related requirements	2
No code of design practice	2
Modification of ready-made products	2
Lacking competence in local units	2
Lacking competence in sales and marketing	2
No interpretation guidelines	1
Insufficient global alignments for safety	1
Non-uniform practices in projects	1
Differing operations by notified bodies	1

Identifying and discovering requirements

The interviews demonstrated that companies must be aware of specific local requirements and those standardised across markets. In addition, companies should identify differences between countries when manufacturing global products. However, five companies' representatives mentioned the lack of documentation as a key issue. If documentation related to product safety is not adequate, it may lead to several overlaps such as similar information being concurrently and/or repeatedly searched:

> 'Sometimes it has been noticed that several persons determine the same issue.'

> 'We have no clear data bank which should be gone through when a new product will come.'

Four companies' representatives admitted to discovering requirements by chance and that it is not always known what should be known:

> 'All the requirements are not clearly known when projects are made. Particularly customer requirements.'

This could create the need for changes in readymade products as well. Sometimes even the origin of the requirements is not known and this could pose difficulties in, for example, following up up-to-dateness of requirements. Especially when a company is smaller, like company F in this research, there is no delegation to follow and identify requirements in advance.

Even though it appears that the EU officially has harmonious legislative requirements for the safety of machinery, most representatives mentioned that the practices and requirements as well as their enforcement vary among member countries; in particular, markets in Germany, the United Kingdom and Sweden pose distinct difficulties:

> 'In Germany there is a strong domestic market and perhaps they are satisfied if the Finnish product does not get to the market so easily. CE –marking is not enough.'

Most representatives also stated that market surveillance is not uniform or truly effective in the EU. This allows for dishonest operations, and participating companies striving to achieve compliance therefore consider it unfair. In addition, one company highlighted the differing operations of notified bodies across member countries as an issue.

More problems concerning the identification of requirements are found outside the EU:

> 'The world outside the EU is mystical. The expert network would be good to have all the way to every country.'

Outside the EU, participating companies cited the United States and Australia as examples of specific market areas. These follow case/common law and where legislation is state-specific/territorial. In the United States, product liability is central, and warnings play a significant role. According to the representatives, companies must be well prepared for the US market, and of particular importance in this context are costs of product liability litigations. One product line manager highlighted as follows:

> 'There is not many actual requirements in the US, what really matters is how the things are documented and by which words.'

In comparison, in Australia, requirements were mentioned to be occasionally stricter than those in other markets were and there is large variety of national standards. The representatives cited extensive requirements in sales contracts and the resultant significance of master contract techniques. In addition, in Australia, personal liability in terms of safety is borne by designers. Companies also face various difficulties with compliance management in the South American and Chinese markets.

Four companies' representatives mentioned it to be difficult to comprehend standards and their interpretations. This can be attributed to the lack of updated

information pertaining to standards in companies. Identifying non-validity after initiating a project can be particularly costly for companies. Further, opinions on the lack of European type-C standards (which are more detailed safety standards for specific machines) appeared to be divided: while some representatives considered it to be a negative factor, others said it was a positive factor. Type-C standards clarify design but at the same time, affect the benefits yielded by the latest and best available safety solutions. Thus, the need for specific standards remains controversial:

> 'We can have advantage if there is no type C standard. We make our solution on safety.'

Interpreting requirements and identifying possible changes in products or operations

The problems relating to the interpretation of requirements include the lack of guidance, poor alignment, and language issues. The representatives expressed the general absence of external bodies or authoritative parties they can approach for support. Five companies' representatives mentioned the lack of help from national authorities in market areas. On the other hand companies may not even try to contact authorities:

> 'We contact authority only if something occurs.'

In addition, four companies' representatives considered their interpretations as tenuous. Some special areas are not always considered in legislation as well. In addition, the new market areas are difficult. The final confirmation tends to be obtained after an adverse event such as a court hearing. Few representatives also mentioned that the Machinery Directive is rather generic and does not offer specific requirements for safe machinery design. In addition, participants of the Machinery Working Group which is dealing the practical application of the Machinery Directive was expressed to be far removed from the actual problems they faced.

Three companies' representatives mentioned that similar requirements can be interpreted repeatedly and/or differently within a company. Further, interpretations are not gathered and comprehensively documented:

'There is no internal guidelines for interpretation.'

Only one representative mentioned their having a system to manage requirements. A documented code of practice for design and consistent global alignments for safety was mentioned as a possible way to unify operations.

Decision of compliance and specifying method of compliance

The companies participating in this research highlighted their positive attitude towards safety and the true will to be compliant. However, different market areas and customer preferences tend to pose difficulties. Several representatives mentioned that, in some market areas, customers cannot afford to buy high-quality products, and thus, all product types that they sell should still be safe. Other problems were also mentioned:

> 'A challenge in compliance management is customers' use of consultants. They may form requirements to create value for their commission fee.'

Some representatives highlighted that it is not always possible to test solutions and achieve a compliant status in the first attempt. Most companies found the US market to be particularly difficult. For instance, in the case of an accident or damage, the court considers whether a company manufactures products with higher safety grades for other markets to meet their market requirements:

> 'We have been advised to destroy all documentation concerning our products for other market areas.'

However, specific contracts concerning business-to-business products have been mentioned to partially solve issues.

Communicating

Representatives of four companies stated that the discovery of information about requirements may even be coincidental; in other words, the requirements are not systematically searched and discovered. Representatives of four companies

highlighted the inadequate flow of information in or among different units of a company. For example, product lines personnel and those working on specific projects may not sufficiently exchange information. This leads to individuals searching for similar information concurrently and repeatedly, which can also be attributed to the lack of systematic documentation and data management. Three companies' representatives stated that they do not systematically compare requirements between different market areas and that information is not consolidated in a single location:

> 'Individual requirements are known but the differences of requirements in different market areas are not known sufficiently enough. Global requirement management system could be a solution.'

> 'Internal sharing of information is based on informal structures. Formal network is build'

An issue that complicates communication is the competence of the local unit and that of sales and marketing. Representatives from companies A and B perceived that sales and marketing and local units' personnel have somewhat insufficient understanding of and competence regarding product safety. Personnel from both teams should consult more with designers before negotiating and informing potential customers; more specifically, it is critical for them to acquire complete information about the requirements and not overpromise to the customer. Local units' personnel play a key role and have expertise in managing local requirements; however, they are more inclined towards sales and marketing expertise and lack competence in safety issues.

Four companies' representatives admitted to the possibility of personnel in the company's local units modifying the product to meet local requirements and of the centralised manufacturing unit being unaware of these modifications:

> 'There may be own business of modifications and also own spare parts in local unit.'

The representatives further mentioned that machine building involves several contracts and thus, the work tends to be divided. In less developed market areas, the

probability of unexpected risks is higher and communication with the customer is not always simple.

Implementing requirements

With regard to implementation, perceived problems in the participating companies are non-uniform practices in projects and unclear responsibilities or operations in the local unit. A global requirements management system and code of design practices were also mentioned as possible measures to control these problems. In addition, most of the companies' representatives considered it essential to define the responsibilities of complying with the requirements and said that this should be done at all stages of the project lifecycle:

> 'In machine building there is many contracts and the doings are split. Challenge is how the requirement specifications move from one place to another.'

Four companies' representatives stated that operations in the local unit are not always known and local modifications are not disclosed. If the parent company is unaware of these actions, it may create more work and obscure responsibility issues. Another issue is that dealers may make local changes to the products. It is imperative for the parent company or centralised manufacturing unit to be aware of such actions, as untoward events can render the associated responsibilities unclear. Some companies' representatives were unclear about who is responsible for overall compliance with requirements. To this effect, the Declaration of Conformity required in the EU was mentioned to be insufficient in this case.

Evaluating and monitoring compliance

Monitoring and evaluation of compliance can be difficult if a company is unaware of the actual problems and risk evaluation is deficient:

> 'From the accidents which take place on the field only a fraction is known and partly accidentally.'

> 'Risk evaluation is made fare too late only when the product is finished.'

Further, the certainty of updated requirements and validity of translations pose difficulties in compliance evaluation in the participating companies. Four companies' representatives mentioned that information about the requirements is sometimes coincidentally discovered and the origin of applied requirements may even be unknown. Two companies' representatives admitted to instances in which conformity issues were raised rather late and readymade products required changes. In particular, local requirements for tailored products must be carefully considered. However, in many cases, local units modify products and do not always inform the parent company:

> 'Local unit may make changes but if they do not ask for advice from the manufacturing unit it will take the responsibility.'

Market areas may also adopt protectionist attitudes towards foreign companies, and these companies have to comply with more stringent requirements or face stricter treatment from the authorities than local companies do. This can complicate the evaluation of compliance. In sum, most companies highlighted the need for more reliable help from authorities or other external parties in ensuring compliance. On the other hand the responsible parties differ between market areas:

> 'If an accident occurs in the US the machine supplier is first attacked. In Europe it is the employer.'

5.1.3 External parties' expectations, role and possibilities in supporting and controlling companies' management of safety-related compliance

The results in this chapter are based on interviews with twelve national and six European external parties' representatives about their perspectives on compliance management. National parties are represented by legislators, authorities, standardisation organisations, inspection bodies, insurers, engineering offices and supporting/promoting organisations. European parties involve represented

legislators, standardisation organisations and supporting/promoting organisations. The interviewees represented personnel with long practical experience on subject.

External parties' expectations, roles and potential influences are presented and titled under similar phases of achieving and managing compliance as those in Chapters 5.1.1 and 5.1.2. Figure 3 illustrates the author's summary of central issues from the perspectives of external parties' representatives highlighted during the interviews. These perspectives are divided into similar phases of compliance management process as those earlier applied in this study.

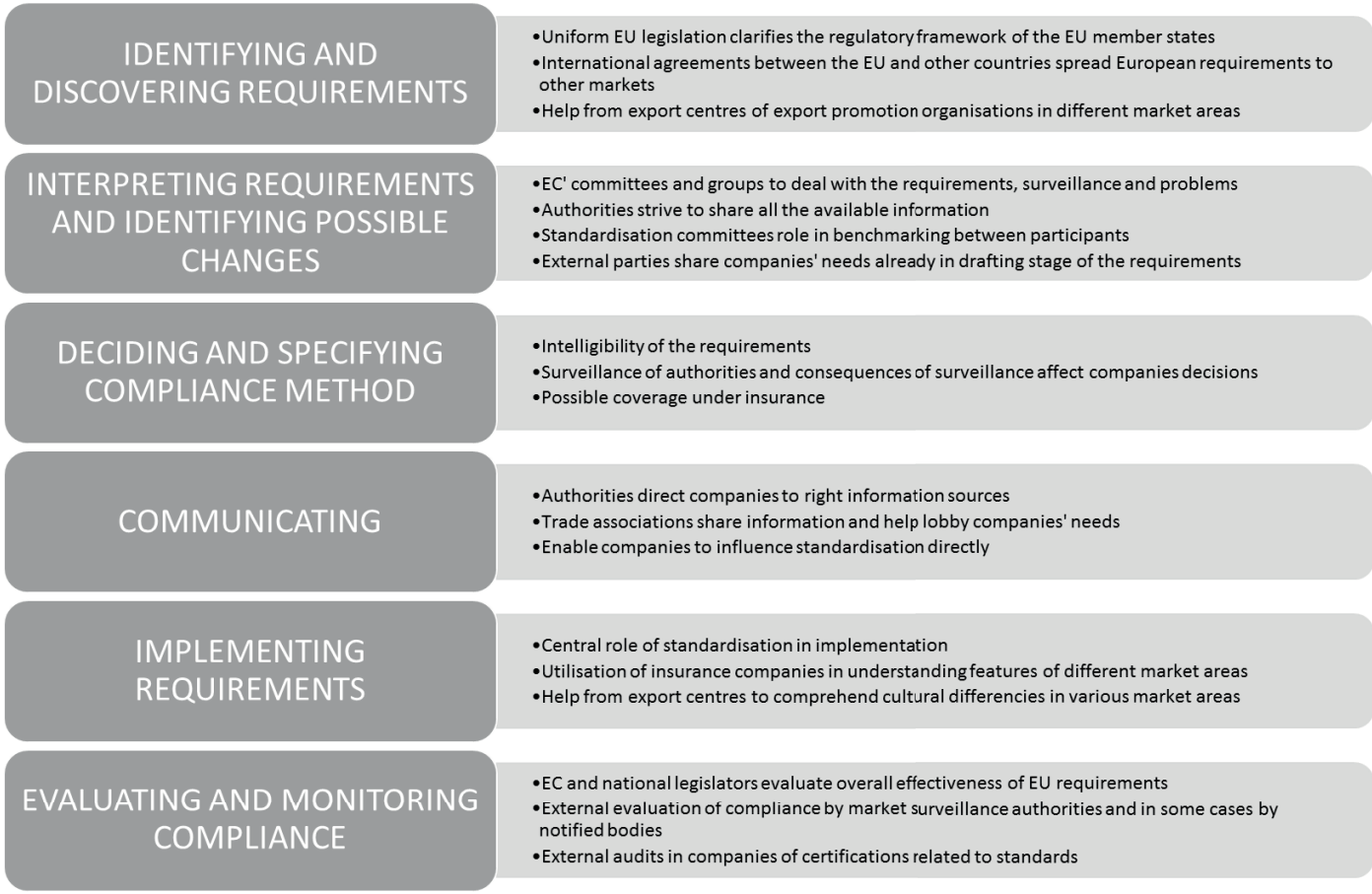

Figure 3. Central issues of external parties' perspectives

Identifying and discovering requirements

According to the external parties, a major problem for companies, particularly smaller ones, is possessing complete knowledge about national and European legislation. According to Finland's national ministries, joining the EU was an effective decision for its regulatory field. For example the Machinery Directive (2006/42/EC) decoded over 40 national regulations in Finland, and this had an overall positive effect on Europe's competitive ability. The Directive is supported by comprehensive guide to application. According to the EC's representatives, the Directive in force will be subject to revisions and may be transformed into immediately enforceable regulation in the future. However, criticism towards comprehensive EU legislation was also expressed by European parties:

> 'EU wants to be good and it will take years before competitors would do the same than Europe.'

The New Approach principle was mentioned as a more functional addition to the European internal market, and the Machinery Directive was one of the first New Approach Directives. According to the Approach, only essential requirements concerning products are included in the Directives. The EC set up a standardisation mandate for certain European standardisation organisations that developed standards in line with the Directive's requirements. The interviewees stated that through the standardisation process, large-scale companies gain information in advance, whereas smaller companies are only aware of older standards.

According to the European legislators, the importance of the national implementation of the EU legislation is decreasing with the shift in trend from drawing up directives to regulations. Regulations are legal acts that become immediately enforceable as laws in all EU member countries, while directives require national actions for implementation across member countries:

> 'However, a company has to clarify for its products if the requirements of the product have been harmonised or have all the aspects been harmonised in the EU.'

The representatives of national authorities direct companies towards correct information sources, and legislation obliges them to advise companies. However, the authorities argue the problem of setting boundaries and clearly distinguishing their role as rather an authority than a consultant. Further, the representatives highlighted their attempts to share all available information and investments in communication, particularly to offer information as soon as possible.

The EC representatives expressed that the EU has a mutual recognition with Switzerland and free trade agreements with South Korea, India, China, South America, Argentina and Canada. The agreements unify and clarify companies' import and export policies between market areas. There has also been long negotiations between the EU and the US of the TTIP agreement for trade and investment but these have been difficult. In addition, CE markings are accepted in African and South American countries with a connection to France and United Kingdom. China and Russia were also cited as regions interested in CE markings:

> 'The acceptation of CE marking in market areas other than the EU will bolster companies at compliance management.'

> 'On the other hand, the European Parliament has a desire to goodism.'

Another party participating in this phase of compliance management is export-promoting organisations. The representatives of these organisations help companies discover requirements through export centres in different market areas. It was also mentioned that part of the information is found abroad only from proper and reliable persons. Export centres can be useful by providing knowledge about local contacts well-versed with local workings and enterprise culture:

> 'There are rules, laws and practices. So long when everything is well the practices are enough.'

However, the situation is difficult in a country characterised by despotism, which suggests that the requirements and their application are unsustainable.

Interpreting requirements and identifying possible changes in products or operations

Interpretations are carried out and supported by several external parties in the EU:

> 'Each DG (department) of the EC has a different committees and groups.'

The Machinery Committee, comprising delegates from each member country, under the DG for Internal Market, Industry, Entrepreneurship and SMEs deals with issues surrounding the Machinery Directive. The Machinery Working Group created by the Machinery Committee focuses on the practical application of the Directive, for example, it approves the guide to application of the machinery directive. The Group consists of participants from the European associations of industry, trade unions, standardisation and notified bodies. An EC representative chairs the group, which gathers few times a year. These committees and groups support the interpretation of the EU legislation, and their representatives may influence potential changes in the requirements. The national parties of the EU member countries may also raise issues through the European association representing them.

Another party mentioned by the EC representatives is the Senior Labour Inspectors Committee (SLIC) of the DG for Employment, Social Affairs and Inclusion. The SLIC possesses a mandate to offer its opinions to the EC on all problems related to the enforcement of the health and safety at work legislation. SLIC includes the representatives of the labour inspection services performed by EU member countries. In addition to the full Committee, there are a number of smaller committees mandated by SLIC to examine specific issues, for example, MACHEX examines machinery-related issues. From the companies' viewpoint, these committees ensure equal treatment by authorities in the EU. The EC was also stated to support and organise cooperation between the market surveillance authorities of products. Such cooperation occurs through, for example, groups of market surveillance authorities such as the Administrative Cooperation Groups (AdCos). The members of these groups are appointed by EU member countries and represent national authorities competent in market surveillance in a specific sector. The issues related to the Machinery Directive are addressed by the Machinery AdCo Group:

> 'The national authorities can take cases to AdCo and can get a European view on the case. If there is a big company against national authority it takes guts of a small country to battle alone.'

The representatives of national authorities expressed that Nordic authorities have also own cooperation around market surveillance. Even though there are several cooperative groups, some interviewees in Brussels suggested insufficient cooperation between different departments and groups in the EC. With regard to machinery, the safety of machinery and occupational safety of the operators are regulated by different departments in the EC.

The national authorities, on the other hand, considered themselves effective at providing instructions, tools and good solutions to companies. They highlighted that authorities' actions should prioritise the accomplishment of sufficient effects through guidance and sanctions would not need to be imposed. Further, the authorities' representatives stated that they do not want to be an affordable consultant, inspection body or auditor for operators. That is, they do not wish for the authority's control mechanisms to become cheaper than operators' own supervision. However, the role of authorities' supervision was mentioned to be more crucial in the case of complex legislation. From the companies' perspective, this indicates the pressures of their own responsibilities and the need to acquire additional paid help.

According to the EC's representatives, the EU revises legislation every five years:

> 'There is wide impact assessment in the EU level. Nationally not much.'

The future of EU legislation was mentioned to be more regulations and less national interpretation in the EU member countries:

> 'National harmonisation and specialties are related to directives, and it is easier to work with directly applicable regulations. In addition, regulation have shorter period of transition.'

However, some interviewed parties stated that this may prove controversial for companies' ability to influence, particularly if there were no concurrent versions in the native language:

> 'Finnish regulatory tradition will be written to nationally harmonised EU legislation if possible and sometimes requirements will be made stricter.'

In addition to actual legislations, official guidelines to interpret legislations can be an important source of support for companies. In the case of the Machinery Directive, a newly edited version of the Guide to Application of the Machinery Directive 2006/42/EC was published in July 2017. However, it is intended to be a living document under the approval of the Machinery Working Group.

Part of the legislative process is to lobby for important considerations. At the EU level, the European representatives mentioned that this is generally done through, for example, industry and trade associations. The interviewees state that since mechanical issues are not that political in nature, they generally do not face processing difficulties at the European Parliament. Once the new legislative requirements are specified, companies may need clarifying guidelines:

> 'If legislators or authorities do not compose guidelines, then the task falls on, for example, industry associations.'

In the EU, there is a unique mono-standard system. In other markets, like the US, there may be competing standardisation organisation and standards may be mandatory:

> 'Standards help companies fulfil legislative requirements and are a tool to minimise effects of globalisation. On the other hand standardisation may sometimes prevent the need to regulate.'

In the EU, the standards are strongly linked to the legislation (i.e. the standards are harmonised):

> 'Standard system was originally industry by industry system but the EU is using it by coincidence The EC aims to maximise harmonisation of standards.'

However, standards are highly technical, and it is not always easy for the EC to accept or reject a proposal for a harmonised standard. Typically, harmonised standards should be published at the same time as the directive or regulation, although this is not entirely realistic. The representatives of standardisation organisation mentioned instances in which the mandates from the EC were late. On other hand, the external parties' would like the standardisation organisations to smoother their own processes.

The standardisation is supervision of own interest to companies:

> 'Companies should have a standardisation strategy. This should include, for example, standardisation committees to be followed, the time at which comments for changes are requested and locations of participation at the national level.'

European machinery safety standards are commonly experienced as positive and the quality of standards is good. Standardisation committees were also mentioned to facilitate a unique environment in which participating companies can establish discussions with competitors. Standards are compiled bottom-up (by companies), and thus, the best time to influence a standard is the compilation stage for the proposal. Representatives of the EC expressed that the EU's aim is a more inclusive standardisation, wherein small companies and countries can participate; however, such participation requires financial support.

Decision of compliance and specifying method of compliance

The authorities' representatives pointed out that the repercussions for noncompliant companies should more noticeable:

> 'The operator only have to pay the testing expenses and acquisition costs of the product.'

However, more common application of the corporate fine be effective in encouraging compliance with requirements. The interviewees also emphasised that when concerning the decision of compliance in a company it must be familiar with the nature of the legislation. For example, the Machinery Directive achieves total harmonisation while occupational directives define minimum requirements and are more consultative. In proportion, in market areas where common law is applied, the legal praxis is more important than legislation. From a regulatee's viewpoint, legislation and complementary standards should be clear enough such that additional guidance is not necessary.

In particular, representatives from insurance companies stress the importance of risk management policies for different markets and for companies to gain an in-depth understanding of the aspects covered by insurance. In addition, it is important to gain awareness about the markets in which the company's products are located. For example in the United States the binding or mandatory requirements may be petty, but the role of courts is significant:

> 'It is usually not worthwhile to import to the US with only a small lot of products.'

The insurance companies' representatives also highlighted the importance of managing the quality of the subcontracting chain in compliance management. That is, it is necessary to be aware of whether, for example, a low-cost component is applied to complex and dangerous operation or if the component lacks safety or property. In the case of components acquired from the EU, the importer's responsibility is missing, which was mentioned to be more distinct.

Communicating

The EC and member countries should arrange that there is enough information available. Information to companies flows more from national parties, like authorities:

> 'We typically direct a company towards the right information source and strive to share all available information.'

In particular, preliminary communication with companies was mentioned to be at the centre of authorities' tasks. However, there could be more targeted communication. In comparison, trade/industry associations communicate in both directions, that is, that acquire information and influence changes in the requirements. The associations' representatives expressed that they also serve as parties lobbying the interests of their member companies:

> 'It is important for companies to be aware of when to express their opinions.'

> 'Manufacturing industry is very important for Europe and it must be supported. If manufacturing industry will go away from Europe, it will be a catastrophe.'

A key possibility for the European companies is influencing requirements at the national and European levels. With regard to standardisation, national participation was mentioned to be direct, although only a member of national standardisation can participate in European and international standardisation. In addition, information sharing between European CEN and CENELEC and ISO is mostly realised through its member parties. Several interviewed parties termed this process somewhat controversial since it is not systematic. In addition, it was highlighted that the ISO standards and specifications are not truly international because certain market areas, such as the United States, protect and favour their own national standards:

> 'US is a member of ISO and they acknowledge some standards.'

On the other hand, it should be considered does the European standardisation effect too much on international standardisation.

Implementing requirements

The insurance companies' representatives recommend companies to analyse their market areas:

> 'If a company's operations are truly global it should follow the requirements of their strictest market area, and compliance

> management should be approached through risk analysis to determine level of compliance.'

Further, the insurance companies' representatives recommend that company should be aware of possible indirect export, that is, when a company's components are utilised as part of another company's product in an unknown environment and market. However, it depends also on the application. For example in the US market, consumer products tend to cause several difficulties, whereas business-to-business products are simpler because contracts between companies may eliminate possible problems. Nevertheless, the representatives of insurance companies expressed that a company must be well aware of specificities in the US market.

The interviewees expressed standards as a tool to reduce globalisation effects and support the implementation of legislations. In particular, the EU emphasises the importance of standards and standards have a strong connection with the legislation. However, according to the interviewees, European standards are not always desired by the industry. Here, an important question is:

> 'Is the competitiveness of the European market declined if standards are directly drafted at the international level rather than first being formulated as a European standardisation?'

In addition, the interviewees mentioned that the more there is own national standards in the EU member countries the weaker is the European internal market.

Evaluating and monitoring compliance

Legislators or their authorised parties evaluate the effectiveness of enforced requirements and plan changes in advance. These evaluations are performed both in the EU and somewhat at the national level. However, the evaluations have sometimes been considered faulty because the desired results are defined beforehand. Certain interviewees highlighted that the evaluation of a legislation to be enforced is inadequate at the national level.

Further, the EC representatives mentioned that in the EU, national market surveillance authorities conduct external evaluations of product compliance for requirements and in case of dangerous products by notified bodies:

> 'The market surveillance examines whether available products are in conformity with the applicable law and it is a key element of the functioning internal market.'

The surveillance is retrospectively performed, that is, after a product is placed on the market, and is based on risk assessments. Manufacturers, importers and dealers are primarily responsible for ensuring product compliance. However, according to the national authorities' representatives, sanctioning illegal operations are insufficient and fines should be more stringent. In addition, sometimes, the evaluation of products' compliance with their requirements may be fulfilled through an intermediary:

> 'When a buyer of a machine requests an external body to assess the new machine, the external body may go on to advise the manufacturer as well.'

According to their representatives, authorities tend to focus on the most risky business when implementing requirements and supervising their compliance:

> 'Today, the supervision is mostly directed towards operators who have most risks related to safety. Supervision is typically project – based. Also competitors may inform on others dangerous products.'

The authorities' risk-based supervision and related risk assessments are considered to be well instructed, and efficient market surveillance should favour honest companies. However, the lack of market surveillance was mentioned to be highlighted by many European parties. Further, like the EU requirements, surveillance should be unified in the EU. Market surveillance was mentioned to be widely experienced as a national operation with insufficient coordination. However, there is actions to unify surveillance with new legislation, coordination and tools for sharing information in the EU:

> 'Legislative entirety Product Safety and Market Surveillance Package is set up as a market surveillance initiative for all non-food products and is under negotiation in the EU. Although there is problems with its acceptance.

Several interviewees also stated the need for cooperation with customs in the EU, which was earlier differentiated to act as market surveillance authority:

> 'Now products incompatible with EU requirements get easier access to the European market, for example, through certain harbours.'

However, at the same time, the interviewees mentioned the capacity of authorities is diminishing in the EU member countries. This will further contribute to a decline in concrete inspections and testing. From the point of view of the companies, the insurance companies' representatives remarked that companies should also have an effective recall plan for harmful products and if possibly repetitive faults in products are noticed.

5.2 New approaches to manage compliance with safety-related requirements more systematically

The empirical results presented in Chapter 5.1 highlighted development needs in managing compliance with safety-related requirements. Some of these needs already had existing solutions but there were needs that required new solutions, i.e. new approaches. The process of constructing new approaches to these needs for managing compliance is examined in this chapter. The construction of new approaches, as presented in chapters 5.2.1–5.2.4, is conducted in line with the phases of the constructive approach (Kasanen et al. 1991, 1993; Pahl & Beitz 1992). This research applied the following phases of constructive research: identification development needs; construction of new approaches in line with essential identified needs; and evaluation of constructed approaches. The identification phase is presented in Chapter 5.2.1. This phase consist of identified needs and suggested solutions. In addition, it summarises what should be sorted out by new solutions. The constructed of new approaches are presented in Chapters 5.2.2 and 5.2.3 and

finally, the evaluation of these approaches is described in Chapter 5.2.4. Given the origin of the empirical findings and the author, this research emphasises European legislation and practices, although the proposed constructs are generic and should be of interest to a wider audience.

5.2.1 Identification of development needs in compliance management

This chapter gathers development needs specified during interviews with the companies and external parties' representatives and accordingly, gathered potential solutions to tackle these needs. These results were also merged with perspectives presented in the literature. The summary of this chapter raises the needs for new approaches.

Table 9 presents the identified development needs in managing compliance and possible solutions. The Related Phases column describes the phases of compliance management process to which the development needs and solutions are related. These phases are the same as those applied in the earlier chapters: identifying and discovering requirements, interpreting requirements and identifying possible changes in products or operations, decision of compliance and specifying method of compliance, communication, implementation of the requirements and monitoring and evaluation of compliance. A more detailed description of development needs and solutions is presented after Table 9.

Table 9. Possible solutions for essential development needs in compliance management

NEEDS	RELATED PHASES	SOLUTIONS
Unclear responsibilities in compliance management	All phases	General and product-specific internal safety plan Compliance/requirements management system in which legislative responsibilities are assigned, presented and validated for each process phase Common conception of product delivery strategies and safety concerns within a company
Requirements are not systematically searched, discovered, documented, processed, interpreted and/or compared	1 and 2	Identify relevant sources to gain information (e.g. local units, customers, maintenance, dealers, other companies and other external organisations) Tangible and intangible information about different global and local safety requirements; systematically gather and document interpretations and safety engineering solutions in organisation Compliance/requirements and product data management systems in use Completeness of requirements specific to market areas (e.g. market research and competitor benchmarking) Comparison of differences in requirements and regulatory systems of various market areas Initiate efforts to prepare for changes Internal strategy to follow-up and participate in the drafting of requirements and standards
Lack of equal understanding and practices of safety issues throughout organisation	Especially 3–5	Rational choice of compliance method Similar level of safety in every market area and manufacturing location International networking among a company's different units
Local modifications of products and lack of awareness about these modifications	Especially 3–6	Design and manufacturing guidelines prepared at once or Local unit seeks permission from the parent company for modifications and informs of changes

Related to phase 1: Identifying and discovering requirements

All participating companies reported problems in the systematic search, discovery and documentation of safety-related requirements. Only one company's representatives mentioned having a requirements management system or system to manage compliance with requirements. A company should have a specific, feasible and permanent system to manage requirements, which may contain, for example, a comprehensive list of safety-related requirements concerning their product portfolio. The standard ISO 19600:2014 emphasises that the requirements should be documented in a manner that is appropriate to company's size, complexity, structure and operations. The system list should be adhered to and properly compared for similar requirements by different market areas in which a company sells products or operates. In addition, it is useful to be aware of possible changes in the regulatory process at an early stage. Differing product delivery strategies can affect the identification and discovery of requirements and have varying points at which requirements must enter the product development process.

In particular, the external parties' representatives highlighted the need for a company with globally marketed products to be able to detect differences in the requirements of different market areas. One way to account for local requirements is to design country-specific packages on the basis of the area. However, compiling the requirements in these packages can be onerous owing to, for example, language issues and difficulties in tracing information. Nevertheless, help can be obtained from a company's local units, customers, maintenance personnel and other companies.

Related to phase 2: Interpreting requirements and identifying possible changes in products or operations

Most participating companies' representatives highlighted problems in the interpretation of requirements. It is important to be aware of future requirements during the drafting stage in order to influence them and/or prepare oneself. The external parties' representatives emphasised that this typically requires knowledge of effective information channels and how to lobby needs to the right parties. To elaborate, if a regulation affects a company's products, it initiates the compliance

process and identifies required changes (Henson & Heasman 1998); however, there may be uncertainty associated with compliance-related changes. Unreliable information or rumours about upcoming changes may lead to unnecessary actions. Thus, it is important to acquire reliable information about specific changes needed to comply with regulations (Henson & Heasman 1998).

The insurance companies' representatives emphasised that a company must have a standardisation plan or strategy, which should contain, for example, the standardisation committees to be followed, the point at which comments regarding changes should be made and regions to participate nationally and internationally. In addition, the companies' representative mentioned that standardisation committees offer a unique environment for companies to initiate discussions with their competitors.

Related to phase 3: Decision of compliance and specifying method of compliance

According to a few companies' representatives, when safety is considered a company's primary value, it should share equal understanding and practices of safety issues with and have a similar level of safety in every market area and manufacturing location. Underpinning the decision of compliance is the understanding of, for example, legal traditions, political systems and regional cultures. The decision of compliance or noncompliance should base on assessment of compliance risks (ISO 19600:2014). An important factor in functional compliance management is a way to manage requirements related to one's own products or operations, for example, a system in which legislative responsibilities are ascribed and presented for each project/process phase. Thus, instead of complying with a single requirement, total compliance can be based on an audited compliance framework, which can serve as an example for a standardised management system like ISO 19600:2014.

Companies' standard product platform was found to be based on either the safety requirements of a single market area (e.g. European) or all their main markets. A company may decouple specific local safety requirements from their standard product platform, and the design standardised safety modules can then be incorporated when required. A company may also have a manufacturing strategy for

new and current products as a part of its business strategy (Sadiq & Governatori 2010).

Occasionally, early anticipation of requirements may be harmful in the case of further changes to the requirements' contents and/or meaning. However, complying with requirements is commonly open to interpretation (Henson & Heasman 1998). Standards facilitate the choice of compliance method by offering solutions of how something should be done.

Related to phase 4: Communicating

According to ISO 19600:2014 a company should determine the need for internal and external communications relevant to the compliance management system. One of the main problems of companies in managing compliance with the safety-related requirements was the lack of documentation. Effective communication can be achieved when all tangible and intangible information about different global and local safety requirements, interpretations and safety engineering solutions in the organisation are gathered, documented, storage and made available to the appropriate persons.

Companies should also be able to react to changes in customer requirements. The representatives admit that if a company truly operates in several market areas, there is a need for networking or connection between its various units to internationally share information and practices. It is also important to understand the adoption of the applied compliance strategy throughout the company (Henson & Heasman 1998).

Related to phase 5: Implementing requirements

Unclear responsibilities in compliance management impede the implementation of requirements. Proper product design and manufacturing warrants that all valid information concerning a product be known. This requires, for example, access to valid tangible and intangible information about the global and local safety requirements and ensuring that interpretation and safety engineering solutions within the organisation are gathered, documented, made available and communicated with the suppliers as necessary. In addition, the common conception of applied product

delivery strategies should be shared throughout the supply chain (Olhager 2003). A more conscious application of product delivery strategies could benefit companies by allowing them to structure safety information and practices related to information analysis. However, ISO 19600:2014 emphasises that compliance must be secured throughout the supply chain to ensure that products meet uniform safety demands.

A company eventually decides on a compliance method. The representatives emphasised that court decisions finally determine the validity of compliance methods. The use of enforcing authorities, inspection bodies, legal offices, insurance companies, customers and competitors may be considered valuable to prevent such escalations. A company may also choose to implement their compliance method before the regulation is implemented and in doing so, gain market benefits (Henson & Heasman 1998). However, this may lead to additional work if the regulation is subjected to further revisions.

Related to phase 6: Evaluating and monitoring compliance

An essential aspect of internal evaluations is a system to manage requirements and compliance with them, wherein responsibilities are assigned and presented for each phase. However, most participating companies did not have such a system. According to the companies' representatives, a new product design has varying milestones when compliance is controlled and safety issues are discussed within a company. Thus, if possible, a department in charge of managing specific technical areas of operations should also monitor compliance with regulatory requirements in those areas (Henson & Heasman 1998).

To evaluate overall compliance with product requirements, it is important for companies to be aware of possible modifications made by local units. However, these modifications are generally not known to the parent company. Only one company's representatives mentioned that their local unit seeks permission from the company's main unit for modifications and informs them of these changes. According to ISO 19600:2014, the key aspects in monitoring compliance evaluations are recognising sources of feedback and information collection methods. For example, in many companies, maintenance personnel seem to play a significant role in information sharing, for example, about possible product problems and accidents. In addition, in the case of product-related issues, a company must have a system

through which it can access all its customers and accordingly, process fluent recalls to avoid wider damage.

Summary of the needs

The empirical results of this research highlight the need to clarify the process of managing compliance with safety-related requirements in a global context. The companies had solutions that cover parts of the compliance management process but there were no existing solutions on comprehensive global compliance management process. In addition, the literature did not provide feasible solutions for managing product safety-related compliance in several market areas. There is earlier studies on requirement-based compliance processes in national level; however, this research focuses on product-based compliance management.

In addition, a more precise understanding of different product delivery strategies and their safety concerns relates to the process of compliance management in global context. This kind of examination was missing in companies. Product delivery strategies are commonly discussed in literature around supply chain management. However, consideration of safety concerns in differing strategies remain scarce.

5.2.2 Model for managing compliance with safety-related requirements

The compiled model is based on author's analysis of this research's results while drawing on Henson & Heasman's (1998) phases of compliance management process. In addition, the researcher applied a flowchart presented in ISO 19600:2014, system life cycle processes defined in ISO 15288:2015 and results of the literature review to the model construction. The basis of each phase and it's contents lean on existing solutions that were gathered from participated companies and external parties as well as solutions presented in literature.

The author designed the final version of the model with help from representatives from the four case companies and five national external organisations that participated in this research. The model may be applied as part of a comprehensive compliance management system introduced in ISO 19600:2014. The proposed model is generic and is able to be applied wider than by machine-manufacturers. The

model for managing compliance with safety-related requirements compiled by the author is presented in Figure 4.

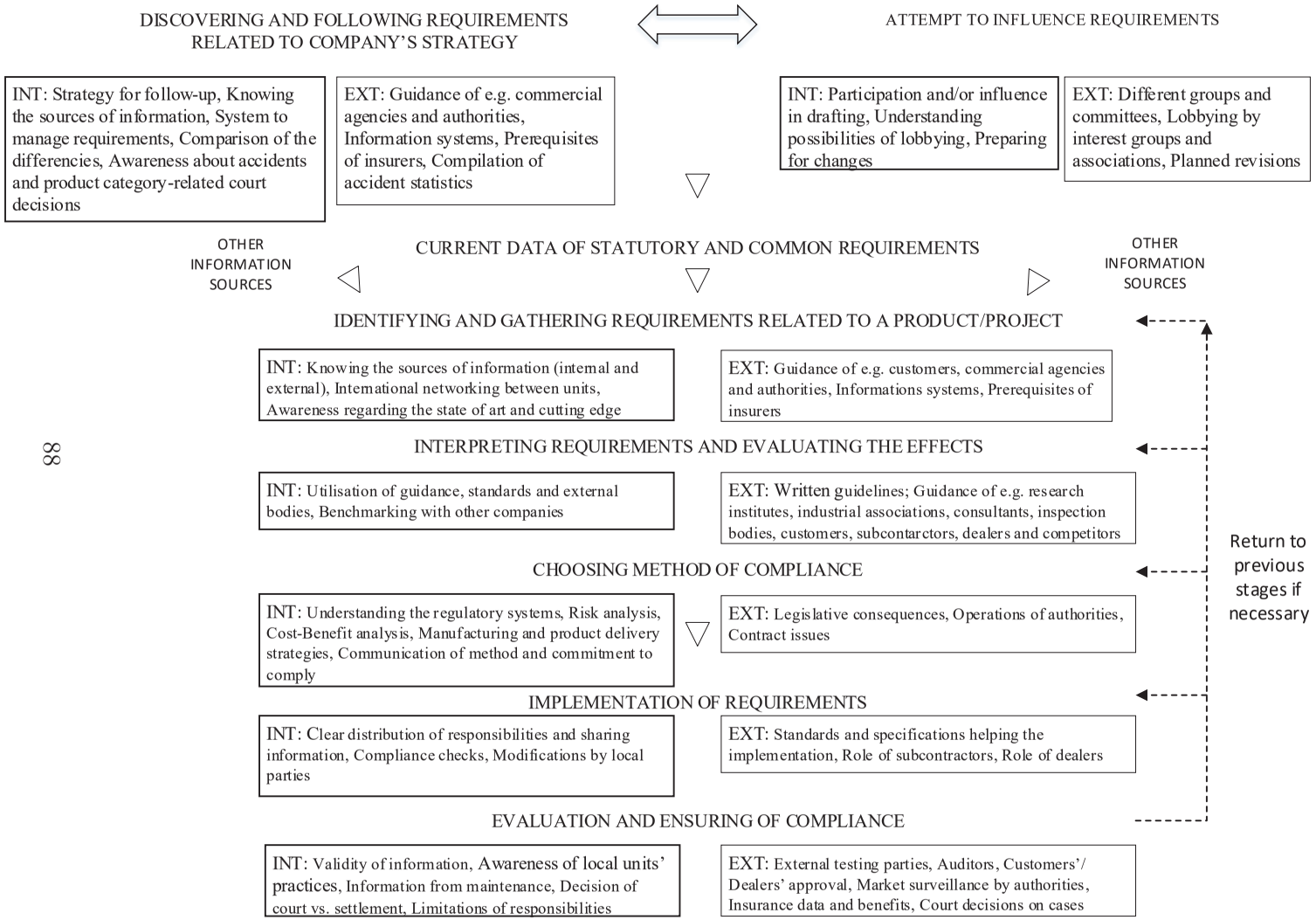

Figure 4. Model for managing compliance with safety-related requirements

The model presents each distinct phase from an internal (INT) and external (EXT) perspective. The internal perspective focuses on the measures an organisation must independently undertake to achieve compliance with safety-related requirements. In comparison, the external perspective presents the role and issues an organisation may expect from external parties. Despite communication not being an independent phase in this model, it is an essential issue to be considered during the whole process of achieving compliance.

The model application must begin with the determination of responsibilities regarding internal tasks and those of external parties in the context of compliance management. The compiled model is bipartite. The first part forms the basis for compliance management and is expected to be a continuous process. As part of its strategy and compliance policy, an organisation should discover and follow requirements (compliance obligations) and sufficiently document them. This concerns a company's operational requirements as a whole, instead of product- or project-specific follow-ups. In addition, a company should be aware of accidents and product category-related court decisions that are closely related to its own or similar products. The follow-up of requirements should be completed with an attempt to influence the requirements, if possible. Gaining information about the requirements in advance allows companies to prepare for potential changes. This warrants participation in different groups and committees and being aware of various information channels. An important issue in the first part of the model is the identification and evaluation of compliance risks and knowledge about the level of compliance risk a company considered acceptable. A reassessment becomes necessary in the case of new or changed requirements, new or changed products, revealed noncompliance with a company's products and/or other major internal or external changes.

The second part of the model is rather operative and focuses on a specific product or project instead of the entire product portfolio. However, compliance must be secured throughout the supply chain to ensure that the products meet uniform safety demands. According to ISO 19600:2014, it is important to recognize that outsourcing generally does not relieve a company of its legal responsibilities or compliance obligations. An organisation must ensure that their outsourced processes are in line with their compliance policies and obligations specified in contracts.

When an organisation is aware of valid requirements concerning their operations, they are not required to subsequently research statutory and common requirements for a specific product or project. Instead, this information may be gathered from available internal documentations. This internal information must be complemented with specific information from other sources, for example, customers and representatives of certain market areas. During the interpretation phase, a company needs to evaluate the effects of requirements on their products. In addition, in this phase, organisations may need the most help from external parties to ensure appropriate understanding of demand and thus, they should be aware of the roles of external parties. For example, in the EU, product (market) surveillance is a subsequent action and the authorities' role does not include the provision of specific interpretations in advance. Nevertheless, the authorities are obligated to provide advice, although the responsibility of solutions remains with the company.

To choose an appropriate compliance method, organisations must be aware of regulatory systems in market areas to which they will export their products; for example, companies must be aware of whether market areas follow the tradition of civil or common law. This is also related to the scale of possible legislative consequences. Comprehensive risk and cost–benefit analyses are means to support the choice of method; however, the choice must also be strategic. Once the method has been selected, its implementation entails the checking of conformance during the project. Defining clear distribution of responsibilities concern both internal and external parties; for instance, a parent organisation must be aware of actions by local units as well as subcontractors and dealers. The final phase of the model is evaluating and ensuring compliance: this phase is closely connected with the tasks performed in the implementations phase. There are several information collection methods and sources to acquire feedback. From the viewpoint of internal parties, maintenance representatives may play an important role as a source of information about product-related problems. The external parties play two types of roles in this phase. The external audit and testing are closely related to a company's operations. However, the actions of external parties such as authorities and courts may be realised long after a product has been placed in the market. This may warrant returning to the earlier stage of compliance or the initiation of a new process, rather than instant corrective actions. When an organisation detects noncompliance, it must take actions

to control and correct it. This information must also be used in improving new product design.

5.2.3 Safety concerns in product delivery strategies

When applying the model to manage compliance with safety-related requirements (Chapter 5.2.2), one should be aware of the point at which different requirements should enter the process. The proper consideration of safety concerns in differing product delivery strategies is one way to rationalise the safety-related compliance management process. Each strategy presents different challenges and possibilities for safety design and compliance management.

Through the complementary interviews, the two main case companies' representatives more accurately clarified the application of product delivery strategies. These interviews highlighted that companies manufacture products in accordance with each of the four product delivery strategies. However, a pure make-to-stock strategy is not common in heavy machinery. Typically, these machine-manufacturing companies strive to postpone supply chain activities until they have a certain customer order. This also allows them to clearly seek, define and understand related legal and customer-specific safety requirements. These interviews suggested that there is no common conception of the applied product delivery strategies across the companies. In particular, the determination of differences in safety issues as part of these strategies need to be better clarified.

Figure 5 presents a summary for the four product delivery strategies and concerns of safety issues related to each strategy on the basis of the interviews and the literature review's results. The objective of this figure is to provide an impulse to decide the direction of companies' operations. Figure 5 draws on Figure 4 from previous chapter such that in different product delivery strategies, the importance of the general discovery of requirements and products or projects based discovering requirements varies. The author created the final versions with help from representatives at the four case companies during the validation meetings of the approaches.

Make-to-stock	Assemble-to-order	Make-to-order	Engineering-to-order
A product is completely designed and made to stock before orders. The order penetration point is furthest from the design. Applicable to cases of certain customer demand in defined period. Products may also be manufactured to dealers' stocks.	A product is built by selecting desired combination of pre-designed standard modules. Applicable especially to cases of broad customer demand and limited variability of product features.	A product is mostly based on standard product platform or standard modules but some changes may be executed by redesign. Applicaple when customer orders include some new or special features that must be accounted for during fabrication and procurement phase.	A product requires extensive new design. The order penetration point is closest to the design. Applicaple when the standard or modified products does not fulfil customer needs. A product is designed e.g. for a new application, new environment or a new market.
Attentions > Need for more accurate understanding of potential market areas and the valid safety requirements to avoid expensive redesign, partial disassembly and reassembly considerably before order penetration point.	**Attentions >** Safety requirements need to be well-defined. The standard modules may be based on safety requirements of a single market area or may simultaneously account for requirements of all the main market areas. There should be awareness of how the overall safety and modules are conjoined.	**Attentions >** The standardised platform/ modules cannot always fulfil e.g. the customer needs or the local safety requirements. Identification of new requirements may be required.	**Attentions >** Allows for the simultaneous analyses of customer and regulatory requirements. There is a need for new identification about possible safety requirements and new extensive engineering designs.

Figure 5. Product delivery strategies and concerns of safety

The make-to-stock strategy warrants the accurate understanding of potential market areas and the validity of safety requirements. The may help avoid expensive redesign as well as partial disassembly and reassembly considerably before the order penetration point. In this strategy, the order penetration point lies after the final assembly and thus, it is not possible to add customer requirements in advance. Thus, the failure to identify and apply the appropriate requirements could cause severe accidents and product liability costs. In certain cases, a parent company's local unit or dealers may order a standard product or a large quantity of products. However, they may modify the products to fulfil local requirements and preferences. This may cause problems in the validity of the conformity (e.g. Declaration of Conformity in the EU). Thus, a parent company must instruct local units to seek permission for modifications to ensure their conformity. In addition, companies must be aware of modifications made by dealers given that the risk of reputation falls on the parent company in the case of an accident.

In the assemble-to-order strategy, an organisation can either base the standard product platform or standard modules on the safety requirements of a single (e.g. European) market area or may simultaneously account for all its main market areas. However, a challenge may be decoupling specific local safety requirements from the standard product platform, then, designing corresponding standardised safety modules, and adding them to the supply chain.

An essential issue in make-to-order strategy is that standardised modules do not always fulfil customer needs or local safety requirements. Changes are executed through a redesigning process and this may require the identification of new requirements. On the other hand, in the engineering-to-order strategy, there is a need for a new identification in line with safety requirements (from both customers and market areas) and extensively new engineering designs. This strategy enables for the simultaneous analyses of customer and regulatory requirements, which can help avoid subsequent modifications. Under the engineering-to-order strategy, products may still be partially based on standard modules.

5.2.4 Evaluation of new approaches

The researcher evaluated the new approaches by verification and validation processes. The verification included comparison of the approaches contents with the identified development needs from interviews and literature. The researcher carried out the comparison first by careful review of all the gathered material and then by help of case companies and external parties representatives. The later was carried out as part of practical validation process were summary of the identified needs were presented for the representatives.

The validation included theoretical and practical validation. Theoretical validation was executed by ensuring the coherency of constructed approaches with earlier researches. The approaches were constructed based on earlier researches and publications. In addition, the researcher constructed new approaches by applying phases defined in earlier studies on achieving compliance, standard ISO 19600:2014 on compliance management and other literature around safety and supply chain management. Before finishing the approaches, the researcher read the literature review anew and searched complementary sources of literature.

Meetings and discussions with key representatives of case companies and external parties carried out the practical validation. The author presented the identified needs and new approaches to 14 representatives of four case companies by new visits to validate usefulness of the approaches in practice. Representatives from two other companies were unable to participate owing to changes in personnel after earlier visits. Overall, the companies' representatives were satisfied with the structure and contents of the new approaches. The representatives also stated that the ways to more systematically manage safety-related compliance corresponded well to the companies' actual operations and will clarify considerations of their own processes in the future. The companies have agreed to apply the suggested solutions while observing their operations. In addition, the representatives were interested to compare their own identified solutions in managing compliance with safety-related requirements with those applied in other companies and suggested in the literature:

> 'It is interesting to see that we have made a lot but still some essential things are missing.'

In addition, the researcher presented the model for managing compliance with safety-related requirements to both the representatives of four case companies and six representatives of five national external organisations that participated earlier in the research. Representatives from other national external parties were unable to participate owing to changes in personnel after earlier visits. The representatives expressed that the model provides a clear presentation of the management process from both the companies' and external parties' viewpoint. In addition, the case companies' representatives mentioned that they perform similar operations but these are not that systematically presented internally:

> 'We are doing similar things but they are not documented.'

On the other hand, there is problems in Europe as the external parties representatives highlighted:

> 'There is still problems with the requirements and consistency in Europe let alone when it is gone elsewhere in the world.'
>
> 'Cheap machines are brought to Europe from China that do not meet the European demands.'

However, the representatives also highlighted that in reality, product development projects are rarely linear. By contrast, projects are cumbersome and the contents of the phases may need to be executed at several stages of the projects:

> 'The projects do not always follow the water flow model if we have for example applied a wrong standard.'
>
> 'It varies when the demands must be ready interpreted.'

The comments suggest that a constructed visual model simplifies reality and potential users must adapt the model to their own operations. Moreover, important issues to consider are the manner in which responsibilities are determined in projects and justify the reasons for performing certain tasks. Then again, the responsibility issues are emphasised in certain projects:

> 'Customised products must succeed at once. There are no prototypes and problems can go up to the customers.'

According to the companies' representatives, the model presented the expected roles and tasks of external parties in partial contradiction with reality. More specifically, they stated that satisfactory external guidance, guidelines and support for interpretation were sometimes missing in real life. However, they also mentioned that external interpretations are not always desired. The interpretations may be unfavourable for a company, but they are still binding. In proportion, the external parties' representatives believed they were helping companies as much their roles permitted, e.g. directing companies to correct information sources and collectively sharing information. However, the authorities' representatives considered as follows:

> 'It is inappropriate that public parties offer detailed advice to individual company.'

> 'The authority does not always have legal possibilities for example to inform about deficiencies.'

From the viewpoint of representatives at the four case companies, presented safety concerns in product delivery strategies are known but they may be unspoken in practise. However, safety concerns are not univocal. From the perspective of a product safety engineer, the engineering-to-order strategy may be simplest but not the best for a company. In the make-to-order strategy, minor changes to standard product platforms may not actually be small since platforms are well finished. New problems with applying make-to-stock strategy may occur if the expected market area of finished products change and the products need to be re-modified to fulfil new market requirements. In addition, it was highlighted that application of certain product delivery strategy is not unambiguous:

> 'Usually it is a mix of product delivery strategies, for example the skeletal structure is make-to-stock.'

Following the verification and validation processes, the researcher finalised the contents of the approaches. The new approaches were in accordance with the identified needs and coherent with the earlier models and publications. The case

companies' and external parties' representatives suggested revisions related to the contents of the model and safety concerns of the product delivery strategies. More specifically, the revisions were stylisations complementing companies' and external parties' tasks in managing safety-related compliance. Every applier will finally modify the approaches according their operations.

6 DISCUSSION

6.1 Review of key results

6.1.1 Performing compliance management process

This chapter answers the first of the five research questions of this dissertation: how do companies manage compliance with product safety-related requirements? If the companies' products are for global market, then they have two options: to try to comply with all the requirements of all their market areas simultaneously in their products or to customise the products to the different markets. It is important to mention that all the six case companies, considered in this work, are strongly committed to managing compliance. Their representatives expressed their dedication to ensuring compliance with the safety-related requirements. Non-compliance was not an option for the case companies.

The first step to implementing a compliance management process in a company with global operations is that the personnel involved in product development should be aware of both universal product safety requirements and the local requirements of the specific market areas. The results of this research show that compliance management practices can be broadly grouped into following phases: identifying and discovering requirements; interpreting requirements and identifying possible changes in products or operations; decision of compliance and specifying method of compliance; communicating; implementing requirements; and evaluating and monitoring compliance (imitating Henson &Heasman 1998; French & Neighbors 1991). These actual practices, however, may vary depending on whether the company is engaged in new product design or the engineering of existing products.

Representatives from the case companies explained that new local information comes from different sources: customers and via new orders, local units and dealers and benchmarking situations. Indirect knowledge can be acquired, for example, by recruitment, government advisors and consultants (Fletcher & Harris 2010). An important issue is ensuring that the information is properly stored and is accessible available and understandable to all the necessary groups and individuals within the

company. The case companies had systems to manage requirements and product data as well as documented design stages to help the flow of information. However, smaller companies may not have the relevant experience, networks or resources to even acquire the required knowledge (Fletcher & Harris 2010). The lack of an adequate and available system for processing the requirements may also pose a challenge to some manufacturing companies.

The participation of company representatives in the process of drafting requirements also aids the interpretation of the requirements (Tala 2001; Henson & Heasman 1998). In this study, all the case companies are large firms with the requisite opportunities and resources to allow participation in the drafting of requirements, at least at the European level. However, the activities linked to participation in standardisation vary according to the company's product categories. For some products, the level of standardisation is much higher than the rest, and this increases the activity load.

At the national and European level, legislations can be enforced through unions and associations. With regard to standards, the participation may be direct at least at the national level. However, smaller companies usually do not have resources to participate in standardisation. In the EU, the standards play a key role in complementing the legislation. Although complying with the standards is not mandatory in the EU, when a standard is not applied, a company must be able to justify that its solution is as safe as the one recommended in the standard. Overall, the advantages of applying standards have been widely debated in literature and in some participating companies. Not all companies are in favour of wide-ranging standardisation (Baram 2007).

Compliance decisions require that a company choose the requirements to be incorporated into its standard products or modules. The literature, of course, does not provide any simple answers on how to make decisions related to safety issues (Sten 2011). Further, such decisions are also a question of resources, and they may be based on trade-offs between the costs and benefits of safe design (Rausand & Utne 2009). If a standard product is to be used globally, a company decides between complying with the requirements of all market areas simultaneously and customising the product to different markets.

A half of the case companies' representatives mentioned that their standard product platform is based on the European market requirements and one company's that the all the main market areas' requirements are simultaneously taken into account in their standard products. However, the safety aspects of customised products are another issue altogether. The differing safety requirements of product delivery strategies (make-to-stock, assemble-to-order, make-to-order and engineering-to-order) are not commonly considered by companies. The cost-effective manufacturing of compliant products for differing customers and markets calls for a more systematic studying of the safety aspects of different product delivery strategies (see e.g. Olhager 2003).

According to Travis et al. (2008), in implementing the safety requirements, companies should identify and refine legal requirements into product requirements and integrate them into their product design and testing processes. The applied product delivery strategy also plays a key role. Local requirements and needs should be taken into account during the initial design and manufacturing or by the personnel or dealers of the local units. In the latter case, local modifiers should communicate and understand the boundaries of local modifications and seek permissions from the parent company. While a dealer may be legally responsible for ensuring the conformity of the modifications, in case of an accident, the reputation of the original manufacturing may be at stake. Therefore, companies should monitor the operations of subcontractors when considering safety-related responsibilities in longer and more complex supply chains. Confirming this viewpoint, the representatives highlighted the importance of being able to trace all the parties in the company's supply chain. It is important to understand how to control supply chains and how the information moves in a supply chain. Commonly used methods to manage the compliance of subcontractors are uniform requirements, auditions, classifications and quality control. Companies must also invest in education and training to build skills and abilities within the supplier network to assure product safety (Marucheck et al. 2011).

Monitoring and evaluation of compliance is partially verified along the projects. In addition, it is essential to define the responsibilities of complying with the requirements at different stages of the project. The case companies' representatives emphasised that their new product design projects had different milestones or project gates, where compliance with requirements were controlled and safety issues

were discussed. Despite these steps, however, a final evaluation is essential before releasing the product to production. The validity of the information is typically confirmed with help of regions, local contacts in market areas, customers and the company's own maintenance personnel. Participation in different external committees, e.g. of standardisation, helps companies benchmark their own interpretations and practices against others. In addition, external parties are involved to confirm companies' own interpretations. In some cases, the involvement of an external party is also imposed, i.e. in the case of external examination or testing.

6.1.2 Problems in managing compliance

This section answers the second research question: what kind of problems do companies confront in managing compliance with safety-related requirements? The problems somewhat depend on the market area, but in many cases, the key issue is the deficient flow of information. Attaining compliance involves both problems of information management and the technological difficulties of fulfilling the requirements. Several participating representatives admitted that requirements are occasionally discovered by chance, and what should be known is not always known. This also leads to situations where changes have to be made to finished products. It is also possible that the origin of some requirement is not known even though it has been applied for a long time.

The requirements determination process is sometimes difficult when common, global requirements must be extracted from disparate, and potentially conflicting, local needs and priorities (Kirsch & Haney 2014). Further, companies often find it difficult to determine what is comprehensive and what an acceptable safety level is. Participating representatives reported that they were sometimes uncertain about their interpretations of the requirements because of lack of external help. This is particularly problematic because ultimately, the companies themselves are responsible for the safety of the products (and services) they provide (European Commission 2017a). In the EU, authorities do not check all the products and neither do they authorise or approve any products or services. (European Commission 2017a). The companies' representatives admitted that the final confirmation of the interpretation is sometimes obtained only from unwanted event such as a court decision.

The representatives also added that there is typically no extensive or systematic international comparison of the requirements, and the existing information is not located at any one place. Individuals may search for similar information concurrently and repeatedly in a company. However, establishing general and detailed product-specific safety plans could be one solution to promoting awareness of all the safety requirements and how they should be addressed (Rausand & Utne 2009). In addition, international manufacturing strategies (export, multi-domestic, global and transnational) can be useful to understand how one's own operations are organised (see Ketchen & Short 2012; St. John et al. 1999).

Even though legislations within the EU are mostly harmonised, the participating companies found that some practices for companies vary within the EU member countries, and the actions of the authorities is not unified. Most of the companies cited the lack of sufficient market surveillance as a major problem in EU for honest and compliance-oriented operations. Outside the EU, the participating companies' representatives identified the US market as particularly difficult. One reason for this is that the legal traditions are different. Continental Europe is governed by civil law, while the US is governed by a common law (University of California at Berkeley 2016). If an accident or an untoward incident occurs in the US market, the court considers whether the company in question has manufactured safer products for some other markets because of that market's requirements. However, with the current changes in the US political system, it is likely that changes will be seen in opportunities to export and operate in the US for foreign companies. Further, the negotiations of the TTIP agreement for trade and investment between the EU and the US are at a standstill.

In most case companies, the products are modified locally by the local units. However, these local modifications are not always communicated to the parent company, and the local operations are not fully known. This raises the question of responsibility and the validity of the original risk analysis. Not surprisingly, some representatives cannot ascertain who is responsible for overall compliance with the requirements. With regard to overall compliance, confirming the relevance of the requirements and the validity of the translations pose difficulties for evaluating compliance.

6.1.3 Consideration of the external parties' perspectives

This section answers the third research question: what are external parties' expectations, roles and potential effects in supporting and controlling companies to manage compliance with safety-related requirements? This research specifically focused on Finnish and European external parties. These parties have several roles; however, the reality in companies may be far removed from expectations. However, as presented in the developed model (see Figure 4), the external parties should be considered at every phase of the compliance management process.

In Europe, efforts to coordinate machine regulations started in 1984, and the original Machinery Directive finally came into force in 1995 (Egan 2001). Today, the principal instrument for regulating machinery safety in Europe is the Machinery Directive, and it is supplemented by harmonised standards (Rausand & Utne 2009; Baram 2007). The representatives of the European Commission discussed the evaluation of the Machinery Directive in 2015. A revision of the directive will possibly started, and the directive may be transformed into a regulation. Further, there is ongoing programme to make EU laws lighter, simpler and less costly as a whole (European Commission 2017f). In Finland, the European requirements are typically attempted to be noticed literally. However, today the importance of a nation-wide implementation of the EU legislation is decreasing since the trend is to move from directives to immediately enforceable regulations. According to the Finnish external parties, one major hurdle for companies, especially smaller ones, is the knowledge of national and European legislation. However, the national legislators' representatives note that joining the EU has simplified the regulations for machine manufacturing.

Part of the legislative process is that different parties try to lobby for important considerations. Companies operate mainly at the national and European level by influencing requirements. With regard to standardisation, national participation may be direct; however, European and international standardisation can be participated through national standardisation actors (Baram 2007). The external parties' representatives highlighted that an important issue for companies is knowledge of different groups/committees under the departments (DG) of European Commission. Primarily, these groups support in the interpretation of requirements,

and they offer a possibility to effect potential changes in the requirements. Even though there are several co-operative groups, some parties believe that there is not enough cooperation between the different departments and groups in the European Commission. Another point of view is that companies and professional associations should develop self-regulation measures. The self-regulatory approach to industrial safety is a particularly strong in Germany, and these regulations can later be adopted by government regulatory programmes.

A wealth of useful information about compliance can be obtained from export promotion organisations, engineering offices and legal offices. On the subject of compliance-based decisions, external parties emphasise the importance of understanding the nature of legislation. For example, in the EU, the Machinery Directive achieves total harmonisation, while occupational directives define minimum requirements for the EU member countries and are more consultative by nature. In market areas governed by common law, the legal praxis is again more important than legislation (University of California at Berkeley 2016). The representatives of insurance companies added that companies should be aware of which the market company's products are sent to. For instance, they found that it is usually not worthwhile to export to the US with only a small lot of products. In addition, if the operations of a company are to be truly global, they should strictly follow the market area's requirements, and compliance management should be approached through careful risk analysis.

Standards can be vital to market access. The external parties' representatives highlighted that in the EU, the standard system is unique. The European standards are strongly connected to legislation (i.e. harmonised). Thus, they support the implementation of the EU legislation, but they are still voluntary. The aim of the European Commission is to ensure as much harmonisation of standards as possible. However, the goal of standardisation in relation to legislation has been achieved. From companies' point of view, the standardisation organisations' representatives emphasised that companies should have a strategy for standardisation. This should cover, for example, which standardisation committees should be followed, when comments for changes should be sought, and which committees should one participate in. Meeting standards in several different markets may, however, be

expensive and create an entry barrier in a new market, especially for smaller companies (Kaplinsky 2010).

Representatives of national authorities explained that they direct companies to the right information source. However, they found it problematic to find the boundary of being rather authority than consultant. The representatives believed that they should be approachable and share instructions, tools and best practices with the companies. However, they also emphasised that they did not want to serve as affordable consultants, an inspection body or an auditor to the operating companies. The authority's implementation and enforcement of a law can be distinguished by its persuasive or sanctioning rights (Bluff 2011). Authorities' representatives believed that they could be effective through the provision of guidance and without the use of sanctions. However, if sanctions were needed, the authority did not have enough actual power to exercise them (Ayres & Braithwaite 1992).

Manufacturers are primarily responsible for ensuring the compliance of their own products and services (European Commission 2017a; Rausand & Utne 2009). The external parties' representatives expressed that is sometimes difficult to understand that the authorities do not check all the products nor do they authorise or approve any products or services. In the EU, market surveillance is carried out retrospectively, and it is directed stages where risks related to the safety appear. However, the efficient system of market surveillance seems to favour honestly operating companies. Unfortunately, the lack of market surveillance has been highlighted by many parties in Europe. Several parties have noted that as the requirements are mostly unified in the EU, the surveillance should also be unified. This problem has been addressed and changes have been proposed, but they have not met with much acceptance (European Commission 2017a).

6.1.4 Systematic managing of compliance with safety-related requirements

Identification of development needs in compliance management

This section of the chapter partially answers the fourth research question: what aspect needs revision to more systematically manage compliance with safety-related requirements in a global context? The author derived potential existing solutions for typical development in managing compliance by analysing the interview responses from case companies and external parties and by combining these results with perspectives presented in the literature. The missing solutions determined the need to construct new solutions (approaches) for compliance management.

According to the companies' representatives, an important factor in functional compliance management is how the requirements are managed. This may be in the form of a system where the legislative responsibilities are defined and presented for each phase of a new product design project. A company should have a specific, feasible and permanent system to manage requirements, and it should be able to detect the differences between the requirements of its market areas if its products are to be globally marketed. In addition, the monitoring of legislation should be a permanent and continuous activity (Henson & Heasman 1998). An important issue here is also to ensure the functional flow of information about the requirements inside a company and within external parties. Managing compliance effectively requires that tangible and intangible information about global and local safety requirements, their interpretations and safety solutions within organisation are documented as comprehensively as possible.

The management of compliance requires both cooperation within a company and the knowledge of the changes taking place in the business environment (Ratsula 2017, 2016). The representatives of external parties encouraged companies to be aware of the changes as early in the regulatory process as possible by seeking the right channels of information. This also offers companies the possibility to lobby for its own needs. In the EU, the standards are connected with the legislation, and according to the external parties' representatives, a company should have a plan for

standardisation and should decide on which standardisation committees to participate in.

The chosen compliance method is eventually always a company's own estimate (Henson & Heasman 1998; Tala 2001). The final stamp of validity for compliance methods is given in the court, but enforcing authorities, inspection bodies, legal offices, insurance companies, customers and competitors may be valuable sources to pre-empt this knowledge. However, no party can provide certain solutions in advance. A company needs its own internal evaluation on compliance. Sometimes, an externally audited standardised management system is a good framework for ensuring compliance.

Model for managing compliance with safety-related requirements

This section of the chapter partially answers the fifth research question: what kind of model suits managing compliance with safety-related requirements? The researcher constructed, verified and validated a model for managing compliance with safety-related requirements in a global context. Because of the origin of the participating organisations, this research emphasises the European (EU) legislation and practices, but the proposed model is generic and should be of interest to a wider audience. Although the EU represents a unified internal market, the practices of the member countries are varied.

The earlier studies on compliance management were based on requirement-based compliance processes (see Henson & Heasman 1998; French & Neighbors 1991), where the effects of one regulatory requirement were processed at a time. However, the phases for managing compliance, presented in chapter 2.3.1, have also been used as a framework for presenting empirical results. The recommended practices from ISO standard 19600:2014 on compliance management and from ISO standard 15288:2015 have also been considered. In this study, a model was compiled by focusing on product-based compliance management and mainly for new product development. This new point of view also considers external parties as part of the compliance process. The study results show that companies' expectations from the external parties are questionable. Indeed, each of the stages/phases presented in the model has two perspectives: internal and external. The internal perspective illustrates the own actions of the company, and the external perspective presents the role of

the external party and the expectations of a company from the external parties. However, a somewhat difficult issue here is the role of subcontractors who act as external parties but are also involved in the internal processes performed by suppliers. The suppliers should have a similar conception of compliance as the contracting company. According to Marucheck et al. (2011), the contracting companies must invest in education and training to build skills and abilities within the supplier network to ensure product safety.

The compiled model is bipartite. The first part covers the discovering of the requirements and the attempt to influence the requirements that should be a continuous process. Depending on the company, several different persons or units may perform this function. It is valuable for a company to influence the upcoming requirements (e.g. regulation, standards) beforehand (Tala 2001). However, the size and resources of companies may affect their ability to influence the requirements in advance. Larger companies may have specific safety personnel as well as legal units with compliance officers. The management of compliance is rarely a single person's task. The second part of the model focuses on a specific project/process: from the identification of requirements to the evaluation of compliance. According to Dowlatshahi (2001), the design of complex products requires considerable data throughout the design process. The overall discovering of the requirements needs to be complemented with product-/process-related requirements. However, compliance management in not a separate process. An important issue for companies to consider is understanding the connection between product delivery strategies and their safety. When applying the compiled model for managing compliance, one should be aware of the point where the different requirements are supposed to enter the process. The usefulness of the compiled model was studied by presenting it to the representatives of four case companies and five external parties.

Safety concerns in product delivery strategies

This section of the chapter completes the answer to the fourth and fifth research questions: what can be revised in order to manage the compliance with safety-related requirements more systematically in a global context? and, what kind of model suits managing compliance with safety-related requirements? A systematic understanding

of the safety concerns of differing product delivery strategies (make-to-stock, assemble-to-order, make-to-order and engineering-to-order) may help rationalise the compliance management process. A more conscious application of the product delivery strategies may allow companies to structure the safety information and their information analysis practices (Olhager 2003). The interview responses in this study showed that the case companies applied all the four product delivery strategies, but the make-to-stock strategy was not commonly used. Unfortunately, the companies' safety design and the management of safety-related compliance were not entirely consistent with the product delivery strategies. Hence, the author has compiled a summary of the product delivery strategies and practical safety issues associated with each strategy.

Each product delivery strategy presents different challenges and possibilities for safety design and managing compliance. The make-to-stock and the assemble-to-order strategies require thorough knowledge and implementation of all the relevant and general safety requirements long before the order penetration point. The product features are defined based on the forecasted customer demands and the requirements of the anticipated market areas. Possible changes in the products may be difficult and expensive to implement afterwards. Hence, companies should consider whether they want to base their standard product platform on the safety requirements of a single market, or if they want to take into account the requirements of all the main market areas simultaneously (Stark 2011).

Interviewed representatives mentioned that they may also manufacture some standard products for dealers' stocks. Further, a parent company's local units may order a standard product and modify the product to fulfil local requirements and preferences. However, this may lead to problems over the legal responsibility of the modified products. Typically, a dealer is legally responsible for the conformity of the modifications that he/she has made. However, in case of an accident, the original manufacturing company's reputation is usually at risk. From the viewpoint of a dealer or a local unit, these situations may appear more like engineering-to-order or make-to-order projects than make-to-stock projects.

In the manufacturing-to-order and the engineering-to-order strategies, the order penetration point is closer to design. It is possible to identify and analyse customer-specific requirements together with the regulatory requirements. This enables a

company to benefit from its customers' expertise. Postponement relates to an aim to halt supply chain activities, for example, until it receives a customer order (Boone 2007). Postponement of product design and production activities may help companies avoid the risk of tying equity to products that may fail to fulfil all the essential safety requirements. These may require expensive redesign, partial disassembly and reassembly. The failure to find and apply the right and valid requirements may cause severe accident losses as well as product liability costs. On the other hand, postponement may extend the product delivery time.

6.2 Research evaluation

6.2.1 Research contributions

This research has three objectives: (1) to present solutions in managing compliance with safety-related requirements in a global business context; (2) to present problems existing in compliance management; and (3) to construct solutions to effectively managing compliance with safety-related requirements in a global market. The empirical results related to the first and second objectives are presented and titled under phases of compliance management on the basis of earlier models and publications on achieving compliance. To satisfy the third objective, the researcher merges the empirical results with those in the literature to provide new ways to structure operations related to compliance with safety-related requirements. Thus, this study has fulfilled its objectives.

Scientific contributions

There are limited studies on concerning product safety in compliance management, safety issues in supply chains in a global business-to-business context and safety aspects of related product delivery strategies. There are, however, several studies on integrating the design of safe and ergonomic products into engineering design process (see Rausand & Utne 2009; Hale et al. 2007). In addition, Marucheck et al. (2011) has raised the role of regulations and standards in ensuring product safety in global supply chains.

This dissertation contributes to the scientific community by providing a comprehensive overview of the problems and solutions in managing safety-related compliance from the perspectives of machine-manufacturing companies and discusses several external parties' expectations, roles and possibilities in supporting and controlling organisations. Bluff (2011 and 2010) stressed the benefit to better understand the exploitation of external parties in the regulatory process. The author also compared the views of the companies and external parties. Since the external parties were interviewed after the companies, their role was discussed in combination with those for the companies. This research adds to discussion on mutual expectations between different parties and whether these expectations are fulfilled. However, an essential scientific contribution is the new model for managing compliance with safety-related requirements in a global context constructed by the author. This model is drawing on Henson & Heasman's (1998) phases of compliance management process and principles of standards ISO 19600:2014 and ISO 15288:2015. In addition, it regards scientific literature around compliance management and related themes. The model adds new perspectives on views of Marucheck et al. (2011) about ensuring product safety in global supply chains as well as Lee (2002) and Roh et al. (2014) elements for success of supply chains. The author completed the model by constructing safety concerns in product delivery strategies. Product delivery strategies are studied earlier by e.g. Olhager (2003) and Sanchis et al. (2012) but this research provides new perspectives for responsibility issues and scheduling.

The identified solutions and problems of the participating companies' in achieving and managing compliance with safety-related requirements are first categorised under phases of compliance management process by applying previously specified phases of compliance achievement but with certain modifications (see Henson & Heasman 1998; French & Neighbors 1991; ISO 19600:2014). The author then identified development needs to construct the model for managing compliance with safety-related requirements and safety concerns in product delivery strategies. The research reveals that certain key problems are the lack of documentation; insufficient help from authorities; and variations in practices, requirements and enforcement among the EU member countries. Essential solutions are the utilisation of external bodies in interpretation, compliance checks in projects, follow-ups of requirements by product safety personnel and participation in the drafting of requirements and

standards. From the viewpoint of manufacturing companies, this research underlines the need for external help, although the expectations are somewhat unrealistic. From the perspective of external parties, this research highlights that even in the EU, regulatory systems need improvements; particularly, market surveillance is unequal in different member countries. However, the ultimate responsibility for the safety of their products is on companies (European Commission 2017a).

This research gathers existing solutions and provides a new model to manage compliance with safety-related requirements for global context and safety concerns in product delivery strategies. The research combines several theoretical areas such as compliance management, supply chain management and decision-making and adds to the field of safety in areas not yet to be covered in earlier studies.

Practical contributions

This research explores the phenomenon of managing safety-related compliance in a global context using multiple lenses. As a practical contribution, this research offers several results for globally operating companies and external parties. From the companies' perspective, this research contributes to the understanding of problems and solutions in managing safety-related compliance. These results may be applied to operational development. Even though this research focuses on manufacturing companies, the results can be applied to various globally operating companies. The broadly gathered results from many external parties at both the national and EU level enable the development of compliance management processes. First, the results allow for the possibility to develop companies' operations and for comparison of compliance management conceptions among various organisations. While the comparison of conceptions among various external parties was not the original effort of this research, it managed to gather results that are valuable in this sense as well.

The major practical contribution of this research is the constructed new approaches to manage compliance with safety-related requirements more systematically; model for managing compliance with safety-related requirements and related safety concerns in product delivery strategies. The supports globally operating companies to avoid typical problems found in compliance management. In addition, the model clarifies the overall process of compliance management for regulators, authorities, companies and other interest groups. Companies may apply the approaches when

developing their own compliance management processes throughout their global supply chains. As for the external parties, the results of this research present new ways to associate with companies and even new business possibilities to support companies in achieving compliance. In sum, this research's results suggest that an important aim for companies is to be aware of future changes as early as is possible. Further, appropriate connections with proper external parties will help achieve this aim and this research strived to visualise the ensemble from the viewpoint of machine-manufacturing companies. The constructs of this research were validated by representatives of four case companies and five national external organisations. They believed that the model provided a clear presentation of the management process from the viewpoint of both companies and external parties. It will help to structure compliance management actions throughout supply chains.

6.2.2 Research quality

This dissertation adopted qualitative and constructive approaches. Semi-structured interviews and a literature review are utilised as research methods. The research is based on several background theories and subjects related to the study. The author gathered the main material for this study between 2012 and 2015. The results were in 2017 presented to most of the case companies and essential external parties.

The quality of studies is generally measured in reliability, validity, generalisability, and carefulness (Stenbacka 2001). A research must attempt to examine participants' conceptions as precisely as possible. However, traditional measures of reliability and validity may not be directly applicable when data are collected from respondents whose answers may change even in the short run. These may be defined differently. (Hirsjärvi & Hurme 2009) In a qualitative research, rigor is also used as a qualitative term instead of reliability and validity as in the case of quantitative research. Qualitative rigor considers related research as a journey of explanation and discovery that does not lend to rigid boundaries. Rigor provides details to reiterate qualitative research using a different sample. (Thomas & Magilvy 2011) To the effect of qualitative rigor, there are four relevant components of trustworthiness: dependability, credibility, transferability and confirmability (Lincoln & Guba 1985; Thomas & Magilvy 2011).

Reliability denotes the ability of measurement methods to produce the same results repeatedly and the researcher and method are seen as separate from each other. In this sense, the concept of reliability does not hold relevance in measuring qualitative research, where the researcher is always part of the study. (Stenbacka 2001) A researcher may be seen as an instrument of the study and who interacts with the study's subjects (Magilvy & Thomas 2009). To a certain extent, the interviews are a result of cooperation between the interviewer and interviewee(s) (Hirsjärvi & Hurme 2009). However, in qualitative terms, dependability is a related concept that occurs when another researcher is able to follow the same decision trail (Thomas & Magilvy 2011). In addition, the reliability of a qualitative research is associated with researchers' actions; in other words, the extent to which a researcher's analysis can be considered reliable (Hirsjärvi & Hurme 2009).

The basic definition of validity, that is, whether the intended object of measurement is actually measured, is generally described to be futile in qualitative research. This is because the objective of qualitative research is n not to measure factors. When generating an understanding of a studied phenomenon, a researcher is interested in comprehending the reality of other persons on the basis of the studied problem area. The understanding of phenomena is valid if the informants are part of the problem area and the studied persons have the opportunity to freely express their opinions. (Stenbacka 2001) Validity may even be divided into internal and external validity: internal validity describes the accuracy of research, while external validity id the generalisation of results (Hirsjärvi & Hurme 2009; Metsämuuronen 2009). In qualitative terms, internal validity relates to credibility. Achieving credibility requires checking for the representativeness of data as a whole. In comparison, external validity is related to transferability. It denotes the ability to transfer research findings or methods to another group. Confirmability occurs when dependability, credibility and transferability are established. (Thomas & Magilvy 2011) Simply put, measurement processes are subjective when humans select measures as well as collect, analyse and interpret data (Muckler and Seven 1992).

The concepts of generalisability and carefulness may also be applied to qualitative research (Stenbacka 2001). Generalisability is related to a criterion similar to the concept of transferability (Lincoln & Guba 1985). Further, generalisability denotes that results are general in respect to theory, not population, since the concept of a

representative sample is not valid in qualitative research. In analytical generalisation, understanding is based on lifting empirical material to a generic level. (Stenbacka 2001, Yin 1989) It is important to choose informants relevant to the study. In comparison, in carefulness, the researcher must be the most careful and systematic in making processes conscious for him-/herself to describe it to users (Stenbacka 2001).

In this research, dependability was enhanced by comprehensively describing the purposes, subjects and phases of the study; posing clear research questions; and analysing interview data. The credibility was ensured by a wide range of interviewees, the nature of semi-structured theme interviews and the application of several perspectives to examine compliance management. In addition, the researcher had a broad understanding of managing requirements given his earlier research projects. The interview framework was related to this study's objectives and the interviewees from machine manufacturing companies as well as national and European external parties.

According to Stenbacka (2001), it is important to carefully select informants. The researcher utilised data source triangulation in the study using several data targets. In addition, the researcher validated the empirical results by referring to the literature where necessary. Interviews were chosen as the main method to collect empirical data in order to obtain an in-depth understanding of the studied topic. The informants (interviewees) were selected to represent knowledge of product safety-related issues in globally operating machine-manufacturing companies that conduct activities in Finland as well and that of external parties affecting compliance management. The researcher charted the field of compliance management with safety-related requirements at the national and European level to contact suitable external parties. The interviewees also had the opportunity to propose other suitable interviewees during the interviews. Despite the limited number of participating companies, the wide-ranging nature of the interviews increased their credibility. In addition, two of the participating companies (companies A and B) were treated as main case companies whose several units were subject to a broader examination. Overall, a total of 90 interviewees were conducted, of which 37 represented the case companies and 53 were from the external parties.

All of the interviewees were given the opportunity to discuss issues that did not fall under the purview of the prepared interview questions. All the interviews were conducted by the same researcher. The interviewees were assured of confidentially, which further encouraged them to discuss issues they considered important. Every interviewee was given similar opportunities to expressing his/hers opinion. The fact that certain interviewees may not for some reason fully express their opinions must be considered an error in the method.

Given the diversity of the interviewees' background, the research findings are somewhat difficult to transfer to an entirely different application target. However, similar methods may be transferred to another group of interviewees. The interviewees were willing to participate and donate their time to the research, indicating their interested in the subject. On the other hand, different participating companies, such as smaller ones, may have been unable to share their practices on managing compliance globally. This research offers an overview from several viewpoints that improves confirmability. However, the identification of the relevant results and their interpretation are strongly dependent on the researcher. The process of constructing new approaches to systematically manage compliance with safety-related requirements combined prior information and this research's results. The basis for the constructs relies on previous research and the interviewees' perceptions.

The generalisability of research was improved by carefully choosing relevant organisations and interviewees. The interviewees representing the participating parties were all volunteers. The careful description of the research process promotes research quality. The quality of research may be evaluated on the basis of how the research achieves its objectives and answers the research questions. This research achieved both aspects within the research scope possible. The results in Chapter 5 are in line with the objectives and the constructed new approaches meet the identified development needs. The researcher constructed the approaches on basis of scientific literature and interviews of this research and these are coherent with the earlier researches and publications. They were later practically validated with help from the participating organisations representatives of this research. This evaluation process of the new approaches is presented in Chapter 5.2.4. Chapter 6.1 presents the answers to five research questions on the basis of the interviews results and literature review. The author has also published a peer-reviewed article 'A qualitative

examination of safety-related compliance challenges for global manufacturing' (Vasara & Kivistö-Rahnasto 2015) and three peer-reviewed conference papers based on parts of this study which offers the possibility to consider the quality and interest of the results when conducting the research.

6.2.3 Suggestions for further research

There is limited research on managing compliance with safety-related requirements of machines in a global context. This research was conducted from the viewpoint of manufacturing machines intended for use at work with focus on European framework. The participating companies were all large-scaled and safety-oriented actors. In addition, the research accounts for the role of external parties affecting companies such as legislators, authorities and standardization organisations. In doing so, it attempted to offer a broad overview from several viewpoints. However, if the research examined, for example, smaller companies, the results regarding essential problems and practices would probably differ. Further research, thus, is needed to better understand the effects of company size on managing compliance and way to support smaller companies. In addition, the participating companies were all parent companies; therefore, it would be valuable to consider subcontracting parties and customers. More perspectives could also be charted by a survey that covers several industries.

The motivation underpinning this dissertation was the interest in the functionality of regulatory systems in different market areas and development of a more in-depth understanding to help organisations manage compliance with requirements. However, the political and thus, regulatory, situation is likely change. For example, the United Kingdom's upcoming possible exit from the EU will have certain effects on the future of the European internal market. Similarly, the political situation in the United States is likely to influence e.g. European companies' export and local operations. Thus, the topic of compliance management needs to be continuously revised given possible changes that are yet unknown. This research strived to enhance the basic understanding of managing safety-related compliance; however, it is noteworthy that the field is not static. Several boundary conditions may affect compliance management and thus, the sustainability of the present results. Even during the present research period, there were several regulatory changes.

This research offered a model for the overall process of compliance management with emphasises on European legislations and Finnish practices. The participating organisations served as separate volunteer information sources and there was no common research project. Moreover, it was not possible to implement the model in the companies since doing would warrant its own development process and funding. Thus, further research is needed to put these results into practice. More specifically, there is a need to develop a better understanding of product delivery strategies in the context of safety-related issues on the basis of this study's results. A more conscious application of the concept of product delivery strategies might help product safety personnel adopt specific processes for safety information management for each delivery strategy. A suitable strategy would be to conduct an action research in which the researcher is an active member of a participating organisation. Action research allows for influences on the functions and environment of the researched phenomenon and accounts for the entire supply chain and all local units in market areas. Another issue left for future research is the overall role of external parties. Companies' expectations from external parties are not always met. In the EU, for example, the functionality and uniformity of market surveillance has been largely criticised. However, the possibility to participate in, for example, the drafting of requirements, heavily depends on a company's size and resources. Attempts have been made to facilitate various parties' participation in the EU and this work should continue in the future.

7 CONCLUSIONS

This research focuses on managing compliance with product safety-related requirements to enhance the understanding of compliance management in a global context. The empirical results of this research are based on the views of six machine-manufacturing companies' representatives and the problems they encountered in compliance management. In addition, this study considers the viewpoints of 12 national and 6 European external parties affecting companies' operations, including legislators, authorities, standardisation organisations, insurers and organisations supporting companies.

The participating case companies seem to satisfy the EU's general requirements. The European integration has even clarified the requirements for product safety. However, varying country-specific practices and requirements along with their enforcement continue to pose difficulties for companies in the EU and elsewhere. This kind of trend may be increasing. In addition, the possible Brexit will affect the European internal market.

A globally operating company's personnel participating in product development must be aware of both universal product safety requirements and local requirements of the market areas, which is the basis for compliance management in companies. Information required from another market is gathered with help from the company's local units, customers, and dealers and through benchmarking situations with other companies. In addition, a company must be able to detect differences in requirements between countries if its products are intended for global markets. Companies' operations may be categorised by manufacturing strategy. In particular, if a company is multinational and applies a transnational strategy for manufacturing, it must follow functional practices to determine valid requirements. However, a multinational company is more likely to identify and discover local requirements than a company located in one country. If a product is to be globally marketed, a company must decide whether it should comply with requirements of all market areas or customise products to different markets.

A key problem among companies is the lack of external help. Companies are responsible for the safety of their products (and services); however, they also believe

that the lack of external help contributes to their uncertain interpretations. However, the true role and tasks of external parties such as authorities are not always clear, which is also confuses the companies. In the EU, market surveillance is conducted retrospectively and authority does not check all products. Another central problem is the lack of an extensive and systematic international comparison of requirements and the absence of a consolidated system with all information in companies. Thus, information about requirements is sometimes even coincidentally discovered. The problems around flow information relates to both inside and between the units of companies.

According to the results of this research, there is a need to clarify the overall process of managing compliance with safety-related requirements in global context. The literature did not provide feasible solutions for managing product safety-related compliance in several market areas. Hence, using the findings of this research, the researcher constructed new approaches to manage compliance with safety-related requirements. The main part of these approaches is model for managing compliance with safety-related requirements. The approaches will help more systematically manage compliance with safety-related requirements in the global market to ensure new and existing products comply with applicable safety requirements in their intended market areas. The results also emphasise European legislations and practices from a Finnish perspective but the participating companies operate globally. While the proposed constructs are generic, it should be of interest to a wider audience.

Earlier studies examine requirement-based compliance processes while accounting for the effects of one regulatory requirement at a time. In this research, however, the constructed model for compliance management focuses on product-based compliance management processes (see Figure 4). The phases of compliance management are adopted from earlier researches, although they are modified to present the empirical results of this research and serve as a basis for the constructed model. The original main phases are identifying and discovering requirements, interpreting requirements and determining possible changes in products or operations, decision of compliance and specifying compliance methods, communicating, implementing requirements and finally, evaluating and monitoring compliance. Importantly, this research introduces a new viewpoint: that is, it

accounts for external parties as part of the compliance process. Companies' expectations from external parties may be flawed. The representatives of both the case companies and external parties expressed that the constructed model provides a clear presentation of the compliance management process. However, the practices in companies may vary by whether it is focuses on new product design or current product engineering. In addition, in reality, product development projects are seldom linear and the contents of the phases may need to be executed at several stages of the projects.

In addition to the previous results, this dissertation presents the relationship between various product delivery strategies and safety issues. Local requirements and needs may be accounted during the initial design and manufacturing or these requirements may be met locally through a local unit's personnel or dealers. One way of manufacturing compliant products cost-effectively for various customers and markets is by more consciously applying the concept of product delivery strategies. This may help especially product safety personnel adopt a safety-based information management process for each delivery strategy.

In conclusion, this dissertation provides an overview of managing compliance with product safety-related requirements with focus on specific industrial sector and business-to-business products. The research contributes to previous studies by outlining problems and solutions in managing compliance from the perspective companies and presenting several external parties' expectations, roles and possibilities in supporting and controlling companies. The constructed new approaches provide new perspectives for both scientific community and practical appliers. In sum, this research enhances the understanding of managing compliance with safety-related requirements, although this field remains transient owing to regulatory, technical and political changes. The various boundary conditions in compliance management may affect the long-term sustainability of the research's results. However, despite changes in certain aspects, the overall process of compliance management remains more stable.

REFERENCES

2006/42/EC. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery , and amending Directive 95/16/EC. Available: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32006L0042. Accessed on 15th February 2018.

85/374/EEC. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. Available http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.1985.210.01.0029.01.ENG. Accessed on 10th October 2017.

Ahoniemi, L., Mertanen, M., Mäkipää, M., Sievänen, M., Suomala, P. & Ruohonen, M. (2007). Massaräätälöinnillä kilpailukykyä (in Finnish). Teknologiateollisuus ry, Finland, 105 p.

American National Standards Institute. (2017). Standards Portal. Available: https://www.standardsportal.org/default.aspx. Accessed on 5 th September 2017.

Aruoma, O.I. (2006). The impact of food regulation on the food supply chain. Toxicology, 22(1), pp. 119-127.

Australian Government. (2017). Occupational health and safety harmonisation. Available: https://www.jobs.gov.au/occupational-health-and-safety-harmonisation. Accessed on 10 th June 2017.

Austrian Standards. (2018). Fair Business Compliance Certificate. Available: http://www.iso19600.org/en/fair-business-compliance-certificate/. Accessed on 15th January 2018.

Ayres, I., and J. Braithwaite. (1992). Responsive regulation: Transcending the deregulation debate. Oxford: Oxford University Press, 205 p.

Banerjee, A., Sarkar, B. & Mukhopadhyay, S.K. (2012). Multiple decoupling point paradigms in a global supply chain syndrome: a relational analysis. International Journal of Production Research, 50(11), pp. 3051-3065.

Baram, M. (2007). Liability and its influence on designing for product and process safety. Safety Science, 45(1-2), pp. 11-30.

Black, J. (2001). Decentring regulation: Understanding the role of regulation and self-regulation in a 'post-regulatory' world. Current Legal Problems, 54(1), pp. 103-146.

Bluff, E. (2011). Something to Think About – Motivations, Attitudes, Perceptions and Skills in Work Health and Safety. A Review of the Literature on Socio-Psychological Factors and Their Influence on Organisations' and Individuals' Responses to Regulation. Report prepared for Safe Work Australia. Available: https://www.safeworkaustralia.gov.au/system/files/documents/1702/something_to_think_about.pdf. Accessed on 20th April 2017.

Bluff, E. (2010). Occupational Health and Safety in the Design and Manufacture of Plant. PhD Thesis. Available: https://www120.secure.griffith.edu.au/rch/file/22b8975b-fef8-0f8e-8cbf-720df924b344/1/Bluff_2010_02Thesis.pdf. Accessed on 20th April 2017.

Bluff, E. (2004). Regulatory Strategies for the Safe Design of Plant. Working Paper 24. Available: https://digitalcollections.anu.edu.au/bitstream/1885/39959/3/WorkingPaper24.pdf. Accessed on 20th April 2017.

Bluff, E. & R. Johnstone. (2004). The Relationship Between 'Reasonably Practicable' and Risk Management Regulation. Working Paper 27. Available: https://digitalcollections.anu.edu.au/bitstream/1885/42687/2/Pract_RiskManWPfinal.pdfBoone 2007. Accessed on 20th April 2017.

Bogan, C.E. & English, M.J. (1994). Benchmarking for best practices: winning through innovative adaptation. McGraw Hill, New York: McGraw Hill, 312 p.

Braithwaite J. (2002). Restorative Justice and Responsive Regulation. Oxford University Press, New York, 314 p.

Braithwaite, J. (1985). To punish or persuade: Enforcement of coal mine safety. State University of New York Press, New York, 209 p.

Brun, A. & M. Zorzini. (2009). Evaluation of product customization strategies through modularization and postponement. International Journal of Production Economics 120, pp. 205-220.

Burgess, K., Singh, P.J. & Koroglu, R. (2006). Supply chain management: a structured literature review and implications for future research. International Journal of Operations & Production Management, 26(7), pp.703-729.

Carroll, P., and M. McGregor-Lowndes. (2002). Managing Regulatory Compliance. Paper presented at the Current Issues In Regulation: Enforcement and Compliance Conference, Melbourne, September 2-3.

Cemarking. (2017). EU and US Regulations on Instructions for Use: Find the Differences. Available: https://cemarking.net/eu-us-regulations-instructions-use-find-differences-part-2/. Accessed on 5th September 2017.

CEN. (2018). What is a Standard? Available: https://www.cen.eu/work/ENdev/whatisEN/Pages/default.aspx. Accessed on 5th February 2018.

Chang, T.-Y. & Tung F.-W. 2013. Re-engaging with Cultural Engagement: Innovative Product Design of Cultural Field Experience. In Rau, P.L.P. (Ed.), Cross-Cultural Design. Method, Parctise and Case Studies. CCD2013, 5th International Conference, Las Vegas, USA.

Christopher, M. & Peck, H. (2004). Building the Resilient Supply Chain. The International Journal of Logistics Management, 15(2), pp. 1-14.

Denzin, N.K. & Lincoln, Y.S. (2005). Introduction: the discipline and practice of qualitative research. In: Denzin, N.K. & Lincoln, Y.S. (Eds.) The SAGE handbook of qualitative research. Fourth edition. Sage Publications Inc., Thousand Oaks, 767 p., pp. 1–32.

Dowlatshahi, S. (2001). The role of product safety and liability in concurrent engineering. Computers & Industrial Engineering, 41(2), pp. 187-209.

Drahos, P., and J. Braithwaite. (2001). The globalisation of regulation. The Journal of Philosophy, 9 (1), pp. 103-128.

Eads, G.C. & Reuter, P.H. (1985). Designing safer products: corporate responses to product liability law and regulation. The Institute for Civil Justice. The Rand Corporation Santa Monica, California, 40 p.

EFTA. (2017). About EFTA. Available: http://www.efta.int/ Accessed on 10th september 2017.

El Kharbili, M., S. Stein, I. Markovic & E. Pulvermüller. (2008). Towards a Framework for Semantic Business Process Compliance Management. Proceedings of GRCIS 2008, Montpellier, June 17.

Ernst, R. & Kamrad, B. (2000). Evaluation of supply chain structures through modularization and postponement. European Journal of Operational Research, 124(3), pp. 495-510.

Eskola, J. & Suoranta, J. (2014). Johdatus laadulliseen tutkimukseen (in Finnish). Kustannusosakeyhtiö Vastapaino, 266 p.

European Commission. (2019a). The Transatlantic Trade and Investment Partnership (TTIP). https://ec.europa.eu/trade/policy/in-focus/ttip/ Accessed on 10th October 2019.

European Commission. (2019b). Machinery Directive – revision. https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-6426989_en. Available: Accessed on 20th March 2019.

European Commission. (2018). CE marking. Available: https://ec.europa.eu/growth/single-market/ce-marking_en. Accessed on 5th February 2018.

European Commission. (2017a). The implementation of market surveillance in Europe. Available: https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en. Accessed on 5 th September 2017.

European Commission. (2017b). Notified Bodies. Available: https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en. Accessed on 2nd September 2017.

European Commission. (2017c). EU Machinery Legislation. Available: http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en. Accessed on 2nd September 2017.

European Commission. (2017d). Liability of defective products. Available: https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/liability-defective-products_en. Accessed on 5 th September 2017.

European Commission. (2017e). European standards. Available: https://ec.europa.eu/growth/single-market/european-standards_en. Accessed on 5 th September 2017.

European Commission. (2017f). Refit – making EU law simpler and less costly. Available: https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-and-less-costly_en. Accessed on 5 th September 2017.

European Commission. (2017g). Transatlantic Trade and Investment Partnership. Available: http://ec.europa.eu/trade/policy/in-focus/ttip/. Accessed on 1st January 2017.

European Commission. (2017h). The European Single Market. Available: https://ec.europa.eu/growth/single-market_en. Accessed on 1 st January 2017.

European Commission. (2017i). Mutual Recognition Agreements. Available: https://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_en. Accessed on 15 th May 2017.

European Commission. (2016a). Mechanical Engineering. Available: https://ec.europa.eu/growth/sectors/mechanical-engineering_en. Accessed on 10th October 2017.

European Commission. (2016b). The 'Blue Guide' on the implementation of EU products rules 2016. Official Journal of the European Union, 2016/C272/01.

European Commission. (2016c). Public consultation on the evaluation of the Machinery Directive 2006/42/EC. Available: http://ec.europa.eu/growth/content/public-consultation-evaluation-machinery-directive-200642ec-0_en. Accessed on 10th June 2017.

European Council. (2017). New product safety and market surveillance rules. Available: http://www.consilium.europa.eu/en/policies/product-safety-market-surveillance/. Accessed on 5th September 2017.

European Parliament. (2017). Fact Sheets on the European Union: Free movement of goods. Available: http://www.europarl.europa.eu/atyourservice/en/displayFtu.html?ftuId=FTU_3.1.2.html. Accessed on 10th September 2017.

European Union. (2018a). European Commission. Available: https://europa.eu/european-union/about-eu/institutions-bodies/european-commission_en. Accessed on 15th January 2018.

European Union. (2018b). The EU in brief. Available: https://europa.eu/european-union/about-eu/eu-in-brief_en. Accessed on 15th January 2018.

Europedia. (2011). EU common standardisation and certification policy. Available: http://www.europedia.moussis.eu/books/Book_2/3/6/02/3/?all=1. Accessed on 5th September 2017.

Fletcher, M. & Harris, S. (2012). Knowledge acquisition for the internationalization of the smaller firm: Content and sources. International Business Review, 21(4), pp. 631-647.

Fogliatto, F. S., G. J. C. da Silveira & D. Borenstein. (2012). The mass customization decade: An updated review of the literature. International Journal of Production Economics, 138(1), pp. 14-25.

Fraser, I. (2010). Guide to application of the Machinery Directive 2006/42/EC. 2nd Edition. European Commission Enterprise and Industry. Available: http://ec.europa.eu/DocsRoom/documents/9483. Accessed on 10th October 2017.

French, M.T. & Neighbors, D. M. (1991). A model of firm costs of compliance with food labeling regulations. In Caswell, J. A. (Ed.) Economics of Food Safety. Elsevier Science Publishing Co., New York, 355 p., pp. 295-325.

Glenn, H.P. (2014). Legal Traditions of the World: Sustainable diversity in law. Oxford University Press, 456 p.

Gosling, J. & M. Naim. (2009). Engineer-to-order supply chain management: A literature review and research agenda. International Journal of Production Economics, 122(2), pp. 741-754.

Gray, W. & Scholz, J. (1993). Does Regulatory Enforcement Work? A panel analysis of OSHA enforcement. Law Society Review, 27 (1), pp. 177-213.

Hale, A., D. Borys, and M. Adams. (2011). Regulatory Overload: A Behavioral Analysis of Regulatory Compliance, Working paper 11-47. Arlington, Mercatus Center, George Mason University.

Hale, A., B. Kirwan & U. Kjellén. (2007). Safe by design: where are we now? Safety Science, 45(1-2), pp. 305-327.

Health and Safety Executive. (2017). Declaration of Conformity. Available: http://www.hse.gov.uk/work-equipment-machinery/declaration-conformity.htm. Accessed on 10 th June 2017.

Henson, S. & M. Heasman. (1998). Food safety regulation and the firm: understanding the compliance process. Food Policy, 23 (1), pp. 9-23.

Hirsjärvi, S. & Hurme, H. (2009) Tutkimushaastattelu. Teemahaastattelun teoria ja Käytäntö (in Finnish). Gaudeamus Helsinki University Press, Helsinki, 213 p.

Holloway, C.M. & Johnson, C.W. (2014). Towards Assessing Necessary Competence. A position statement. Available: https://arxiv.org/ftp/arxiv/papers/1404/1404.6803.pdf. Accessed on 5 th September 2017.

Idox. (2018). Certification of your compliance management system according to ISO 19600. Available: https://www.compliance.idoxgroup.com/en/compliance-solutions/management-support/support-optimisation/iso-19600-certification.html. Accessed on 15th January 2017.

ILO. (2019). About the ILO. Available: https://www.ilo.org/global/lang--en/index.htm. Accessed on 20th February 2019

ILO. (2017a). Occupational safety and health country profile: Australia. Available: http://www.ilo.org/safework/countries/asia/australia/lang--en/index.htm. Accessed on 10th April 2018.

ILO. (2017b). Labour Inspection Convention, 1947 (No. 81). Available: https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12100:0::NO::P12100_ILO_CODE:C081. Accessed on 20th February 2019.

ILO. (2001). Guidelines on occupational safety and health management systems ILO-OSH 2001. Available: http://www.ilo.org/wcmsp5/groups/public/@ed_protect/@protrav/@safework/documents/normativeinstrument/wcms_107727.pdf. Accessed on 10th February 2019.

ISO 45001:2018. Occupational health and safety management systems - Requirements with guidance for use. International Organization for Standardization, Genava, Switzerland, 41 p.

ISO 9000:2015. Quality management systems. Fundamentals and vocabulary. International Organization for Standardization, Genava, Switzerland, 57 p.

ISO 15288:2015. Systems and software engineering – System life cycle processes. International Organization for Standardization, Genava, Switzerland, 108 p.

ISO 19600:2014. Compliance management systems – Guidelines. International Organization for Standardization, Genava, Switzerland, 28 p.

ISO 12100:2010. Safety of machinery – General principles for design: Risk assessment and risk reduction. International Organization for Standardization, Genava, Switzerland, 77 p.

ISO 31000:2009. Risk management – principles and guidelines. International Organization for Standardization, Genava, Switzerland, 24 p.

ISO/IEC Guide 51:2014. Safety aspects – Guidelines for their inclusion in standards. International Organization for Standardization, Genava, Switzerland, 15 p.

ISO. (2019). Management system standards Available: https://www.iso.org/management-system-standards.html Accessed on 20th February 2019.

ISO. (2017). ANSI United States. Available: https://www.iso.org/member/2188.html. Accessed on 5th September 2017.

ISO. (2014) New ISO standard on compliance management cuts challenges and costs. Available: https://www.iso.org/news/2014/12/Ref1919.html. Accessed on 5th August 2018.

Johnson, C.W. (2012) The competency gap: the failure of regulation in workplace safety. WOS 2012 Book of Abstracts. In 6th International Conference Working on Safety, September 11-14 2012, Sopot, Poland.

Kara, S. & Kayis, B. (2004). Manufacturing flexibility and variability: an overview. Journal of Manufacturing Technology Management, 15(6), pp.466-478.

Kara, S., B. Kayis & S. O'Kane. 2002. The Role of Human Factors in Flexibility Management: A Survey. Human Factors and Ergonomics in Manufacturing, 12 (1), pp. 75-119.

Kasanen, E., Lukka, K. & Siitonen, A. (1991). Konstruktiivinen tutkimusote liiketaloustieteessä (in Finnish). Liiketaloudellinen aikakauskirja, 40(3), pp. 301-329.

Kasanen, E., Lukka, K. & Siitonen, A. (1993). The constructive approach in management accounting research. Journal of Management Accounting Research, 5, pp. 243-264.

Ketchen, D. & J. Short. (2012). Strategic Management: Evaluation and Execution. Available: http://2012books.lardbucket.org/books/strategic-management-evaluation-and-execution/index.htmlKirsch and Haney 2014. Accessed on 10th June 2017.

Khan, O., Christopher, M. & Burnes, B. (2008). The impact of product design on suplly chain risk: a case study. International Journal of Physical Distribution & Logistics Management, 38(5), pp. 412-432.

Kivistö-Rahnasto, J. (2000). Machine safety design. An approach fullfilling European safety requirents. VTT Publications 411. Otamedia Oy, Espoo, 99 p.

Lee, H.L. (2002). Aligning Supply Chain Strategies with Product Uncertainties. California Management Review, 44(3), pp. 105–119.

Lincoln, Y.S., & Guba, E. G. (1985). Naturalistic inquiry. Sage Publications, USA, 417 p.

Lu, R., S. Sadiq. & G. Governatori. (2008). Compliance Aware Business Process Design. In ter Hofstede, A., Benatallah, B. & H.-Y. Paik (Eds.). Business Process Management Workshops. Springer-Verlag, Berlin, 522 p., pp. 120-131.

Lucas, J.R. (1993). Responsibility. Oxford University Press, 306 p.

Lummus, R.R. & Vokurka, R.J. (1999). Defining supply chain management: a historical perspective and practical guidelines. Industrial Management & Data Systems, 99(1), pp.11-17.

Macdonald, D. (2004). Practical Machinery Safety. Newness, Burlington, 304 p.

Magilvy, J. K., & Thomas, E. (2009). A first qualitative project: Qualitative descriptive design for novice researchers. Journal for Specialists in Pediatric Nursing, 14(4), pp. 298–300.

March, J.G. & Simon, H.A. (1993). Organizations (2nd edition). Cambridge, MA, Oxford: Blackwell, 287 p.

Marucheck, A., N. Greis, C. Mena & L. Cai. (2011). Product safety and security in the global supply chain: Issues, challenges and research opportunities. Journal of Operations Management, 29(7-8), pp. 707-720.

May, P. J. (2004). Compliance Motivations: Affirmative and Negative Bases. Law & Society Review, 38 (1), pp. 41-68.

McRoberts, S. (2005). Risk management of product safety. In 2005 IEEE Symposium on Product Safety Engineering, October 3-4, 2005, Schaumberg, USA.

Mentzer, J. T., W. DeWitt, J. S. Keebler, S. Min, N. W. Nix, C. D. Smith & Z. G. Zacharia. (2001). Defining supply chain management. Journal of Business Logistics, 22(2), pp. 1-25.

Metsämuuronen, J. (2009). Tutkimuksen tekemisen perusteet ihmistieteissä (in Finnish). International Methelp Oy, 1632 s.

Ministry of Economic Affairs and Employment. (2017). Product safety and market surveillance package. Available: http://tem.fi/en/product-safety. Accessed on

Mondaq. (2017). Developments In US Product Liability Law And The Issues Relevant To Foreign Manufacturers. Available: http://www.mondaq.com/unitedstates/x/89684/Product+Liability+Safety/Developments+In+US+Product+Liability+Law+And+The+Issues+Relevant+To+Foreign+Manufacturers. Accessed on 10th September 2017.

Mononen, M. (2004). Yritysten välinen tuotevastuu (in Finnish). Talentum Media Oy, 346 p.

Muckler, F.A. & Seven, S.A. (1992). Selecting Performance Measures: "Objective" versus "Subjective" Measurement. Human Factors: The Journal of the Human Factors and Ergonomics Society, 34(4), pp. 441-455.

Murthy, D.N.P., Rausand, M. & Østerås, T. (2008). Product Reliability: Specification and Performance. Springer, London, 284 p.

National Research Centre for Occupational Health and Safety Regulation. (2002). Towards a Regulatory Regime for Safe Design. A review of regulatory approaches and enforcement strategies. Available: http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/288/TowardsARegulatoryRegimeForSafeDesign_2000_PDF.pdf. Accessed on 12th June 2017.

Naylor, J.B., Naim, M.M. & Berry, D. (1999). Leagility: Integrating the lean and agile manufacturing paradigms in the total supply chain. International Journal of Production Economics, 62(1-2), pp. 107-118.

New England Chapter of the System Safety Society. (2002). System Safety: A Science and Technology Primer. 40 p.

Niiniluoto, I. (2002). Johdatus tieteen filosofiaan (in Finnish). Otavan Kirjapaino Oy, Keuruu, 314 p.

Occupational Safety and Health Administration. (2008). Koneturvallisuus: Koneiden tekniset vaatimukset ja vaatimustenmukaisuus (in Finnish). Available: https://www.tyosuojelu.fi/documents/14660/2426906/Koneturvallisuus_tso_16-2009.pdf/6ae406a0-29fc-45fa-a4a6-19e38af399cc.Accessed on 15th May 2017.

Office of the United States Trade Representative. (2017). Transatlantic Trade and Investment Partnership. Available: https://ustr.gov/ttip. Accessed on 2nd September 2017.

Olhager, J. (2003). Strategic positioning of the order penetration point. International Journal of Production Economics, 85(3), pp. 319-329.

Olkkonen, T. (1994). Johdatus teolisuustalouden tutkimustyöhön (in Finnish). Aalto-yliopisto, Perustieteiden korkeakoulu, Tuotantotalouden laitoksen kirjasto, 143 p.

Pahl, G. & Beitz, W. (1992). Koneensuunnitteluoppi (translated in Finnish). Original book: Konstruktionslehre, Handbuch für Studium und Praxis. WSOY:n graafiset laitokset, Porvoo, 608 p.

Raisch, M.J. (2006). Religious Legal Systems in Comparative Law: A Guide to Introductory Research. Available: http://www.nyulawglobal.org/globalex/Religious_Legal_Systems.html. Accessed on 10th December 2017.

Ratsula, N. (2017). Code of Conduct (in Finnish). Available: http://www.codeofconduct.fi/. Accessed on 2nd February 2018.

Ratsula, N. (2016). Compliance – Eettinen ja vastuullinen liike-toiminta (in Finnish). E-book: Talentum.

Rausand, M. & I. B. Utne. (2009). Product safety – Principles and practices in a life cycle perspective. Safety Science, 47(7), pp. 939-947.

Reimann, M. (2003a). Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard? The American Journal of Comparative Law, 51(4), pp. 751-838.

Reimann, M. (2003b). Product Liability in a Global Context: the Hollow Victory of the European Model. European Review of Private Law, 11(2), pp. 128-154.

Roh, J., Hing. P. & Min, H. (2014). Implementation of a responsive supply chain strategy in global complexity: The case of manufacturing firms. International Journal of Production Economics, 147(Part B), pp. 198-210.

Ryan, N. (1996). A Comparison of Three Approaches to Programme Implementation. International Journal of Public Sector Management, 9(4), pp. 34 – 41.

Sanchis, R., E. Saiz, E. Castellano, and R. Poler. (2012). Order Fulfilment Strategies in the Capital Goods Sector. An Empirical Research. In Sethi, S. P., Bogataj, M. & Ros-McDonnel, L. (Eds.). Industrial Engineering: Innovative Network. Proceedings of the 5th International Conference on Industrial Engineering and Industrial Management. Springer-Verlag, London, 398 p., pp. 257-264.

Sadiq, S. & G. Governatori. (2010). Managing Regulatory Compliance in Business Processes. In vom Brocke, J. & Rosemann, M. (Eds.). Handbook on Business Process Management 2. Strategic Alignment, Governance, People and Culture. Springer-Verlag, Berlin, 616 p., pp. 265-287.

Sheffi, Y. & Rice Jr. J.B. (2005). A Supply Chain View of the Resilient Enterprise. MIT Sloan Management Review, 47(1), pp. 41-48.

Stark, J. (2011). Product Lifecycle Management: 21st Century Paradigm for Product Realisation. Springer-Verlag, London, 562 p.

Sten, T. (2011). Methods of Safety Decision Making. Available: http://www.iloencyclopaedia.org/component/k2/item/985-methods-of-safety-decision-making. Accessed on 15th May 2017.

Stenbacka, C. (2001). Qualitative research requires quality concepts of its own. Management Decision, 39(7), pp. 551-556.

St. John, C. H., S. T. Young, and J. L. Miller. (1999). Coordinating Manufacturing and Marketing in International Firms. Journal of World Business, 34 (2), pp. 109-127.

Subramaniam, M. & N. Venkatraman. (2001). Determinants of Transnational New Product Development Capability: Testing the Influence of Transferring and Deploying Tacit Overseas Knowledge. Strategic Management Journal, 22 (4), pp. 359-378.

Sutinen, J. G. & K. Kuperan. (1999). A socio-economic theory of regulatory compliance. International Journal of Social Economics, 26 (1), pp. 174-193.

Swaminathan, J.M. & Lee, H.L. (2003). Design for Postponement. Handbooks in Operations Research and Management Science, 11, pp. 199-226.

Tala, J. (2008). Selvitys vaihtoehtojen hyödyntämisestä erityisesti yrityksiin vaikuttavan lainsäädännön valmistelussa (in Finnish). Available: https://tem.fi/documents/1410877/2608155/S%C3%A4%C3%A4ntelyn_vaihtoehdot.pdf/1b3259ef-cd9c-4d95-97d3-46123697dfff. Accessed on 20th May 2017.

Tala, J. (2005). Lakien laadinta ja vaikutukset (in Finnish). Edita Publishing Oy, Finland, 250 p.

Tala, J. (2001). The effects of legislation: Objectives of a Law Reform and their Realization from the Perspective of the Theory on Legislation (in Finnish). Oikeuspoliittisen tutkimuslaitoksen julkaisuja 177, Hakapaino Oy, Helsinki, 380 p.

Tallberg, J. (2002). Paths to Compliance: Enforcement, Management, and the European Union. International Organization, 56(3), pp. 609-643.

Tan, K.C. (2001). A framework of supply chain management literature. European Journal of Purchasing & Supply Management, 7(1), pp. 39-48.

Technopolis Group. (2017). Evaluation of European Machinery Directive. Available: http://www.technopolis-group.com/new-report-evaluation-european-machinery-directive/. Accessed on 10th February 2018.

Thomas, E.T. & Magilvy, J.K. (2011). Qualitative Rigor or Research Validity in Qualitative Research. Journal for Specialists in Pediatric Nursing, 16(2), pp. 151-155.

TÜV SÜD United Kingdom. (2017). Machinery Directive - 2006/42/EC. Available: https://www.tuv-sud.co.uk/uk-en/product-certification/european-approvals/ce-marking-gain-access-to-the-european-market/machinery-directive-2006-42-ec. Accessed on 2nd September 2017.

Trienekens, J. & Zuurbier, P. (2008). Quality and safety standards in the food industry, developments and challenges. International Journal of Production Economics, 113(1), pp. 107-122.

United States Government. (2017). How Laws Are Made and How to Research Them. Available: https://www.usa.gov/how-laws-are-made. Accessed on 5th September 2017.

University of California at Berkeley. (2016). The Robbins Collection. Available: https://www.law.berkeley.edu/library/robbins/overview_collection.html. Accessed on 15th November 2017.

van Hoek, R.I. (2001). The rediscovery of postponement a literature review and directions for research. Journal of Operations Management, 19(2), pp. 161-184.

Vasara, J. & Kivistö-Rahnasto, J. (2015). A qualitative examination of safety-related compliance challenges for global manufacturing. Theoretical Issues in Ergonomics Science, 16(4), pp. 429-446.

Wang, F. & Xiaohua, L. (2010). Three-dimensional model of customer order decoupling point position in mass customisation. International Journal of Production Research, 48(13), pp- 3741-3757.

Wikner, J. & M. Rudberg. (2005). Integrating production and engineering perspectives on the customer order decoupling point. International Journal of Operations & Production Management, 25 (7), pp. 623-641.

Yin, R.K. (2013). Case Study Research: Design and Methods, 5th edition. Sage Publications, USA, 213 p.

Äijö, T., Kuivalainen, O., Saarenketo, S., Lindqvist, J. & Hanninen, H. (2005). Internationalization handbook for the software business. Available: https://www.lut.fi/documents/27578/101342/internationalization-handbook-for-+the-software-business.pdf/3caa0aef-4f81-47b1-bf6d-50cc2c7d5985. Accessed on 10th June 2017.