



Article

Defining Material Compliance—A Comprehensive Analysis

Lorena Buckreus ¹, Anne-Kathrin Nuffer ^{2,*}, Robert Mieke ² and Alexander Sauer ^{1,2}

¹ Institute for Energy Efficiency in Production (EEP), University of Stuttgart, 70569 Stuttgart, Germany; lorena.buckreus@ipa-extern.fraunhofer.de (L.B.); alexander.sauer@ipa.fraunhofer.de (A.S.)

² Fraunhofer Institute for Manufacturing Engineering and Automation IPA, University of Stuttgart, 70569 Stuttgart, Germany; robert.mieke@ipa.fraunhofer.de

* Correspondence: anne-kathrin.nuffer@ipa.fraunhofer.de

Abstract: The increase in the number of environmental regulations has resulted in great challenges for corporations in the manufacturing industry, especially within the electronic and electrical and the mechanical engineering sector. To address these compliance requirements, specialized management fields such as environmental compliance, substructures and management approaches have been implemented in industry. Recently, adherence to requirements concerning the composition of products and the use of materials and substances within products has become increasingly important and is referred to as material compliance (MC). Although the topic is of increasing importance, there is no generally accepted definition for MC nor a management framework. Corporations are thus unable to systematically address MC, and compliance violations occur frequently. We derived a definition for MC based on extensive literature research, which we subsequently evaluated in a quantitative survey. Our results indicate that MC is commonly understood as the adherence to requirements concerning the composition of a product and the use of substances and materials within products. By proposing a definition for MC, we aim to introduce a common understanding, enable future research to systematically address the topic and develop a framework for the management of MC.

Keywords: material compliance; environmental compliance; product compliance; hazardous materials management; hazardous substance management



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1. Introduction

Ensuring compliance (the conformity of a corporation with rules, e.g., laws and legislations [1–3]) is of increasing importance. This is mainly driven by the large amount, growing number and stricter enforcement of legal and regulatory rules [4,5]. The rising complexity makes it increasingly difficult for corporations to ensure their conformity with the abundance of existing requirements [3]. Furthermore, violations can have considerable adverse effects such as high monetary fines, loss of the operating license and other legal claims, which might even result in existential threats for the respective corporation [2]. Due to the increased awareness of the public and business partners, violations may further lead to indirect costs caused by reputational damages [2,4]. Consequently, ensuring compliance has become a crucial factor for corporate success [4,6].

As rules address increasingly specific topics, distinct compliance sub-types have emerged, which are continuously diversifying. Compliance can thus be considered as an umbrella term, which includes several sub-types of compliance such as environmental compliance, product compliance, import compliance, etc., each addressing the conformity with rules regarding a specific subject.

While ensuring overall compliance is crucial for each corporation, the composition of relevant sub-types, which the respective corporations must consider to ensure overall compliance, might differ with regard to the respective corporate background and industry sector.

In the manufacturing industry, the term Material Compliance (MC) has emerged and is used to describe the adherence to requirements concerning a products composition and the use of substances and materials within products. The VDMA, for example, which represents the interests of the mechanical engineering industry [7], uses the term to describe the conformity with product requirements arising from the REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) regulation ((EC) No 1907/2006) and the RoHS (Restriction of the use of certain Hazardous Substances) directive (2011/65/EU) [8]. While MC is a relatively new topic in research [9], its practical importance for industry is increasing rapidly. According to Müller [9], the number of product-related regulations concerning chemical substances in products considerably increased between 2003 and 2019 (factor five) and made up the largest part of the total amount of environmental regulations in 2019. Figure 1 demonstrates that corporations faced a continuous increase in the complexity of the regulatory environment and the number of legislations and requirements concerning the composition of products and the use of substances and materials within products and other environmental requirements throughout the past years [10,11].

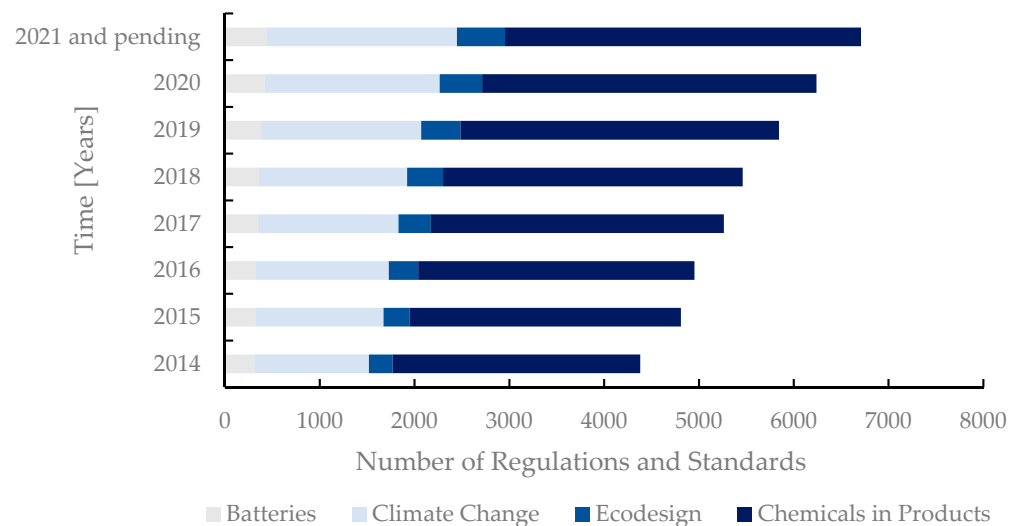


Figure 1. Development of the introduction of regulations and standards concerning the composition of products and the use of materials/substances within products and other environmental requirements (own illustration according to data retrieved from the Compliance2Product platform (C2P) on 11 October 2021) [12].

Aside from this evident increase, a further accelerated introduction of new restrictions can be expected [13], e.g., due to the expanding activities of the respective authorities such as the European Chemicals Agency, which is responsible for implementing the European Union's chemical legislation [14,15].

Geographically varying legislation and requirements, the continuous modification and adaptation of legislation [11,16] and diverging customer requirements [9,17] further complicate the assurance of compliance with product-related requirements.

Previous studies have already demonstrated that the rising requirements result in demanding tasks and challenges for corporations in the manufacturing industry. The lack of knowledge about relevant requirements and necessary information, e.g., through the loss of information throughout the supply chain or the unavailability of information due to an insufficient data management, pose major challenges [9,11,18,19]. From a management perspective, the insufficient designation of responsibilities as well as the lack of organizational or technical approaches to systematically address the assurance of compliance results in demanding tasks for corporations [9,11,19].

At the same time, the potential negative impacts of non-compliance on corporations or responsible individuals are significant [20], including high fines, criminal charges, marketing bans, loss of market access, revenues, and reputation [9,20], to name only a few.

Nevertheless, the results of several studies show that violations within this field frequently occur [21–23]. This demonstrates that, while the possible consequences of compliance violations in this subfield are threatening, corporations struggle to meet the respective requirements or deliberately accept the risks arising from marketing non-compliant products.

While the assurance of compliance with requirements concerning a products composition or the use of materials and substances within products is primarily a corporate topic, its societal implications should not be underestimated. Supporting corporations in their endeavors to ensure compliance with the requirements in this subfield contributes to overall societal welfare. The reason is that the respective requirements often aim to protect the environment or human health (e.g., (EC) No 1907/2006, article 1 REACH regulation and 2011/65/EU, article 1 RoHS directive). Avoiding compliance violations is thus of immediate importance to ensure economic, environmental and social welfare, e.g., by avoiding hazardous substances that pollute the environment or threaten human health or the extraction of resources that supports armed conflicts. Despite its importance for industrial corporate practice, the number of publications and scientific literature findings concerning MC are only marginal. There is no adequate management framework, nor has a generally accepted definition for MC been established. Existing definitions primarily represent the respective author's subjective understanding of MC as they are commonly not based on scientific considerations or the use of scientific methods. In contrast to this, we aimed to elaborate a definition for MC with a high degree of objectivity by basing it on the results of an explorative literature review and evaluating it using a quantitative survey.

As of now, the precise meaning and adequate operationalization of MC within corporations is unclear. This paper addresses this research gap and aims to provide a common understanding of the term MC, thereby paving the way for the systematic development of a comprehensive management framework.

2. Materials and Methods

Through the conduction of a literature review, we comprehensively analyzed the use and the presented understanding of the term in literature. Relevant records were identified following a search string according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Records were identified by searching for the term “material compliance” and combinations of this term with “hazardous materials management”, “environmental management”, “environmental compliance”, “product compliance” and “hazardous substance management”. All records addressing medicinal topics or functional properties of materials were excluded as they were out of scope for this research. Only sources which addressed the management of substances and/or materials in industry and specifically used the term MC were included. Based on the findings of this explorative analysis of literature, a definition was elaborated.

A quantitative survey further assessed the understanding of MC in industry and whether there was some consensus about the meaning of MC. The accuracy of the elaborated definition was evaluated directly by the participants of the survey during its conduction and further assessed by comparing the definition with the understanding of MC in industry, which was analyzed through the survey. The results presented in this paper were derived within the frame of a more extensive internal study addressing MC. The relevant excerpts of the questionnaire are included in the Appendix A of this paper.

We excluded sensitive information about the corporations such as their management form and ownership structure and the respective parts of the questionnaire used to obtain this information.

The data retrieved from the survey were then statistically analyzed and interpreted. The research process of this study is illustrated in Figure 2.

Due to the large mechanical engineering and electrical and electronics sector in Germany (approximately 2248 corporations [24]), the selection of a sample ($n = 24$) was necessary [25]. The sample size was considered sufficient as professionals, working practically within the field of MC, were selected as interviewees. Their opinions thus provide valuable

insights into the practical understanding of MC. Concerning the scope and possibilities of the study, it was determined that the intentional selection of elements that were to be included in the survey was a functional approach, as we aimed to provide first insights into a relatively unexplored research area [26].

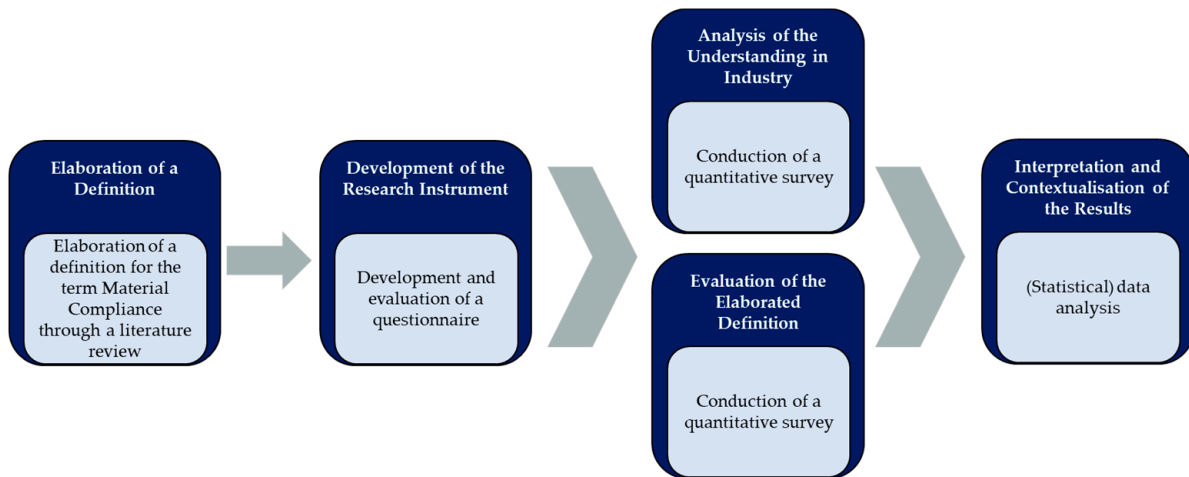


Figure 2. Demonstration of the research process of this study (own presentation).

To receive access to suitable elements of the target group, participants of the expert forum “Global Environmental Compliance”, an industry working group which addresses MC and is regularly organized by the Fraunhofer Institute for Manufacturing Engineering and Automation IPA, were asked to participate in the survey and represent their employer (corporations belonging to the mechanical engineering or electrical and electronics sector). The participants of the expert forum were considered suitable representatives of the respective corporations, as they are professionally involved in the management of MC and are familiar with the topic. It was thus expected that they can provide the required information and complete the questionnaire. The questionnaire was evaluated and revised through the conduction of a pre-test, prior to the actual survey.

A standardized survey [27] was conducted by combining an online questionnaire (created with the CRM-system CAS genesisWorld X11 (CAS genesisWorld X11, version V21.1.6.11811, <https://www.cas-mittelstand.de>, accessed on 18 June 2021)) with a phone interview. This combination was meant to ensure higher response rates by increasing the binding character of the survey [28]. Simultaneously, this allowed the use of complex questions as comprehensive problems could be solved directly during telephone interviews [29] and questions could be supported visually using the online questionnaire [30].

The interviews were conducted using Microsoft Teams (Microsoft Teams, Version 1.4.00.11161, <https://www.microsoft.com/de-de/microsoft-teams/download-app>, accessed on 18 June 2021). During the interview, the camera was turned off, the interviewer opened the online questionnaire and shared the desktop with the participant so that the participant could view the questionnaire. The questions were then read to the participants by the interviewer, who noted the answers.

To acquire unbiased answers, the participants’ understanding of MC was assessed first. The participants were asked to state what was understood under the term MC in the respective corporation in their own words. The provided answers were quantified using a qualitative content analysis, which was conducted using the program MAXQDA Analytics Pro 2020 Network. Categories were inductively derived from the obtained data [31]; subsequently, their frequency was determined, which allowed for a statistical analysis [31,32]. The participants were then asked to select regulations they consider relevant for MC from a list. To avoid relevant regulations being overlooked, participants could add regulations. To provide a manageable number of answer categories, only the European legislation was explicitly named, while international legislation was included

within the categories but not explicitly named. In the following item of the questionnaire, the definition for MC derived from the previously conducted literature review (Section 3.1.) was presented to the participants. The participants were then asked to evaluate whether they thought that the definition was correct by providing an answer on a bipolar, numerical rating scale with numerically labelled answer categories ranging from 1 (positive) to 6 (negative) and verbally labelled categories at both pole ends [33]. The obtained results were statistically analyzed using Microsoft Excel.

3. Results and Discussion

3.1. Literature Review

Following a search string according to the PRISMA guidelines, relevant literature sources were identified. This process is schematically illustrated in Figure 3.

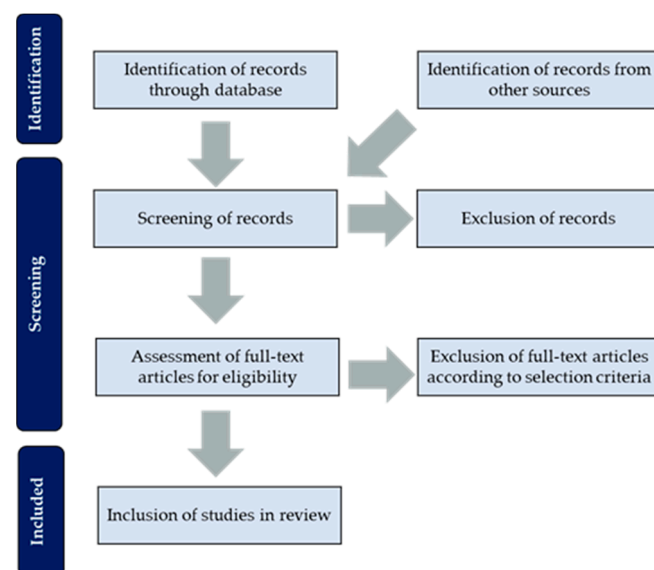


Figure 3. String of search for the selection of relevant literature sources (own illustration according to the PRISMA 2020 guidelines [34]).

In total, six sources were included in the review. Through the analysis and comparison of the application of the term MC in these sources, which is described in the following, a definition was derived.

Quevedo (1995) already applied the term MC in 1995 in the context of adherence to regulations concerning hazardous materials and waste streams [35]. In a more recent publication, Phyper et al. (2004) defined MC as “[. . .] the activities and processes used to ensure an organization is compliant with legislation related to hazardous (regulated) goods across all aspects of business [. . .]” [36]. While Phyper et al. present a broad scope of MC by including a wide range of legislations and corresponding requirements (e.g., concerning the registration, notification and listing of chemicals, as well as transport requirements [36]) several other publications restrict the scope of MC to the conformity of products.

Nieser and Reusch (2017) relate MC to the conformity of products by stating that it is a product characteristic that needs to be ensured to avoid product deficiency. They further define MC as the adherence to all material related requirements (e.g., concerning the use of substances or materials) arising from laws, norms, directives and customer specifications, as well as industry-specific regulations [17]. Markmann and Nieser (2020) provide a corresponding perspective and refer to MC as the conformity of products with legally or contractually determined requirements regarding the material composition [37].

Other authors provide a similar perspective on MC: Takhar and Liyanage (2018) apply the term to describe the adherence to regulations concerning the use of hazardous chemical substances within products [38]. In accordance with this, Bachmann (2010) refers

to MC as the conformity with requirements concerning the use of regulated substances within products arising from national and international regulations, laws, and customer requirements [39]. While some authors use the term substance when referring to chemicals (e.g., [38]), the term material is not further specified by the respective authors. It is thus unclear whether the terms need to be differentiated or if they are used redundantly.

Summarizing the previous findings, the term MC is predominately used to describe the adherence to legal requirements concerning the composition of products [17,37] and the use of materials and/or substances within products [17,38,39]. These requirements may arise from legislation [35,37], customer requirements [17,37,39] or norms [17]. Norms are, in general, not legally binding [40] unless their application is explicitly required by legislation.

With respect to these findings, we define MC as the conformity of products with all relevant requirements regarding their composition, as well as the conformity of materials and substances with all relevant requirements regarding their use within products.

According to this definition, MC includes the adherence to all legally binding as well as other relevant requirements arising, for example, from laws, regulations, norms, directives, industry-specific regulations and customer specifications. As corporations not only use substances in the form of a specific chemical but rather a material (e.g., glue [9]), the conformity of both materials and substances is included within the scope of MC according to this definition.

3.2. Evaluation of the Elaborated Definition for Material Compliance and Analysis of the Understanding of Material Compliance in the Mechanical Engineering and Electrical and Electronics Industry

The provided answers concerning the participants understanding of MC were quantified using a content analysis. Four categories were derived from the answer material representing different aspects of the understanding of MC: adherence to legal requirements (legal) and adherence to requirements concerning products (product), substances (substance) or materials (material). For several answers, more than one of these aspects were assigned. The results illustrated in Figure 4 show that the majority of participants understood MC as adherence to legal requirements (66.67%) and requirements concerning products (58.33%), while a large part further included adherence to requirements concerning substances (33.33%) and materials (20.83%).

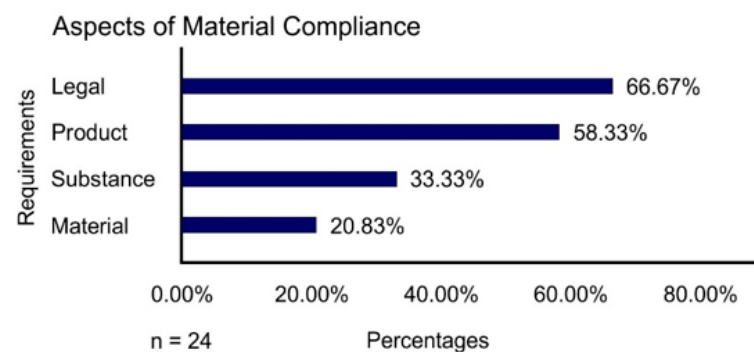


Figure 4. Analysis of the participants understanding of material compliance.

Since there was a consensus about the most important aspects of MC, the results indicate that there is at least a partial common understanding for MC. The results further correspond to the elaborated definition, which includes all the identified aspects, indicating that the definition is accurate.

This is further supported by the rating results of the elaborated definition, which participants rated on a scale from 1 (accurate) to 6 (not accurate). The results illustrated in Figure 5 show that the participants generally considered the elaborated definition accurate as the values ranged between 1 and 4 (1 and 3 when excluding the outlier). Thus, none of the participants rejected the definition entirely, and half of the participants provided a

positive rating by selecting categories 1 or 2. On average, participants rated the definition with 1.58 (mean). The standard deviation was 0.93, and the median was 1.

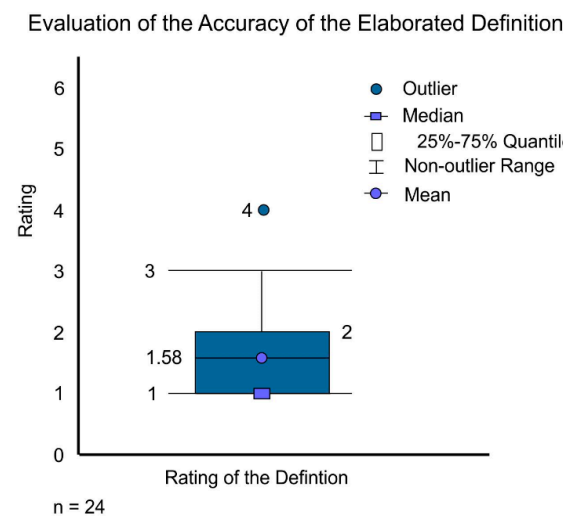


Figure 5. Rating of the accuracy of the elaborated definition for material compliance.

Participants were further asked to provide reasons if they did not consider the elaborated definition accurate. However, the provided answers were diverse, and categories or frequencies could not be determined. This divergence might result from the lack of an official definition and a differing understanding of MC depending on the respective corporate background and situation.

To provide further insights into the understanding of MC, it was analyzed which regulations participants considered relevant for MC. The results illustrated in Figure 6 show that the participants considered all listed regulations as relevant, primarily the RoHS directive (2011/65/EU) and the REACH regulation ((EC) No 1907/2006) (100%), followed by the regulation (EU) 2019/2021 (Persistent Organic Pollutants (POP) regulation) (91.67%), regulations regarding conflict minerals and directive 2012/19/EU (Waste Electrical and Electronic Equipment (WEEE) directive) (79.17%). While 54.17% of the participants chose to add other regulations, this number is compromised by the fact that several participants added regulations that were already included in the answer categories as similar international regulations, or participants added requirements which could not be considered as regulations, e.g., customer-specific requirements. Thus, only 12.5% of the participants added regulations not previously included in the answer categories.

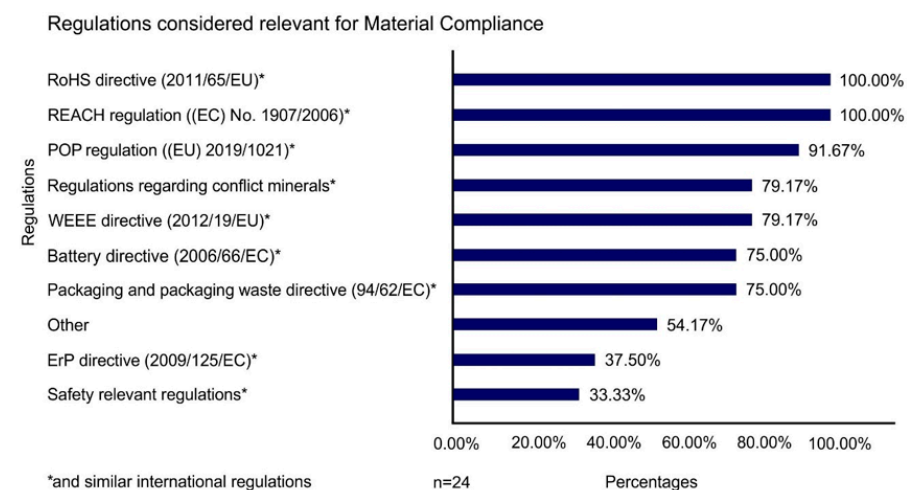


Figure 6. Relevance of different regulations for material compliance.

These results partially correspond to the previous findings and support the assumption that the elaborated definition might be considered accurate as the most prominent regulations (RoHS directive, REACH and POP regulation, regulations concerning conflict minerals and the Battery directive (2006/66/EC)) regulate the use of substances/materials in products (2011/65/EU, Article 1; (EC) No 1907/2006, Article 1(2); (EU) 2019/1021, Article 1, Article 3; 2006/66/EG, Article 2(1), Article 4) and are therefore in line with the definition. However, the results further indicate that the understanding of MC differs, since several regulations not corresponding to the elaborated definition were considered relevant by the participants (e.g., the WEEE directive, which addresses the generation and management of waste from electrical and electronic equipment (2012/19/EU, Article 1)). While this indicates that there are differences in the understanding of MC, it should also be noted that it could be assumed that regulations that have not yet been assigned to another topic might be included within the topic of MC.

4. Conclusions

Based on an assessment of existing sources of literature, we defined MC as the conformity of products with all relevant requirements regarding their composition, as well as the conformity of materials and substances with all relevant requirements regarding their use within products.

It is essential to point out that this definition does not limit MC to the adherence to substance/material restrictions or prohibitions but includes all requirements regarding their use within products. Some examples are information requirements concerning the use of a substance arising from article 33 of the REACH regulation ((EC) No 1907/2006, Article 33) and regulations concerning conflict minerals which do not generally prohibit the use of a substance but require responsible sourcing [41]. This is in accordance with the presented exemplary understanding of MC in industry, as according to the results of the survey, regulations which address social aspects such as the sourcing of conflict minerals are considered relevant for MC.

The results of the quantitative survey further demonstrate that the participants generally considered the elaborated definition as accurate. Furthermore, the results indicate some consensus about the significant aspects of MC and a partial common understanding of MC, but there are individual differences. When interpreting these results, it should also be considered that they only apply for the selected sample. The demonstrated understanding applies to the mechanical engineering and electrical and electronics sector and might differ to the understanding in other industry sectors such as the chemical industry, where MC could be considered as the conformity with requirements concerning substances and not materials. Due to the participants' regular attendance at the expert forum, a similar understanding of MC might have been established within this sample. Nevertheless, as the definition is based on existing literature and supported by the survey results, we assume that it may provide a first approach towards defining MC.

The obtained results further demonstrate that MC cannot be equated with other forms of compliance. Although there are intersections with other compliance types, MC is considered as a distinct compliance sub-type. One might intuitively assign MC thematically to product or environmental compliance. However, while MC concerns products, it cannot be equated to product compliance, which is limited to the conformity of the finished product and primarily focuses on the reduction of the product-specific risks for the product user [9]. In contrast, MC includes the adherence to requirements concerning the use of substances and materials within products and thus goes beyond the conformity of the finished product by addressing the conformity of substances, materials, components, parts, etc., that make up the finished product. It can neither be equated with environmental compliance, which, according to Labinsky [42], can be understood as the conformity with environmental regulations. Although relevant regulations address environmental aspects, such as the REACH regulation ((EC) No 1907/2006), Article 1), MC goes beyond this, as demonstrated by the results discussed in Section 3.2, as MC additionally includes social

aspects, e.g., the responsible sourcing of conflict minerals [43]; Public law No. 111–203, Section 1502 [44]. Thus, MC must be considered as a distinct form of compliance and as a part and requirement for the overall compliance of a corporation.

In this study, we derived and evaluated a definition for MC to provide the necessary conditions to address the topic in research and corporate practice systematically. As corporations face a complex regulatory environment, developing a management framework to ensure MC remains an essential task for future research.

While this study provides the first insights into this relatively new topic, the applied method of sample selection, its composition and size should be considered when interpreting the results. Due to the non-random selection of participants, the results can statistically not be generalized [45]. Nevertheless, this method was considered applicable as the participating corporations are expected to address MC proactively and might function as trendsetters for the rest of the industry. Furthermore, the participants of the survey are professionals within the field of MC and can provide valuable insights as the management of MC is part of their everyday business. Their opinions and judgement are thus regarded as highly relevant.

Considering these limitations, we do not claim representativeness of the results. Instead, this study aims to provide a first systematic insight and to generate a reference point for future research.

5. Summary and Outlook

In this study, we aimed to analyze the understanding of MC in industry, as well as the literature, and develop a definition for the term MC with a high degree of objectivity. Therefore, we conducted an explorative literature review and compared the use and application of the term MC in literature. Based on the results of this literature review, we derived a definition for MC. In a quantitative survey, we analyzed the understanding of MC in industry, determined whether there was a consensus and identified the aspects considered relevant for MC.

We compared the analyzed understanding of MC to the previously elaborated definition and discussed whether the definition matched this understanding. Additionally, we evaluated the definition directly during the conduction of the survey by asking participants to rate the accuracy of the definition.

The results demonstrate that, although there is no generally accepted definition for the term MC, there is some consensus about the relevant aspects and regulations, which need to be considered to ensure MC. It was further demonstrated that the elaborated definition matched this understanding of MC and was generally considered as accurate by the participants.

Through the elaboration and evaluation of a definition for MC, we aim to facilitate communication and knowledge exchange and provide the necessary conditions to address the topic in research and corporate practice systematically. Thereby enabling further progress in the management of MC.

Previous research in this field has so far focused on the management of data and information and the design of processes and structures required to ensure MC. It should be noted that some of the relevant publications do not use the term MC, as it has not yet become established in scientific literature.

The adequate management of data and information necessary to ensure MC has been the subject of several publications (e.g., [16,39,46]). Although there is a consensus about the fact that a standardized and uniform system for data exchange is required to ensure MC [39,46], the authors of the respective publications recommend several software solutions (e.g., [16,39]). It thus remains a task for future research to develop an adequate and standardized solution for the management of data and information to ensure MC. The processes required to ensure MC have been discussed in several publications with varying degrees of detail (e.g., [9,11,17,20,37]). While Müller has developed a reference model describing the actions necessary to ensure MC [9] there is currently no standardized

process, nor has the practical applicability of the discussed processes been tested. Although the management of data and information as well as processes require the establishment of adequate corporate structures, this has only marginally been addressed in literature (e.g., in [17,47]). The identification of the required corporate structures therefore remains an additional task for future research.

As of now, existing studies have not provided a holistic approach for the management of MC but focus on several aspects separately. A systematic approach would require an integration of the management of data and information, required processes and structures. Developing such a management framework to ensure MC thus remains another essential objective for future research.

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Appendix A

Question 14: Please state in one to two sentences what's understood under the term Material Compliance in your corporation.

Question 15: Which of the following regulations would you assign to the topic of Material Compliance? Instruction: multiple answer categories can be selected. Please name other relevant regulations in the provided space if they are not included in the list of answer categories.

- REACH regulation ((EC) No. 1907/2006) and similar international regulations
- RoHS directive (2011/65/EU) and similar international regulations
- WEEE directive (2012/19/EU) and similar international regulations
- Regulations regarding conflict minerals (e.g., Section 1502 des Dodd-Frank Acts or the European conflict minerals regulation ((EU) 2017/821)) and similar international regulations
- POP (persistent organic pollutants) Regulation ((EU) 2019/1021) and similar international regulations
- ErP directive (2009/125/EC) and similar international regulations
- Packaging and packaging waste directive (94/62/EC) and similar international regulations
- Battery directive 2006/66/EC and similar international regulations
- Safety relevant regulations (e.g., regulations requiring the CE marking such as machinery directive (2006/42/EC)) and similar international regulations
- Other: _____

Question 16: Do you consider the provided definition as accurate? "Material Compliance is defined as the conformity of materials, substances and products with all relevant requirements regarding their use, composition and constitution".

(accurate) (1) — (2) — (3) — (4) — (5) — (6) (not accurate)

Please provide reasons for your decisions (e.g., missing aspects):

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