Monitoring and Management of Regulatory Compliance: A Literature Review

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Abstract
Governments and regulators are saddled with the burden of introducing and enforcing compliance to the right laws and regulations in order to address specific needs of our dynamic contemporary society. Irrespective of the instruments or mechanisms they use, they are often concerned with over or under-regulation, as well as regulatory effectiveness. Despite advances in the use of Information Systems to better facilitate compliance, little research has been done to explore how regulators enforce compliance or determine the effectiveness of regulations. Research on regulatory compliance has increased over the past few years, but the challenges regulators face are rarely addressed. This literature review explores and analyses how regulators currently monitor and manage regulatory compliance. The nine papers selected out of the 1207 candidates indicate a paucity of information in the regulatory compliance domain and suggests that exploring how regulators facilitate enacting and enforcing regulations should be of urgent concern today.

Keywords: Frameworks, Information Management, Models, Methods, Literature Review, Regulators, Regulatory Compliance.

1. Introduction

Governments around the world enact acts, laws, legislations, policies, regulations and rules (broadly referred to as regulations or policies in this article), in order to govern societal interactions. Regulations essentially impose many types of demands on organizations and their activity systems. These regulations are administered by bodies (typically known as regulators) established and mandated to enforce compliance independently or with oversight by a government organization. Regulatory compliance involves the act and process of ensuring adherence to regulations [1]. Regulators carry out regulatory compliance by interpreting regulations to enable understanding, compliance and conformance by regulated parties. They also carry out inspections to monitor compliance, introduce penalties or fines to punish defaulters, and engage in consultations with regulated parties to address any concerns.

Enforcing regulatory compliance does not come without challenges. Regulated parties frequently accuse regulators of burdening them excessively. Regulators often insist the regulations are insufficient, while governments and citizens question whether they work at all. The recent regulatory policy outlook of the Organization for Economic Co-operation and Development (OECD) affirms that more could be done to improve the way regulations are designed, implemented and evaluated [2]. A common practice among most regulators is to administer regulatory compliance with the use of impact assessments such as Environmental Impact Assessment (EIA) or Regulatory Impact Assessment (RIA) [3]. An impact assessment is a combination of procedures, methods and tools that enhance the empirical basis of political decisions behind regulations. They also enable improvement of the quality and coherence of the development and implementation process through identifying likely positive or negative impacts [4]. In its application, an impact assessment is either \textit{ex ante}, i.e., informing the decision making processes before regulations are formulated, or \textit{ex post}, i.e., informing the evaluation after their implementation. Regardless of the type of impact assessment applied, questions still arise about their usefulness in producing measures of regulatory performance [5].

The challenge of determining the effectiveness of regulations is observed in the continued preoccupation with the existing literature on noncompliance [6]. Some of the key issues include a lack
of consensus on how to actually measure compliance [7], the frequent changes in regulations due to the dynamic nature of society, as well as inadequate monitoring of compliance [8]. These issues are thought to derive primarily from the prescriptive nature of regulations, which specifies what should be done to be compliant, i.e., how compliance should be achieved, rather than what attaining compliance should look like [9][10]. As a result, with a prescriptive regulation, it is hard to determine how close or far a regulated party is from being compliant. Additionally, with regulations often dependent on and linked to each other, these dependencies also frustrate evaluations of the effectiveness of any specific regulation. Changes in a regulation therefore have to be carefully monitored and managed to ensure that these dependencies are also addressed. These challenges indicate that continued research on identifying approaches to monitoring and measuring compliance will improve our knowledge of regulatory effectiveness.

The concerns related to ascertaining the effectiveness of regulatory compliance have encouraged an outcome-based approach with a focus on examining the original intention of regulations. Research in requirements engineering, specifically goal-oriented modelling, currently leads in this direction with frameworks, methods and models that enable stakeholders to reason better about regulatory compliance [11]. With this new emphasis however, there needs to be a shift from the current focus of optimizing ways of ensuring the regulated parties comply with regulations. More emphasis should be directed at the effectiveness of regulations through proper information management and analysis of their performance [12]. Such performance analysis will provide useful insights about regulations indicating occurrences of over-regulation or under-regulation. It will also enhance the decision-making process of regulators and regulated parties towards meeting their respective objectives while complying with relevant regulations. This literature review highlights the need for focusing on research that addresses the monitoring and management of the effectiveness of regulations. The review focuses on identifying frameworks, models or methods regulators use to measure, assess and evaluate regulatory compliance. Such knowledge is important because it may lead to the discovery of implicit information system requirements related to monitoring and management that would otherwise be missed.

The rest of this paper is organized as follows. Section 2 discusses related work and expounds on the concept of monitoring and managing regulatory compliance. Section 3 describes the methodology used to do the systematic literature review. In Section 4, we report and discuss the nine articles obtained from the review process, while in Section 5 we address threats to the validity of the work. We conclude in Section 6 with a summary and recommendations.

2. Related Work

The seminal work by Otto and Antón [13] set the tone towards using a systematic literature review in the regulatory compliance domain. They utilized 38 articles out of 150 candidates to identify efforts over a 50-year period in handling legal texts for use in requirements engineering and system development. Nine categories were identified in the process: symbolic logic, knowledge representation, deontic logic, defeasible logic, first-order temporal logic, access control, mark-up-based representation, goal modelling and reusable requirements catalogues. The COMPAs project [14] showed how prominent compliance languages at the time addressed useful features for specification found in compliance legislation from 98 articles reviewed. Amongst others, they came up with four features for compliance requirement specification: heterogeneity, expressive power, manageability and usability. El Kharbili [15] explored approaches within business process management research that handled compliance checking, arriving at two types of approaches, namely forward checking and backward checking, from a review of 22 articles.

Turki and Bjekovic [16], using 15 articles, investigated the practice of regulations analysis but solely from the point of view of extracting rights and obligations, modelling regulations, business processes and traceability support for compliance across any domain. Methods based on key performance indicators (KPI) used for measuring compliance of business processes against policies and laws were the focus of Shamsaei et al. [17]. They utilized 32 articles out of 198 candidates and came up with five categories of measurement methods: compliance frameworks and standards, compliance levels, discovery and control of non-compliance business processes, goal-oriented techniques and KPIs, and finally methods not accommodated...
by the other four categories. Ghanavati et al. [18] explored goal-oriented frameworks that help organizations establish legal compliance and manage the evolution of their compliance with 88 articles selected from a pool of 800, arriving at eight groups of activities these frameworks support. The categories are: activities involving the use of requirements engineering frameworks for managing compliance, activities involving goal modelling approaches, activities of business process compliance, legal requirements extraction activities, activities that involve providing law-compliant business process templates, activities for prioritizing legal requirements, activities that utilize tool support, and other activities that address legal compliance issues not fitting the other categories.

El Kharbili [19] utilized 32 articles for a comparative study of proposed regulatory compliance management approaches identifying their strengths and limitations. A taxonomy of requirements suggested to aid the understanding of regulatory compliance management from different viewpoints drawn from the same 32 studies reviewed was used. Becker et al. [20], in an attempt to explore compliance checking approaches of process models, reviewed 48 articles out of a pool of 788 articles. The motivation was the possibility of generalizing outcomes of compliance checking approaches and the availability of appropriate evaluation mechanisms. It was observed that current approaches focus mainly on special modelling techniques and/or a restricted set of types of compliance rules. Most of the approaches also did not address real-world problems, hence questioning their practical applicability.

Finally, the need to provide a comprehensive landscape of the research on business process compliance was the motivation of Fellman and Zasda’s work [21]. They took a compliance approach focus, which argues that two different areas of compliance approaches aid discerning between research studies that contribute significantly or those that are just exploratory research and prototypes. 84 articles were selected out of a pool of 430. A faceted classification approach was then used to classify these different points of view across four different dimensions: scope, lifecycle phase, formality and contribution type. We observe from these reviews that the focus has been on exploring compliance from the point of view of the regulated parties: how compliance requirements are extracted and represented and checked for compliance.

It is interesting to note that according to a recent literature survey [12] of 342 research publications in the domain of regulatory compliance, only sixteen percent (16%) target compliance analysis and four percent (4%) target compliance enactment. While compliance analysis enables us gain insight on the state and levels of compliance, compliance enactment address change concerns while complying. In monitoring and managing regulatory compliance, compliance analysis and enactment are addressed. In simple terms, while monitoring means to \textit{check the progress or quality of (something) over a period of time} [22], managing means to \textit{have executive control or authority} [23]. This suggests that while monitoring applies to observing for a period, managing means exerting some control over a process. When this notion is applied to regulatory compliance, monitoring implies getting insights on the state of compliance at certain instant of time (daily, monthly, annually, etc.). The activities involved can be referred to as compliance analysis tasks. Similarly, management implies getting insights on the state of compliance at certain instance (when compliance is done, when a violation occurs, etc.) within a compliance process with activities involved referred to as compliance enactment tasks [12].

Regulators monitor compliance by taking snapshots at different times in the compliance lifecycle of a regulation to analyze how regulated parties comply with defined objectives. In contrast, to manage compliance, regulators look at the entire compliance lifecycle of a regulation to analyze if the regulated parties meet defined objectives. Triggers for starting a regulatory compliance monitoring or management process are changes in either the regulations or regulated parties. These triggers can be assessed and their outcomes addressed periodically in the monitoring process. In the management process, they are evaluated and evolved over the different phases of the regulations. Regulators monitor regulatory compliance using measurement parameters assessed at intervals of the regulatory compliance lifecycle while they manage regulatory compliance using measurement parameters evaluated for the entire compliance lifecycle.
3. Systematic Literature Review: Methodology and Discussion

Systematic literature reviews are gradually becoming an integral part of research across most domains in academia. This is because of the clarity, thoroughness and quality this literature review methodology can lend to understanding a specific topic or domain if applied appropriately [24]. We utilized these characteristics of systematic literature reviews to provide a clear understanding of how regulators currently monitor and manage regulatory compliance. The review was carried out in three phases: planning the review, conducting the review and reporting the review [25]. The planning and reviewing phases, which cover the process of selecting articles to be reviewed, are described in this section while our findings are discussed in the reporting phase described in Section 4.

3.1. Planning Phase

We established two research questions that capture the essence of this literature review and identified keywords which were combined in a query that addressed these questions. We also identified target search engines where relevant articles could be found and defined inclusion and exclusion criteria to decide upon articles selected for the review. The research questions are:

1. What are frameworks, methods or models used by regulators to measure, assess, or evaluate regulatory compliance?

2. How effective are these frameworks, methods, or models in determining the effectiveness of regulations?

The keywords we selected based on these research questions falls into three categories. The first addresses the regulators mandated to administer and enforce regulatory compliance:

Regulatory Agency, Regulatory Authority, Regulatory Body, Regulatory Department, Regulatory Organization, Regulating Agency, Regulating Authority, Regulating Body, Regulating Department, Regulating Organization

The second category addresses how regulators go about measuring, assessing, monitoring, evaluating, and managing regulatory compliance. The keywords chosen accommodate many variations with wildcards (*):

Assess*, Evaluat*, Manag*, Measur*, Monitor*

The final category addresses what artefacts the regulators use to assess, evaluate, manage, measure, or monitor regulatory compliance:

Framework, Method, Methodology, Model, Compliance, Policy, Regulation

The abstract query used here is a combination of all keywords in three main categories:

("Regulatory Agency" OR "Regulatory Authority" OR "Regulatory Body" OR "Regulatory Department" OR "Regulatory Organization" OR "Regulating Agency" OR "Regulating Authority" OR "Regulating Body" OR "Regulating Department" OR "Regulating Organization")

AND

("Framework" OR "Method" OR "Methodology" OR "Model")

AND

("Assess*" OR "Evaluat*" OR "Manag*" OR "Measur*" OR "Monitor*")

AND

("Compliance" OR "Policy" OR "Regulation")

In identifying databases to search on, we took a domain-generic approach to address many types of regulators and domains. We also consulted with a librarian at the University of Ottawa. The databases
chosen offer articles that are not domain specific. These databases are divided into two categories. The first category is for academic sources, which provide academic and in most cases peer-reviewed articles, and the other for non-academic sources, which capture the view of regulatory practitioners. The identified databases, which included eleven academic ones and four non-academic ones, are identified in Table 1.

<table>
<thead>
<tr>
<th>Database</th>
<th>Type</th>
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<tbody>
<tr>
<td>Annual Review (AR)</td>
<td>Non-Academic</td>
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<tr>
<td>Business Source Complete (BSC)</td>
<td>Academic</td>
</tr>
<tr>
<td>Canadian Periodical Index Quarterly (CPIQ)</td>
<td>Non-Academic</td>
</tr>
<tr>
<td>Columbia International Affairs Online (CIAO)</td>
<td>Academic</td>
</tr>
<tr>
<td>Ebrary</td>
<td>Academic</td>
</tr>
<tr>
<td>Econpapers (EP)</td>
<td>Academic</td>
</tr>
<tr>
<td>Factiva (FA)</td>
<td>Academic</td>
</tr>
<tr>
<td>National Bureau of Economic Research (NBER)</td>
<td>Academic</td>
</tr>
<tr>
<td>Organization for Economic Cooperation and Development (OECD)</td>
<td>Non-Academic</td>
</tr>
<tr>
<td>ProQuest (PQ)</td>
<td>Non-Academic</td>
</tr>
<tr>
<td>PubMed (PM)</td>
<td>Academic</td>
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<tr>
<td>ScienceDirect (SD)</td>
<td>Academic</td>
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<tr>
<td>Scopus (SC)</td>
<td>Academic</td>
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<tr>
<td>Social Science Research Network (SSRN)</td>
<td>Academic</td>
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<tr>
<td>Web of Science (WOS)</td>
<td>Academic</td>
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</table>

Finally, in the planning stage, we identified five sets of inclusion criteria and three sets of exclusion criteria with which we selected appropriate articles from all search results obtained. The selected inclusion criteria (all necessary) were:

1. The abstract of the articles is written in English and addresses a regulator and regulations or policies.
2. The article includes at least one mention of the word “compliance”.
3. The article includes at least one mention of any of the words assessment, evaluation, measurement, monitoring or management. It may also include these words in any of their wildcard forms expressed in the search query.
4. The article includes at least a mention of any of the words: framework, model or method.
5. The article addresses a regulator, compliance with a regulation or policy, and a measurement, assessment, monitoring, evaluation, or management using a framework, model or method.

For the exclusion criteria, we rejected:

1. Articles that did not address regulators as a body or agency mandated to enforce compliance with a regulation or policy.
2. Articles where the keywords (compliance, assessment, evaluation, monitor, management, framework, model or method) were not addressed directly in the article. This includes mentions only in the references or titles.
3. Articles where the keyword “method” signified a research approach and not the way regulators measure, assess, monitor, evaluate or manage regulatory compliance.

3.2. Reviewing Phase

In the reviewing phase, we applied the search query to the 15 databases selected. The abstract query was adapted to the unique search criteria and constraints identified in each database. As a result of this adaptation, we were forced to simplify the query for searches on the non-academic databases to address just the function of regulatory compliance. The query used for the four selected non-academic databases was therefore limited to “Regulatory Compliance”. Of the eleven academic databases selected, only seven were robust and flexible enough to handle the search query. The databases, search options, and search hits received are shown in Table 2. After the searches, we read through the abstract and introduction of each article obtained. Relevant articles that met the first inclusion
and did not meet the first exclusion criteria were selected. After the application of the first round of inclusion and exclusion criteria, we obtained a total of 1207 articles, whose list can be accessed online\(^1\). The databases, number of search hits recorded, and articles selected are shown in Table 3.

<table>
<thead>
<tr>
<th>Table 2. Search options and hits for the selected databases</th>
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<tbody>
<tr>
<td><strong>Database</strong></td>
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<td>AR</td>
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<td>BSC</td>
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<tr>
<td>CPIQ</td>
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<td>CIAO</td>
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<td>EB</td>
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<tr>
<td>EP</td>
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<td>FA</td>
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<td>NBER</td>
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<td>OECD</td>
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<td>PQ</td>
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<td>PM</td>
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<tr>
<td>SD</td>
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<tr>
<td>SC</td>
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<tr>
<td>SSRN</td>
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<td>WOS</td>
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<table>
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<tr>
<th>Table 3. Databases and articles selected after the first set of inclusion/exclusion criteria</th>
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<tr>
<td><strong>Database</strong></td>
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<td>AR</td>
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<td>BSC</td>
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<td>EP</td>
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<td>NBER</td>
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<td>OECD</td>
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<td>PM</td>
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<td>PQ</td>
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<td>SC</td>
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<tr>
<td>SD</td>
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<tr>
<td>WOS</td>
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<tr>
<td><strong>TOTAL</strong></td>
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<tr>
<td><strong>TOTAL WITHOUT DUPLICATES</strong></td>
</tr>
</tbody>
</table>

For the next round, we employed only the inclusion criteria. Using a text mining approach on the 1207 articles from the previous round, we selected articles that included keywords in the second, third and fourth inclusion criteria. For the text mining, we used the advanced search option available in Adobe Reader XI on the PDF articles, as shown in Figure 1. At this stage, we reduced the set to 694 articles.

For the last round of inclusion/exclusion criteria, we read through all 694 articles left, and used the final set of inclusion and exclusion criteria. We were left with 241 articles, of which 114 were articles published by the International Monetary Fund (IMF) and 47 by the OECD. These articles, although giving the practitioner’s perspective, were not empirically done. They did not address specifically a regulator, compliance with a regulation, and a measurement, assessment, monitoring, evaluation or management using a framework, model or method. They rather provided summaries of assessments or evaluations countries had on regulations or policies, and offered recommendations on what areas needed improvement. These summaries were neither detailed nor specific (see [26][27]) and were also excluded, resulting in 80 articles left.

\(^1\) https://www.dropbox.com/s/a39yuvqatetu9nw/PaperList.docx?dl=0
After reading the 80 articles left, only nine addressed a regulator, compliance with a regulation or policy, and a measurement, assessment, management, evaluation or monitoring using a framework, model or method, often supported by information systems. These articles are discussed in Section 4. A summary of each stage of the inclusion/exclusion criteria and final nine articles selected after the application of all eight inclusion and exclusion criteria are shown in Table 4 and Table 5 respectively.
Table 4. Summary of inclusion/exclusion criteria applied and articles selected at each stage

<table>
<thead>
<tr>
<th>No.</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Available Articles</th>
<th>Selected Articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Inclusion Abstract of the article is written in English, addresses a regulator, a regulation, regulations, policy or policies.</td>
<td>2531</td>
<td>1207</td>
</tr>
<tr>
<td></td>
<td>Exclusion Article does not address regulators as a body or agency mandated to enforce regulatory compliance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Inclusion Article includes at least a mention of the word “compliance”.</td>
<td>1207</td>
<td>699</td>
</tr>
<tr>
<td></td>
<td>Article includes at least a mention of “assessment, evaluation, measurement, monitoring or management”. It may also include these words in any of their wildcard forms expressed in the search query.</td>
<td>699</td>
<td>696</td>
</tr>
<tr>
<td>3</td>
<td>Inclusion Article includes at least a mention of “framework, model or method”.</td>
<td>696</td>
<td>694</td>
</tr>
<tr>
<td></td>
<td>Inclusion Article addresses a regulator, compliance with a regulation or policy and a measurement, assessment, monitoring, evaluation or management using a framework, model or method.</td>
<td>Keywords are addressed in the article</td>
<td>694</td>
</tr>
<tr>
<td></td>
<td>Exclusion Keywords are not addressed directly in the article. Mentioned in reference, title etc. Use of “method” is in reference to research approach and not a way regulator used to</td>
<td>Remove IMF and OECD articles</td>
<td>241</td>
</tr>
<tr>
<td></td>
<td>Inclusion Addresses a regulator, compliance with a regulation or policy and a measurement, assessment, monitoring, evaluation or management using a framework, model or method.</td>
<td></td>
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</tr>
</tbody>
</table>

Table 5. Final list of articles selected after application of inclusion/exclusion criteria

<table>
<thead>
<tr>
<th>Article</th>
<th>Title</th>
<th>Year</th>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1[28]</td>
<td>A framework for understanding individual response to regulation</td>
<td>2010</td>
<td>Agriculture</td>
</tr>
<tr>
<td>3[30]</td>
<td>A risk appraisal system regarding the implementation of maritime regulations by a ship operator</td>
<td>2014</td>
<td>Transport</td>
</tr>
<tr>
<td>5[32]</td>
<td>Development of a framework to measure health profession regulation strengthening</td>
<td>2014</td>
<td>Health</td>
</tr>
<tr>
<td>6[33]</td>
<td>From punishment to prevention: A French case study of the introduction of co-regulation in enforcing food safety</td>
<td>2012</td>
<td>Agriculture</td>
</tr>
<tr>
<td>7[34]</td>
<td>The use of simple models in the regulation of the impact of fish farms on water quality in Scottish sea lochs</td>
<td>1997</td>
<td>Environment</td>
</tr>
<tr>
<td>8[35]</td>
<td>Towards medicines regulatory authorities’ quality performance improvement: value for public health</td>
<td>2016</td>
<td>Health</td>
</tr>
<tr>
<td>9[36]</td>
<td>Use of measurement uncertainty in a probabilistic scheme to assess compliance of bottled water with drinking water standards</td>
<td>2010</td>
<td>Environment</td>
</tr>
</tbody>
</table>

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4. Reporting Phase and Discussion

The nine articles selected from over 1207 candidates highlight a scarcity of empirical research across all domains related to how regulators enforce compliance or determine the effectiveness of regulations. An analysis of what was obtained however is necessary to provide insight and lay a foundation for future research. In the reporting phase, these nine articles were analyzed based on their domain of reference and years of publication. The functions which the respective frameworks, models or methods performed were further evaluated in relation to the effectiveness of the respective regulations. These functions include a measurement, assessment, management, evaluation or monitoring of regulatory compliance and a regulator, or compliance with a regulation or policy.

4.1. Domain and Years of Publication

Pertaining to the first research question described in the planning phase, of the final list of articles reviewed, research in the environment domain indicates the highest number of occurrences (4). The health and agriculture domains were next in terms of frequency with two occurrences each and finally the transportation domain with one occurrence. It is surprising to note that recent global disruptive technology trends (like Uber for taxis or Airbnb for lodging), crisis in the banking sector, and privacy concerns are not reflected in the selected articles. In contrast, environmental concerns, which brought about the first case of impact assessments of regulations with the signing of the National Environment Policy Act by President Richard Nixon of the USA in 1970 [37], are still at the forefront of research on the effectiveness of regulations.

In regards to the years the articles were published, we observed that all but one of the articles has been published in the last 20 years. The distributions of years and categories (even if the sample is very small) suggest that research in the environment domain addressing regulators managing or monitoring regulatory compliance or determining effectiveness of regulations appears to be diminishing. The last relevant article was published in 2010. Research in the agriculture domain however, appears to be picking up consistently since the period between 2006 and 2010, while research in the transport domain and particularly the health domain appears promising. However, these observed trends are based on a very small number of papers and hence may not be entirely reflecting actual trends in these areas.

4.2. Monitoring and Managing Regulatory Compliance

Monitoring of regulatory compliance involves regulators taking snapshots at different times in the compliance lifecycle of a regulation to analyze how regulated parties meet defined goals and objectives. Similarly, management of regulatory compliance involves regulators looking at the entire compliance lifecycle of a regulation to analyze if the regulated parties meet defined goals and objectives. We observed that all nine selected articles addressed monitoring of regulatory compliance while only five articles addressed the management of regulatory compliance:

- Kaine et al. [28] worked on monitoring the intensity of an individual’s motivation to decide to comply with a regulation, using a conceptual framework.
- Hsu [29] addressed the monitoring of habitat conservation plan’s (HCP) compliance with the United States of America’s Endangered Species Act (ESA). Also addressed was the management of negotiations and regulatory bargains between regulatory agencies and regulated parties using an empirical framework, a mathematical economic game theory and an analytical method.
- Karahalios et al. [30] discussed the monitoring of compliance by ship operators to the International Maritime Organization (IMO) regulations. They also discussed the management of regulation implementation performance using a mathematical model and a methodology involving the Analytical Hierarchal Process (AHP) and fuzzy set theory methods.
- Crabtree et al. [31] addressed the monitoring of compliance with river quality and pollution control standards, and the management of pollution control standards using a statistical framework, models and methods.
• In McCarthy et al. [32], a capability maturity model was used to monitor the compliance of countries to respective health regulations for health professionals. It was also used to manage compliance of the same health professionals to continuing professional development (CPD) programs.

• In Rouvière & Caswel [33], the monitoring of firms’ compliance with food safety regulations and the management of self-regulation of these firms through their food safety records were performed with a conceptual framework.

• Gillibrand & Turrell [34] monitored the impact of new and existing fish farms on the water quality of the Scottish loch using three simple computer models. The annual usage of a common insecticide found in these fish farms in relation to the environmental quality standard (EQS) was used as a method.

• Pejović & Filipović [35] monitored the quality performance of national medicines regulatory authorities in Europe using principles from the Total Quality Management (TQM) as a framework and model.

• Demetriades [36] used a probabilistic method based on the robust analysis of variance (RANOVA) for monitoring the compliance of bottled water analytical results with statutory standards defined by the European Union (EU).

4.3. Frameworks, Models and Methods

In the nine articles selected, five frameworks, six models and five methods in use to measure, assess or evaluate the monitoring and management of regulatory compliance was identified. Although the sample is small and may not be entirely reflective of reality, they are illustrated in Figure 2 below.

![Figure 2. List of Selected Articles and the Frameworks, Models and Methods they used](image)

1. Of the five frameworks identified, conceptual frameworks (with two appearances) are the most frequently used [28][33]. Other frameworks include an empirical framework [29], a statistical framework [31] and the Total Quality Management framework [35]. The use of conceptual frameworks was based on a hypothesis that assessed whether compliance with regulations led to favorable or unfavorable outcomes. The focus was on the monitoring of regulatory compliance and no model or method was involved. Concepts relating to the respective regulatory ecosystem were operationalized to provide empirical indicators that were measured and assessed in relation to the hypothesis. Concerning these conceptual frameworks:

   • In Kaine et al. [28], the conceptual framework, namely the I3 Response Framework, tested whether an individual’s response to a regulation depends on the intensity and source of involvement with regards to that regulation. Involvement was operationalized and measured as the intensity of an individual’s motivation in regards to a decision, in this case whether to comply. The framework was then used
to assess involvement with regards to issues the regulation addresses and the intervention used to implement and enforce that regulation.

- For Rouvière & Caswel [33], the conceptual framework, which focused on enforcing food safety regulation, tested whether co-regulation moves regulatory enforcements from a punishment to a prevention mode by providing incentives and information. A firm’s safety effort was operationalized and measured as the number of safety analyses per one-million Euros sales. The framework was then used to assess if co-regulation, as indicated by a firm’s cost in self-regulating, induced a change from punishment to a preventive mode of regulatory enforcement.

The approach taken in the empirical and statistical frameworks was to identify quantifiable parties in the regulatory ecosystem and measure them. Mathematical models and methods were then used to relate these quantifiable parties to indicate respective values of monitored or managed aspects of regulatory compliance.

- In Hsu [29], the empirical framework was used for assessing the effectiveness of regulators in regulatory negotiations. Also assessed were the measured potential profit of a planned habitat development, external social damages resulting from the habitat development, and the quality of the property as a habitat. An economic game theory model was then used to analyze their relationships in compliance with the Environmental Safety Act (ESA), and negotiations or regulatory bargains between regulators and regulated parties.

- In Crabtree et al. [31], the statistical framework was used for pollution control. The time it takes for water quality to exceed the 95th percentile standard specified in the corresponding water regulations was measured. A statistical model was then used to analyze compliance between this measured time and times in the standards for river quality and pollution control.

The final framework is the Total Quality Management (TQM) framework. This framework was used to assess understanding and usefulness of TQM principles for the continuous improvement of regulatory functions. Critical success factors based on TQM were set and used to assess regulatory performances of ten European national medicines regulatory authorities (NMRA).

2. There were two types of models observed amongst the six identified. These are mathematical models [29][30][31][34] and models based on established principles such as the capability maturity model (CMM) [38] and TQM management [39]. The principles based models are from McCarthy et al. [32] for CMM and Pejović & Filipović [35] for TQM. Mathematical models are used to relate quantifiable entities in a regulatory ecosystem to indicate values of monitored or managed aspects of regulatory compliance. These models, built on already established principles, take advantage of these principles in application to the regulators and regulatory compliance management and monitoring. All of the six identified models were used in combination with a method. The mathematical models are:

- In Hsu [29], a simple economic game theory model was identified. It is used with the empirical framework as a simple habitat conservation plan model (HCP Simple Model) and a habitat conservation plan bargaining model (HCP Bargaining Model).

- In Karahalios et al. [30], a unification of methods was brought together as an advanced mathematical model. This enabled the measurement by ship operators of implementation benefits and costs for a newly introduced or existing maritime regulation.

- In Crabtree et al. [31], a statistical model used to set standards for river quality and pollution control using the 95th percentile as a basis was identified. The model simulates the probability distribution of the river quality and has both stochastic components for the generation of model inputs and a deterministic component to route them through the river system.

- In Gillibrand and Turrell [34], a set of computer models designed to measure the concentration of chemicals and insecticides to provide basic estimates of nutrients...
enhancements and chemical dispersion was identified. These models were used to assess the relative potential impact on new and existing fish farms on the water quality of the Scottish sea lochs.

The capability maturity model in McCarty et al. [32] applies a stepwise series of performance levels describing the sophistication of processes necessary to achieve an organization’s objective. Several regulatory functions used to measure the progress of countries towards compliance with respective health regulations, and progressive stages to assess each function were identified. These are used to monitor compliance with respective health regulations and management of continuing professional development of health professionals. Finally, the TQM model in Pejović & Filipović [35] is generic and used to meet public health objectives. The model is comprised of TQM principles and common regulatory and societal objectives across various national medicines regulatory authorities (NMRA).

3. Methods were observed to be used along with the identified mathematical models. Their use is to indicate steps or procedures for connecting identified quantifiable entities in the regulatory ecosystem to indicate respective values of monitored or managed aspects of regulatory compliance. Five methods were identified in the nine selected articles as follows:

- In Hsu [29], an analytical method is employed to critically examine regulatory negotiated agreements.
- In Karahalios et al. [30], an analytic hierarchy process (AHP) combined with a fuzzy set theory method are used as a methodology involving a system of hierarchical score cards for measuring performance.
- The statistical method in Crabtree et al. [31] is divided into two groups based on their functions: those that address single river sites and those that address multiple river sites. The single site methods include fixed standards, simple mass balance, analytical mass balance and Monte Carlo simulation while those that address multiple sites are TOMCAT, SIMCAT and STREAMS.
- Finally, in Gillibrand & Turrell [34], the method used is the annual usage of dichlorvos (an insecticide). This is the maximum permissible amount of dichlorvos (in kg) that may be used annually in each loch without exceeding an environmental quality standard of 0.4 nanogram per litre (0.4 ng/l).

4.4. Effectiveness of Frameworks, Models and Methods

As regards the second research question pertaining to effectiveness of the frameworks, models or methods in determining the effectiveness of the target regulations described in the planning phase, we observed that only the two articles with a conceptual framework did a test for the effectiveness of their approach. The other seven articles speculated that their approaches were successful and did not include any test of effectiveness. Since the conceptual frameworks were used to assess only the monitoring of regulatory compliance, this implies that there was no test for the effectiveness of the management of regulatory compliance. We observed that none of the articles were written by a regulator but rather they were written to analyze a regulator [31][32][34][35] or written as a proposal for regulators to use [28][29][30][33][36]. As such, this could be a reason why a test of the effectiveness of their approaches towards determining the effectiveness of the respective regulations was not done. The articles where the effectiveness was tested are the following:

- In Rouvière & Caswel [33], a case study involving a change in regulatory enforcement regimes from the regulatory alone enforcing compliance to co-regulation with the regulated parties was used. The case study tested if the conceptual framework was effective in determining the effectiveness of enforced self-regulations. Herein, the regulations are set and designed by regulators and then enforced by the coordinated action of the regulators and regulated parties. The result was a successful move from a punishment to a prevention mode indicating the regulated parties were self-regulated.
In Kaine et al. [28], a case study was also used involving individuals’ responses to changes in regulations about zoning classification to test the effectiveness of the I3 Response Framework. The framework identified four categories of involvement regulators used to address individual responses to regulations: low involvement with the intervention, high involvement with the intervention, high involvement with the issue, and low involvement with the issue. The result of the case study indicates a success in the regulators’ ability to predict an individual’s possible behavioral response to a regulation. This enables the regulators to develop strategies aiming to enhance compliance.

5. Threats to Validity

In this literature review, we endeavored to collect and analyze the most appropriate articles that address regulators managing or monitoring regulatory compliance as well as determining the effectiveness of regulations irrespective of the domain in question. This was done using a systematic literature review. With such a review, it is anticipated that the process and conclusions will be limited by factors that threaten the validity of the work. To address these concerns, we did a validity analysis that enabled us to identify and address potential threats to the study [40]. The threats identified and addressed are concerned with construct validity and external validity. Since we made no causal references in our study and since there were no statically significant effects on the outcome, internal and conclusion validity are not a severe concern.

5.1. Construct Validity

Construct validity focuses on the relation between the theory behind the study and what was observed in the study [40]. This questions whether the concepts of monitoring and managing regulatory compliance are in accordance with the research questions addressing measuring, assessing, or evaluating regulatory compliance by the frameworks, method, and models identified in the studies. To mitigate this threat, we sought multiple sources for evidence of this relationship with a domain generic approach in the systematic literature review. This allowed us to explore the concepts from articles obtained from multiple databases, academic and non-academic in nature. The databases cater to different domains involving regulators. Also the search query applied to these databases was validated by a librarian at the University of Ottawa. Finally, the text-mining approach and mixture of both inclusion and exclusion criteria in progression enabled us identify the nine articles selected.

5.2. External Validity

External validity is concerned with whether we can generalize the results outside the scope of our study or a broader population [40]. The trends we reported were based on a very small number of papers involving regulators monitoring or managing regulatory compliance, therefore it is difficult to generalize. Also, while our analysis may not be entirely reflective of actual trends, it provides an empirical basis for discussions and research on regulators enforcing regulatory compliance and determining the effectiveness of regulations across different domains. Our future studies will propose methodology regulators can use in this regards as well as a model to ascertain the maturity of the process.

6. Conclusion

We used a systematic literature review to gain insight on the current state of research on regulatory compliance and effectiveness of regulations from the point of view of the regulator. We systematically selected and reviewed articles that addressed regulators managing or monitoring regulatory compliance through measurements, assessments, or evaluations using a framework, model, or method. While regulators monitor compliance by taking snapshots at different times in the compliance lifecycle of a regulation, they manage compliance by looking at the entire compliance lifecycle. In monitoring, they analyze how regulated parties comply with defined objective at different instants in time. In managing
analyze if the regulated parties meet the defined objectives at different instances of the compliance lifecycle of a regulation.

From a research body of 1207 articles selected from seven academic and four non-academic databases, we systematically selected nine articles using five inclusion and three exclusion criteria to answer two research questions. The questions sought to identify how regulators manage and monitor regulatory compliance as well as determine the effectiveness of regulations they enforce. The approach was domain generic. While our study has undoubtedly missed a number of important concerns, it however has highlighted some of the key issues concerning how regulators enforce compliance to regulations today. The results of the systematic literature review indicate that:

- There is a paucity of research addressing regulators and regulatory compliance measurements.
- Research tends to focus on the transportation, agriculture, health and environment domains.
- Regulators use frameworks in enforcing regulatory compliance to test hypotheses about how compliance leads to favorable or unfavorable outcomes. Types of frameworks used are conceptual or empirical in nature, with conceptual frameworks being the most used.
- Regulators use models to relate quantifiable entities in their respective regulatory ecosystems. Two types are used: mathematical models and models based on existing principles such as the Capability Maturity Model (CMM) and, surprisingly, Total Quality Management (TQM).
- Regulators use methods to indicate steps or procedures for connecting identified quantifiable entities in the regulatory ecosystems. Analytical and statistical methods are always used with mathematical models.
- Only articles with a conceptual framework tested the effectiveness of the respective regulations. As such, regulators determine the effectiveness of regulations when they monitor regulatory compliance but not when they manage it.
- Articles written from the point of view of regulators were not empirical in nature.
- None of the articles in the review was written by a regulator. They were all written by researchers either analyzing regulators or proposing approaches they deem useful to monitor or manage regulatory compliance. Regulators should be encouraged to share their experience and lessons learned, ideally with empirical evidence.

Finally, the results obtained from this systematic literature review indicate a unique opportunity for research in the regulatory compliance domain to explore how regulators enforce compliance and the challenges they face in doing so. Such a shift in focus will address concerns of perceived ambiguity in regulations or policies, under or over regulation or ways of addressing evolution of regulations, concerns that current research in the domain seeks to address. A recommended practical start will be to explore how regulators can assess their relative proficiency in enforcing regulatory compliance and if there is any utility in the application of a maturity model to this regards. In addressing this, pertinent issues within the regulatory ecosystem will be identified and better situated towards improvement. In the long term, better monitoring and management of regulations through proper information systems might lead to situations where there is enough evidence to predict the impact of new regulations (or versions thereof) prior to their implementation. Better and more systematic monitoring and management could hence become a source of requirements for regulations themselves.

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8. References