

Foreword

Non-financial (also referred to as extra-financial, pre-financial, ESG) risks can have an impact on the long-term viability of organizations. This means that organizations now have to think beyond a one and two year perspective to a much longer term horizon as they evaluate the potential impacts and outcomes from non-financial risks. Like it or not, non-financial risks, such as those mentioned in the 2018 study by the World Economic Forum, are mainstream and they have to be part of an Enterprise Risk Management (ERM) process. Actually, they should be part of an overall risk assessment and monitoring in the marketplace of emerging risks.

The report by the World Economic Forum identifies the top five risks from an impact standpoint, four of which would sit under the Environmental, Social, Governance (ESG) umbrella, including extreme weather events, natural disasters, climate change: mitigation and adaptation to name a few.

ERM is not something that one can do part time or something that can be bolted on to some existing process. ERM should be interwoven throughout all aspects of an organization, so one should be able to see it winding through the vision, mission and core values, the setting of business objectives, the performance of risk management, and ultimately in enhancing the organisation's value.

There are challenges with non-financial risks. First of all, measurement is difficult. It's hard to measure exactly what the outcome is going to be, how severe it might be, and that makes it a little more difficult. However, as organizations begin to recognize the fact that they have to act, they will start to think of innovative ways they can deal with these risks. Another characteristic that is worth noting in these risks is that they tend to be very long term in nature. Some risks are just a blip on the radar screen, they can be managed, mitigated then you move on. Others though have an impact on the long-term viability. Companies need to pay attention to both.

Paul Sobel

Chairman

The Committee of Sponsoring Organizations of the Treadway Commission (COSO) Vice President and Chief Risk Officer at Georgia-Pacific LLC

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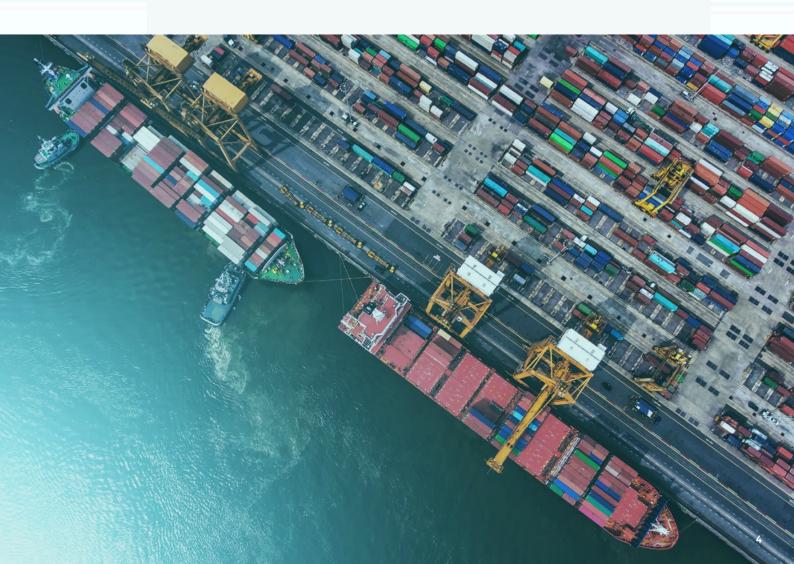
Executive Summary

The voice of policymakers is one of the most material for business. Policymakers are powerful stakeholders, as their requests can be enforced by law and sanctioned by penalties in the case of lack of compliance. Moreover, their policy making activity carries important forward looking signals on which issues and risk factors are emerging and gaining importance. This study explores in what direction and on what topics policymakers are focusing, providing essential insights for decision makers.

Since 2013, there has been a 72 percent increase in the number of recorded regulations concerning non-financial (often referred as Environment, Social and Governance (ESG), pre-financial or extra-financial) issues. There are now more than 4,000 non-financial regulatory initiatives - including mandatory regulations and voluntary initiatives. The evolution of accountability shows us it is only a matter of time before prominent voluntary initiatives will become mandatory regulations, as such being ahead of the curve

will help business preparedness. A good example of this trend is the EU Non-financial Directive, it started as a voluntary initiative and by 2016 became a mandatory regulation, after allowing member states a transition period of two years.

How to navigate the complexity of the constantly evolving ESG regulatory landscape is a question that businesses need to get to grips with in today's world. The Global Insights Report addresses this question by analyzing data from Datamaran's "Observe" module. It focuses on a subset of those regulations, including a total of 439 regulations that apply to the Financial Services, Healthcare and Pharmaceutical, as well as the Utilities sectors in Canada, the United States of America (US), and the United Kingdom (UK). Those sectors are traditionally among the most regulated, as such this report used those as a particular example of global trends.



Key takeaways

ESG regulations are constantly evolving

The regulatory landscape is not stagnant, in fact, it is constantly evolving. After 2015, 43 new or updated regulations and initiatives impacted the Financial Services sector in the UK. The 87 percent increase highlights the need for companies in all sectors to closely monitor trends and regulations horizon, especially considering how quickly ESG regulations arrive.

Voluntary initiatives have influence

In the last year alone, organisations such as: the Task Force for Climate-Related Financial Disclosure (TCFD), The World Economic Forum (WEF), The World Federation of Exchanges (WFE), and a joint work by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and the World Business Council for Sustainable Development (WBCSD) - have all published their recommendations on how they expect companies to manage and disclose their non-financial risks. All of them already have or will in the future have a major effect on how companies disclose their non-financial information. While those recommendations are voluntary, they set a milestone for regulators to step in and write mandatory policies. Adapting early and driving the conversation around those recommendations allows for potential influence in defining future mandatory policies. From a business perspective, being ahead of the curve offers a distinct advantage. Datamaran enables it through an ongoing monitoring process.

The most regulated regions and sectors in the recent years

- Most of the regulations in the UK were introduced in the last three years (80 new or updated regulations since 2015 compared to 31 between 2012 and 2014) especially in the field of Governance (48 new or updated regulations after 2015 compared to 20 between 2012 and 2014).
- After 2015, regulators took a tough stance on the Utilities and Healthcare and Pharmaceutical sectors across all countries. Notably, 18 of 20 of sector specific regulations in the US Utilities are mandatory (8 of 9 in the UK) and 13 out of 17 in the US Healthcare and Pharmaceuticals sector.
- Financial Services regulatory scope increased from 23 regulations and initiatives introduced or updated between 2012 and 2014 to 43 after 2015 in the US. In the UK regulations and initiatives increased as well comparing 21 regulations and initiatives introduced or updated between 2012 and 2014 to 43 after 2015.

Social and environmental topics are becoming more prominent in recent regulations

While in the Healthcare and Pharmaceuticals sector, social issues became more regulated, environmental regulations accelerated in the Financial Services and Utilities sectors. The issue of Climate Change in Financial Services and Consumer Rights in US Utilities sector have also shown growth. As expected, topics that are directly related to business activities are still the most regulated. For example, Energy Use in the US Utilities sector, Product and Service Safety across all regions in the Healthcare and Pharmaceutical sector, and Business Ethics in the Financial Services sector across all regions.

Interestingly, the top expected regulations across sectors are in Supply Chain Management and Business Ethics. They are closely followed by Biodiversity, Climate Change, Employee Development, Human Rights and Labour Rights as well as Local Economy.

Regional and Local Legislators are the most active policymakers

The most active policymakers in the US are Local Legislature. Across regions, International Governmental Organizations have been fairly active after 2015. Regional Organizations publish the majority of sector free regulations that apply to all organizations in the UK. Those regulations are implemented by the European Union and European Commission to regulate and align its member countries in various issues. The Canadian business environment is mostly regulated by National Legislature, which published nine regulations in the last three years. Non-profit organizations continue to drive voluntary initiatives across regions with 15 voluntary initiatives published in the last six years.

The influx of non-financial regulations together with a tougher hand from policymakers, who are favouring mandatory regulations, are sending strong signals to businesses that non-financial risks are now mainstream. This means companies need to think beyond one or two years to a much longer term horizon to evaluate the potential impacts and outcomes from non-financial risks. This report suggests that the best way for business to manage those risks is as part of an overall risk assessment and monitoring - the Enterprise Risk Management (ERM) process.

Introduction

History has shown us that it is only a matter of time before prominent voluntary initiatives become mandatory. A good example of this was the practice of non-financial reporting, which was born as a voluntary commitment, but then, with the introduction of The EU Non-financial Directive, took the form of a mandatory regulation by 2016. Over the years, an increasing amount of highly impactful regulations have shaped the business landscape in the US, Canada and the UK. Policymakers started to address under-regulated ESG issues, for example, human trafficking and modern slavery with the Modern Slavery Act of 2015 in the UK.

Policymakers now, more than ever, have become diversified. Regulations and initiatives are being issued by governments and regional organisations, additionally, industry associations and market regulators have started playing a significant role in self-regulating their markets with recommendations and frameworks.

This report takes a deep-dive into regulatory data and unwinds the complex landscape into easy to-read data points, which were extracted through Natural Language Processing (NLP) capabilities of Datamaran - the leading non-financial risk monitoring platform that converts qualitative data into comparable quantitative metrics.

The objective of this report is to guide the reader through the complex landscape of regulatory data and show trends in the policy making activity through the analysis of the ESG related provisions in regulations and initiatives introduced in the US, Canada and UK in the Utilities, Healthcare and Pharmaceuticals, and Financial Services sectors.

This report is not aiming at building a regulatory analysis in the perspective of compliance assessments. Rather, the analytical approach adopted aims at identifying, in a data-driven way, evidence of issues' materiality from the

perspective of policy making. In other terms, the results are representative of the direction and focus of the stakeholder policymakers, answering the overarching research question "what issues will be material according to policymakers?" With a 72 percent increase since 2013 in the number of recorded regulations concerning non-financial issues, there are now more than 4,000 non-financial regulatory initiatives, including mandatory regulations and voluntary initiatives, and this trend looks set to continue.

In the last year alone, organisations such as: the Task Force for Climate-Related Financial Disclosure (TCFD), The World Economic Forum (WEF), The World Federation of Exchanges (WFE), and the joint work by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and the World Business Council for Sustainable Development (WBCSD) - have all published their recommendations on how they expect companies to manage and disclose their non-financial risks.

Navigating the complex and evolving landscape of environment, social, and governance (ESG) regulations can be difficult for organizations. The following five guiding questions are asked and answered throughout the report in order to help companies understand how these ESG-regulations can impact their business.

- 1. What is the evolution of non-financial regulations?
- 2. What voluntary initiatives are worth considering?
- **3.** What is the best way to identify trends across the most regulated regions and sectors, so businesses can prepare for what is coming in their own home regions and sectors?
- **4.** What material non-financial topics are emerging and developing?
- **5.** What impact do the different policymakers have on the different sectors?

The Scope of the Research

This report is using data derived from Datamaran's Observe module, which is tracking 4800+ regulations from eight sectors and 200+ countries. This Global Insights Report is focusing on a subset of those regulations, including a total of 439 regulations and initiatives that apply to the Financial Services, Healthcare and Pharmaceutical and Utilities sectors in Canada, the United States of America (US), and the United Kingdom (UK).

The scope of the research includes regulations that apply to the local economy (national) and for the greater economy (international). For the purposes of making data more useful for companies, the report splits the regulations and initiatives on a sector specific and cross sector or general basis.

Each regulation or initiative has one or more ESG-related topics defined. Additionally, each regulation or initiative is clustered into two time periods; "before 2015", which applies to regulations or initiatives that came into force from 2012 to 2014 or have been updated in this time period. It also looks at regulations or initiatives that came into force in 2015 or later ("after 2015") or have been updated in this time period. On top of the regulations that are active, this report also gives an outlook on expected regulations or initiatives, which are tagged with the same meta-information. Each regulation is identified as either mandatory or compulsory (regulation or hard law) or voluntary nature (initiative or soft law) [except expected regulations], which defines if companies have to or may want to disclose information on topics outlined in the regulation or initiative in their public reporting.

Each regulation is also marked as to which categorical classification it relates to (environmental, social, governance, economic, employment) and which type of policymaker issued the regulation or initiative. This ranges from National Legislator to International Organisations and Market Regulators to Non-Governmental Organisations (NGOs). This report includes regulations and initiatives from the universe of Datamaran Observe module, retrieved on the 15th May 2018.

Getting the data insights, this report assesses the counts of regulations and the counts of topics in regulations (one regulation can hold multiple topics). Those metrics are in some parts clustered in percentage, showing, for example, the ratio of mandatory regulations to voluntary initiatives on a topic level.

This research is only picturing the regulatory scope and does not go into detail about existing ERM processes or benchmarking activities of specific companies.



This is an excellent data-driven report that highlights just how much the regulatory pressure is heating up on various ESG aspects in key markets. While there are public data sources for subsets of ESG aspects, Datamaran has, to the best of my knowledge, the most comprehensive data base on regulatory Environmental, Social and Governance developments in this decade. Any corporation considering investing abroad or just wanting to conduct a deep dive in its upcoming regulatory requirements will very likely find useful information on the platform. In fact, we have used Datamaran's regulatory data in our academic work, for instance to understand the contextual factors motivating formal public commitments to responsible investing."

Prof. Andreas G. F. Hoepner, Ph.D.

Full Professor of Operational Risk, Banking and Finance Smurfit Graduate Business School and Quinn School of Business, University College Dublin Member, Technical Expert Group on Sustainable Finance, DG FISMA, European Union



Chapter I General Regulatory Landscape

The first chapter of this report focuses on regulatory trends that impact not just a single sector but also the macro environment of the countries researched in this report. It is outlining the growth of ESG regulations by category (ESG categories of environmental, social and governance issues - additionally looking into economic and employment issues) in each country and sector. Moreover, it is looking at regulations and initiatives that apply to all sectors in the researched countries.



As seen in figure one, sector specific regulation in the Healthcare and Pharmaceuticals sector in the US increased significantly over the last 3 years, introducing or updating 17 new regulations and initiatives, representing an increase of 143 percent. Moreover, the US introduced or updated a staggering amount of new Financial Services regulations (35 in just three years) representing an increase of 67 percent compared to the previous time period.

The UK focused its regulatory efforts heavily on regulating the Financial Services sector with increasing the sector specific regulations by 87 percent compared to 2012 to 2014 time period.

When measuring a total number of regulations, Canada appears to be the country, that is the least active in the regulatory space. However, it did increase the sector specific

regulations in the field of Financial Services and Utilities by 50 percent after 2015 compared to 2012 to 2014.

This overall sector specific trend goes hand in hand with regulations released in relation to the general business environment across all three countries. As seen from figure two, all countries at least doubled their general regulations and initiatives over the last three years compared to the preceding period. While the UK only released or updated 31 general regulations and initiatives in the time period between 2012 and 2014, it published or updated 80 within the last three years, signalling an increase in activity from policymakers.

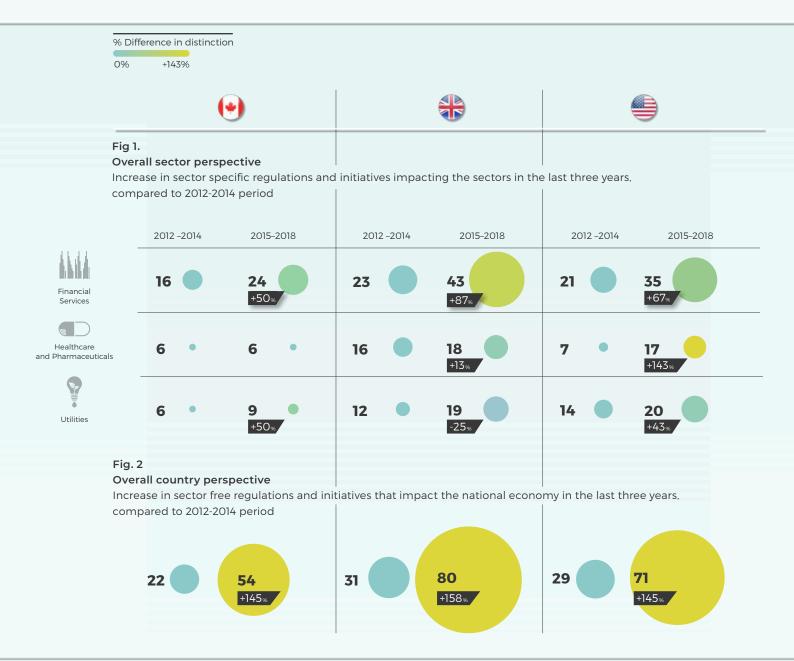


Fig. 3 Overview: sector free regulations

Rise of general sector-free ESG regulations in proportion between periods 2012 - 2014 and 2015 - 2018



In figure three, it becomes evident that sector free regulation increased from 2015 to 2018 when compared to the regulations that came into force or that have been updated between 2012 and 2014. The UK became increasingly regulated in the field of governance with 71 percent of regulations and initiatives that came into force or have been updated in the last six years did so in the last three years. Across regions, economic regulations seem to see the slowest increase compared to other non-financial regulatory categories.

At the end of 2015, the TCFD introduced their recommendations on climate-related financial disclosure which has since seen major recognition across sectors which Financial Services being the numerical lead in signatories (around 50%). The aim was to establish rules for consistent, comparable, reliable, clear and efficient reporting on climate issues. The Task Force on Climate-related Disclosures sought to encourage disclosures that help financial market participants understand their climate-related risks. They did this to promote more informed investment, credit [or lending], and insurance underwriting decisions. The initiative is still of voluntary nature but due to its influence, policymakers are in discussions to make this a mandatory regulation over time.

When looking at policymakers that are most active in regulating the general economy in each country, Local Legisla-

ture has played the most active part in the US over the last three years, with 15 regulations published or updated after 2015.

Regional Organizations publish the majority of sector free or general regulations that apply to all business in the UK. Those regulations are implemented by the European Union and European Commission to regulate and align its member countries in various issues.

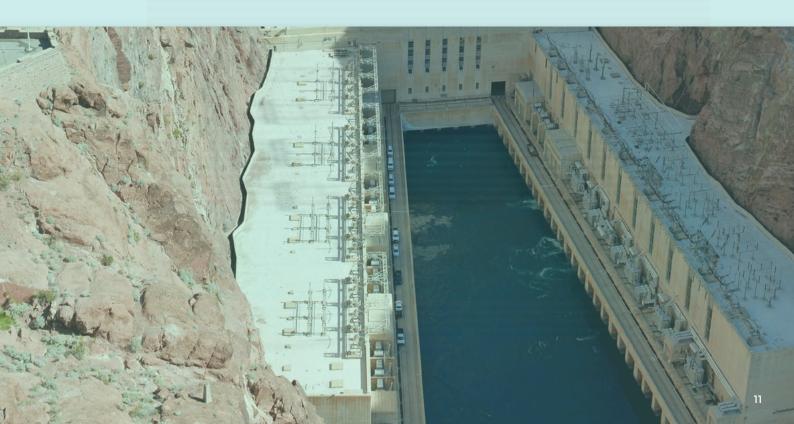
The Canadian business environment is mostly regulated by National Legislature, which published nine regulations in the recent three years.

Across regions, International Governmental Organizations have also been fairly active after 2015, with four regulations that are considered hard law and 10 new voluntary initiatives. Non-profit organizations continue to drive voluntary initiatives across regions with 15 voluntary initiatives published in the last six years. Next to their range of voluntary initiatives, the Fair Labor Association (FLA) also published 'Principles of Fair Labor and Responsible Production' as a mandatory regulation in 2015, which applies to all regions. Those production principles apply to FLA-affiliated suppliers and brands' owned production facilities and address issues such as workplace health and safety, personnel training, grievance mechanisms for employees and public consultation with the community.



Chapter II Regulatory Landscape Across Sectors

The second chapter of this report focuses on the Utilities, Healthcare and Pharmaceuticals, as well as Financial Services sectors. This section is looking at growth and development of ESG regulations over the past six years and gives an outlook to upcoming trends. Moreover, it provides context by highlighting important regulations, policymakers and ESG topics that have influence on the regulatory landscape for each sector in the different countries. Throughout this chapter, multiple comments from companies that operate in the researched sectors will provide external context to the trends analyzed by Datamaran.





Utilities

After looking at the general overview of released regulations and initiatives in the previous chapter, this section will focus on the Utilities sector.

When looking at figure four, and comparing the decrease of sector specific regulations from figure one, it appears that almost all new governance, economic and employment regulations and initiatives are of general nature in the UK. There are only very few sector specific regulations in the environmental and social category.

The US published more Utilities sector specific regulations and initiatives covering environmental topics than any other country in the analysis. 58 percent of all regulations and initiatives published from 2012 to 2018 were released in the last three years. The same trend can be seen in social regulations and initiatives, that see a staggering increase

in sector free regulations in the US. This goes in line with the trend of increased sector specific regulations in that category. Moreover, the only five sector specific regulations on governance in the last six years have been released or updated in the last three years.

Canada's most published sector specific regulations are covering environmental and employment topics, with both seeing a slight increase over the last time period. The only two economic sector specific regulations in Canada that have been published or updated in the last six years have been released in the last three years.

TOPICS

To know which categories are most emphasised in each region, it is key to look at the top regulatory topics per country to narrow each countries' approach towards the sector. As it can be seen from figure five, Canada is focusing its sector specific approach towards regulating Harmful Substances, Occupational Health, and Emission Trading after 2015. While the US heavily focuses on Consumer Rights, Energy Use, and Air Emissions regulations. The UK is equally focusing on energy related topics, such as, Energy Use, Energy Reduction and Efficiencies. However, it is also considering more niche topics, such as, Emissions Trading, which is not in the top regulatory topics for the Utilities sector in the US.

Fig. 4
Overview across countries

Utilities sector specific ESG regulations since 2012 by category in proportion between periods 2012 - 2014 and 2015 - 2018



All three Business Ethics regulations and initiatives impacting Utilities companies in the US were introduced or updated in the last three years without a single regulation being introduced or updated in the time period between 2012 and 2014 showing a growing interest in the topic by policymakers. Similarly, regulators increasingly regulated Consumer Rights in the US, with six from a total of eight regulations and initiatives that were introduced after 2015, compared with two in the time period from 2012 to 2014.

Fig. 5 Number of sector specific regulations ranked by top topics

Top Utilities sector specific ESG regulatory topics after 2015

(*)							
	Harmful Substances	3	Energy Reduct. & Efficier	ncies 2	@ @ 	Consumer Rights	6
	Occup. Health & Safety	3	Product Labelling	2		Energy Use	6
	Emission Trading	2	Emission Trading	2	i	Air Emissions	5
⊕ 0	Board Composition	1	Energy Use	2	Au	Business Ethics	3
@ @ 	Consumer Rights	1	Greenhouse Gases	2		Greenhouse Gases	3
	Impact Investing Products	1	Air Emissions	2	*	Harmful Substances	3
Ø	Solvency & Fin. Management	1	Product & Service Safety	2	&	Hazardous Waste	3
	Greenhouse Gases	1				Renewables & Alternative	es 3





The growing demand for ESG transparency and its relevance to financial performance is clearly signaling how quickly it is becoming embedded in financial analysis. What started with research organizations assessing companies' ESG performance has now spread to credit rating agencies, lenders, investors, policymakers among others who are taking a closer look.

In the U.S., the electric utility sector is taking the lead to address the ESG needs of investors. Through the industry's trade group, Edison Electric Institute, more than 40 investor-owned utilities have come together and developed an ESG/Sustainability Report template – qualitative and quantitative – that was officially launched this summer. What makes this so unique is not that it is only the first sector to address this challenge directly, it is that the template was developed collaboratively with investors, research organizations and others to ensure its usefulness.

While the ESG/Sustainability Report template is largely focused on the "E" in ESG, social issues are gaining more traction and significance with stakeholders, prompting the need for a broader internal ESG response team. For example, questions about human capital management to support future business strategy are bringing the Human Resources part of the business into the conversation with investors for the first time. As ESG becomes more mainstream and integrated, it will automatically be part of all investment criteria, due diligence and analysis. In the meantime, we will continue to take our cue from investors and other stakeholders to keep us focused on what is most material.

Sandy Nessing

Managing Director, Corporate Sustainability

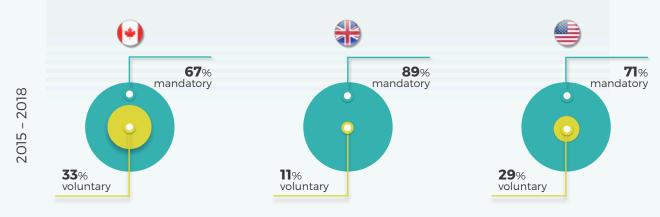


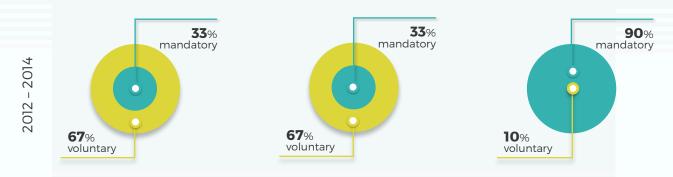
DEGREE OF BINDING

In general, the regulatory landscape of the Utilities sector seems to become more mandatory driven in Canada after 2015, with 67 percent of regulations being compulsory, compared to 33 percent from the previous period. The US and UK both see a higher percentage of mandatory regulations in the recent years compared to the 2012 to 2014. 90 percent of regulations in the US released in the last three

years were mandatory (89 percent in the UK). Voluntary initiatives seem to have slowed down compared to the period between 2012 and 2014. This indicates that the Utilities sector is being controlled more across all regions. Even a country like Canada, which was previously softer on regulation, seeming to tighten its boundaries.

Fig. 6
Sector specific regulations divided by degree of binding
Utilities sector specific ESG policies by degree of binding since 2012







POLICYMAKERS



UNITED STATES

Looking at the stakeholders that publish policies regulating the Utilities sector in the US directly, it is evident that National Government and National Legislature has been increasing their effort to control the sector with mandatory regulations after 2015 compared to the previous period. Interestingly, this is the influence of Market Regulators on the sector. Seven mandatory regulations on the sector have been released by Independent Governmental Institutions over the last six years. Those market regulations come from Commissions in different states within the US such as Texas and Oklahoma but also from the Federal Energy Regulatory Commission (FERC).

In 2017, the Electric Power Supply Association (EPSA) updated its 2006 code of ethics for Electric Power Suppliers implementing, among other changes, a compliance program designed to ensure appropriate, timely and ongoing review of reliability and power trading practices, regulatory requirements, and compliance regarding the substance of this code. Hard law comes from Market Regulators and National Governments/ Legislature, while soft law gets introduced by Non-Profit Organizations (NGOs), such as, the 'Initiative Climate Bonds' with its general standards across sectors and International Governmental Organizations, such as, the International Labour Organization with its 'Code of practice' (pre-2015).



UNITED KINGDOM

When looking at policymakers that influence the regulatory scope for the Utilities sector in the UK, only Regional Organizations and the National Government issued mandatory regulations for the sector in the previous six years. The European Union and European Commission have consistently been most active in regulating the Utilities sector in the UK over the last six years. With regards to Brexit, this might bring up multiple issues the National Government has to overcome after March 2019. It would be interesting to follow the influence of Market Regulators in a post-brexit future. Can they take on the role of the National Government to regulate the sector in the future, coming closer to a US model of jurisdiction?



CANADA

Canadian Local Legislatures in Quebec and Ontario have been driving the mandatory regulatory scope over the past three years with 50 percent increase of mandatory regulations for the Utilities sector. The landscape also shows a lack of Market Regulators, similar to the UK. In 2017, the National Legislature updated its Nuclear Safety and Control Act of Canada, which initially had been introduced in 2000. Since introducing the act, it has been updated a total of 11 times, including administrative sanctions, criminal sanctions, civil fines and injunctions.

FUTURE OUTLOOK

The top expected regulations for the Utilities sector - similarly to the other two sectors - are in Supply Chain Management and Business Ethics. They are closely followed by Biodiversity, Climate Change, Employee Development, Human Rights and Labour Rights as well as Local Economy.



Healthcare and Pharmaceuticals

When looking at figure seven, it can be seen that Health-care and Pharmaceuticals regulations and initiatives seem to focus on social issues. In the UK and US, those regulations that cover social topics see the most numerical increase in policies over the last three years. Employment regulations, specifically designed to regulate the Healthcare and Pharmaceuticals sector have only been introduced in Canada in the last three years.

Overview across countries

Healthcare and Pharmaceuticals sector specific ESG regulations since 2012 by category in proportion between periods 2012 – 2014 and 2015 – 2018



TOPICS

Zooming in towards topic level in figure eight, it can be observed that the top regulated topic in the sector is Product and Service Safety. In the UK, 10 regulations and initiatives directly regulate the sector on this topic, with eight Product Safety regulations published in the US. Moreover, Product Labelling and Clinical Trials are both very sector specific regulations across all regions. Harmful Substances is also in the top five regulated topics in the UK (three regulations) and Canada (two regulations).

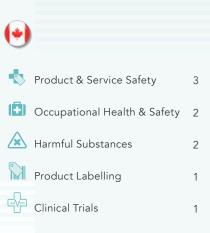
When talking about Product and Service Safety it is important to compare regulators activeness across countries.

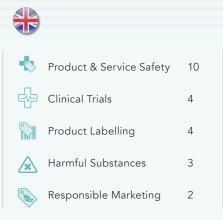
While in the UK the topic is continuing to be the most regulated topic in both time sequels from 2012 and 2014 (six regulations and initiatives) and after 2015 (10 regulations and initiatives). In Canada and the US, this topic was fairly untouched in the 2012 to 2014 time period and only accelerated after 2015. A similar case is Clinical Trials and Product Labelling in the US - while Clinical Trials in both time periods sees four regulations introduced or updated and therefore, sees the trend continuing, Product Labelling was untouched by regulators from 2012 to 2014 and saw four new or updated regulations only after 2015.

Fig. 8

Number of sector specific regulations ranked by top topics

Top Healthcare and Pharmaceuticals sector specific ESG regulatory topics after 2015









We, at MSD*, observe this trend too and acknowledge the role that effective management of environmental, social and governance (ESG) issues can play in managing risks, reducing costs, and serving as a key differentiator in competitive markets. In fact, the number of inquiries from external stakeholders related to ESG issues increased about five-fold at MSD in 2016, and we anticipate that the uptick in inquiries about ESG issues will only continue.

We understand that one reason for this uptick in inquiries is that some stakeholders, including investors, believe that a company's awareness of, and ability to manage, its ESG risks and opportunities is reflective of the quality of the company's risk management systems and processes overall. A strong commitment to corporate responsibility, reflected in proactive and thoughtful management of ESG issues, is therefore viewed as an indicator of effective governance. This has obvious implications for assessing a company's value over the long term. Therefore, from an investment perspective, companies are now also being evaluated based on their social responsibility performance.

Many are recognizing that companies that adopt a "business value" mindset about corporate responsibility can experience gains beyond the "softer" indicators that are so often used to tout its benefits.

MSD's approach to corporate responsibility – focusing on access to health, environmental sustainability, ethics and transparency, and our employees – is directly aligned with the issues that matter most to our stakeholders and our business. This is not coincidental. Effective management of these key issues benefits our business."

Brenda D. Colatrella

Executive Director, Corporate Responsibility



*MSD is a trade name of **Merck & Co**., Inc. Kenilworth, NJ, USA



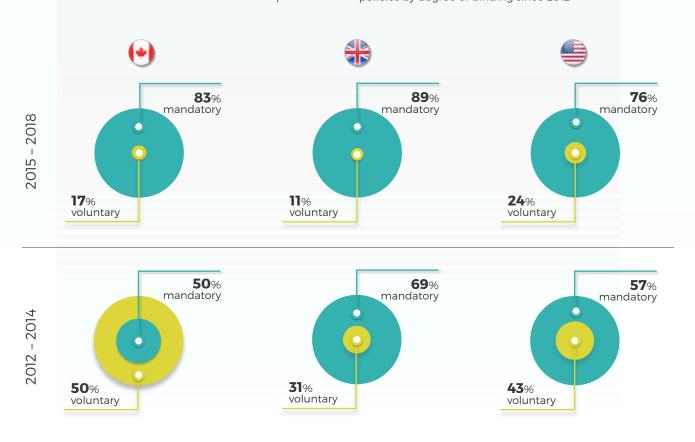
DEGREE OF BINDING

Exploring the split between voluntary initiatives and mandatory regulations that apply in each region in the Healthcare and Pharmaceuticals sector, it can be seen that this sector is heavily dominated by hard law. While between 2012 and 2014 only 43 percent of sector specific regulations in the US were mandatory, in the last three years 76 percent of regulations that impacted the sector directly became mandatory.

Between 2012 and 2014 Canada saw a 50/50 split between voluntary and mandatory regulations. However in the time period after 2015, 83 percent of the regulations that impacted Canadian Healthcare and Pharmaceutical companies

became mandatory. The same trend can also be observed in the UK, where 89 percent of new regulations over the last three years have been mandatory. This indicates a tougher hand from regulators towards the sector switching from introducing more voluntary regulations (US, 2012-2014), to almost only mandatory regulations (US, 2015-2018).

Fig. 9
Sector specific regulations divided by degree of binding
Healthcare and Pharmaceuticals sector specific ESG
policies by degree of binding since 2012



POLICYMAKERS



UNITED STATES

The Healthcare and Pharmaceuticals sector in the US is heavily regulated by the National Government and Local Legislature. National Legislature has been active over the last six years. It is interesting to see that both the Utilities and Financial Services sector have Market Regulators pushing mandatory regulations on the sector. In contrary, the Healthcare and Pharmaceuticals sector has been fairly inactive over the past six years with only updating the 'Dot Com disclosures' from the year 2000 issued by the Federal Trade Commission covering changes in regards to online advertising. Industry Associations published two voluntary initiatives in the recent three years introducing 'Principles on conduct of clinical trials and communication of clinical trial results' providing a framework of rules concerning clinical research, to avoid and limit both risks to the participants and to society at large.



UNITED KINGDOM

Similar to the Utilities sector, the Healthcare and Pharmaceuticals sector is highly regulated from a Regional Organization approach. The European Commission and European Union have the major influence on the sector in the UK. Recently, the European Union introduced and updated three major regulations for the sector, covering 'Cosmetic Products' (entry in 2013, updated 2017), 'Medical Devices' (entry in 2017) and 'Clinical Trials on Medical Products for Human Use' (entry in 2016). Those regulations, among others, will only be enforced in the UK until March 2019. With Brexit around the corner, those major regulations need to be considered when reshaping the regulatory ground for a post-brexit Healthcare and Pharmaceuticals market in the country.

Next to the Regional Organizations, Industry Associations, such as, The Proprietary Association of Great Britain (PAGB), have a significant influence in shaping the regulatory landscape in the previous years. In 2016, the PAGB released its 'Medicines Advertising Codes' to ensure that all over-the-counter medicines that were advertising and aimed at consumers, were approved by the PAGB prior to its release into the public domain.



CANADA

In Canada, the National Government released more than 50 percent of the mandatory regulations in the Healthcare and Pharmaceuticals sector in the last three years. The 'Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use)' introduced in 2015 by the National Government of Canada, focuses on plain language labelling, with the objective of improving the safe and effective use of drugs. Next to the National Government, the World Health Organization (WHO) as a International Governmental Organizations also published a very influential regulation on public disclosure of results from clinical trials ('Joint statement on public disclosure of results from clinical trials').

Besides mandatory regulations in the past, Industry Associations have been active in soft law by issuing voluntary initiatives that also apply in Canada. One of which is the 2015 initiative 'Good pharmacovigilance principles and considerations for biotherapeutic medicines' paper published by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) stressing the importance of Pharmacovigilance and reporting to adverse reactions to medicines, to ensure the safety of medicinal products.

FUTURE OUTLOOK

The top expected regulations for the Healthcare and Pharmaceuticals sector - similarly to the other two sectors - are in Supply Chain Management and Business Ethics. They are closely followed by Biodiversity, Climate Change, Employee Development, Human Rights and Labour Rights as well as Local Economy.





The Global Insights Report findings reflect well what we experience: investors, policymakers and regulators are all pushing companies to provide more disclosure of their ESG-related risks and opportunities. And for good reason, for this kind of information can indeed be a useful indication of a company's competitive position - what some investors refer to as 'looking for alpha'. At Novo Nordisk we refer to these issues as 'pre-financials'; indicators that determine the performance of our business and ultimately our ability to be a sustainable business.

There is a plethora of requests for these pre-financial or ESG-related information - from issue-specific investor coalitions, such as, CDP and reporting initiatives, such as, the UN Guiding Principles Reporting Framework to regulatory disclosure requirements, such as, the UK Modern Slavery Act. We make an effort to be responsive to these requests because we hold ourselves accountable to stakeholders for our performance. However, we have to admit that it can be hard to keep up with them, and to provide good, exhaustive answers to all the questions we are met with. And honestly, sometimes we wonder how the requested information may be used to inform decision-making.

Therefore, what would be incredibly useful is to have more coherence, and more dialogue about what matters. To provide meaningful disclosures of prefinancial issues that can actually drive performance, we need to arrive at an agreement of what to disclose

and how. In my view, it ultimately comes down to understanding a company's governance, strategy and metrics, while at the receiving end it will be helpful to share how all of these requirements are interpreted.

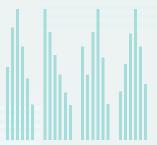
At Novo Nordisk we have been an early mover in reporting on performance in a holistic perspective. Our objective was to enable users of this information to better evaluate the company's performance. However, a big challenge remains: As of yet, there is no uniform way to determine the value of ESG factors. Unlike financial value, for which we have robust and universally accepted methods. As a result, I would argue that good management of pre-financial issues is an asset that is simply under-valued, because it is not reported on the balance sheet, and nor are such risks quantified like financial risks.

As we seek to understand and address this complex topic we seek inspiration from recommendations provided by organizations such as COSO, the TCFD and the World Federation of Exchanges. For several years, we have used the COSO framework to determine what is material for us to report on. And now we look to latch on to the COSO's Enterprise Risk Management (ERM) process to identify pre-financial risks with an aim to have a more robust approach to risk management."

Susanne Stormer

Vice President, Corporate Sustainability





Financial Services

With an increasing amount of Financial Services companies reporting on environmental issues, such as Climate Change, it is the task of regulators to provide companies with the right compliance frameworks to achieve a complex environment reporting by the sector. As it can be seen on figure 10, sector specific environmental regulations increased significantly over the last three years. This shows the general increase in sector specific ESG regulations in the Financial Services sector. Social and governance regulations specifically designed to regulate the Financial

Services industry are increasing significantly in the UK and the US. 71 percent of the published sector specific social regulations of the last six years have been published in the last three years which shows a growing trend, which is also visible in the US with 68 percent of the regulations of the last six years being published in the previous three years. The highest volume of sector specific regulations are in the governance area in the UK.

Fig. 10Financial Services sector specific ESG regulations since 2012 by category and in proportion between periods 2012 - 2014 and 2015 - 2018







The Impact of Climate Change on Risk Management

The issue of climate change has been thrust into the mainstream by the number of regulations that have recently been released. In the last three years alone for financial services, utilities and pharmaceuticals, there have been 23 new or updated regulations in the UK, USA and Canada. However, even though there are new legislations around climate change, Zurich Insurance Group (Zurich), in its recent report "Managing the impacts of climate change: risk management responses" suggests that that it is not enough. This coupled with the slow progress in carbon pricing means that the likelihood that we will meet the Paris Agreement of two-degree goal is low. Climate change's main challenge is to act now. As one of the most complex risks facing society today there needs to be a total transformation of the economy if we are going to stop global warming.

Using the Task Force on Climate-related Financial Disclosures (TCFD) framework has allowed Zurich to understand the risks and opportunities linked to both physical and transition risk, and has allowed us to develop a strategy to help mitigate these in connection to climate change. In the recent report "Managing the impacts of climate change: risk management responses" Zurich details two scenarios it designed in order to comprehend the challenges and opportunities of climate change.

Scenario one - the too little too late:

Governments and companies failed to act and do too little, too late to tackle climate change, with a temperature rising steadily to well above two-degree relative to pre-industrial levels. In this scenario, there is a steady rise in physical risks.

Scenario two - two-degree compliant world:

Governments, society and companies reduce carbon emission effectively. Keeping the rise of global temperature below two degrees relative to pre-industrial levels by 2100. This is consistent with the main aim of the COP 21 Paris Agreement however it has a number of transition risks attached.

Is two-degree compliant world possible and what it takes to achieve it?

The transition to a low-carbon economy will be disruptive and there will be an increase of transition risks, however, with these risks, there will be advantages. One example would be the positive effect on the economy, as it will create opportunities on a global scale. Achieving a two-degree compliant world would be such a major feat that it will be likened to other historical technological transformations. For those companies and sectors who failed to adapt their survival would not be guaranteed and would more likely stand to lose. While these changes will only be seen in the longer term, there are some sizeable opportunities in the near-term, such as the accelerated expansion of renewable energy. Estimates by the UN Framework Convention on Climate Change (UNFCCC) and the International Energy Agency (IEA) suggest that an investment of more than USD 90 trillion will be required over the next 15 years.

Unfortunately, we observe that momentum around regulation and media attention to climate change appear to have slipped, after having peaked at around the time of the Paris Agreement. The latest data therefore reinforce our view that progress is still not consistent with a two-degree trajectory.

It is to be hoped that technological breakthroughs, such as in carbon capture or electricity storage, can significantly alter the profile of climate change and the commensurate risks and opportunities that present themselves. If not, the longer it takes to adequately tackle global warming, the greater the efforts and disruption will be needed in the decades ahead to counter the rise in extreme weather events.

Scorecard: Slow progress in critical areas



Source: Datamaran, World Bank Group, IEA (International Energy Agency), BP, IMF, MSCI, Bloomberg NEF (New Energy Finance), ZIG (Zurich Insurance Group)

- Carbon pricing
 Corporate action and positioning
 CCS technology
- 4. Social trends
- 5. Energy supply6. Legislation
- 7. Energy demand and efficiency
- 8. CO2 emissions
- Investment
- 10. Energy integration and storage
- Fossil fuel subsidies
- 12. Electrical vehicles



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Risk management responses: How to support a positive change?

Over the next decades, climate change will progress and bring with it severe weather along with other harsh physical impacts. The questions that every sector and government is facing is "how will this impact my physical assets and how can I adapt to these changes?" In short, organizations need to understand how to create climate-resilient infrastructures.

Broadly, risk management responses to climate change risks fall into two categories; adaptation to the consequences of climate change (largely physical impacts) and mitigation of Greenhouse Gases (GHG) emissions (largely linked to transition risks).

For businesses to be truly resilient they need to develop a strategy to compact climate change and act on it. To support our customers to be better prepared to manage their climate risks, Zurich has outlined a number of activities business should undertake below.

Alison Martin, Group Chief Risk Officer at Zurich summarizes our approach: "Responding to climate change-related risks need to be embedded across the company. At a strategic level, companies should determine the risks and opportunities linked to profound mid and long-term changes that climate change will bring to their business ecosystem. At an operational level, risk managers should build risk scenario impacts into strategic scenario planning to further determine which risk management response to have as an integral part of the company's enterprise risk management (ERM) framework."

1. Developing a climate resilience adaptation strategy

Climate resilience adaptation strategy can be defined in three key steps:

Step One - Identify the broad business and strategic risks

For this we recommend using the following scenario-based approach developed by the TCFD: 1)Governance: Define the company's governance around climate-related risks and opportunities 2)Strategy: Identify actual and potential impacts of climate-related risks and opportunities on the company's businesses, strategy and financial planning 3)Risk management: Define how the company identifies, assesses and manages climate-related risks 4)Metrics and targets: Implement metrics and targets used to assess and manage relevant climate-related risks and opportunities.

Step Two - Develop a granular view of the risks involved including, for example, individual locations

Determine the magnitude of risk and prioritize according to the company's particular circumstances (industry, maturity and risk appetite).

Step Three - Develop a mitigation strategy involving insurance and resilience

For those locations defined in the second step as at risk, a deterministic scenario-based loss estimate should be developed, based on detailed information regarding site vulnerabilities (physical and organizational). Local hazard maps, where available, are used and assumptions applied regarding climate change effects in the scenario process.

2. Mitigation of greenhouse gas emissions

Building an enterprise GHG emission mitigation strategy and framework, especially in carbon-intensive industries, will help to actively manage the downside and capitalize on the upside of climate change. That strategy must be in place before there is an adoption of any operational issues.

3. Harnessing risk management tools and practices

A number of risk management tools and practices at companies' disposal can help to build their response to climate change.

Standard risk management framework approach:



It is also necessary to look at the **indirect effects of climate change** as part of an effective scenario analysis and risk mitigation plan. Effective risk management requires taking interdependencies between risks into account, and more than ever demands a truly holistic risk management approach. Against this backdrop, it is necessary to look beyond the risks directly related to climate change and also look at how these will also impact other interconnected risks.

Carbon pricing should be considered as part of a company's overall climate change strategy, with anticipating potential increases in the price over the coming years.

Finally, we believe applying of a structured risk assessment process, such as **Zurich's Total Risk Profiling (TRP) approach** will help to better assess hazard level, exposure and controls.

More detailed explanation of Zurich approaches to manage climate risks and opportunities can be found in our report "Managing the impacts of climate change: risk management responses".

Linda Freiner

Group Head of Sustainability, Zurich Insurance Group

TOPICS

When taking into consideration the legal cases, like Wells Fargo that impacted the Financial Services, it is not surprising that regulations on Business Ethics are the largest. The rise in regulations that deal with Consumer Rights is also closely related to the legal cases mentioned above. Climate Change regulations are also growing across all regions. In the US, seven regulations and initiatives around Climate Change have been introduced or updated. While the US and Canada also started to heavily regulate Impact Investing Products, it has not been priority in the UK over the past three years. On the contrary they have increased regulations and/or initiatives on Investor Relations. While Canada and the UK also include stakeholder inclusion in their top five regulated topics in the last three years, the US focused on Consumer Rights.

Impact Investing Products were not regulated in either region in the time period between 2012 and 2014, but an

increased interest by policymakers can be seen after 2015 with five regulations and initiatives impacting Financial Services companies in the UK and US respectively and four directly impacting Canadian Financial services companies. Climate Change is not just a highly regulated topic across regions, policymakers are also picking up speed.

While in 2012 to 2014 only one regulation impacting Financial Services companies in each country was introduced or updated, after 2015 US Financial Services companies saw seven regulations and/or initiatives introduced or updated. This trend was the same for the UK that saw six regulations and/or initiatives introduced or updated in the period after 2015, and in Canada five regulations and/or initiatives introduced or updated. This shows an acceleration from policymakers in regulating climate-related disclosure in the Financial Services sector.

Fig. 11

Number of sector specific regulations ranked by top topics

Top Financial Services sector specific ESG regulatory topics after 2015







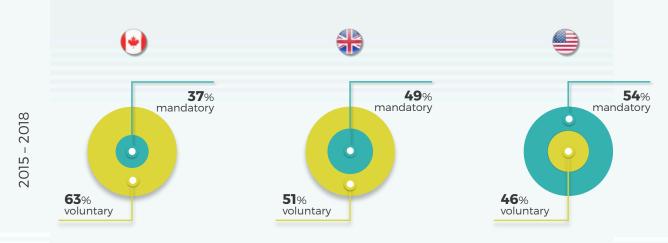


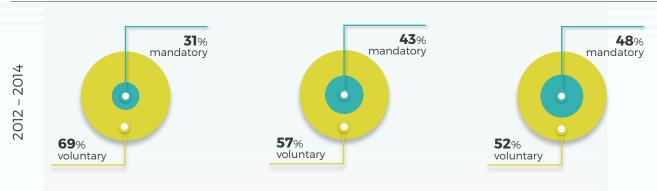
DEGREE OF BINDING

In the recent years, regulation in the sector has become slightly more mandatory across all regions. The Canadian regulatory landscape, although becoming more mandatory in the recent years, is still more voluntary driven with 63 percent of all policies in the last three years being voluntary

compared to 46 percent in the US. The UK sees an even distribution of regulations in its degree of binding, with 51 percent of policies in the last three years being voluntary and 49 percent mandatory. Compared to other sectors, this is a fairly low percentage of mandatory regulations.

Fig. 12
Sector specific regulations divided by degree of binding
Financial Services sector specific ESG policies by degree of binding since 2012







POLICYMAKERS



UNITED STATES

When looking at policymakers that regulate American Financial Services companies, it can be observed that, compared to other sectors, there are more regulatory bodies involved in regulating the market. As for the US in general the Local Legislature is very active in the individual states. However, unlike other sectors such as Healthcare and Pharmaceuticals, Market Regulators play a significant role in this sector, with five newly introduced or updated regulations.

The New York State Department of Financial Services (NYSDFS) released their 'Cybersecurity Requirements for Financial Services Companies' in 2017, which set regulatory minimum standards for protecting the customer information and information systems of the financial services industry. Furthermore, the NYSDFS also published its 'Regulations of the Superintendent of Financial Services: Virtual Currencies' in 2015 to regulate the conduct of business involving Virtual Currency. It requires providers of digital-currency services operating in New York State—in particular, those with custody of customers' funds and which exchange virtual currencies for dollars and other fiat currencies—to apply for a License from the Department of Financial Services (DFS). Those two regulations hint to the fact that digital regulation (social) is pressed by Market Regulators while governance issues, such as, Business Ethics is regulated on national government level. One example for a National Government regulation that has been introduced in 2015 is the 'Integrated Mortgage Disclosure Rule Under the Real Estate Settlement Procedures Act and the Truth in Lending Act' by the Consumer Financial Protection Bureau (CFPB). It combines certain disclosures that consumers receive in connection with applying for and closing on a mortgage loan under the 'Truth in Lending Act (Regulation Z) and the Real Estate Settlement Procedures Act (Regulation X)'.



UNITED KINGDOM

Similar to the Financial Services sector in the US, the sector sees a wider range of regulatory bodies regulating the sector in the UK. Regional Organizations, such as, the European Union play a huge role in introducing a hard law perspective. The European Union released eight different mandatory regulations since 2015, including regulations about payment services, money laundering and terrorist financing, network security, solvency, general financial instruments, transparency and investments.

Unlike other sectors in the UK, Market Regulators such as the Financial Conduct Authority (FCA) already increased their actions to regulate the sector on issues such as financial crime, transparency and remuneration. The 'Financial Crime: A Guide for Firms' which was initially released in 2011, was updated by the FCA in 2016 to help firms establish, implement and maintain more effective financial crime policies, systems and controls. This regulation also provides guidance on steps to be taken to reduce financial crime risk by offering examples of best practice and providing clear procedures for whistleblowing and reporting suspicions and

communicating these to staff.

Next to mandatory regulations, voluntary initiatives increased significantly in the sector of Financial Services in the UK over the last three years, especially from Industry Associations, which published or updated eight initiatives. One of which is the 'Climate Change Investment Solutions: A Guide for Asset Owners' by the Institutional Investor Group on Climate Change (IIGCC). This guide sets out strategies and solutions for investors to better address Climate Change issues. It encourages them to drive their efforts towards the inclusion of low carbon investment strategies, the management of carbon exposure in portfolios and engagement in investing in clean energies. International Governmental Organizations such as the United Nations also contributed with their 2016 introduced 'Sustainable Real Estate Investment - Implementing the Paris Climate Agreement: An Action Framework' which was designed to help investment stakeholders identify the key drivers and overcome the main barriers in the integration of ESG and Climate Change risk into their decision making processes.



CANADA

In Canada, it can be identified that National and Local Legislature published or updated the most amount of mandatory regulations for the Financial Services sector. One example of a 2015 introduced regulation by a National Legislature is the 'Digital Privacy Act of Canada' by the Parliament of Canada to create legal obligations for companies that experience a security breach involving personal information and make those companies required to report any breach of security safeguards involving personal information to the Privacy Commissioner if it creates a real risk of significant harm. A failure to notify can be punished by a fine up to \$100.000 in civil fines.

Moreover, it can also be observed that the majority of policies published in the previous six years, that apply to Canadian Financial Services companies, are voluntary coming from Industry Associations and International Governmental Organizations. In order to strengthen Consumer Rights in Canada, the Canadian Securities Administrators (CSA), as a Market Association released their 'National Instrument 94-102 Derivatives: Customer Clearing and Protection of Customer Collateral and Positions and Related Companion Policy', which contains requirements for the treatment of customer collateral. In addition, the Financial Consumer Agency of Canada (FCAC) as a Market Regulator introduced the 'Code of Conduct for the Credit and Debit Card Industry in Canada' in 2015, which has the purpose to demonstrate the industry's commitment to ensuring, among others, that merchants are fully aware of the costs associated with accepting credit and debit card payments.

FUTURE OUTLOOK

The top expected regulations for the Financial Services sector - similarly to the other two sectors - are in Supply Chain Management and Business Ethics. They are closely

Conclusion and recommendations

As a result of this research, two major trends have been identified in the last three years - a rapid increase in non-financial regulations and a tougher stance from policymakers favouring mandatory regulations.

A sharp increase in mandatory regulations, as outlined in the report, sends a clear signal to businesses that non-financial risks are seen as material by policymakers. Given non-financial risks' long-term nature, this means companies need to think beyond one or two years to a much longer term horizon to evaluate their potential impacts and outcomes.

As pointed out by a number of organizations in the report, including COSO, Zurich Insurance, and Novo Nordisk the best way for business to manage those risks is as part of the overall risk assessment and monitoring - the Enterprise Risk Management (ERM) process.

From the policymaker perspective it is interesting to note that the European Union and European Commission have consistently been active in regulating the UK overall in the scope of this research. With regards to Brexit, this might bring up multiple issues the UK National Government has to navigate after March 2019. An interesting follow-up would be to examine the influence of Market Regulators in a post-Brexit future.

An analysis of other sectors using the same methodology used here is suggested. The evolution of non-compliance penalties within these non-financial regulations could also present a good scope for further research. Finally, connecting the degree of non-financial risk integration to companies financial performance could present an ample source of information on how non-financial risk mitigation impacts the bottom line.



Terminology

Brexit

Abbreviation for the process of the UK leaving the European Union

Categorical classification

The topics are organised in five categories: economic, environmental, social, governance and employment. The nature of a topic is expressed by the perspective from which it looks into its target matter. In practical terms, it is defined by the different kinds of sentences that are retrieved by the search terms.

EDM

Enterprise Risk Management

ESG

Environmental, Social and Governance

European Union

The European Union is a group of 28 countries that operates as a cohesive economic and political block.

FCA

Financial Conduct Authority

Initiative

A policy or recommendation with voluntary degree of binding

Policymaker

Regulatory body that issues regulations and initiatives

Regulation

A policy or act with mandatory degree of binding

Regulatory landscape

All regulations and initiatives that apply in a certain region and/or sector

Sector

A segment of an economy/business or economic activity (i.e. Financial Services etc.)

The Task Force on Climate-related Financial Disclosures (TCFD)

The FSB Task Force on Climate-related Financial Disclosures develops voluntary, consistent climate-related financial risk disclosures for use by companies in providing information to investors, lenders, insurers, and other stakeholders.

The Committee of Sponsoring Organizations of the Treadway Commission (COSO)

Joint initiative of five private sector organizations that is dedicated to providing thought leadership through the development of frameworks and guidance on enterprise risk management, internal control and fraud deterrence.

Topic

A theme within an ESG category. Currently, Datamaran tracks 95 topics, which are clustered in the core categories of ESG, such as Climate Change, Business Ethics and Human Rights among others. Topics are Datamaran's unit of analysis to annotate and assess the ESG issues mentioned in a selected document from a selected source (in this case the Datamaran "Observe" module).

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ABOUT DATAMARAN

Datamaran is the global leader in Software as a Service (SaaS) solutions for non-financial risk management.

Datamaran enables a business process for continuous issues monitoring fully owned by the sustainability and risk teams. It harnesses technology to support decision-makers with an improved materiality analysis process – one that seamlessly integrates into Enterprise Risk Management (ERM) and corporate strategy.

Datamaran's global clientele of blue-chip companies have replaced the dated and expensive manual processes used for benchmarking, materiality and non-financial risk analysis as well as issues monitoring.

The insights Datamaran users gather are used across multiple business teams (governance, risk, compliance, sustainability) to identify and monitor risks and opportunities and to inform corporate strategy.

If you would like to learn more about Datamaran please email saskia@datamaran.com or call on +44 2077029595.

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